Sixth Edition

GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers

VOLUME 1

With Checklists and Software Package

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Contents

Introduction

Numerous publications discuss quality control or quality assurance, and justify the need to perform quality audits. While the methods of auditing in the various publications may differ, the objectives are almost always the same: to evaluate the status of an operation or system, and provide assurance of quality to management.

Although the same quality-assurance objectives are pertinent to the pharmaceutical and the medical device industries, there are additional aspects that need to be considered. Product liability and regulatory situations in these industries necessitate that certain parameters be added to the quality-assurance program to assure compliance with regulations and prevent quality problems.

The intent of this book is to address the product-quality and regulatory-compliance risks in these regulated industries by providing the basic tools needed to perform compliance audits. Pragmatic guidance in structuring and performing audits is provided. Also included are detailed explanations of the various audit types.

A significant portion of this manual has been devoted to detailed audit questionnaires or checklists. The manual is intended to be of value not only to finished-product manufacturers, but also to contract manufacturers and suppliers interested in supplying goods and services to the pharmaceutical and medical device industries. For those companies supplying these industries, the manual will provide information about what can be expected when a quality audit is anticipated.

It is the author's hope that the application of the principles and checklists contained in the manual will result in superior quality and compliance assurance for healthcare manufacturers and their associated suppliers.

About the Author

Mr. Steinborn has over thirty-four years of experience in quality control, quality assurance, and compliance in the medical device and pharmaceutical industries. In addition to significant working knowledge in Good Manufacturing Practice regulations, he is an ISO-Certified Lead Auditor through the IRCA (International Registry of Certificated Auditors).

Mr. Steinborn gained his experience from the ground up, starting as a laboratory technician and advancing through quality engineering, validation, and auditing positions, to manager and director levels. Individual contributor successes led to supervisory positions in pilot-plant production, government-contract review/approval, complaint handling, incoming inspection, document control, and supplier qualification. As a manager, he developed auditing, training, document control, third-party QA, and supplier-control systems in their entirety for such notable companies as Hollister, American Critical Care, Searle, and Abbott Laboratories.

As Director of Quality Control for Searle Laboratories, he was responsible for all facets of quality control, quality assurance, and compliance at a facility that produced tablets, aerosols, suppositories, time-released capsules, medical devices, and small-volume parenterals. During his tenure, he successfully accommodated multiple US FDA NDA/ANDA product approval inspections, annual inspections, and DEA (Drug Enforcement Agency) controlled drug inspections.

As manager of the internal audit function at Abbott Laboratories, he presented the internal audit system on multiple occasions to FDA inspectors with no resulting observations.

In 1984, he wrote and published the first quality audit manual of its kind. Its worldwide use and recognition earned him inclusion in the GMP Institute Hall of Fame for "exemplary commitment to the ideals of Good Manufacturing Practice and Total Quality Management" in 1993. The manual continues to be an acknowledged industry standard and has been revised five times to provide medical device and drug industry professionals with a current useful management tool

Although widely recognized in the audit field, his knowledge and experience in compliance, training, validation, supplier, and contractor management have earned him respect among colleagues as an industry expert. Mr. Steinborn recently decided to fulfill his ultimate career goal of being able to share his knowledge and experience with others as a consultant and can be reached via e-mail at LenSteinborn@aol.com.

Preface

The sixth edition of the *Quality Audit Manual* reflects recent significant changes in the global compliance requirements for the drug and medical device industries, as well as for bulk chemical suppliers. The following is a listing of important changes and the resultant approach taken by the author to address them in the checklists.

UNITED STATES FOOD AND DRUG ADMINISTRATION

- 21 CFR, Part 11—Electronic Records; Electronic Signatures
  A new regulation has been issued that governs electronic records and signatures. The Computer Systems, Documentation Controls, and Quality Records section of all internal and contractor checklists have been expanded to address these requirements. The bulk-chemical checklist also includes 21 CFR 11 because GMP is directly applicable to that type of supplier.

- QSIT—Quality System Inspection Technique
  A new method of performing United States Food and Drug Administration (FDA) inspections has been in use for a few years in the medical device industry. In February 2002, it was approved for use on drug industry inspections as well. A separate chapter has been added to explain this new approach and the Product Audit Checklist (FDA Approach) contained in previous editions of this manual has been revised to enable internal auditors to simulate this FDA inspection technique. Although the system approach is similar for devices and drug inspections, there were enough differences to justify separate checklists for each product type.

- 21 CFR, Part 820, Quality System Regulation
  Users of the new Quality System Regulation should be careful in usage of the abbreviation QSR. The use of this abbreviation could cause confusion with a section of the regulation entitled Quality System Record. The following abbreviations are accepted practice by FDA:
  Quality System Regulation—QSReg.
  Quality System Record—QSR

NORME EUROPEAN (EN)

- CEN/CENELEC has adopted ISO 13485 as equivalent to EN 46001. The European standard has been dropped. Consequently ISO 13485 is included in the checklists and EN 46001 has been deleted.

- CEN/CENELEC has adopted ISO 13488 as equivalent to EN 46002. The European standard has been dropped. Consequently, ISO 13488 is included in the checklists and EN 46002 has been deleted.

- CEN/CENELEC has adopted ISO 17025 as equivalent to EN 45001. The European standard has been dropped. Consequently, ISO 17025 is included in the checklist and EN 45001 has been deleted.

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)

- ISO 9001:2000 has replaced ISO 9001:1994, 9002:1994, and 9003:1994. Consequently, ISO 9002 and ISO 9003 have been dropped from the checklist.

  Note: ISO 9001:1994 has been retained in the checklist because it is still a referenced standard in ISO 9000-3, ISO 13485, and ISO 13488. ISO is working on combining 13485 and 13488 into a stand-alone standard (13485), but it will not be finalized for at least a year. The author is unaware of when ISO 9000–3 will get updated to reflect ISO 9001:2000.

- ISO 9001:2000 was approved on December 15, 2000. Companies have three years to bring their systems into compliance.

- ISO 17025 standard for testing and calibration laboratories was issued as a global replacement for EN 45001.

Documents Referenced in the Checklists

UNITED STATES REGULATORY DOCUMENTS REFERENCED IN THE CHECKLISTS:

- The United States Code of Federal Regulations 21 CFR, Part 11—Electronic Records; Electronic Signatures
- The United States Code of Federal Regulations 21 CFR, Sections 803.17 and 803.18 for Medical Device Reporting
- The United States Code of Federal Regulations 21 CFR, Section 806.10 for Corrections and Removals (Recalls)
- The United States Code of Federal Regulations 21 CFR, Section 821.25 for Medical Device Tracking
- The United States Code of Federal Regulations 21 CFR, Part 820—Quality System Regulation (QSReg.), Current Good Manufacturing Practice (CGMP) Requirements for Medical Devices
- The United States Code of Federal Regulations 21 CFR, Part 211, Current Good Manufacturing Practice for Finished Pharmaceuticals
- The United States Food and Drug Administration (FDA) and ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients
  Note: Approved as a replacement for the European GMP Guideline for Active Ingredient Manufacturers; published by the European Federation of Pharmaceutical Industries Associations and the European Chemical Industry Council.
- The United States Code of Federal Regulations 21 CFR, Part 1301–1307, Requirements for Controlled Drug Substances.
- The United States Military Specification Quality Program Requirements (MIL-Q-9858A)
- The United States Military Standard—790 (MIL-STD-790) Standard Practice for Established Reliability and High Reliability Qualified Products List (QPL) Systems for Electrical, Electronic, and Fiber Optic Parts Specifications

EUROPEAN COMMUNITY (EC) GUIDELINES REFERENCED IN THE CHECKLISTS:

- The European Community (EC) Guide to Good Manufacturing Practices (GMP) for Medicinal Products, including Annexes 1 and 16

INTERNATIONAL PHARMACEUTICAL EXCIPIENTS COUNCIL (IPEC) DOCUMENTS REFERENCED IN THE CHECKLISTS:

- Good Manufacturing Practices Guide For Bulk Pharmaceutical Excipients

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO) DOCUMENTS REFERENCED IN THE CHECKLISTS:

- International Organization for Standardization (ISO) 9000–3:1997, Guidelines for the Application of ISO 9001:1994 to the Development, Supply, Installation and Maintenance of Computer Software
- International Organization for Standardization (ISO) 9001:1994, Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation and Servicing
- International Organization for Standardization (ISO) 9001:2000, Quality Management Systems—Requirements
  Notes:
  a. ISO 9001:2000 replaces ISO 9001:1994.
  b. ISO 9001:2000 replaces ISO 9002:1994 and ISO 9003:1994.
  c. ISO 9001:1994 remains referenced in the checklists because ISO 9000–3 is still linked to it, as are the new ISO 13485 and 13488 standards.
- International Organization for Standardization (ISO) 13485:1996, Quality Systems – Medical Devices—Particular Requirements for the Application of ISO 9001
  Note: ISO 13485 has been approved by the European Community as a replacement for EN 46001.
- International Organization for Standardization (ISO) 13488:1996, Quality Systems—Medical Devices—Particular Requirements for the Application of ISO 9002.
  Note: ISO 13488 has been approved by the European Community as a replacement for EN 46002.
- International Organization for Standardization (ISO) 17025:1999, General Requirements for the Competence of Testing and Calibration Laboratories
  Note: ISO 17025 has been approved by the European Community as a replacement for EN 45001, General Criteria for the Operation of Testing Laboratories.
- International Organization for Standardization (ISO) 10011–1:1990, 2:1991, and 3:1991; Guidelines for Auditing Quality Systems: Auditing; Qualification Criteria for Quality System; Auditors and Management of Audit Programmes

How To Use This Manual

This manual contains two separate sections:

SECTION I—QUALITY ASSURANCE THEORY AND PRACTICE

The reader is advised to read this section as a foundation for understanding, deriving, and implementing an effective quality-assurance audit system.

SECTION II—CHECKLISTS

This section details the areas to be assessed during quality audits.

QUALITY AUDIT
PURPOSE/PRACTICE

1 Regulatory Considerations

Although quality assurance is a necessity in almost every industry, it is uniquely critical in the drug and medical device industries. This has always been due to the financial risks associated with healthcare-product liabilities. Unlike other industries, correcting a quality problem in the healthcare field may involve a product recall of many batches (lots) of manufactured product. This could entail thousands of units at significant cost. If someone buys a package labeled as a 90-watt light bulb and finds that the bulb in the package is 60 watts, he or she returns it for another. If you buy a drug or medical device product and it is mislabeled, the entire batch gets recalled.

One would think that the financial risks associated with drug and medical device products would be sufficient alone to warrant all companies in this field of endeavor to have comprehensive quality-assurance programs. Unfortunately, this has not been the case, and governments around the world have been called into action to protect the public against safety risks associated with quality problems. Government regulations and standards have been instituted in many countries as an aid in assuring that only safe, quality products will be distributed. The creation of such standards and regulations has resulted in a specialized field called **Compliance**.

The field of Compliance is dedicated to assuring that a company developing, manufacturing, or servicing the drug or medical device industries has the proper systems, facilities, and personnel to assure the quality of their products and to assure compliance with regulations and standards. This may appear to be a rather simple task until one begins to investigate the variety and depth of the requirements governing the drug and medical device industries around the world.

One of the best-known sets of regulations that has had a major impact on drug and medical device industries is called **Good Manufacturing Practices (GMP)**. These regulations describe the minimum requirements that governments consider necessary for the production of drugs and medical device products. Although there are many types of GMP regulations, they are common in that they address the manufacturing methods, facilities, testing, packaging, storage, distribution, installation, and servicing for medical device and drug operations. They have, however, not been common in their inclusion of standards that address the development (design control) requirements for products. This has recently become a significant issue. It has resulted in countries and independent standard organizations updating the requirements to include preproduction requirements. The new replacement regulations for the United States Medical Device GMPs, now called the Quality System Regulation (QSReg.), were revised in format to match ISO 9001, but more importantly, were revised to include design-control requirements.

The concern for conformance to quality standards is not unique to the healthcare industry. The issuance of the ISO 9000 series by the International Organization for Standardization (ISO) was an attempt to solidify and standardize quality requirements for all types of suppliers regardless of the industries they serve. The ISO guidelines have been utilized by healthcare manufacturers to upgrade their quality profiles to a recognizable “certified” level. ISO 9000 certification has become not only a recognized voluntary standard, but also a requirement for a company to market in the European Community (EC).

Although revisions to the United States Device GMPs better aligned the American regulation to the ISO 9000 series, the European community did not have something specific for medical devices. As a consequence, the joint European Standards Institution developed EN 46001 and EN 46002. EN 46001 and 46002 are extensions of ISO 9001 and 9002 as applied to medical device manufacturers. But the EN 46000 series were only specific to Europe. As a result of the global acceptance of the European standards 46001 and 46002, ISO developed its own global counterparts (ISO 13845 and 13488) to the EN series. ISO 13845 and 13488 have now been accepted as global replacements for EN 46001 and 46002.

Additional regulations and standards have evolved for bulk-chemical sources; one for active-ingredient manufacturers and one for excipient manufacturers. Both have been included in the bulk-chemical supplier audit checklist.

To assure compliance with all requirements, quality auditing has become very complex. Audits for quality assurance have been substantially increased in number and diversified in scope. To operate in violation or noncompliance with regulations, standards, and guidelines could place an entire company in jeopardy. This vulnerability demands an effective system for monitoring compliance to assure that nonconforming areas will be recognized and addressed. Even the regulations and standards strongly emphasize the management responsibility of monitoring its own quality system through internal audits.

In addition to previously mentioned regulations, standards, and guidelines, companies need to concern themselves with product-specific registration requirements. This particular product-specific registration field is commonly referred to as "Regulatory Affairs." Depending upon the organizational structure of the company, the compliance function may or may not be part of the regulatory-affairs department. The compliance function is focused more on systems of control, whereas the regulatory-affairs function is focused more on particular individual product-registration requirements. It would require an encyclopedia to address all of the different product-registration requirements, especially on an international basis. Consequently, the subject matter in this manual is limited in scope to the *quality-system* aspects of compliance and not the *regulatory-affairs* aspects.

The negative publicity that can arise from a field-quality problem has always been a concern for drug and medical device companies. But in some countries, there are additional product liabilities even if no field-quality problems have occurred. If you market in the United States, the Food and Drug Administration (FDA) performs inspections on all drug and medical-device manufacturing operations. These inspections result in a formal inspection report that is completed by the FDA inspector or inspection team. If an inspector makes an observation about something that in his or her opinion could be considered as being in noncompliance with a regulation, this information is formally documented. The information gained from the inspection can be used as a basis for further regulatory actions, including product recalls. This can occur even if there are no known field quality problems.

In the United States and for foreign firms shipping products to the United States, an inspector's observation is formally documented on a form FD483. When the inspector completes the inspection, a copy of the form FD483 may be left with the company or sent to it later. In addition to the notice of adverse findings (form FD483), an associated detailed report of the inspector's surveillance activities is completed. This report is known as the Establishment Inspection Report (EIR). The EIR and form FD483 are available to the general public. The United States Freedom of Information Act (FOI) provides that the public may obtain copies of this inspection information. All of the observations and comments, except those that may reveal proprietary information, are available to the competition as well as the general public.

The implications of this public information can be substantial. Even though a company may not have a field-quality problem, the observations of noncompliance made during an inspection can result in significant negative publicity for the company. There are publications whose sole purpose is to publicize the findings of such inspections. It is therefore in a company's best interest to assure that no negative observations are written by an inspector and that all inspections result in a favorable report.

The best way a company can help protect itself against the negative impacts of these noncompliance situations is to prevent them from happening in the first place. This requires that every employee be aware of the requirements and do his or her part to assure that each area within the company is in compliance with regulations and standards. As with quality, compliance is everyone's responsibility. It also is the responsibility of management to assure that the quality system addressing all of the previously mentioned expectations is operating effectively.

Effective audits must be performed so that management will have current information on the compliance profile of the company and thereby take appropriate actions to address noncompliance situations. For this reason, the checklists in this manual have referenced the appropriate compliance regulations and standards.

Although the checklists in this manual include references to the many regulations and standards, knowledge of just those documents alone is insufficient to perform a truly comprehensive audit. The checklists themselves are a guide and a reminder of what to look for, but they are not a stand-alone training manual. Even though the following chapters address how to perform an audit, and the checklists are a valuable aid, they alone do not and cannot provide the depth of compliance knowledge needed to be a fully qualified auditor. The regulations and standards are subject to interpretation, and the auditors must have command of these interpretive aspects to perform effective audits.

There are many subguidelines and texts that provide the additional information needed to help with interpretations. Many auditees will ask an auditor, "Where did you get that observation from?" "Where does it say in the GMPs or ISO requirements that I need to do that?" Answering those questions requires a total understanding of the interpretation of the GMP/QSReg./ISO documents and the sources of the pertinent interpretive information. This issue is of such significance that many regulatory agencies and organizations have developed supplemental training manuals and guidelines. These are intended not only for company usage, but for government-inspector guidance as well. Although they may not be the official rule, they are considered the official interpretation. Noncompliance to them can result in observations on inspection.

Becoming familiar with these supplemental documents is no small task. The following list includes just a few of the documents that an auditor in the United States needs to be familiar with. There are many others like these that are generated by other governments and standards organizations.

- HHS Publication (US FDA) 85–4179, Device Good Manufacturing Practices Manual
- US FDA Program 7382.830, Inspection of Medical Device Manufacturers
- United States Inspection Operations Manual (IOM), Subchapter 550, Good Manufacturing Practices (Devices)
- US FDA Program 7382.830A, Sterilization of Medical Devices
- US FDA Guideline for the Manufacturer of In-Vitro Diagnostics Products
- US FDA Program 7383.001, Medical Device Premarket Approval and Postmarket Inspections
- US FDA Guidelines on General Principles of Process Validation
- US Federal Standard 209E, Clean Room and Work Station Requirements, Controlled Environment

- US FDA Program 7382.830B, Contract Sterilizers
- US FDA Guide to Inspections of Validation of Cleaning Processes
- US FDA Compliance Policy Guide 7132, Drugs (general)
- US FDA Compliance Policy Guide 7132a/7132b, Drugs (adulteration/misbranding)
- US FDA Code of Federal Regulations 21 CFR, Parts 1301–1307 Requirements for Controlled Drug Substances
- United States Inspection Operations Manual (IOM), Subchapter 540, Good Manufacturing Practices (Drugs)
- US FDA Guideline on Sterile Drug Products Produced by Aseptic Processing
- US FDA Program 7356.02, Drug Manufacturing Inspections
- US FDA Guide to Inspection of Computerized Systems in Drug Processing
- US FDA Guide to Inspection of Lyophilization of Parenterals
- US FDA Guide to Inspection of Sterile Drug Substance Manufacturers
- US FDA Guide to Inspections of Pharmaceutical Q.C. Laboratories
- US FDA Guide to Inspections of Microbiological Pharmaceutical Q.C. Laboratories

Such requirements and additional guidance information are not unique to the United States. There are supplements as well for the European Community (EC) and for ISO standards. Some good examples are:

- ISO Guide 2, General terms and their definitions concerning standardization and related activities
- ISO Guide 38, General requirements for the acceptance of testing laboratories
- ISO Guide 43, Development and operation of laboratory proficiency testing
- ISO 10013, Guideline for development of a quality manual
- ISO Guide 49, Guidelines for development of a quality manual for testing laboratory

It would be nice if the checklists in this manual could have included questions and references to all of these documents, but the end result would have been checklists so filled with references that there would have been insufficient room for the questions.

2 Quality Audits

It is the responsibility of management to provide its departments with the tools needed to perform functions properly and produce a high-quality product. Just as each department has requirements that need to be satisfied to perform its functions properly, management also needs tools available to properly manage product quality and compliance. One of these tools is the *quality audit*.

A quality audit is a formal review of control systems for conformance with quality standards. Quality audits may be of varying types and performed in various ways; the ultimate objective, however, is to provide valuable information about the operations within a company that affect the quality of an item being developed, manufactured, installed, or serviced. This need is critical in the pharmaceutical and medical device industries because the financial implications of noncompliant product can be, quite literally, vital.

TYPES OF QUALITY AUDITS

There are five common types of audits: Internal, contractor, supplier, project, and QSIT.

Internal Audit

An internal quality audit is a commonly employed practice to assess the status of quality systems in the pharmaceutical and medical device industries. The internal audit consists of a methodical review. These audits are performed by visits to the locations where development, manufacturing, testing, warehousing, and other associated operations are performed. The audits also include visits to the supporting areas, such as planning, product-complaint handling, training, purchasing, and so on.

Contractor Audits

The major difference between contractor and internal audits is that contractor audits are performed at facilities and on systems operated by another company (or by a different division of the same company). In performing a contractor audit, one is not only evaluating the operations within that company against external standards, but also against quality requirements that have been agreed upon via a contract. Contractor audits can focus on many different functions including manufacturing, packaging, testing, calibration, product-development functions, distribution, and installation services. It is expected that contract situations between different divisions within a company will be audited in the same manner as external contractors.

Supplier Quality Audits

A supplier quality audit is an evaluation of a source who supplies materials that are used in the manufacture of products. The audit procedure consists of the review of facility operations that have

potential impact on the quality of the procured item, as well as assessment against applicable regulations/standards.

Product-Specific Quality Audits

This type of review is an internal audit that is limited in scope to the evaluation of one specific product. The product audit is characterized by an intense critique of systems as they pertain to specific product-quality parameters. Where appropriate, the product audit may include evaluations of associated supplier and contractor systems.

QSIT (Quality System Inspection Technique) Audits

This type of audit simulates the latest Food and Drug Administration (FDA) inspection approach. It is a system audit, with an initial focus on four systems in device inspections and six systems in drug inspections. It can lead to the inspection of other areas of the quality system if initial findings justify such effort and if time permits it. These types of audits are further detailed in Chapters 3 through 7.

CHARACTERISTICS

It is a common understanding that the audit functions assess the quality systems in a company, but it is only recently that the audit function has been considered a system unto itself.

In the past, quality audits have been considered the responsibility of the audit function. Viewing the audit as a system, it becomes clear that the auditing activities are only one part of a much bigger system. The auditors, auditees, and management are integral parts of the audit system. Each shares in the responsibility to assure that the audit system is effective.

While it is the auditor's responsibility to execute the evaluation segment of the system in an effective manner, it is incumbent upon the auditees to respond accordingly with appropriate and effective corrective and preventive actions.

It is the responsibility of both the auditor and auditees to include management in the process to assure that corrective and preventive actions will not only be effectuated, but maintained. Presentation of audit findings in a proper manner, including trend analysis, will provide management with the information needed to implement and maintain quality systems that will assure quality and compliance.

Management support and participation is the key to an effective audit system. This is an expectation that is reflected in many regulations and standards as a specific section entitled "Management Responsibility." It is expected that an audit of such management responsibility actually be on the audit schedule.

The following characteristics are vital to the successful performance of an audit:

- It must be an **objective** effort.
- It must be performed by **qualified** individuals.
- It must be performed against a **standard (internal or external)**.
- It must be performed via an approved **procedure**.
- It must provide formal, quantifiable **results**.
- It must provide for **correction/preventive actions** in response to observations.
- It must provide for **verification** of actions taken.
- It must determine the **effectiveness** of actions taken.

CONSIDERATIONS

Objectivity is a critical aspect of performing quality audits. Subjective audits can produce inaccurate and misleading conclusions. Typical situations that can result in a poor or misleading quality audit are:

- Auditor bias for or against an operation due to prior work experiences;
- Ulterior political motives against one or more individuals within the organization to be audited;
- The use of personal, subjective standards for acceptability;
- Employing individuals to perform the audit who have some responsibility for the operation or other reason to fear negative findings.

Qualifications of auditors are of prime importance for successful audits. The credibility of auditors should be beyond reproach. The use of unqualified individuals will result in a superficial audit that will lack sufficient depth to assure validity. Auditors must not only be knowledgeable about the requirements, they must also be trained in auditing techniques and have sufficient auditing experience before leading an audit on their own.

Auditors are actually acting as consultants to management. They need to be capable not only of identifying problems, but also of recommending solutions. Inexperienced, unqualified individuals cannot perform such functions properly.

Standards for reference help assure objective and efficient audits. These evaluation criteria usually are in the form of external standards (ISO/GMP, and so on) and internal requirements (policies, procedures, specifications, test methods, blueprints, and other types of approved company practices).

Procedures must exist that detail all aspects of the preparation, performance, conclusion, reporting, corrective/preventive action, and follow-up phases that comprise a quality-assurance audit.

The procedures and schedules generated by the audit function must reference the standards to be utilized and detail what the auditor will be looking for specifically. Many companies in the United States have received form FD483 observations for not detailing sufficiently what is actually audited. ISO assessors expect to see similar detail. It is insufficient simply to have a procedure that says audits are performed for compliance against ISO or GMP. It is also inadequate just to list sections of the regulations and standards in an operating procedure and have that be sufficient. On multiple occasions, this author was able to satisfy ISO auditors and FDA inspectors only with a comprehensive checklist that showed them what specifically was being audited.

Results of audits need to be constructive, accurate, and quantifiable for management to have confidence in the information provided. The auditor must be able to demonstrate that a successful audit has been achieved. This is not to suggest that numerous observations need be made, for the key to a successful audit is not in the *quantity* but the *quality* of the findings.

One problem with some quality audits is that the results reveal only the negative or problematic areas. This can be very misleading to management because it does not provide a total picture. An operation may be excellent in quality with just a few minor items in question, yet the presentation of only those items could project an impression that the operation is significantly out of compliance.

To properly convey the status of an operation to management, results should be quantified in some manner to indicate the total quality profile of the operation. By presenting the positive aspects as well as the negative ones, management will be better informed about the total status of the operation. This will enable management to address its quality responsibilities more efficiently and effectively.

Quantification of results allows trending of conditions and measurement of improvement. The use of metrics from audits are invaluable in this regard because management is accustomed to dealing with information in a numerical format. This need for quantification can be achieved with a rating system.

A rating system provides numerical values to the assessment of areas. It can be as simple or as sophisticated as management deems necessary. The easiest way to install and maintain the system is to employ it as a feature associated with a standard audit checklist. While performing the audit against a checklist, the auditor assigns a value to the impression of the item evaluated.

Corrections, and corrective and preventive actions in response to observations constitute the most important reason for auditing: to instigate improvement where necessary. There is little purpose in performing audits if identified deficiencies are not going to be corrected.

Corrections are those items that can immediately resolve a situation (e.g., line out, correct the item, explain why it was incorrect, then sign and date it).

Corrective actions are those initiatives that alleviate the immediate condition that was discovered and prevent it from occurring in that particular area again. In this regard, the corrective action may include the preventive action. Stand-alone preventive actions take into account other areas that could be vulnerable to the same problem. The preventive action is global in scope and may include other locations to assure against the same situation occurring elsewhere. Both the corrective and preventive resolutions require the use of root-cause analysis to assure that the undesirable situation or condition will not reoccur. Both require specific detail about what the action is and when it will be completed. The following example contrasts correction, corrective action, and preventive actions:

A product with a 2–8 degrees Centigrade storage requirement was found to be improperly stored in the room temperature warehouse.

Corrections:

- The product had been in the room temperature warehouse long enough to exceed product-quality requirements. It was removed and rejected.
- 100% inspect all other products in ambient storage location and remove non-compliant stored product.

Corrective action:

- Cooler space was insufficient so personnel had no choice but to store at ambient conditions; a project is required to permanently resolve the problem, and, in the interim, temporary off-site cooler space is to be utilized. Corrective action is to secure additional space.

Preventive actions:

- Audit all other cooler and freezer locations for acceptable storage space.
- Review growth plans/needs for additional coolers and freezers. Provide conclusions to management.

Note: Not all audit observations require both a corrective action and preventive actions. In some situations, the corrective action may inherently be a preventive action as well.

Verification consists of verifying that the corrective and preventive action plans have been implemented as planned. Such verification can be in the form of an actual follow-up visit to the location where the observation was made or the verification can consist of the obtainment, review, and

approval of objective evidence that the planned actions have been taken. Proof of such verification activity must be included as a follow-up item for the next audit. The audit file should reflect that the verification took place, what the verification consisted of, and whether additional follow-up is needed.

Effectiveness of the corrective and preventive actions is one of the most critical aspects of any audit system. It is insufficient only to verify that corrective and preventive actions have been completed. If the actions taken have not been effective, then all of the audit efforts have been for naught. There is no purpose in performing audits if there is no assurance that the actions taken as a result of the audit have been effective. It is necessary to assure that the cause of the problem has truly been addressed.

Considerable thought needs to be given to how the effectiveness of the actions taken will be monitored and measured. This aspect is of importance not only for the internal audit system, but also for any other system where there is a corrective or preventive action taken, e.g., failure-investigation corrective actions from a product complaint or an internal failure in manufacturing. It is necessary to assure that corrective and preventive actions taken for any reason be verified to assure that the implementation was effective.

Evaluation of the effectiveness of the corrective or preventive action may be achievable as part of the verification process, but in many cases an additional period of time needs to transpire before the effectiveness can truly be evaluated. It may be necessary to await the next audit to determine the effectiveness of the actions taken. In such cases, the audit file should indicate that such will take place on the next audit. Effectiveness can also be ascertained in other ways, such as having the auditee monitor and provide metrics that show improvement.

3 Internal Facility Audits

Quality-assurance audits of internal facilities are performed to assess the status of a manufacturing operation, laboratory, or any other support function as it pertains to the development, manufacture, packaging, storage, and distribution of a product. Support functions such as purchasing, planning, document control, complaint handling, and servicing are areas also reviewed routinely. Substantial amounts of information are provided to management through the normal reporting relationships; however, the internal audit offers the advantage of providing objective information that does not contain bias for any reason.

While internal audits are performed by many companies to determine the quality and compliance status of an operation, the actual approach employed and philosophies associated with the performance of the audit are varied. This is primarily due to the complexity of the task involved. Human factors play a substantial role in the preparation, performance, conclusion, report, and follow-up steps of an internal audit. The following sections detail the five major steps that need to be accomplished for an internal quality audit to be considered successful.

PREPARATION

In preparing to perform an audit of a facility, it is important to recognize that it may be considered a negative and skeptical act by those individuals who will have their departments audited. Although individuals may diplomatically extend their cooperation to an auditor, it may be only an act of courtesy. It is human nature to avoid or disdain being evaluated by someone. Even though the auditor will be evaluating the systems, processes, and functions of a facility, the audit nonetheless may be viewed as a *personal* evaluation and critique. The auditor needs to be prepared to encounter a reluctance on the part of some individuals to respond freely to questions.

The attitudes of auditors and individuals being audited can make a substantial difference in whether or not a successful audit will be accomplished. One way that an auditor can assure himself or herself of succeeding is to work at gaining the confidence of those individuals being audited. Although this sounds difficult to accomplish, it is achievable by preparing oneself psychologically as suggested in the following approach.

Establish and continue to reestablish that it is your responsibility not only to assess the status of an operation but also to assist the areas being audited in achieving success in the performance of their function. The auditor may be able to substantially assist those departments being audited in procuring equipment, personnel, and systems that they may have been unable to obtain through their own organizations. The auditor has the advantage of being independent and not politically associated with the operation being audited. By openly discussing situations with the auditor, the individuals being audited will be helping themselves, their operation, and the company to achieve quality.

The auditor should not display an authoritarian or condescending expert attitude. Even though the auditor may have substantial technical expertise, the people who are responsible for the departments being audited know substantially more about the intricacies of their areas than the auditor does.

The auditor is responsible for obtaining as much information as needed to perform a successful assessment of the operation. This is subsequently a learning process, requiring the cooperation of those individuals contacted throughout the audit experience. It is therefore in the best interest of the auditor to ask for the cooperation of supervisors and other personnel in educating him or her about the functions, systems, and status of their operations. Intimidating the individuals audited will only result in difficulty in obtaining the information needed to perform the audit properly.

In preparing to perform an internal quality audit, there are two approaches employed by companies. One approach is to prepare not only the audit team but also the facility to be audited by issuing advance notice. The second approach consists of preparing the auditors, but surprising the auditees on the first day of the audit without prior warning.

The justification used for performing surprise or unannounced audits is that it provides assurance of auditing an operation in its normal routine state of affairs. The facility does not have time to go through a special preparation for the audit. This is viewed as desirable by many companies because they know that government inspections might be unannounced as well. The logic employed is that unannounced audits allow auditors to view the facility unprepared, as a government agency would, and help to train people to be prepared for unannounced government inspections.

Although there are advantages to performing a surprise audit, in this author's opinion, the disadvantages significantly outweigh the advantages. Surprise audits may be construed as demonstrating a lack of trust on the part of management toward a particular facility. As a consequence, the individuals in the facility may not trust the objective of the audit. They would have just cause to become defensive and uncooperative. Although the auditor is an employee of the same company, he or she may be considered the adversary in a cat-and-mouse game. Unannounced audits sometimes are construed to have strong political stigmas associated with them. Individuals questioned throughout the audit may preoccupy themselves subsequently with why a question is being asked rather than with answering the actual question itself.

An audit must not only reveal results; it must also stimulate corrective action. But surprise audits can easily result in a "We versus Them" attitude that is not conducive to effective corrective-action planning.

The unannounced audit may occur at a time that could be very detrimental to the successful operation of facility. Audits require the time and the cooperation of many individuals within an operation. If a major important company function is in progress (such as the validation of a new product), the audit may be too disruptive and untimely.

Last, and perhaps most important, if an audit schedule does not exist because of the surprise approach, there is no way to demonstrate to governmental agencies that internal audits are going to take place. This would most assuredly result in an observation by an external auditor or inspector.

When employing the announced approach, an issued schedule of dates and scopes of audits is a necessity. The schedule should assure that an audit can be accommodated in a professional, constructive, and informative manner. In addition to the general information, the schedule should indicate what sections of ISO, GMP, and so forth will be primarily addressed by the individual audits. This is necessary to demonstrate that the audit system is effectively addressing all applicable sections of the regulations and standards.

PERFORMANCE

The actual performance of an internal quality audit is an extremely difficult function to expedite successfully because it requires the auditor to exercise a variety of capabilities skillfully.

The audit involves the review of records, data, equipment, systems, and procedures; however, the review is effectuated through interactions with people. As a consequence, the ability of an auditor to interact properly with previously unknown personnel is a major requirement for obtaining the proper information. The successful auditor is one who is competent in technical areas, and who possesses diplomatic and communication skills as well.

It is the auditor's responsibility to be the initiator and promoter of good interactions with personnel to achieve success. The auditor must recognize that he or she is a guest of those individuals providing information and that those individuals are assisting the auditor as an additional function to their own jobs. In the performance of an audit, the auditor should be considerate of others and attempt to minimize interruptions of those individuals' job functions.

The auditor should therefore begin with a preliminary meeting with appropriate facility personnel to review the agenda of activities. By defining a predetermined course of evaluation, the auditor will have a foundation for demonstrating objectivity and professionalism.

Throughout the audit, the auditor should be evaluating procedures from five perspectives:

1. Do required procedures exist?
2. Are the procedures that are in place current?
3. Is there objective evidence that personnel have been trained on the procedures?
4. Are the procedures being followed?
5. Are the procedures adequate in their satisfaction of internal and external requirements?

Although the auditor should review the documentation pertinent to the functions while evaluating in a chronological sequence, he or she should be careful not to be sidetracked by associated support systems. For example, while auditing the manufacturing operation, the auditor should review the documents pertinent to the operation such as batch records and procedures. The auditor should not, however, be sidetracked into investigating how batch records and procedures are derived and issued to that manufacturing operation.

Having reviewed the flow of production, the auditor should then audit those areas that support production, such as purchasing, quality-control laboratory testing, engineering, maintenance, materials management, and so on. In the audit of these support systems and departments, the auditor should review the previously mentioned systems for derivation, issuance, and revision control of procedures and batch records.

Regardless of the type of audit, individual sensitivities should be taken into consideration to help obtain valid information. The auditor should always review an area of the facility with the appropriate supervisor responsible for that section. By involving the supervisors of the areas to be audited, they have the opportunity to contribute and clearly define how operations, systems, and procedures are performed. Their involvement will minimize the possibility of an auditor misinterpreting information or obtaining a false impression.

The auditor should provide the auditees with an impression of the quality and compliance status of their areas. At the conclusion of the audit, the auditor will discuss results and, through the cooperative efforts of the employees responsible for the sections audited, instigate necessary corrective actions. It is in the auditor's best interest to establish a working relationship with the various key individuals contacted during the audit. Meaningful communication between the auditor and the individuals responsible for the areas audited is necessary to prevent surprises and confrontations in the close-out meeting. Some auditors and auditees have daily summary meetings at the end of the day to assure that the audit is going smoothly and concerns are properly understood.

Many individuals are naturally curious and seek the opinion of competent auditors. Individuals performing audit functions should provide positive and negative feedback. The relating of positive observations should be one of the auditor's objectives because it reinforces compliance and quality. The auditor should not limit the scope of an audit just to finding things that are unsatisfactory. The auditor should try not only to obtain information for management, but also to provide a constructive service to the auditees.

The successful audit is one that is properly planned. An auditor should comply with the original audit schedule. He or she should not prolong audits unnecessarily. The objective is to obtain information in a timely manner. The auditor should be conscious of the time involved and attempt to refrain from investigating one particular area so thoroughly as to not have sufficient time to evaluate all the areas that were on the agenda.

At times, it may be difficult to balance the time to investigate a particular area of concern with the time necessary for the rest of the investigation. When this happens, the auditor should discuss the situation with the auditee to determine whether an additional, separate audit session will be needed or whether the area will be addressed in the next audit.

If an auditor finds a particular area to be of such great concern that the agenda should be revised to accommodate more in-depth auditing of it, then by all means it should be done. One should not, however, confuse a significant area of concern with personal preference, expertise, or desire. In general, unless duly warranted, auditors should comply with the agenda.

An auditor would be considered naive if he or she did not realize that there are always two audits going on simultaneously. The auditor should recognize that while he or she is evaluating a facility, the employees of that facility are evaluating the auditor. The auditor can rest assured that there will be some form of feedback from the facility to management about how the auditor conducted himself or herself. Diplomacy, objectivity, accuracy, efficiency, technical capability, and a constructive attitude are prime ingredients for satisfactory audit feedback.

CONCLUDING THE AUDIT

Having properly planned and performed an audit, the auditor must next bring the activities to a proper conclusion. This consists of concluding all audit activities in a timely manner such that subsequent visits, phone calls, and memos are not needed to bring the audit to a final conclusion.

The closing meeting or session is a very important phase of the audit because it is the time when misinterpretations can get reconciled. It should be viewed as a collaborative effort between the auditors and auditees to reconfirm positive and negative aspects of the findings. One of the objectives of the close-out meeting should be to provide assurance that the audit report will not contain surprises. Everything in the subsequent audit report should be a formalization of those issues detailed in the close-out meeting.

The approach to summary or wrap-up sessions varies from company to company, depending upon individual preference. The following possible practices and options should be considered by the auditors and management prior to the concluding session.

Should the audited facility receive a copy of the auditor's initially completed checklist and written list of observations?

The major advantage of providing copies of completed checklists to the facility management is to assure that all observations have been discussed. The disadvantage in providing instant, formal information to the facility is that it does not permit the auditor's immediate responsible management

the opportunity to critique the findings or review the appropriateness and pertinence of them prior to formal documentation. Unbeknownst to an auditor, an observation that has been made may be changed or discarded upon review by his or her management.

Another disadvantage of providing the information formally at the close-out meeting is that the handwritten observations and copies of checklists will not be sufficiently controlled to assure confidentiality and destruction at a later date. Because the information contained in an audit is extremely confidential, it needs to be appropriately controlled. Normally, a facility will not feel the need to have immediate handwritten copies of observations or photocopies of checklists if they have the assurance that all of the observations have been communicated and that they will receive a copy of the final audit report that will not contain surprises.

If a negative observation has been corrected by the facility prior to the concluding session, should it still be included in the auditor's findings?

The audited facility may take the position that because the area has been corrected, it is no longer a valid observation and should not be included in the auditor's findings or in the auditor's report that is sent to management. This is usually considered a rather weak reason for nullifying previously noted observations.

The purpose of a quality audit is to evaluate systems and determine their status in regard to compliance and quality. It is not a race to determine how many unsatisfactory conditions can be corrected before the audit is concluded. If all of the negative observations made by an auditor were corrected prior to the conclusion of an audit, and the auditor deleted such items, the management of the company would receive a report that is not truly indicative of how the system had been operating.

In addition, management should have some indication that the auditor was actually performing his or her function properly by uncovering areas of concern. If all of the negative observations were corrected and not reported, management would not be aware that the auditor had properly performed his or her function.

Certainly, there needs to be positive reinforcement and credit given to the facility that recognizes unsatisfactory conditions and then addresses them expeditiously. There are ways that the facility can be recognized for such dedication — other than by eliminating the original negative observations. For example, the auditor can indicate the original observation in the final report, but also state that corrective action is not necessary because the facility diligently corrected the situation once it had been brought to their attention. By handling the situation in this manner, management receives the information that is appropriate and the facility is recognized for taking proper interest and action.

In cases of an observation requiring corrective action, should the auditor provide or stipulate the corrective actions to be taken?

This question arises when facilities that have been audited are given a list of unsatisfactory conditions and are left to themselves to find a solution when they may not have the expertise to do so. They may respond by accusing the auditor of being a hit-and-run artist.

On the other hand, many auditees object to an auditor providing or stipulating the corrective action plan. They may take the position that they are the most familiar with their operation and that they should be given the responsibility to determine the corrective actions to be taken. The easiest way to solve the dilemma is to present the facility with an option. The facility management should

be permitted either to pursue a corrective action plan of their own or to obtain the corrective action suggestions from the audit team. By providing the facility with an option, the egos of the individuals involved in the audit will be satisfied. The auditors, however, are not required to provide a corrective and preventive action if they are not confident in the solution. Per ISO Standard 10011, auditors are only responsible to identify instances of nonconformance, not to correct them.

The conclusion of an audit should consist of a summary session with the responsible individuals in the facility organization. The number of individuals at the meeting should be kept to a minimum for efficiency purposes.

To prepare properly for the closing session, the auditor should review the audit observations and the ratings assigned to each question. The auditor should be prepared to reinforce the positive aspects observed during the audit and to substantiate those observations that were interpreted as being negative in quality or compliance. Observations made that may be too subjective or vague should be eliminated. Questionable observations can detract from or raise questions about the validity of other major observations and issues that need to be addressed.

Agreement on the observations should be reached at the closing meeting. If agreement cannot be reached, the auditor should indicate that he or she recognizes the auditees' position, but that the observation will still need to be included in the audit report. The auditees can restate their disagreement in the response to the audit report, and these differences can be reconciled by the Management Review process (ISO/EN/QSReg., requirement for Management Review).

REPORT

The purpose of performing a quality audit is to provide management with information on the quality and compliance status of operations. This is best achieved through a formal report that has been generated by the leader of the audit team and reviewed by that individual's immediate manager.

The essential elements of the audit report should include:

1. Distribution list
2. Dates of the audit
3. Scope of the audit
4. Name of lead auditor
5. Names of other team members and their positions on the team, e.g., auditor, subject-matter expert, auditor in training, guest, and so on
6. Standards of reference used in the audit
7. Date of opening meeting with list of attendees and position titles
8. Date of closing meeting with list of attendees and position titles
9. General strengths
10. General weaknesses
11. Specific observations requiring corrective and/or preventive actions
12. Request for corrective and preventive action plans for each observation
13. Due date for the response to the audit report

Information contained in audit reports is highly confidential, therefore copies of the audit reports should be controlled. Many companies use unique paper or numbering methods to control the copies.

FOLLOW-UP

Having planned, performed, concluded, and reported the audit, there remains one more activity to be pursued. It consists of continuing to follow and track the corrective and preventive actions. Too frequently, the generation of the audit report is considered to be the end of the audit. It really is the beginning of a number of additional activities:

1. Tracking the response to an audit report
2. Approval of corrective and preventive action plans
3. Approval of due dates for corrective and preventive action plans
4. Tracking of corrective and preventive action plan completion
5. Verification of corrective and preventive action plan completion
6. Evaluation of the effectiveness of verified corrective and preventive action completion
7. Determination of follow-up verification/evaluation for effectiveness activities that need to extend into the next audit
8. Trending of audit results for continuous improvement

With the need to trend audit findings and monitor the effectiveness of corrective/preventive actions, it is no longer easy to determine when an audit is considered "closed out." In actuality, the audit is not really completely closed out until all observations have been verified as effectively corrected. Because monitoring for effectiveness could take a long time (a year or more), some auditors elect to close out the audit once the corrective and preventive actions have been verified as completed. The effectiveness and trending aspects are considered to be beyond the closure of the audit. This is an acceptable approach as long as the audit function can demonstrate that the closure of the audit does not curtail the yet needed evaluation of the effectiveness of actions taken.

4 Supplier Audits

The quality of pharmaceutical and medical device products is dependent upon the quality of the raw materials and other components used by the manufacturer. Supplier audits are normally performed by finished-product manufacturers to investigate specific quality problem(s) being experienced, to evaluate a potential new source, or to monitor ongoing quality on a routine basis.

QUALITY-PROBLEM INVESTIGATION AUDITS

This type of audit is initiated when a quality problem has occurred, and it is deemed desirable to identify the underlying cause to prevent repeated problems. Unfortunately, this type of audit occurs after the accident has already happened, and the tone of the audit tends to be negative. The auditor visits the supplier to find out what is wrong, get it corrected, or recommend other alternatives to the situation. The supplier is in the unenviable position of needing to overcome a questionable quality image that, depending on reject history and severity, could result in a discontinued business relationship.

While *problem-solving* audits are a good method to correct poor quality situations, *monitoring* audits can help prevent these problems from occurring. By performing audits before new sources begin to provide items and by continuing periodic audits, a good supplier relationship can exist that will minimize quality problems, audit suspiciousness, and supplier defensiveness.

POTENTIAL NEW-SOURCE AUDITS

Audits of potential new sources are performed to determine whether the quality level desired is obtainable from a particular source before actual procurement begins. These audits are usually part of a total supplier-qualification program that frequently includes obtaining sample material ahead of time to assess its acceptability against current specifications. Although this kind of audit is primarily a precautionary measure to help prevent rejected material from being received, the audit also can ascertain whether the supply line could be interrupted because of compliance or quality problems at the supplier's facility.

Unlike the quality-problem audit, potential new-source audits are not negative in nature. The supplier usually realizes that an audit could lead to new business. It could also mean new business even if unacceptable conditions exit, provided they are corrected. Actually, negative findings can be used to a supplier's advantage if they are corrected, indicating a sincere desire to satisfy quality requirements.

The auditor, not having been exposed to rejects and other problems, tends to be less skeptical and suspicious on new-supplier audits. If handled in the spirit of trying to assess and establish a quality standard for operations, the audit can be a very positive and enjoyable experience for all involved.

ONGOING OR MONITORING QUALITY AUDITS

Of the three general types of supplier audits, ongoing quality audits are probably the least frequently performed, understood, or appreciated. This is unfortunate, because they help prevent costly quality or compliance problems.

During the passage of time, many changes occur in a supplier's operations, necessitating continual monitoring. Changes in ownership, production processes, or personnel may affect the quality of the item being procured. In cases where the supplier has been certified (use of certificate for release), monitoring audits are critical to assure that the certificates still represent valid homogeneous batches received. There are also additional benefits to performing routine audits:

Reinforcement. By periodic visits to the facility, the client's quality objectives are reinforced to the supplier. A lack of attention may be interpreted by the supplier as a lack of concern about quality. Material that has a questionable quality status may be released because monitoring audits are not occurring, and the supplier is not fully aware of the client's position on quality.

Problem Solving. It is not unusual during the course of an audit for questions to arise from the supplier regarding specifications, testing, and other requirements that may be unclear. Frequently, many questions are not considered substantial enough to warrant a phone call by the supplier. A supplier's employee may have the feeling that by calling and asking questions, he or she will appear to be a nuisance or incompetent. Periodic audits encourage questions and reaffirmation about requirements.

Awareness. Perhaps one of the most important benefits of the routine audit is the discovery of changes in manufacturing processes, facilities, or management that could affect the quality of the product. Major changes in personnel affect the quality of the product because the new employee may not be fully cognizant of requirements. The audit, therefore, leads to awareness of change and provides a training vehicle for the supplier, thereby reinforcing quality.

New Opportunities. The audit can be a learning experience for the auditor as well as the company procuring the item. New testing methodologies or process improvements may be available that would be of major significance to the procuring company. Additionally, the supplier may be in the processes of developing a new item that could be of significant interest to the procuring company.

Sampling/Testing Assessment. By periodically auditing the supplier and reviewing quality histories, the procuring company can determine whether the present level of testing and inspection needs to be increased or can be decreased.

CHEMICAL SUPPLIERS

There are additional reasons that justify periodic audits of chemical sources. Bulk chemicals are usually sampled under the assumption that the total batch received is homogeneous. There may be specific sampling plans that determine how many drums within a given lot are to be sampled; however, it is still necessary to have assurance that the lot is homogeneous and that the sampling is truly indicative of the entire batch. Since one cannot realistically perform a 100 percent inspection of bulk chemicals, the assurance that the batch is homogeneous and free of microbial contamination is a necessity. Periodic audits help assure that microbial contamination is not occurring in the manufacturing process and that the bulk chemical is being uniformly manufactured.

It is not uncommon in the industry to accept qualified certificates of analysis from the supplier in lieu of performing certain testing on bulk chemicals. This is done for a variety of reasons; the most common one being a substantial cost savings. The procuring company may elect not to purchase a very sophisticated, expensive piece of equipment necessary to perform a test on a specific chemical. Even if the testing equipment is available, the procuring company may elect to qualify the certificate of analysis from the supplier to decrease the testing workload in the quality-control laboratory.

The acceptance of certificates of analysis on bulk chemicals in lieu of actual testing further dramatizes the need to assure that the supplier's manufacturing and laboratory testing operations are satisfactory. Periodic audits of the manufacturing and laboratory testing facilities help provide assurance that the certificates of analysis being received are truly indicative of the material that has been procured.

Another reason to audit chemical suppliers is to determine whether any changes to the actual material being procured has taken place. Although testing performed upon receipt does give insight into certain quality, purity, and strength parameters, it is usually not all-encompassing. It is certainly possible that the chemical manufacturer could make formula revisions or change sources of feed stocks that would go unnoticed by the procuring company's quality-control testing. Sometimes the differences are found only when the procuring company detects irregularities or changes in the finished product manufactured. By auditing the supplier on a periodic basis, one may be able to ascertain whether changes have been made (or at least one will be reminded by the audit checklist to ask whether they have been changed).

PACKAGING AND OTHER BASIC-COMPONENT SUPPLIERS

Some of the purposes discussed for auditing suppliers of chemicals also are applicable to suppliers of other components. Packaging and other components in direct contact with the product may be viewed as chemicals for audit purposes. Changes in the formulation could have a definite effect on product quality. The procurement of a primary component demands that changes in formulations be detected. While receiving inspections of components are useful, they usually just address the visual and physical parameters of the item. Rarely are detailed chemical analyses performed on the actual formula of the material (e.g., plastic-resin identification, purity, grade of material). Therefore, it is necessary to audit for control of all aspects of the item.

PRINTED MATERIAL

For suppliers who manufacture printed materials, audits are necessary to assure that systems exist to prevent wrong/obsolete revisions of labeling from being printed or items from becoming mixed. Labeling that is incorrect is considered "adulterated" and subject to a product "recall." The criticality of assurance needed from supplier audits is obvious.

SOFTWARE SUPPLIERS

The software supplier has become an extremely visible risk factor in recent years. The proper design, control, supply, and maintenance of software is critical to the proper validation of products and manufacturing processes in the healthcare industry. Regardless of whether the software is "off-the-shelf" or "custom," the software supplier (or contractor, if you prefer) is a foundation that is critical to all the functions it supports.

All of the prior justifications for supplier audits cited in this chapter apply to the software source — and then some. Many products are "recalled" from the marketplace, not for manufacturing-quality defects, but for design defects that are not detectable, or correctable, by manufacturing and quality-control inspection-history functions. Both the International Organization for Standardization (ISO) and Good Manufacturing Practice (GMP) now strongly address this issue, and the design/control of software is in the main arena in this regard. Therefore, comprehensive audits are considered a "must" not only to gain confidence in the software being procured, but

confidence in the compliance profile as well. The cost of an audit is negligible when compared to the compliance and product-liability risks associated with software. Software suppliers are really viewed more like contract manufacturers and developers in the eyes of the (Food and Drug Administration (FDA) and ISO.

PLANNING THE AUDIT

It is difficult to achieve a successful audit without proper planning in advance. What can happen when audits are not adequately planned is reflected by the incidents in "An Auditor's Nightmare" (p. 23).

The following should be taken into consideration when planning a successful vendor audit:

- Clearly establish the purpose(s) for the audit.
- Based on the established purpose(s), determine what area(s) needs to be investigated and what specific personnel need to be available for the auditor to obtain information.
- Obtain as much information as possible about the supplier before the visit. In cases of a currently employed source, quality histories from receiving inspection and manufacturing should be obtained and reviewed. Previous audit reports should be reviewed as a guide to promised corrective actions that should be verified on the audit.

  If the audit's purpose is to determine the acceptability of a new prospective source, files should be checked to determine whether this source has been audited previously. Perhaps the results of a previous audit were of a nature as to not warrant further consideration. Additionally, an internal search should be made to determine whether this source has ever been employed before and possibly dropped for some reason.
- Determine whether purchasing, research, or other groups are considering procuring other items from the supplier.
- Determine whether any other audits are imminent in the same general vicinity of the facility to be audited. With the high cost of travel, it is beneficial to maximize the return on travel costs by combining more than one audit into single trip.
- Check to make sure that key personnel will be available for questioning during the time of the visit.
- Verify that the items intended for procurement will actually be in manufacture at the time of the visit. In cases where it may not be feasible to view the actual item in manufacturing, the visit should be planned at a time when a similar item is being produced.
- Schedule the audit so that the auditor will be able to view operations while they are running. Find out how many shifts there are and the hours of each shift.
- If applicable, coordinate plans with other interested internal departments. Visits to facilities by various department representatives can be successful provided they are properly planned beforehand. Arrangements should be made so that the quality auditor is not prevented from investigating areas of importance because of other individuals' discussions with company representatives. As long as individual needs are arranged for and properly accommodated, multidepartmental visits can be achieved to the satisfaction of all concerned.
- Check flight schedules and other methods of transportation to assure that the appropriate amount of time will be available at the actual facility to properly perform the audit. Travel and visit arrangements sometimes are made through the purchasing agent responsible for the type of item. It is very important for the auditor to follow up and assure that the arrangements made are adequate.

AN AUDITOR'S NIGHTMARE

The purchasing department of XYZ Company in Chicago, Illinois has identified a substantially lower-cost source for one of their materials. A quality audit has been completely arranged by the responsible purchasing agent, who will accompany an auditor on a visit to the supplier's plant in Cleveland, Ohio. It is urgent that the audit be performed immediately because a purchase order for two year's worth of material is now imminent.

Wednesday – Les, the purchasing agent, advises the quality-assurance auditor, Jerry, that all arrangements have been made for the facility audit to take place the following day. Jerry and Les agree to meet at the airport at 7:00 am.

Thursday 7:30 am – Les arrives 30 minutes late at the airport to find an anxiously awaiting Jerry, who was worried about whether Les would show up or not. Les had previously made the flight arrangements and had the tickets with him.

7:40 am – Jerry notices that the flight to Cleveland has two stops and does not arrive until 10:40 am. Les explains that the nonstop flight arriving at 8:30 am would have cost $50.00 more. In his opinion, everything could be covered in a few hours that afternoon.

11:00 am – The flight arrives in Cleveland 20 minutes late.

11:10 am – Les and Jerry are greeted in the terminal by Patti, the sales representative for the supplier.

11:30 am – Patti advises that the plant personnel go to lunch at noon and that it would probably be in their best interest to do the same now.

12:10 pm – Patti, Les, and Jerry arrive at the Chateau Slo, a very fancy restaurant that serves seven-course lunches.

2:20 pm – They arrive at the plant and are escorted into a conference room.

2:30 pm – Les, Jerry, and Patti are joined by the sales manager, Joe, who inquires how Les and Jerry would like to spend the afternoon. Les responds by stating what the typical order quantity would be.

2:45 pm – After Les relates the order quantities, Joe responds that XYZ Company is now paying $2.00 per unit for what will cost only 7¢ per unit from his company.

3:00 pm – Joe asks Jerry if he has any questions or desires. Jerry responds that a plant tour accompanied by either the production manager, plant manager, or quality-control manager would sincerely be appreciated. Joe leaves the conference room to make appropriate arrangements.

3:05 pm – Joe returns and explains that the plant manager is at an annual financial-review meeting, the quality-control manager is on vacation, and the production manager had to leave early due to illness. Joe offers Patti's services as a tour guide, while he and Les discuss delivery schedules.

3:07 pm – Patti walks through the plant and explains that they will need to hurry because the production working hours are 7:30 am to 3:30 pm.

3:10 pm – Jerry, somewhat frenzied, rapidly starts asking all kinds of questions, none of which are answerable by Patti. She explains that this is only her second visit to the plant. She just joined the company three weeks ago. Patti advises Jerry to write down his questions and promises that she will obtain answers for him early the next day from the plant manager.

3:45 pm – Les, Jerry, Patti, and Joe convene in the conference room. Joe advises that although the return flight leaves Cleveland at 6:30, the rush hour is a major problem and that they should probably depart immediately.

3:50 pm – Les and Jerry depart, being driven by Patti.

4:10 pm – They arrive at the airport. Patti states that the light traffic was very unusual and that she has never driven to the airport in 20 minutes before.

Friday 9:00 am – Patti calls Jerry to regretfully inform him that she somehow misplaced his list of questions and wonders if he remembers them. He does not.

10:00 am – Jerry's boss calls for a quality opinion on the prospective vendor because purchasing is ready to place a large order that will save the company millions of dollars. He needs a decision immediately. Jerry, obviously having no information to provide, regretfully informs his boss that he was unable to obtain any information of value.

Monday 9:00 am – Jerry arrives at the office of Mr. Jim Savior, an employment-agency counselor.

- Many auditors debate whether they should rent automobiles or rely on the supplier to escort them to and from the plant. Many factors should be taken into account when determining whether to drive or be escorted by a company representative, such as:
  - Is the auditor familiar enough with the area so that he or she will not get lost and waste valuable time?
  - Is there sufficient confidence in the company to assure that transportation to and from the plant will be prompt and the trip objectives not jeopardized?

AUDIT EXECUTION

The actual audit should begin with a brief meeting of the auditor(s) and responsible personnel from the facility, preferably including the managers of quality control and manufacturing. Auditors should establish the objectives of the visit and identify the areas they desire to audit.

Request that knowledgeable personnel be available to answer questions. This will expedite the audit and prevent misunderstandings. Auditors should inquire about plant safety and other policies to assure that they will not be in violation during the visit. This is especially important in plants that are "unionized," because the auditor does not want to be the cause of a union grievance.

An audit manual or checklist should be employed by auditors as a reminder to audit the specific areas that need to be addressed. This helps increase objectivity and decrease subjectivity. It also provides an easy method for taking notes and making observations that be recalled for subsequent report writing.

Auditors should always be diplomatic. They are representing their company and, as such, should put forth the best possible image. To do otherwise could result in the supplier not wanting to do business with your company, even though your company may ultimately want to do business with the supplier.

Auditors should not hesitate to point out concerns or unacceptable conditions throughout the audit. A constructive approach is always the most beneficial to all concerned. Areas that are found to be superior or acceptable should be noted and the escort informed of the status to reinforce quality.

CONCLUDING THE AUDIT

The conclusion of the audit is just as important as the planning. An audit is not considered successfully completed without a concluding session and report.

Frequently, suppliers complain that the auditor departs without revealing results. This situation usually occurs when an auditor has found many deficiencies and feels that it would require his or her full attention for a substantial period of time to work with the supplier and bring the operation up to a satisfactory level.

The audited company is entitled to know what their current situation is in regard to procurement. If the situation is undesirable, the auditor should meet with appropriate management of the company and inform them that conditions are not suitable at this time due to a wide variety of deficiencies that will require substantial efforts to correct. The auditor merely needs to give highlights and recommend that the supplier hire professional consultants who can assist them in developing an acceptable operation.

In cases where the auditor feels that only a few items need to be addressed, these should be detailed in the wrap-up session. If requested, the auditor might provide specific suggestions about how to correct the unacceptable situations.

Another question that frequently arises is whether or not the supplier should be permitted to receive a copy of the auditor's notes and checklists. This is not recommended. A comprehensive wrap-up session that is honest and constructive in nature generally eliminates the need to provide the vendor with copies of auditor notes. Instead, the auditor should provide the supplier with a written report and a neatly completed checklist, after having time to reflect upon the findings.

The auditor should restrict his or her comments to the actual audit findings. While he or she may convey a general quality opinion of the facility, the auditor may not be in a position to state whether the supplier is approved or not. Other factors may need to be taken into consideration before the final approval is given. It would be very embarrassing for the auditor to indicate such approval status and then find out the supplier is not going to be employed due to unsatisfactory pricing, something legal in nature, a material-compatibility problem, or some other reason unknown at the time of the audit wrap-up.

REPORT WRITING

The audit report should provide management with a permanent record of activities and findings. The report should be written as soon after the audit as possible. The longer an individual waits, the less crisp the audit findings are in his or her mind.

Audit reports should be objective and factual in nature. The credibility of an audit will be challenged if subjective comments are made by the auditor. The use of a checklist and a rating system is a valuable aid to the auditor in properly presenting objective findings.

Once the report has been written, it should be shared with the supplier, because this will reinforce an honest relationship.

5 Contractor Audits

Contractor quality-assurance audits are performed to evaluate the status of a manufacturing operation, laboratory, testing service, or any other function performed by one company for another. It is important to recognize the reasons a company employs a contract manufacturing facility so that the auditor can determine what unique elements need to be taken into consideration in performing quality audits of these facilities.

CONTRACT MANUFACTURING RATIONALE

There are many reasons to use contractors. The following are common reasons.

Distribution Advantage

The manufacturing operation of the procuring company may be geographically located in an area that prevents them from being competitive in other areas. For example, a company that manufactures products in the United States may not be cost competitive in Europe or Asia. It may be determined that by manufacturing those products in Europe or Asia via a contract manufacturing arrangement, the company can then market the products competitively. The use of a contract manufacturing operation in these instances also permits the company to fully evaluate the marketing situation without spending large sums of money to build its own manufacturing facilities.

New-Product Introduction

The introduction of new product into the marketplace is a significant expenditure. A company may initially employ a contract manufacturer to minimize the amount of investment in manufacturing equipment and facilities until such time that it is assured the product is or will be successful. This also is an advantage to the contractor who has the equipment needed to manufacture the product, even if the additional business is only temporary.

Production Capacity

A company may not have available the production capacity to accommodate a new product or increased demands for an existing product. In such cases, a contract manufacturing facility may be approached on a temporary basis. A procuring company may continue to contract manufacture this item until the company is confident that the increase in demand for the product is not temporary.

Hazardous Materials

A company may decide that the characteristics of a product do not warrant the risks of manufacturing it in their own facilities. For example, the manufacture of aerosol product has inherent safety risks. A company may decide to employ a contract manufacturer already in that particular business rather than assume the risks itself.

Regulatory Considerations

For certain products, the regulatory situation is of a nature that it may be in the best interest of a company to employ a contract manufacturer who is more experienced in accommodating those requirements. When employing a contract manufacturing facility, the contractor has assumed certain responsibilities; however, the contractor is still manufacturing an item that will bear the name of the company that markets the product. Even though the contractor may assume any cost liabilities if product problems develop, the company procuring the item still risks the exposure of negative publicity if there is a quality problem. Therefore, it is in the best interest of the procuring company to have substantial assurance that the contract manufacturing facility complies with quality standards and regulatory requirements.

The manufacture of a product at an internal facility has the advantage of communication lines between the facility and its management. Problems or situations that occur at an internal facility can be very quickly recognized and addressed. In the case of a contract manufacturing operation, the procuring company normally does not have the daily "hands-on" information available for monitoring product quality. The quality audit, therefore, takes on additional significance in its ability to provide assurance that the contract manufacturer is fulfilling its contractual obligations properly.

AUDIT STEPS

There are three critical steps in performing contractor audits.

Preparation

The auditor needs to review the specifics of the contractual agreement to perform a quality audit efficiently. As European Good Manufacturing Practice (GMP) requirements have long recognized, the specific contractual relationships between the contracting parties must be in writing that clearly delineates the responsibilities of each.

The International Organization for Standardization (ISO) series and new U.S. Quality System Regulation (QSReg.) also place strong emphasis on such formal agreements. It would be substantially embarrassing for someone to audit a contract manufacturing facility only to find that the contractor was not required to perform a specific function. It could be even more embarrassing and problematic if the function were necessary but neither the contractor nor the procuring company was performing the function due to misunderstandings. For example, who will retain samples of the finished product? If the contracting company assumes that the client is retaining samples while the client is assuming that the contractor is retaining samples, none may be retained.

Performance

A contractor audit is somewhat like a supplier audit and an internal-facility audit combined. The supplier-audit approach should be employed from the planning perspective. The auditor should establish a clear purpose for the audit, obtain as much information as possible about the contractor, and employ a formal checklist. As in the case of internal audits, one needs to determine whether announced or unannounced audits should be employed.

In the case of unannounced audits, such a program should be agreed upon with the other company. The performance of a surprise audit at a contractor facility without a previous agreement that such events are permissible could be very damaging to the relationship between the two companies. In general, contract manufacturers do not appreciate surprise audits. They are not recommended.

Wrap-Up and Report Writing

As with supplier and internal audits, a properly executed wrap-up and report is vital to the successful conclusion of a contractor audit. The candid approach that was recommended for concluding supplier audits is appropriate. The corrective-action planning associated with internal audits is appropriate as well.

The final audit report should reflect the findings of the audit from a technical perspective and indicate how well the contractual agreement is proceeding. If there are areas of confusion or misunderstanding between the two companies, these should be clearly indicated in the report.

6 Product Audits

A product audit is a contractor or internal audit that is focused on determining the cause of a problem unique to a product, or a problem that appears unique to a single product. The approach is similar to the one commonly employed by the Food and Drug Administration (FDA) inspectors in the United States for many years. Recently, the FDA has modified their approach, especially for routine audits, by using something called QSIT (Quality System Inspection Technique). QSIT is covered in the next chapter.

Unlike system audits that sample many products in the course of system assessment, the product audit starts with the field-quality profile of one product and proceeds in a failure-investigation manner.

The audit commences with either prior knowledge of a quality problem or analysis of field-quality trends to select products experiencing the most frequent or most concerning customer complaints. If the company is fortunate to not have any complaints of significant frequency or concern, the auditor can use internal manufacturing-nonconformance data to select a product for audit. Keep in mind that you do not need to have a field-quality problem to have a noncompliance problem.

The product audit consists of evaluating all factors that could lead to the actual weakness in the quality system that caused the quality problem. The audit begins with the review of product complaints and, based on the auditor's instincts, can lead into the product-release test results, stability results, specifications, test methods, sampling methods, calibration, manufacturing operations, validations, storage facilities, maintenance procedures, suppliers, and any other factor(s) pertaining to the specific quality problem being investigated.

The easiest way to facilitate the audit is to start with the finished product and proceed backward through the release records. As with system audits, many quality records of different types need to be retrieved. The difference is that on a product audit, all the records from the various systems will be pulled for only one particular product. The information obtained will form a continuous thread throughout all of the quality systems. One can ascertain thereby the entire product profile within the overall quality system. The following is a summary of the approach for performing this type of audit. Greater detail may be found in the audit checklist for this subject.

- Begin with the review of complaint files to determine the types of problems being experienced by customers. Determine whether the problem appears to be unique to one particular product or common across multiple products. If it appears to be a multiple-product situation, the auditor will need to expand the scope to evaluate common component specifications, procedures, validations, lab equipment calibration, personnel, and so on — not just those specific to one product.
- Compare the actual product performance in the field with the product labeling and current specification requirements. Review the change history against the original development information to determine whether changes have deviated too far from the original validated design.

- Determine whether any changes to documents or systems coincide with an increase in complaints.
- In-process and finished-product test results from historical files (including stability results) should be obtained and reviewed to determine trends.
- Test methods should be reviewed to see if changes in the methodology resulted in an inability to detect problems.
- Completed production batch records should be reviewed to determine whether any production-quality problems have occurred. Is the problem limited to one batch? To one shift? Is it recurring? Can a starting point be identified?
- If believed to be warranted, the manufacturing system, associated facility, utility, equipment, software validations, and environmental-control system should be audited.
- If suspected, storage facilities, including distribution centers, should be reviewed to determine whether storage requirements are being followed and whether the product is being handled correctly.
- If components and/or their suppliers are questionable, incoming records should be reviewed extensively for all items employed in the manufacture of the product. If deemed warranted, supplier audits may need to be pursued.
- Consider auditing any other system not previously mentioned if it appears to be a suspect area. Once the root cause of any problem has been determined, the audit needs to be directed in a different direction to determine why the problem was not detected. Various review steps, statistical methods, and possibly even the internal audit program need to be critiqued to determine why an external quality problem was not identified by internal systems.

At this point, someone who has performed failure investigations on product complaints might say that his or her routine procedure is not different from the approach being delineated here as a product audit. They probably have a valid point, assuming that the failure investigation truly pursues the root cause of the problem, its correction, and actions to prevent recurrence. If failure investigations are performed by subject-matter experts, remember that they may or may not be quality-system experts. The ideal situation is to have both capabilities. An experienced quality-system auditor combined with a subject-matter expert comprise a powerful combination. They are much more effective together than either one is independently.

There is, however, one significant vulnerability in using the product-audit approach, and that is the decision that some companies have made to audit only in this manner. The product-audit approach is “reactive” in nature. It pursues the cause of problems that already exist. The systems-audit approach assesses the quality system as a “preventive” approach. Systems audits are aimed at discovering weaknesses so that they can be eliminated and therefore prevent the kinds of quality problems that trigger the need for the product audit.

In the author’s opinion, it is not a matter of choosing between the system-audit and the product-audit approaches, but rather the desirability of performing both. In the healthcare field, with its significant product-liability risks and noncompliance business-interruption risks, we can ill afford to ignore any approach that can provide quality and compliance assurance.

7 QSIT Audits

The previous chapter discussed the performance of product audits. The associated checklist to perform product audits simulates the methodology previously used by the Food and Drug Administration (FDA) to perform inspections.

OLD FDA INSPECTION METHOD

The method of inspection used to begin with a review of the product-complaint-handling system to determine whether it was adequately receiving, processing, and resolving product complaints. During the analysis of the complaint system, specific products were selected and analyzed in great depth. Large quantities (if they existed) of complaints on a particular product were comprehensively audited.

If an audit of the complaint files did not convince the inspector that effective corrective and preventive action had taken place, the inspection would then pursue the following course of action:

1. Review finished-product test results including ongoing stability-testing results.
2. Review rejected-as well as released-product testing data and, in the case of rejections, review corrective and preventive actions.
3. Review the validity of specifications, test methods, and sampling plans.
4. Review batch records for production compliance with manufacturing requirements.
5. Inspect manufacturing and quality-control testing operations.
6. Review engineering and maintenance practices.
7. Review pertinent validation practices.
8. Inspect product-storage facilities and procedures.
9. Investigate supplier quality control and raw-material history specific to the product being audited.

All of these inspection activities were specific to a given product and could lead the inspector into other areas of the quality system if he or she suspected a problem. Normally, the inspector completed the action sequence, then went back to inspect ancillary support functions that had become a concern.

A number of factors resulted in the FDA reviewing the use of this method of inspection:

- Limited resources and limited time to do the inspections. They needed to be more expedient and effective.
- The ISO standards and rewrite of the Quality System Regulation (QSReg — the Good Manufacturing Practices or GMP) for medical devices focused on a quality-system approach to quality and compliance, with heavy emphasis on management responsibility.
- Companies were having continuous individual product problems that were found to be more indicative of an inadequate corrective and preventive action system, with insufficient involvement or support from management. The FDA's solution to this inspection concern

was the evolution of the QSIT approach to inspections. QSIT stands for Quality System Inspection Technique.

NEW FDA INSPECTION METHOD (QSIT)

The QSIT is a methodology that uses a different approach than the previous product audits. The old product approach is being reserved for use when an inspection is initiated in response to a complaint or multiple complaints received by the FDA on a specific product. Routine, or annual, inspections are using the QSIT approach, both on drug and device inspections.

The QSIT process is based on a "top-down" approach, starting with management responsibility, especially those management functions associated with the quality function. The process was designed to address the time constraints placed on field investigators when performing inspections. It is believed that if inspectors focus their effort on the *key elements* of a company's quality system, they can evaluate more efficiently and effectively the general compliance status of the operation.

When an inspection begins by looking at one or more instances of quality problems, and then works back through the records of the system, that is considered a "bottom-up" inspection. While that method may be effective in zeroing on individual problems and the company's response to them, the "top-down" approach allows a view of the company's "systems" for addressing quality up front before inspecting specific product problems.

The "top-down" approach begins by dividing the overall quality system into four key subsystems for device inspections and six subsystems for drug inspections. For medical-device company inspections, seven subsystems are identified. FDA believes that four of the subsystems are the foundation for all seven, so the QSIT only addresses those four. Items 1, 2, 3, and 4 comprise the QSIT device inspection.

1. management responsibility;
2. corrective and preventive action (including medical device reporting, corrections and removals, and medical device tracking);
3. design controls;
4. production and process controls (including sterilization);
5. materials controls;
6. facility and equipment controls; and
7. records or documents and change controls;

For drug firm inspections, the six areas of focus are:

1. quality system,
2. facilities and equipment,
3. materials,
4. production,
5. packaging and labeling, and
6. laboratory control.

Inspection may continue into the other areas as time allows and need indicates. Products that have been known to be problematic will be used as the sampling for the documentation to be reviewed.

Note: Although the FDA focuses on these systems, the company's internal audit system is expected to cover all parts of the system on an annual basis. From a compliance and business-risk perspective, a company cannot rely on auditing only the systems covered in a QSIT inspection as its assurance program for product quality and compliance. The FDA expects these full-scale audits to occur in a timely manner on all parts of the quality system at least once per year. It is routine for the FDA to request a copy of the audit schedule to determine that all sections of the regulations are being addressed by the audit function.

A common thread throughout the QSIT inspection is to determine first if the company has "established" the system by defining and documenting the requirements through policy and procedure. The second step for each facet of the inspection is to request and review objective evidence (e.g., records, data) of compliance with the requirements.

It has always been the FDA's mission to protect the consumer. One way to do that is to perform inspections and assure that a company is not putting a consumer at risk. To assure the effectiveness of these inspections, the FDA inspectors are trained to be proficient in communications and in reviewing records to obtain evidence that could be used against the company if the FDA decides that action is warranted to protect the consumer. The QSIT merely represents a new approach to performing the inspection needed to obtain objective evidence. It is critical for all companies to understand the objectives that each inspector is expected to achieve. The objectives are not just product-quality focused, but, more accurately and appropriately, management focused.

The following are typical objectives of medical device and drug company inspections. Items unique to medical-device inspections have an asterisk (*) following them.

- To verify that a quality policy,* Management Review and quality-audit procedures, quality plan* and quality-system procedures and instructions have been defined and documented.
  Note: FDA will ask for each one of these items and devote a significant amount of time evaluating each of them.
- To verify that a quality policy* and objectives* have been implemented.
  Note: The company must demonstrate how the quality policy is conveyed to personnel and how the objectives of that policy have been implemented. Individuals will be asked to state the quality policy.
- To review the organizational structure to confirm that it includes provisions for responsibilities, authorities, and necessary resources.
  Note: The entire organizational structure will be reviewed, with particular emphasis on quality-reporting relationships. This part of the inspection usually leads to requests for job descriptions, training plans for personnel in those positions, and proof that training has been performed in accordance with the training plans.
- To confirm that a management representative* has been appointed and evaluate the purview of that management representative.
  Note: The management representatives will be interrogated to determine their understanding of their responsibilities and to obtain evidence that they are addressing those responsibilities.
- To verify that Management Reviews, including a review of the suitability and effectiveness of the quality system, are being conducted.
  Note: A Management Review schedule and procedure will be requested. The procedure must include the minimum quality-system aspects that are presented and analyzed at the Management Reviews. Records of the reviews and, possibly review minutes may be requested.

- To verify that quality audits of the quality system, including reaudits of deficient matters, are being conducted.

  Note: The audit schedule and procedures will be comprehensively reviewed to assure that management is aware of the schedule and findings. Quality-audit findings are expected to be a routine Management Review item. The FDA will expect a comprehensive procedure (including checklists) to demonstrate that the FDA does not need to inspect all areas of the quality system because the company is doing so. If the audit system appears to be weak, the FDA will inspect for a longer time and into more areas than the original systems intended to be inspected.
- To evaluate and conclude whether management with executive responsibility ensures that an adequate and effective quality system has been established and maintained.

  Note: The inspector is expected to combine inspection findings into an opinion of management responsibility. The summary will be used to determine not only whether possible observations will be made, but also whether further regulatory actions are justified (e.g., warning letters, consent decrees). It is critical that executive management be able to understand and discuss the quality system. It is no longer acceptable for executive management to defer this responsibility to the head of the quality assurance or operations function. Executive management must understand terminology and the quality system, and demonstrate an awareness of what the status of the quality system is.
- To evaluate the qualifications and training of personnel.

  Note: If personnel are found not to be qualified or trained, product lots can be deemed adulterated by the FDA and subject to recall. Formally approved qualification and training criteria are expected to be in place for each job, and quality records that demonstrate individuals are in compliance to those expectations must exist.

Companies need to be cognizant of the fact that FDA inspectors are looking for patterns and not just individual incidents that can be written as form FD483 observations. Determination of an unacceptable pattern can be used to impose further regulatory action, such as warning letters, recalls, consent decrees, and so on. The following is a list of patterns that an inspector is looking for as they ask questions, review documents, and critique quality records:

- Failure to review and approve procedures properly
- Failure to document the execution of operations
- Failure to review properly documentation generated by operations
- Failure to conduct investigations and resolve discrepancies, failures, deviations, or complaints properly.
- Failure to assess systems properly to assure compliance with GMP and the company's internal requirements.
- Potential for contamination of environment, materials, equipment, laboratories, and so on.
- Failure to validate cleaning procedures
- Inadequate change-control systems for facilities, equipment, processes, specifications, test methods, and so on
- Failure to validate computer-controlled systems or automated equipment
- Release of nonconforming material to operation and distribution
- Inability to retrieve comprehensive and orderly batch records
- High incidence of nonconformances and deviations from actual practice
- Inadequate packaging and labeling controls

- Test methods not validated, or changes to methods not validated
- Failure to retain raw data, or raw data suspect in origin
- Not adhering to stability-test points
- Stability failures occurring and/or not investigated

It is highly recommended that the QSIT be used as a type of audit to prepare management for this type of inspection. Auditors should have direct access to executives to ask them the kinds of questions that surely will be posed by inspectors on QSIT inspections. It is not unusual for FDA inspectors to request to speak with executives and ask them questions. Many companies actually have developed courses for internal training of personnel on how to accommodate inspections; this includes performing trial inspection drills to check for prompt retrieval and presentation of information, as well as proper conduct.

An FDA inspection will proceed much more expediently and with fewer problems if personnel have been trained on what the expectations are and how to satisfy them.

Glossary

Acceptance Criteria The product specifications and limits, such as acceptable quality level and unacceptable quality level, that are necessary for making a decision to accept or reject a lot or batch.[2]

Active Ingredient Any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure of any function of the body of humans or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.[2]

Actual Yield The quantity that is actually produced at any appropriate phase of manufacture, processing, or packaging of a particular drug product.[2] See also *Theoretical Yield*.

Announced Audits An audit that is scheduled with the party to be audited prior to enactment of the audit itself.

ANDA Abbreviated New Drug Application (see generic drug)

ANSI American National Standards Institute.

ANSI/ASQC Q90–94 Series American equivalent to ISO 9000 Series.

Appropriate A requirement that is expected to be implemented or applicable if the failure to implement it could reasonably be expected to result in a product not meeting its specified requirements or the manufacturer not being able to carry out any necessary corrective action.

ASQ American Society for Quality.

Assessment An audit.

Attribute Inspection Inspection whereby either the unit is classified simply as defective or not defective, or the number of defects in the unit of product is counted with respect to a given requirement or set of requirements.[3]

Audit A documented activity performed in accordance with written procedures on a periodic basis to verify, by examination and evaluation of objective evidence, compliance with those elements of a quality-assurance program under review.[1]

Batch A specific quantity of a drug or other material that is intended to have uniform characteristics and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.[2]

Batch Number See *Control Number.*

Calibration A set of operations that establishes, under controlled conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a reference standard.[5]

Certificate of Analysis A listing of actual test results for a particular lot of component, in-process item or finished product.

CFR United States Code of Federal Regulations.

CGMP Current Good Manufacturing Practice. See *GMP*.

Clinical Investigations Evaluation of product with human subjects to obtain data for regulatory submissions.

Complaint Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, or effectiveness of performance of a product after it is released for distribution.[1]

Compliance Activities performed to assure that an operation or company complies with appropriate and pertinent governmental and/or company requirements for drug or medical device manufacture and quality.

Component Any ingredient, material, substance, piece, part, or assembly used during drug or medical device manufacture that is intended to be included in the finished medical device or drug product.[1,2]

Contamination Unintended, nonprocess-related impurities of a chemical or microbiological nature, or of foreign matter, into or onto a material during production, sampling, packaging, repackaging, storage, or transit.

Contractor One who enters into a binding agreement to provide goods or services. A company that provides a custom-designed component, contracted product/packaging-manufacturing operations, or support services. Contractors and suppliers who custom-designed components are viewed as subject to GMP.

Controlled Drug A drug that is subject to the controls and provisions of the United States Controlled Drug Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the United States Controlled Substances Import and Export Act (84 Stat. 1285; U.S.C. 951). Enforced by the DEA. *Note: Many countries have different lists of drugs and medical devices that are "controlled" according to their own regulations.*

Control Number Any distinctive combination of letters or numbers, or both, from which the complete history of the manufacture, control, packaging, and distribution of a production run, lot, or batch of finished medical devices or drug products can be determined.[1, 2]

DEA United States Drug Enforcement Agency.

Design History File (DHF) A compilation of records that describes the design history of a product.

Design Input The physical and performance requirements that are used as a basis for product design.

Design Output The results of a design effort at each design phase and at the end of the total design effort. For devices, the output is the basis for the Device Master Record (DMR).

Design Review A documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.

Design Validation See *Validation (Design)*.

Device History Record (DHR) A compilation of records containing the complete production history of a finished medical device.[1]

Device Industry Manufacturers of medical device products.

Device Master Record (DMR) A compilation of records containing the design, formulation, specification, complete manufacturing procedures, quality-assurance requirements, and labeling of a finished medical device.[1]

Device Product See *Medical Device*.

Drug Product A finished dosage form that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.[2]

EN Abbreviation for CEN/CENELEC Internal Regulations that are European Standards and that bind Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

EPA United States Environmental Protection Agency.

Establish Define, document (in writing or electronically), and implement.

Establishment Inspection Report (EIR) Formal documentation of the inspection activities, information, and findings derived from FDA inspection of a medical device– or drug-manufacturing facility.

FDA United States Food and Drug Administration.

Fiber Any particulate contaminant, with a length at least three times greater than its width.[2]

Finished Device Any medical device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.[1]

FOI United States Freedom of Information Act.

Form FD482 Notice of inspection. Used by the FDA as a formal notice that an inspection is to take place.

Form FD483 Notice of adverse findings. Used by the FDA to record observations for submission to the government and to provide documentation of same to the company inspected.

Gang Printing Printing of different items on the same printing plate.

Generic Drug A drug product approved via an Abbreviated New Drug Application (ANDA) and by definition a drug whose patent has expired.

GMP Good Manufacturing Practices.

Good Manufacturing Practices Regulations, guidelines, or advice published by a recognized body (governmental or nongovernmental) outlining minimum manufacturing, quality-control, and quality-assurance requirements for the preparation of drug or medical device products.

Healthcare Manufacturer Collective term describing a manufacturing company producing pharmaceuticals, diagnostic products, or medical devices.

Impurity Any component present in the active ingredient other than the substance defined as the active ingredient. A contaminant is a particular form of an impurity.

Inactive Ingredient Any component other than an "active ingredient."[2]

In-process Material Any material fabricated, compounded, or derived by chemical reaction that is produced for, and used in, the preparation of a product.

Inspection The procession of measuring, examining, testing, or otherwise comparing the item to requirements.[3]

In Vitro (medical device) A mechanism or item employed for use outside the body. Example, a hearing aid.

In Vivo (medical device) A mechanism or item used inside the body. Example, an artificial heart valve.

ISO International Organization for Standardization.

ISO 9000–9004 Standards for quality systems.

Label All written, printed, or graphic matter on any product, container, or information accompanying a product that provides identification, technical information, and/or usage information.[4]

Lot A batch, or a specified identifiable portion of a batch, having uniform character and quality within specified limits; or, in the case of a drug product produced by a continuous process, a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits.[2]

Lot Number See *Control Number*.

Major Defect A defect, other than a critical defect, that is likely to result in failure or reduction in the suitability of use of a unit for its intended purpose.[3]

Management with Executive Responsibility Those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer's quality policy and quality system.

Manufacturer Any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, or processes a finished medical device or drug product.[1]

Manufacturing Material Any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a by-product constituent produced during the manufacturing process that is present in or on the product as a residue or impurity not by design or intent of the manufacturer.

Medical Device Any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap;
- investigation, replacement, or modification of the anatomy or of a physiological process; and/or
- control of conception

and that does not achieve its principal intended action in or on the human body by pharmaco-logical, immunological, or metabolic means, but which may be assisted in its function by such means.

Minor Defect A defect that is not likely to reduce the material feasibility of the unit of product for its intended purpose or, as departure from established standards, having little bearing on the effective use or operation of the unit.[3]

New Drug Application (NDA) Compilation of documents submitted to the FDA requesting government approval to manufacture and market a new drug.

Nonconformance Nonfulfillment of a specified requirement.

Observation A formal documentation of a nonconforming condition.

Percent Theoretical Yield The ratio of the actual yield to the theoretical yield stated as a percentage. This calculation can be applied to any stage of the manufacturing process or to the total process. See also *Actual Yield* and *Theoretical Yield*.

Pharmaceutical Industry Manufacturers of medicinal products.

Process-Capability Study A determination and evaluation of a particular piece of equipment or process in order to determine its capabilities and limitations.

Process Validation See *Validation (Process/Method)*.

Product The components, manufacturing materials, in-process drugs/devices, finished drugs/devices, and returned drugs/devices.[1]

Product Complaint See *Complaint*.

Proficiency Testing Determination of laboratory testing performance by means of interlaboratory test comparisons.

QSIT (Quality System Inspection Technique) More recent method of inspection employed by the FDA inspectors

Quality Assurance Activities and systems necessary to assure and verify that operations are operating in compliance with predetermined standards, guidelines, and regulations.

Quality Audit A formal review of a product or its associated development process, manufacturing process, equipment, facilities, and systems for conformance with predetermined standards.

Quality Control Test and inspection activities employed to determine the level of conformance of an item to its specification.

Quality Policy The overall intentions and direction of an organization with respect to quality, as established by management with executive responsibility.

Quality System The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Quality System Record (QSR) Procedures and activities that are not specific to a particular type of device (contrasted with Device Master Record [DMR] procedures, which are product specific).

Quality System Regulation (QSReg.) The United States regulation that provides the Good Manufacturing Practices (GMP) for medical devices.

Quarantine The status of materials awaiting release or rejection disposition.

Raw Material See *Component*.

Recall A voluntary or involuntary action or activity that results in the removal of a product from the distribution chain and/or the marketplace.

Recovery Any treatment of materials by a process intended to make them suitable for further use.

Refurbishing The processing or reprocessing of a product to specified requirements.

Remanufacturer Any person who processes, conditions, renovates, repackages, restores, or performs any other act on a finished product that significantly changes the performance or safety specifications, or the intended use.

Remanufacturing Processing, conditioning, renovating, repackaging, restorating, or any other act performed on a product that significantly changes the product's performance, safety specifications, or intended use.[1]

Representative Sample A sample that consists of a number of units that are drawn based on a rational criterion, such as random sampling, that is intended to assure that the sample accurately portrays the material being sampled.[2]

Rework An action taken on a nonconforming product so that it will fulfill the specified requirements before it is released for distribution.

Sampling Method The actual method employed by an individual to obtain or pool the sample from its container.

Sampling Plans A statistical approach or plan to obtain representative samples of an item to ascertain quality.

Seizure Action An activity carried out by the FDA whereby a specific product or series of products are seized and placed in the possession of the United States government to prevent distribution.

Specification Any requirement with which a product, process, service, or any other activity must conform.

Strength The concentration of the drug substances and/or the potency.

Supplier The provider of a component for incorporation into a product or for use in the manufacture of a product.

Surprise Audits The performance of an audit without prior warning being given to the individuals, departments, or facilities to be audited.

Test Technical operation that consists of the determination of one or more characteristics of a given item according to a specified method.

Test Method Specified technical procedure for performing a test.

Theoretical Yield The quantity that would be produced at any appropriate phase of manufacture, processing, or packaging of a particular drug product based upon the quantity of components to be used, in the absence of any loss or error in actual production.[2] See also *Actual Yield* and *Percent Theoretical Yield*.

Unannounced Audits See *Surprise Audits*.

Validation (Design) Establishing by objective evidence that device specifications conform with user needs and intended use(s). Synonymous with Clinical Investigations.[1]

Validation (Process/Method) A formal methodology employed to provide assurance that a process, test method, cleaning method, and so forth can reliably perform its intended function in an acceptable manner (against predetermined specifications).

Vendor A supplier.

Verification Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.[1]

[1] United States Code of Federal Regulations 21 CFR, Section 820.3, Quality System Regulation, Current Good Manufacturing Practices Requirements for Medical Devices

[2] United States Code of Federal Regulations 21 CFR, Section 210.3, Current Good Manufacturing Practices in Manufacturing, Processing, Packing or Holding of Drugs: General

[3] United States Military Standard — 105-E, Sampling Procedures and Tables for Inspection by Attributes.

QUALITY AUDIT CHECKLISTS

Section II

QUALITY AUDIT CHECKLISTS

INTERNAL DEVICE
MFR/DEV AUDIT

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Scope: This checklist should be utilized to audit the internal facilities of a device manufacturer or developer. Internal operations that perform their own supply functions, such as electronic components, printing of materials, and so on, should utilize the appropriate "Supplier" audit checklist as an adjunct to the internal evaluation process.

This checklist covers the following areas:

A. Development and Design Control
B. Contract Review
C. Purchasing
D. Receiving/In-Process-Material Handling and Storage
E. Production/Packaging/In-Process Control
F. Final Inspection
G. Final-Product Handling, Storage, Distribution, Installation, and Servicing
H. Laboratories and Calibration
I. Computer Systems, Documentation Controls, and Quality Records
J. Internal Audits
K. Training
L. Validation
M. Facility Engineering and Maintenance
N. Complaint Handling
O. Medical Device Tracking, Reporting, and Recalls
P. Quality Systems Management and Responsibility

The questions in this checklist include references to:

1. The United States Code of Federal Regulations 21 CFR, Part 820 — Quality System Regulation (QSReg.), Current Good Manufacturing Practice (CGMP) Requirements for Medical Devices.
2. The United States Code of Federal Regulations 21 CFR, Sections 803.17 and 803.18 for Medical Device Reporting
3. The United States Code of Federal Regulations 21 CFR, Section 806.10 for Corrections and Removals (Recalls)
4. The United States Code of Federal Regulations 21 CFR, Section 821.25 for Medical Device Tracking

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

5. The United States Code of Federal Regulations 21 CFR Part 11 — Electronic Records; Electronic Signatures. These questions are located in the Computer Systems, Documentation Controls, and Quality Records section of the checklist.
   Note: References in the checklist column is indicated with squared brackets [ ].
6. International Organization for Standardization (ISO) documents, ISO 9001:1994, Quality Systems — Model for Quality Assurance in Design, Development, Production, Installation and Servicing, and ISO 9001:2000, Quality Management System — Requirements
7. International Organization for Standardization (ISO) documents ISO 13485:1996, Quality systems — Medical Devices — Particular Requirements for the Application of ISO 9001, and ISO 13488:1996, Quality Systems — Medical Devices — Particular Requirements for the Application of ISO 9002
   Note: References to ISO 13488 are indicated in the checklist by parenthesis ( ).
8. International Organization for Standardization (ISO) 10011–1:1990, 2:1991, and 3:1991; Guidelines for Auditing Quality Systems: Auditing; Qualification Criteria for Quality System; and Management of Audit Programmes (American ISO equivalent: ANSI/ASQC Q10011–1, 2, and 3)
   Note: References to this standard are indicated under each appropriate question in the checklist.
9. International Organization for Standardization (ISO) document 17025:1999, General Requirements for the Competence of Testing and Calibration Laboratories
   Note: References to ISO 17025 are indicated in the checklist by arrow brackets < >.

Because internal facility audits may be performed by more than one person, signature spaces are provided at the end of each section to provide a record of each individual auditor's activities.

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Date(s) of Audit _____

Facility Location Name _____

Address _____

Audit Leader Name _____

Title _____

Audit Team Members Name _____

Function on Team _____

Name _____

Function on Team _____

Name _____

Function on Team _____

Name _____

Function on Team _____

Scope of Audit _____

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Applicable Regulations/Standards _____

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Opening Meeting Date _____

Attendees _____

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INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Closing (Wrap-up) Meeting Date _____

Attendees _____

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Audit Report Date Issued _____

Date Response Received _____

Date Response and Action Plan Approved _____

Date Actions Completed _____

Date Completed Actions Verified as Completed _____

Date Completed Actions Verified as Effective _____

Date Closed Out _____

Future Follow-up Items _____

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INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

QUALITY RATING SYSTEM

Rating	*Meaning*	*Interpretation*
3	Excellent	Item/area/system/knowledge is superior
2	Adequate	Item/area/system/knowledge meets basic minimum requirements.
1	Deficient	Item/area/system/knowledge is weak and not up to acceptable standards.
0	Unsatisfactory	Item/area/system/knowledge is missing or of a nature to warrant serious quality/compliance concerns.
NA	Not Applicable	Question is not applicable to type of operation, or item unable to be addressed during the audit.

Comment: Some users of the checklist may find the responses to some questions difficult to quantify on a 0–3 scale and may prefer to use a simple "yes" or "no" approach. In such cases, a "yes" should be assigned a "2" value, and a "no" should be assigned a "0" value.

CHECKLIST RESULTS AND RATING

	Number of Occurrences			
Section	**3s**	**2s**	**1s**	**0s**
A. Development and Design Control				
B. Contract Review				
C. Purchasing				
D. Received/In-Process-Material Handling and Storage				
E. Production/Packaging/In-Process Control				
F. Final Inspection				
G. Final-Product Handling, Storage, Distribution, Installation, and Servicing				
H. Laboratories and Calibration				
I. Computer Systems, Documentation Controls, and Quality Records				
J. Internal Audits				
K. Training				
L. Validation				
M. Facility Engineering and Maintenance				
N. Complaint Handling				
O. Medical Device Tracking, Reporting, and Recalls				
P. Quality-Systems Management and Responsibility				
Totals				

Audit Findings Summary

Number of questions rated excellent ( ) Times 3 = ( )
Number of questions rated adequate ( ) Times 2 = ( )
Number of questions rated deficient ( ) Times 1 = ( )
Number of questions rated unsatisfactory (_____) Times 0 = (_____)

Total Number of Questions Answered = (_____) Rating Total = (_____)

"Rating Total" divided by "Number of Questions Answered" = _____ Audit Rating

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

I. Strengths

1. _____
2. _____
3. _____
4. _____
5. _____

II. Weaknesses

1. _____
2. _____
3. _____
4. _____
5. _____

III. Recommendations

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INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
A. Development and Design Control					
1. For projects relating to new or modified products, service, or processes, is there a written plan that identifies each activity required and the person responsible?	☐ ☐ ☐ ☐ ☐	4.4.1 4.4.2	7.3.1	4.4.1 4.4.2	820.30
2. Do the plans address and define the following:		4.4.1 4.4.2	7.3.1	4.4.1 4.4.2	820.30
a. Purpose/scope of project?	☐ ☐ ☐ ☐ ☐				
b. Strategy for development?	☐ ☐ ☐ ☐ ☐				
c. Configuration management?	☐ ☐ ☐ ☐ ☐				
d. Verification strategy?	☐ ☐ ☐ ☐ ☐				
e. Validation strategy?	☐ ☐ ☐ ☐ ☐				
f. Design standards, methodologies, practices, and conventions to be followed?	☐ ☐ ☐ ☐ ☐				
g. Design tools to be used?	☐ ☐ ☐ ☐ ☐				
h. Document control, approval, and distribution?	☐ ☐ ☐ ☐ ☐				
i. Training strategy?	☐ ☐ ☐ ☐ ☐				
j. Deliverables at each phase of development?	☐ ☐ ☐ ☐ ☐				
k. Acceptance criteria for moving into next phase?	☐ ☐ ☐ ☐ ☐				
l. Interfaces of groups and their responsibilities?	☐ ☐ ☐ ☐ ☐				
Examples: – Marketing—Customer requirements – Engineering—Design requirements – Regulatory—Premarket approval – Purchasing—Supplier requirements – Manufacturing—Pilot runs – Quality Assurance—Testing/Design reviews					
3. Are all design and development plans approved and under revision control?	☐ ☐ ☐ ☐ ☐	4.4.1 4.4.2 4.4.9	7.3.1 7.3.7	4.4.1 4.4.2	820.30
4. Is there a project-development schedule under revision control that identifies tasks, responsibilities, time required, and interrelationships/dependencies between tasks?	☐ ☐ ☐ ☐ ☐	4.4.1 4.4.2	7.3.1	4.4.1 4.4.2	820.30
5. Is appropriate design input obtained to assure the needs of the user and patient (including safety)?	☐ ☐ ☐ ☐ ☐	4.4.4	7.2.1 7.3.2	4.4.4	820.30
6. Is the design output defined in terms that allow an adequate evaluation of conformance to design-input requirements?	☐ ☐ ☐ ☐ ☐	4.4.5	7.3.3	4.4.5	820.30
7. Is there a design review after each phase?	☐ ☐ ☐ ☐ ☐	4.4.6	7.3.4	4.4.6	820.30

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
A. Development and Design Control (continued)					
8. Does the design review address each of the following items:		4.4.6	7.3.4	4.4.6	820.30
a. Comparison of customer needs with technical specifications for materials, products, and processes?	☐ ☐ ☐ ☐ ☐				
b. Validation of the design through prototype tests?	☐ ☐ ☐ ☐ ☐				
c. Ability to perform under expected conditions of use and environments?	☐ ☐ ☐ ☐ ☐				
d. Considerations of unintended uses and misuses?	☐ ☐ ☐ ☐ ☐				
e. Safety and environmental compatibility?	☐ ☐ ☐ ☐ ☐				
f. Compliance with regulatory requirements, national and international standards, and corporate practices?	☐ ☐ ☐ ☐ ☐				
g. Comparisons with competitive designs?	☐ ☐ ☐ ☐ ☐				
h. Comparisons with similar designs, especially analysis of internal and external problem history, to avoid repeating problems?	☐ ☐ ☐ ☐ ☐				
i. Reliability, serviceability, and maintainability?	☐ ☐ ☐ ☐ ☐				
j. Permissible tolerances and comparison with process capabilities?	☐ ☐ ☐ ☐ ☐				
k. Product-acceptance/rejection criteria?	☐ ☐ ☐ ☐ ☐				
l. Installability, ease of assembly, storage needs, shelf life, and disposability?	☐ ☐ ☐ ☐ ☐				
m. Benign failure and fail-safe characteristics?	☐ ☐ ☐ ☐ ☐				
n. Failure modes and effects analyses, and fault tree analysis?	☐ ☐ ☐ ☐ ☐				
o. Ability to diagnose and correct problems?	☐ ☐ ☐ ☐ ☐				
p. Manufacturability of the design, including special process needs, mechanization, automation, assembly, and installation of components?	☐ ☐ ☐ ☐ ☐				
q. Capability to inspect and test the design, including special inspection and test requirements?	☐ ☐ ☐ ☐ ☐				
r. Specification of materials, components, and subassemblies, including approved suppliers?	☐ ☐ ☐ ☐ ☐				
s. Packaging, handling, storage, and shelf-life requirements?	☐ ☐ ☐ ☐ ☐				
t. Safety factors relating to incoming and outgoing items?	☐ ☐ ☐ ☐ ☐				
9. Is there a formal design-verification procedure (including clinical-investigation information) to confirm that the formalized, desired design output is adequate for its intended use?	☐ ☐ ☐ ☐ ☐		4.4.7	7.3.5	4.4.7

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
A. Development and Design Control (continued)					
10. Is there a design validation performed under defined operating conditions that demonstrates the device conforms to the defined user needs and intended uses?	□ □ □ □ □	4.4.8	7.3.6	4.4.8	820.30
11. Is there a procedure to assure the design of components is correctly translated/transferred into production documents?	□ □ □ □ □	4.4.7	7.3.5		820.30
12. Is there a design change-control procedure?	□ □ □ □ □	4.4.9 4.5.2	7.3.7	4.4.9 4.5.2	820.30
13. Is there a market readiness review before launch that addresses the following:					820.30
a. Availability and adequacy of installation, operation, maintenance, and repair manuals?	□ □ □ □ □				
b. Existence of an adequate distribution and customer-service organization?	□ □ □ □ □				
c. Training of field personnel?	□ □ □ □ □				
d. Availability of spare parts?	□ □ □ □ □				
14. Is there a Design History File (record) for each design that demonstrates it was developed in accord with all requirements?	□ □ □ □ □	4.4 4.16	4.2.4	4.4 4.16	820.30
15. Is there a sufficient number of people to address all activities?	□ □ □ □ □	4.1	6.1 6.2.1	4.1 <4.1.5>	820.20 820.25

Total Number of Boxes Checked for Section A 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
B. Contract Review					
1. Are the requirements, including specifications and acceptance criteria, adequately detailed in a contract?	☐ ☐ ☐ ☐ ☐	4.3	5.2 7.2.1	4.3 (4.3) <4.4.1>	
2. Does the contract, or other document, specify how amendments are made and communicated to affected functions?	☐ ☐ ☐ ☐ ☐	4.3	7.2.2	4.3 (4.3) <4.4.1> <4.4.4> <4.4.5>	
3. Is the contract formally agreed to before execution?	☐ ☐ ☐ ☐ ☐	4.3	5.2 7.2	4.3 (4.3) <4.4.1>	
4. Are the contracts periodically reviewed for adequacy?	☐ ☐ ☐ ☐ ☐	4.3	7.2.2	4.3 (4.3) <4.4.2>	
5. Are records of these periodic reviews maintained for a specified period of time?	☐ ☐ ☐ ☐ ☐	4.3 4.16	4.24 7.2.2	4.3 (4.3) <4.4.2>	
6. For standard (noncustom) items, is there a product/service catalog/list that is revision controlled to assure that the contents are current and correct?	☐ ☐ ☐ ☐ ☐	4.3	5.2 7.2.2 7.2.3	4.3 (4.3)	
7. For standard (noncustom) items, does the catalog/list provide enough information to assure the purchaser will receive what is expected?	☐ ☐ ☐ ☐ ☐	4.3	5.2 7.2.1 7.2.3	4.3 (4.3)	
8. Is there a procedure established and being followed that describes how verbal and formal orders are to be processed?	☐ ☐ ☐ ☐ ☐	4.3	7.2.3	4.3 (4.3) <4.4.1>	
9. Is there a procedure for resolving processed-order problems?	☐ ☐ ☐ ☐ ☐	4.3	7.2.3	4.3 (4.3) <4.4.2> <4.7> <4.8>	
10. Are subcontract intentions approved by the customer first?	☐ ☐ ☐ ☐ ☐			<4.5>	

Total Number of Boxes Checked for Section B 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
C. Purchasing					
1. Is there a listing of qualified suppliers?	□ □ □ □ □	4.6.2	7.4.1	4.6.2 (4.6.2) <4.6.1>	820.50
2. Is the methodology used to qualify the supplier documented? Does it include, where appropriate, supplier audits?	□ □ □ □ □	4.6.2	7.4.1	4.6.2 (4.6.2) <4.6.4>	820.50
3. Are purchasing documents reviewed for accuracy and completeness before release to the supplier?	□ □ □ □ □	4.6.3	7.4.2	4.6.3 (4.6.3) <4.6.3>	820.50
4. Is there a clear agreement between the supplier and purchaser on the requirements of the purchase and how such conformance will be verified?	□ □ □ □ □	4.2 4.6.3	7.4.2	4.3 4.6.3 <4.6.3>	820.50
5. Are there agreements with suppliers that commit them to notification of proposed changes on a component?	□ □ □ □ □	4.3 4.6.1	7.4.2	4.6.1 (4.6.1)	820.50
6. Does there appear to be a sufficient number of personnel to address all the activities?	□ □ □ □ □	4.1	6.1	4.1 (4.1) <4.1.5>	820.20 820.25

Total Number of Boxes Checked for Section C 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
D. Received/In-Process-Material Handling and Storage					
1. Are receiving bays designed to avoid intrusion from weather, dust, insects, etc.?	☐ ☐ ☐ ☐ ☐	4.15.2	7.5.5	4.15.2 (4.15.2) <5.8>	820.140
2. Does the receiving quality-control function check incoming shipments against the requirements of the purchase order, specifications, and applicable drawings prior to release to manufacturing?	☐ ☐ ☐ ☐ ☐	4.10.1	7.1 8.1	4.10.1 <4.6.2>	820.80
3. Where appropriate, are material-weight checks made, or counts verified, upon receipt?	☐ ☐ ☐ ☐ ☐	4.10.1	7.1 8.1	4.10.1 <4.6.2>	820.80
4. Are records of receiving activities properly stored?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4	4.16 <4.6.2>	820.80 820.180
5. Are inspected items properly segregated from the material awaiting inspection?	☐ ☐ ☐ ☐ ☐	4.10.1	7.1 8.1	4.10.1 <4.6.2> <5.8>	820.60 820.86 820.140 820.150
6. Is there a procedure to prevent acceptance of material from unqualified suppliers?	☐ ☐ ☐ ☐ ☐	4.6.4	7.4.3	4.6.4 <4.6.1> <4.6.2>	820.50 820.80 820.86
7. Are the sampling plans employed by quality control sufficient?	☐ ☐ ☐ ☐ ☐	4.20	8.1	4.20 (4.20) <4.6.1> <5.7>	820.80 820.250
8. If multiple shipments of the same lot of the same item are received at various points in time, is each one sampled, tested, and released independently?	☐ ☐ ☐ ☐ ☐	4.10.1	7.1 8.1	4.10.1 (4.10.1) <4.6.1>	820.80 820.86 820.140
9. If a received shipment contains more than one lot number for the same item, is each lot tested and released separately?	☐ ☐ ☐ ☐ ☐	4.10	7.1	4.10 <4.6.1>	820.60 820.80 820.86 820.140
10. Is the sampling of received materials performed in a separate area or with proper controls?	☐ ☐ ☐ ☐ ☐	4.15.3	8.1	4.15.3 (4.15.3) <4.6.1>	820.86 820.140
11. Do receiving inspection records indicate acceptance or rejection of incoming material?	☐ ☐ ☐ ☐ ☐	4.10.2 4.13	7.4.3 7.5.3 8.2.4	4.10.1 4.13 (4.13) (4.10.1) <4.6.2>	820.60 820.80 820.86 820.90
12. Is rejected material adequately controlled?	☐ ☐ ☐ ☐ ☐	4.10.1 4.10.2 4.12 4.13	7.4.3 7.5.3 8.2.4 8.3	4.12 4.13 (4.12) (4.13) <4.6.2> <5.8>	820.60 820.86 820.90 820.140

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
D. Received/In-Process-Material Handling and Storage (continued)					
13. Do receiving inspection records reflect the reasons for rejection?	□ □ □ □ □	4.10.2 4.13	7.4.3 7.5.3 8.2.4	4.13 (4.13) <4.6.2>	820.80 820.90
14. Is the cause for rejection of material determined; are corrective and preventive actions initiated; and is follow-up pursued?	□ □ □ □ □	4.13 4.14	7.4.3 7.5.3 8.2.4 8.3 8.5.2 8.5.3	4.13 4.14 (4.13) (4.14) <4.6.2> <4.9> <4.10> <4.11>	820.90 820.100
15. Are component control numbers, material status, and other identifications on the storage containers easily viewable?	□ □ □ □ □	4.8	7.5.3	4.8 (4.8) <4.9>	820.60 820.86
16. Is there an adequate procedure for the handling and disposition of returned goods from customers or distributors?	□ □ □ □ □	4.14	8.3		820.60 820.80 820.86 820.140
17. Is access to stockrooms and materials-storage areas restricted to authorized personnel?	□ □ □ □ □	4.15.3	7.5.5	4.15.3 (4.15.3) <4.6.1> <5.8>	820.150
18. Are materials stored in a manner that will prevent damage, contamination, mix-up, and/or loss?	□ □ □ □ □	4.8 4.10.1 4.15.3	7.5.3	4.8 (4.8) <4.6.1> <5.8>	820.60 820.150
19. Are accountability records kept to permit traceability?	□ □ □ □ □	4.8 4.10 4.16	4.2.4 7.5.3	4.8 4.10 4.16 (4.8) (4.10) (4.16) <5.8>	820.80 820.180
20. Are stocks reinspected and tested at intervals?	□ □ □ □ □	4.15.3	7.5.5	4.15.3 (4.15.3) <4.6.1>	820.150
21. Are stocks rotated and, if not, is there a justifiable reason?	□ □ □ □ □	4.15	7.5.5	4.15 (4.15)	820.150
22. Is the storage for labels distinct and in a proper area?	□ □ □ □ □				820.120 820.140 820.150
23. Is there a sufficient accountability system for labels?	□ □ □ □ □	4.15	7.5.5		820.120 820.140 820.150

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
D. Received/In-Process-Material Handling and Storage (continued)					
24. Is there a reconciliation of labeling issued, used, and returned? *Note: Reconciliation may be waived for art or roll labeling if a 100% inspection is performed during or after completion of finishing operations.*	☐ ☐ ☐ ☐ ☐				820.120 820.140 820.150
25. Is gang-print labeling prohibited unless adequately differentiated by size, shape, or color to assure against possible mix-ups? How about ability to detect such mix-ups?	☐ ☐ ☐ ☐ ☐				820.120 820.140 820.150
26. Are there specified restrictions on authority for access to labels and other labeling?	☐ ☐ ☐ ☐ ☐				820.120 820.150
27. Are labels proofread for accuracy before being released to inventory?	☐ ☐ ☐ ☐ ☐				820.120
28. Are obsolete and outdated printed materials destroyed?	☐ ☐ ☐ ☐ ☐				820.120 820.140 820.150
29. Is there an adequate procedure governing the return and salvage of products?	☐ ☐ ☐ ☐ ☐			4.8 (4.8)	820.140
30. Does there appear to be a sufficient number of personnel to address all activities?	☐ ☐ ☐ ☐ ☐	4.1	6.1 6.2.1	4.1 (4.1) <4.1.5>	820.20 820.25

Total Number of Boxes Checked for Section D 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
E. Production/Packaging/In-Process Control					
1. Do the production employees appear to be neat, clean, suitably attired, organized, and operating efficiently?	☐ ☐ ☐ ☐ ☐	4.9 4.18	6.2.2 7.5.1	4.9 4.18 (4.9) (4.18)	820.25 820.70
2. Are there written procedures for production and process control?	☐ ☐ ☐ ☐ ☐	4.9	4.2.3 7.5.1 7.5.2	4.9 (4.9)	820.70
3. Are the in-process procedures adequate for control of fabrication and services?	☐ ☐ ☐ ☐ ☐	4.9	4.2.3 7.5.1 7.5.2	4.9 (4.9)	820.70
4. Are the written procedures being followed?	☐ ☐ ☐ ☐ ☐	4.9	4.2.3 7.5.1	4.9 (4.9)	820.70
5. Does the production equipment appear to be appropriately designed, constructed, and maintained?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1 7.5.2	4.9 (4.9)	820.70 820.75
6. Are utensils cleaned to prevent contamination between different product usages?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	820.70
7. Are production areas sufficient in size, construction, and location to accommodate the needs of the intended operation, including environmental requirements?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	820.70
8. Are appropriate exhaust and vacuum systems employed in operations to minimize air contamination?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	820.70
9. Are equipment-cleaning/use logs and schedules being maintained?	☐ ☐ ☐ ☐ ☐	4.9 4.16	4.2.4 7.5.1	4.9 (4.9)	820.70
10. Are production records properly assembled and sufficient in the following content:		4.8 4.9 4.16	4.2.4 7.5.1 7.5.2 7.5.3	4.8 4.9 4.16 (4.8) (4.9) (4.16)	820.40 820.70 820.184
a. Is each prepared, dated, and signed in full signature by one person and independently checked, dated, and signed by a second person?	☐ ☐ ☐ ☐ ☐				
b. Are the name, strength, and description of the dosage form included?	☐ ☐ ☐ ☐ ☐				
c. Are the name, weight, and measure of each active ingredient, and the total weight indicated?	☐ ☐ ☐ ☐ ☐				
d. Is a complete list of components provided?	☐ ☐ ☐ ☐ ☐				
e. Is an accurate statement of the correct measure or weight of each component made? Is the same weighing system used for each component?	☐ ☐ ☐ ☐ ☐				
f. Are statements made concerning any calculated excess of components?	☐ ☐ ☐ ☐ ☐				
g. Is the theoretical weight or measure at appropriate phases of production indicated?	☐ ☐ ☐ ☐ ☐				

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
	3 2 1 0 NA				
E. Production/Packaging/In-Process Control (continued)					
h. Is there a description of the drug containers, closures, and packaging materials, including a specimen or copy of each label and other labeling?	☐ ☐ ☐ ☐ ☐				
i. Are there complete manufacturing and control instructions that include any special notations or precautions that are needed?	☐ ☐ ☐ ☐ ☐				
j. Is there documentation that each significant step in the manufacture, packaging or holding was accomplished, including:					
i. Dates?	☐ ☐ ☐ ☐ ☐				
ii. Identity of major equipment and lines used?	☐ ☐ ☐ ☐ ☐				
iii. Identification of each batch of component used?	☐ ☐ ☐ ☐ ☐				
iv. Weights and measures of components used?	☐ ☐ ☐ ☐ ☐				
v. In-process laboratory control results?	☐ ☐ ☐ ☐ ☐				
vi. Inspection of the packaging and labeling area before and after use?	☐ ☐ ☐ ☐ ☐				
k. Where environmental conditions can prevent a product from satisfying requirements, are such environmental conditions monitored and recorded for traceability on a per-lot/batch basis?	☐ ☐ ☐ ☐ ☐				
11. Are line-clearance procedures employed to prevent packaging and labeling mix-ups?	☐ ☐ ☐ ☐ ☐	4.8 4.9	4.2.3 7.5.1	4.8 4.9 (4.8) (4.9)	820.60 820.70 820.140
12. Are there acceptable written procedures for reprocessing batches?	☐ ☐ ☐ ☐ ☐	4.9 4.13.1	4.2.3 7.5.1 7.5.2 8.3	4.9 4.13.1 (4.9) (4.13.1)	820.70 820.75 820.90
13. Are the batch records and process "limits" information kept at the workstations during the entire operation? Are the directions strictly followed?	☐ ☐ ☐ ☐ ☐	4.9 4.16	4.2.4 7.5.1	4.9 4.16 (4.9) (4.16)	820.40 820.70
14. Have time limitations on the holding of processing and in-process items been established, and are they being adhered to?	☐ ☐ ☐ ☐ ☐	4.9 4.16	4.2.4 7.5.1 7.5.2	4.9 4.16 (4.9) (4.16)	820.70 820.75
15. Are changes to the issued batch records approved prior to the start of work and documented on the batch records?	☐ ☐ ☐ ☐ ☐	4.4 4.5.2 4.5.3 4.9 4.16	4.2.3 4.2.4 7.5.1	4.4 4.5.2 4.5.3 4.9 4.16 (4.4) (4.5.2) (4.5.3) (4.9) (4.16)	820.40 820.70 820.75

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
E. Production/Packaging/In-Process Control (continued)					
16. Are proper gowning techniques and coverings employed?	□ □ □ □ □	4.9	7.5.1	4.9 (4.9)	820.25 820.70
17. Do the production employees use acceptable techniques?	□ □ □ □ □	4.9 4.18	7.5.1	4.9 4.18 (4.9) (4.18)	820.25 820.70 820.75
18. Are bagged or boxed components stored off the floor?	□ □ □ □ □				820.140
19. Are lubricants and coolants controlled properly so that they cannot come into contact with product containers, closures, in-process materials, or finished products?	□ □ □ □ □	4.9	7.5.1	4.9	820.70 820.184
20. Is issued labeling examined for identity, correct expiration date, control number, storage conditions, handling instructions, and additional processing instructions?	□ □ □ □ □				820.60 820.70 820.140 820.184
21. Is the aforementioned labeling inspection documented to include the date and person performing the inspection? Is the inspection included in the history record?	□ □ □ □ □				820.70 820.120 820.130 820.184
22. Are packaging lines spatially or physically separated in a manner designed to prevent mix-ups?	□ □ □ □ □	4.9	7.5.1	4.9 (4.9)	820.60 820.70 820.120
23. Do all components, in-process and final-product items reflect the inspection/testing "status"?	□ □ □ □ □	4.8 4.10.2 4.10.3 4.12	7.5.1 7.5.3	4.8 4.10.2 4.10.3 4.12 (4.8) (4.10.2) (4.10.3) (4.12)	820.86
24. Are filled containers, or other unlabeled product, that are set aside and held for subsequent labeling stored and identified properly to prevent mix-ups? (This identification must include the names, strengths, quantities of contents, and lot or control numbers of the containers/products.)	□ □ □ □ □	4.9	7.5.1	4.9 (4.9)	820.60 820.70 820.140 820.150
25. Are in-process materials "held" pending inspection/testing results?	□ □ □ □ □	4.10.23 4.12	7.5.3 8.2.4	4.10.3 (4.10.3) 4.12 (4.12)	820.20 820.80 820.86
26. Are charts used for monitoring time, temperature, pressure, etc., and are they filed properly?	□ □ □ □ □	4.9 4.16	4.2.4 7.5.1	4.9 4.16 (4.9) (4.16)	820.70 820.75 820.184

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
	3 2 1 0 NA				
E. Production/Packaging/In-Process Control (continued)					
27. Is there a procedure to inspect manufacturing and control systems periodically, and are the inspections documented?	☐ ☐ ☐ ☐ ☐	4.9 4.16	4.2.4 7.5.1	4.9 4.16 (4.9) (4.16)	820.70
28. When nonemployees such as visitors are in the area, are they observed by the designated responsible person?	☐ ☐ ☐ ☐ ☐				820.25
29. Does there appear to be a sufficient number of personnel to address all of the activities?	☐ ☐ ☐ ☐ ☐	4.1	6.1 6.2.1	4.1 (4.1)	820.20 820.25

Total Number of Boxes Checked for Section E 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
F. Final Inspection					
1. Is there a final inspection performed by quality control on a batch-by-batch basis?	□ □ □ □ □	4.10.3 4.10.4	8.2.4	4.10.3 4.10.4 (4.10.3) (4.10.4)	820.80 820.86
2. Does quality assurance approve/reject product manufactured, processed, packaged, or held under contract by another company?	□ □ □ □ □	4.6.2 4.6.4 4.7	7.4.1 7.4.3 7.5.4	4.6.2 4.6.4 4.7 (4.6.2) (4.6.4) (4.7)	820.20 820.80
3. Does quality control have written procedures to assure that production records are reviewed prior to release?	□ □ □ □ □	4.10.4 4.16	4.2.4 8.2.4	4.10.4 4.16 (4.10.4) (4.16)	820.80 820.184
4. Is there an adequate ongoing marketed-product stability program?	□ □ □ □ □	4.13			
5. Is there a thorough investigation of any discrepancies found during the final review of the production documents?	□ □ □ □ □	4.13.1	8.3	4.13 4.13.1 (4.13) (4.13.1) <4.10>	820.90 820.100 820.184
6. Is the product checked for correct expiration dating?	□ □ □ □ □	4.8	7.5.3		820.60 820.80 820.184
7. Are records of inspection and test data maintained? Do they include the identity of the person performing the inspection or test?	□ □ □ □ □	4.10.5 4.16	4.2.4 7.5.3 8.2.4	4.10.5 4.16 (4.10.5) (4.16) <4.12>	820.80
8. Are inspection and test activities carried out by personnel independent of those responsible for the work being performed?	□ □ □ □ □	4.1.2.1 4.10	5.5.1	4.1 (4.1) 4.10 (4.10)	820.5 820.20
9. Are valid sampling plans used?	□ □ □ □ □	4.20	8.1	4.20 (4.20) <5.4.4> <5.4.5> <5.7>	820.250
10. Do the sampling procedures specify the manner in which the samples are to be obtained and by whom?	□ □ □ □ □	4.20	8.1	4.20 (4.20) <5.7>	820.250

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
F. Final Inspection (continued)					
11. Is there a classification of defects?	☐ ☐ ☐ ☐ ☐	4.10.5	7.1 8.1	4.10.5 (4.10.5)	820.80 820.181
12. Are reserve samples of finished products maintained to verify product-complaint validity?	☐ ☐ ☐ ☐ ☐				820.198
13. Have the accuracy, sensitivity, specificity, and reproducibility of test methods been demonstrated via validation?	☐ ☐ ☐ ☐ ☐	4.11	7.6	4.11 (4.11) <5.4>	820.72 820.80
14. In cases of final-product rejections that result in reprocessing, is another complete final inspection performed?	☐ ☐ ☐ ☐ ☐	4.10.4 4.13.2	8.2.4 8.3	4.10.4 4.13.2 (4.10.4) (4.13.2)	820.70 820.80 820.90
15. In cases where a product does not meet performance specifications, is there a formal investigation, including regulatory-requirement considerations, with identification/follow up of corrective/preventive actions to be taken?	☐ ☐ ☐ ☐ ☐	4.13.2 4.14	8.3 8.5.2 8.5.3	4.13.2 4.14 (4.13.2) (4.14) <4.9> <4.10> <4.11>	820.90 820.100
16. Does there appear to be a sufficient number of personnel to address all of the activities?	☐ ☐ ☐ ☐ ☐	4.1	6.1	4.1 (4.1) <4.1.5>	820.20 820.25

Total Number of Boxes Checked for Section F 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
	3 2 1 0 NA				
G. Final-Product Handling, Storage, Distribution, Installation, and Servicing					
1. Is a checklist used to verify shipping requirements?	☐ ☐ ☐ ☐ ☐				820.160
2. Is product configuration verified prior to shipments?	☐ ☐ ☐ ☐ ☐	4.16	7.55		820.60 820.86 820.160
3. Do packing and shipping records identify the individuals performing and inspecting the shipping operations?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4 7.5.5		820.160
4. Are adequate storage facilities available and in use to safeguard the quality of the product between final acceptance and shipping?	☐ ☐ ☐ ☐ ☐	4.15.3	7.5.5	4.15.3 (4.15.3)	820.86 820.140 820.150
5. Is a rotated-stock system employed to assure that oldest approved devices are shipped first?	☐ ☐ ☐ ☐ ☐	4.15.1	7.5.5		820.150
6. Are the packing and shipping containers acceptable to protect the product?	☐ ☐ ☐ ☐ ☐	4.15.4	7.5.5	4.15.4 (4.15.4)	820.130
7. Is there a system to assure that only products approved for release are distributed?	☐ ☐ ☐ ☐ ☐	4.12 4.13 4.15.5	7.5.3 7.5.5 8.3	4.12 4.13 4.15.5 (4.12) (4.13) (4.15.5)	820.86 820.160
8. Do distribution records indicate the location of the following:		4.16	4.2.4		820.160
a. Name and address of the consignee?	☐ ☐ ☐ ☐ ☐				
b. Date shipped?	☐ ☐ ☐ ☐ ☐				
c. Name and quantity of the item?	☐ ☐ ☐ ☐ ☐				
d. Control numbers of the item?	☐ ☐ ☐ ☐ ☐				
9. Is there an adequate recall procedure?	☐ ☐ ☐ ☐ ☐			4.8 4.14 (4.8) (4.14)	820.60 820.65 820.160 820.180 820.184
10. Are there an acceptable procedure and records verifying correct installation of devices?	☐ ☐ ☐ ☐ ☐	4.8 4.9	7.5.1 7.5.3	4.8 4.9 (4.8) (4.9)	80.170
11. Is there an adequate backup system of spare parts, competent servicing, etc.?	☐ ☐ ☐ ☐ ☐	4.19	7.5.1	4.19	80.200
12. Are installation and service instructions for use suitable for the intended reader?	☐ ☐ ☐ ☐ ☐	4.19	7.5.1	4.19 (4.19)	820.170 820.200

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
	3 2 1 0 NA				
G. Final-Product Handling, Storage, Distribution, Installation, and Servicing (continued)					
13. Are appropriate records of servicing maintained?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4 7.5.1 7.5.3	4.16 (4.16)	820.200
14. Are there sufficient controls and Validation of field or field-service measurement and test equipment?	☐ ☐ ☐ ☐ ☐	4.11 4.19	7.5.1 7.6	4.11 4.19 (4.11) (4.19)	820.72
15. Does there appear to be a sufficient number of people available to address all of the activities?	☐ ☐ ☐ ☐ ☐	4.1	6.1	4.1 (4.1)	820.20 820.25

Total Number of Boxes Checked for Section G 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
H. Laboratories and Calibration					
1. Are the laboratories adequate?	□ □ □ □ □	4.11	7.6	4.11 (4.11) <5.3> <5.5>	820.20 820.72 820.80
2. Do the facilities have adequate equipment and associated controls for the performance of testing and inspection functions?	□ □ □ □ □	4.11	7.6	4.11 (4.11) <5.3> <5.5>	820.72
3. Are test procedures and results properly documented?	□ □ □ □ □	4.10.1 4.10.2	7.1 7.5.3 8.1 8.2.4	4.10.1 4.10.2 (4.10.1) (4.10.2) <5.4> <5.5> <5.10>	820.80 820.184
4. Is there an index of testing documents?	□ □ □ □ □	4.10.1 4.10.2	7.1 8.1	4.10.1 4.10.2 (4.10.1) (4.10.2) <5.4>	820.80
5. Are there specific procedures that address the identification, collection, handling, storage, treatment, and disposal of samples?	□ □ □ □ □	4.2 4.10		<5.4> <5.7>	
6. Are raw-material file samples maintained for future reference?	□ □ □ □ □			<5.6> <5.7>	
7. Are the laboratory reagents and other chemical supplies identified, properly stored, and expiration dated?	□ □ □ □ □			<5.3> <5.4> <5.5> <5.6>	
8. Are the instruments requiring calibration:		4.11	7.6 8.1	4.11 (4.11)	820.72
a. Maintained according to the calibration procedures?	□ □ □ □ □			<5.3> <5.4>	
b. Identified to reflect the date due for net calibration?	□ □ □ □ □			<5.5>	
c. Stored properly?	□ □ □ □ □			<5.6>	
d. Calibrated to traceable standards?	□ □ □ □ □				
9. Does there appear to be a sufficient number of personnel to address all of the activities?	□ □ □ □ □	4.1	6.1	4.1 (4.1) <4.1.5>	820.20 820.25

Total Number of Boxes Checked for Section H 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
	3 2 1 0 NA				
I. Computer Systems, Documentation Controls, and Quality Records					
1. Are adequate controls in effect to assure that current drawings, change notices, and specifications are available at the place of the operations?	☐ ☐ ☐ ☐ ☐	4.5.1 4.5.2	4.2.3	4.5.1 4.5.2 (4.5.1) (4.5.2) <4.3.1>	820.40
2. Are the documents up-to-date, and are unneeded/obsolete documents removed from use?	☐ ☐ ☐ ☐ ☐	4.5.1 4.5.2	4.2.3	4.5.1 4.5.2 (4.5.1) (4.5.2) <4.3.2>	820.40
3. Is at least one copy of each document, including obsolete documents, retained for at least the life of the product?	☐ ☐ ☐ ☐ ☐	4.5.2	4.2.3 7.2.1 7.3.2	4.5.2 (4.5.2)	820.40 820.180
4. Are the documents comprehensive in context?	☐ ☐ ☐ ☐ ☐	4.2 4.4.4	4.2.3 7.2.1 7.3.2	4.2 4.4.4 (4.2) <4.3.1>	820.40
5. Do written procedures exist governing a document change-control system, and are they being followed?	☐ ☐ ☐ ☐ ☐	4.5	4.2.3	4.5 (4.5) <4.3.3>	820.40
6. Are changes evaluated to determine if a regulatory submission is required?	☐ ☐ ☐ ☐ ☐				820.40
7. Is there a list of "current" documents?	☐ ☐ ☐ ☐ ☐				820.40
8. Are production records retained for appropriate time periods?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4	4.16 (4.16)	820.180
9. Is there a product "master record" for each product, and does it include:					820.181
a. Production specifications?	☐ ☐ ☐ ☐ ☐				
b. Product drawings?	☐ ☐ ☐ ☐ ☐				
c. Product composition?	☐ ☐ ☐ ☐ ☐				
d. Product formulation?	☐ ☐ ☐ ☐ ☐				
e. Compendial references?	☐ ☐ ☐ ☐ ☐				
f. Component specifications?	☐ ☐ ☐ ☐ ☐				
g. Production-process specifications?	☐ ☐ ☐ ☐ ☐				
h. Production equipment?	☐ ☐ ☐ ☐ ☐				
i. Special precautions?	☐ ☐ ☐ ☐ ☐				
j. Production methods?	☐ ☐ ☐ ☐ ☐				
k. Cleaning methods?	☐ ☐ ☐ ☐ ☐				
l. Production procedures?	☐ ☐ ☐ ☐ ☐				
m. Production environmental specifications?	☐ ☐ ☐ ☐ ☐				

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
	3 2 1 0 NA				
I. Computer Systems, Documentation Controls, and Quality Records (continued)					
n. Quality-assurance procedures?	☐ ☐ ☐ ☐ ☐				
o. Quality-assurance specifications?	☐ ☐ ☐ ☐ ☐				
p. Quality-assurance checks peq.Expected yields?	☐ ☐ ☐ ☐ ☐				
r. Quality-assurance apparatus used?	☐ ☐ ☐ ☐ ☐				
s. Packaging and labeling specifications?	☐ ☐ ☐ ☐ ☐				
t. Packaging and labeling methods?	☐ ☐ ☐ ☐ ☐				
u. Packaging and labeling procedures?	☐ ☐ ☐ ☐ ☐				
v. Full information on components, suppliers, and specifications?	☐ ☐ ☐ ☐ ☐				
w. Copies of critical-component supplier agreements?	☐ ☐ ☐ ☐ ☐				
x. Copies of labels, labeling, and associated labeling procedures?	☐ ☐ ☐ ☐ ☐				
y. Storage conditions?	☐ ☐ ☐ ☐ ☐				
z. Shelf-life information?	☐ ☐ ☐ ☐ ☐				
	☐ ☐ ☐ ☐ ☐				
10. Does a product "history record" exist for each batch of product, and does it include the following:		4.9 4.16	4.2.4 7.5.1 7.5.2	4.9 4.16	
a. Date and times of manufacture?	☐ ☐ ☐ ☐ ☐				
b. Identity of equipment used?	☐ ☐ ☐ ☐ ☐				
c. Quantity released for distribution?	☐ ☐ ☐ ☐ ☐				
d. Control number used?	☐ ☐ ☐ ☐ ☐				
e. Specific label used?	☐ ☐ ☐ ☐ ☐				
f. Control number of each component used in the manufacture of the item?	☐ ☐ ☐ ☐ ☐				
g. Weights and measure units of each component used?	☐ ☐ ☐ ☐ ☐				
h. Acceptance record of the components?	☐ ☐ ☐ ☐ ☐				
i. Inspections and test results, dates, and signatures of individuals performing the inspection?	☐ ☐ ☐ ☐ ☐				
j. Line-clearance sign-off?	☐ ☐ ☐ ☐ ☐				
k. Complete labeling-control records?	☐ ☐ ☐ ☐ ☐				
l. Sampling performed?	☐ ☐ ☐ ☐ ☐				
m. Identification of persons performing and supervising significant steps?	☐ ☐ ☐ ☐ ☐				
n. Product yield versus theoretical yield?	☐ ☐ ☐ ☐ ☐				
o. Any deviations/investigations made?	☐ ☐ ☐ ☐ ☐				
11. Is there a Quality System Record (QSR) that is a listing of non-product-specific documents, organized by type (e.g., maintenance procedures, manufacturing procedures, environmental monitoring procedures)?	☐ ☐ ☐ ☐ ☐				

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
I. Computer Systems, Documentation Controls, and Quality Records (continued)					
12. Are records of activities properly generated and maintained to provide evidence of conformity to requirements?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4	4.16 (4.16) <4.12> <5.10>	820.180
13. Are the records legible, readily identifiable, and easily retrievable?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4	4.16 (4.16) <4.12>	
14. Is there a procedure that describes how to make changes to entry errors?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4	(4.16) <4.12>	
15. Is there an established retention schedule for quality records, and does it include the controls for identification, storage, and protection?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4	(4.16) <4.12>	
16. Does there appear to be a sufficient number of personnel to address all of the activities?	☐ ☐ ☐ ☐ ☐	4.1	6.1	4.1 (4.1) <4.1.5>	820.20 820.25

Note: Complete the following checklist questions if the computer system creates, modifies, maintains, stores, archives, retrieves, transmits, records, or documents data, or the computer system produces or stores data, records, or documents used in FDA submissions.

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR [Part 11]
17. Does the computer system have the ability to detect invalid or altered records?	☐ ☐ ☐ ☐ ☐				[11.10a]
18. Can accurate and complete records (including metadata) be generated in human-readable and electronic forms, such as screen display or printout, or copied to a media for review?	☐ ☐ ☐ ☐ ☐				[11.10b]
19. Does a retrieval mechanism exist to ensure the records (including the metadata) are available throughout the entire record-retention period?	☐ ☐ ☐ ☐ ☐				[11.10c]
20. Are controls, such as password AND user identification, in place to limit access to the computer system?	☐ ☐ ☐ ☐ ☐				[11.10d]
21. Does the computer system generate secure computer-generated audit-trail information?	☐ ☐ ☐ ☐ ☐				[11.10e]
22. Does the audit trail capture operator entries or actions that create, modify, or delete a record?	☐ ☐ ☐ ☐ ☐				[11.10e]
23. Does the audit trail have User ID, time, and date stamps?	☐ ☐ ☐ ☐ ☐				[11.10e]

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR [Part 11]
	3 2 1 0 NA				
I. Computer Systems, Documentation Controls, and Quality Records (continued)					
24. Is the original data still accessible and not obscured for records that have been changed?	☐ ☐ ☐ ☐ ☐				[11.10e]
25. Are electronic audit trails kept as long as the respective record?	☐ ☐ ☐ ☐ ☐				[11.10e]
26. Are electronic audit trails available for FDA review and copying?	☐ ☐ ☐ ☐ ☐				[11.10e]
27. Does the computer system (or systems) force the sequence of process steps or events during operations (as applicable)?	☐ ☐ ☐ ☐ ☐				[11.10f]
28. Does the computer system (or systems) control these sequences?	☐ ☐ ☐ ☐ ☐				[11.10f]
29. Are there system checks, including authorization, level of access, and privileges, for access to the computer system (or systems)?	☐ ☐ ☐ ☐ ☐				[11.10g]
30. Are there system checks to verify input-device identification (as applicable)?	☐ ☐ ☐ ☐ ☐				[11.10h]
31. Is access to the system and records controlled by a designated security unit (i.e., closed system)?	☐ ☐ ☐ ☐ ☐				[11.30]
32. For an OPEN system, is document encryption (or alternative) used to protect confidentiality of the electronic records during transfer?	☐ ☐ ☐ ☐ ☐				[11.30]
33. For an OPEN system, are digital signatures (or alternative) used to protect the authenticity, confidentiality, and integrity of the electronic records of the systems?	☐ ☐ ☐ ☐ ☐				[11.30]
If the computer system uses electronic signatures, continue with the following questions.					
34. Is the electronic signature indicated on screen displays, printouts, and other human-readable formats?	☐ ☐ ☐ ☐ ☐				[11.50]
35. Does the electronic signature contain the printed name of the signer, date and time of the signing, and the meaning (review, approval, authorship) of the signature?	☐ ☐ ☐ ☐ ☐				[11.50]
36. Is the electronic or handwritten signature linked to the associated record such that it may not be removed, copied, or transferred by ordinary means, or repudiated?	☐ ☐ ☐ ☐ ☐				[11.70]
37. Are the e-signatures unique to the user only?	☐ ☐ ☐ ☐ ☐				[11.100a]

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR [Part 11]
	3 2 1 0 NA				
I. Computer Systems, Documentation Controls, and Quality Records (continued)					
38. Are there procedures/mechanisms to prevent user IDs from being reused, reissued, or shared?	☐ ☐ ☐ ☐ ☐				[11.100b]
39. Do all nonbiometric signatures contain, at a minimum, 2 components, such as a user ID and password?	☐ ☐ ☐ ☐ ☐				[11.200a]
40. Does the computer system enforce the 2 components for a single e-signature event?	☐ ☐ ☐ ☐ ☐				[11.200a]
41. Does the computer system have a mechanism to terminate an extended idle session during a continuous session when an individual could execute a series of e-signatures?	☐ ☐ ☐ ☐ ☐				[11.200a]
42. Does the computer-system design prevent another individual from altering a signed record, thus leaving the original individual's e-signature intact?	☐ ☐ ☐ ☐ ☐				[11.200a]
43. Is the password encrypted?	☐ ☐ ☐ ☐ ☐				[11.200a]
44. Does the system force the user to reset passwords after the initial administration setting?	☐ ☐ ☐ ☐ ☐				[11.200a]
45. Does the biometric signature capture an individual's unique physical feature or action (as applicable)?	☐ ☐ ☐ ☐ ☐				[11.200b]
46. Is there a control system/procedure/computer-system design to ensure that passwords and/or ID tokens are aged or not reissued?	☐ ☐ ☐ ☐ ☐				[11.300b]
47. Is there a control system/procedure that ensures the ID/password combinations are unique and revised periodically (e.g., every 90 days)?	☐ ☐ ☐ ☐ ☐				[11.300b]
48. Does the computer-system design include detection procedures/alarms to detect and report attempted security breaches?	☐ ☐ ☐ ☐ ☐				[11.300d]
49. Is there a procedure(s) to back up and restore, archive, and retrieve data/records from the computer system?	☐ ☐ ☐ ☐ ☐				[11.10c]
50. Is there a procedure(s) for computer-system security? Does it include user access and responsibility?	☐ ☐ ☐ ☐ ☐				[11.10d]
51. Is there documented evidence of appropriate qualifications and training of system developers, users (supplier based), and maintenance personnel?	☐ ☐ ☐ ☐ ☐				[11.10I]
52. Is there a procedure(s) in place governing access to and use of documents containing sensitive information (e.g., password maintenance)?	☐ ☐ ☐ ☐ ☐				[11.10k]

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR [Part 11]
	3 2 1 0 NA				
I. Computer Systems, Documentation Controls, and Quality Records (continued)					
53. Is there a procedure(s) for change control of computer-system documentation, including audit trail?	□ □ □ □ □				[11.10k]
54. Is there a procedure(s) to verify and document individual identity prior to issuing an electronic signature (supplier based)?	□ □ □ □ □				[11.100b]
55. Is there a procedure to limit use of electronic signatures to the genuine owner only (supplier based)?	□ □ □ □ □				[11.200b]
56. Is there a procedure(s) to periodically check the ID code and password issuance (supplier based)?	□ □ □ □ □				[11.300a]

Total Number of Boxes Checked for Section I 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
J. Internal Audits					
1. Is there a formal procedure for performing internal audits? ISO 10011–3, Part 4.6.3	☐ ☐ ☐ ☐ ☐	4.1 4.17	5.5.1 5.6.1 8.2.2 8.5.1	4.1 4.17 (4.1) (4.17) <4.13>	820.20 820.22
2. Are audits performed by individuals not having direct responsibility for that which is being audited? ISO 10011–1, Part 4.2.1.4 ISO 10011–3, Part 4.1	☐ ☐ ☐ ☐ ☐	4.17	8.2.2	4.17 (4.17) <4.13>	820.22
3. If the audit team includes experts with specialized background, auditor trainees, or observers, are they indicated as such in the audit report and not listed as auditors? ISO 10011–1, Part 4.2.1.1	☐ ☐ ☐ ☐ ☐	4.17	8.2.2	4.17 (4.17) <4.13>	
4. Does the frequency of audits take into consideration significant changes in management, organization, techniques, or technologies that could affect the results of previous audits? ISO 10011–1, Part 5.1.2	☐ ☐ ☐ ☐ ☐	4.17	5.6.2 8.2.2	4.17 (4.17) <4.13>	
5. Is there an audit plan that includes the following: a. Objective and scope of audit? b. Identification of intended reference standards/regulations to be used on the audit? c. Identification of audit team members? d. Date and place of audit? e. Agenda of items to be audited? f. Identification of the individuals having direct responsibility for the areas to be audited? g. Expected time and duration for each audit activity? h. An opening and closing meeting? ISO 10011–1, Part 5.2.1 ISO 10011–3, Part 4.2	☐ ☐	4.17	8.2.2 8.2.3	4.17 (4.17) <4.13>	
6. Is there a closing meeting where audit results are presented and discussed? ISO 10011–1, Part 5.2.1 ISO 10011–1, Part 5.3.3	☐ ☐ ☐ ☐ ☐	4.1 4.17	5.6.2 8.2.2	4.1 4.17 (4.1) (4.17) <4.13>	820.20 820.22
7. Is there a formal audit report, with a distribution list that contains all audit observations and the specific requirements of the standard, regulation, or other document against which the observation was made? ISO 10011–1, Part 5.2.1 ISO 10011–1, Part 5.3.2.2 ISO 10011–3, Part 4.2 ISO 10011–3, Part 4.6.4	☐ ☐ ☐ ☐ ☐	4.1 4.16 4.17	4.2.4 5.6.2 8.2.2	4.1 4.17 (4.1) (4.17) <4.13>	820.20 820.22

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	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
J. Internal Audits (continued)					
8. Are documented corrective and preventive actions taken on noted audit deficiencies? ISO 10011–1, Part 7.0 ISO 10011–3, Part 4.6.5	□ □ □ □ □	4.1 4.14 4.16 4.17	4.2.4 5.5.1 5.6.2 8.2.2 8.5.2 8.5.3	4.1 4.14 4.16 4.17 (4.1) (4.14) (4.16) (4.17) <4.9> <4.10> <4.11> <4.13>	820.20 820.22 820.100
9. Do auditors have the required education, training, and experience? ISO 10011–2, Part 4.0 ISO 10011–2, Part 5.0 ISO 10011–2, Part 6.0 ISO 10011–3, Part 4.3.1 ISO 10011–3, Part 4.5.3	□ □ □ □ □	4.1 4.17 4.18	8.2.2	4.1 4.17 4.18 (4.1) (4.17) (4.18) <4.13> <5.2>	820.20 820.22
10. Does there appear to be a sufficient number of personnel to accomplish audit-program objectives? ISO 10011–3, Part 4.6.2	□ □ □ □ □	4.1	6.1	4.1 (4.1) <4.1.5>	820.20 820.25

Total Number of Boxes Checked for Section J 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
K. Training					
1. Is there a training procedure for new employees that includes good manufacturing practices (GMPs)?	☐ ☐ ☐ ☐ ☐	4.18	6.2.2	4.18 (4.18) <5.2>	820.25
2. Are all employees made aware of defects that may occur from improper performance of their respective jobs?	☐ ☐ ☐ ☐ ☐	4.1 4.18	6.1 6.2.2	4.1 4.18 (4.1) (4.18) <5.2>	820.25
3. Is the training of employees properly documented?	☐ ☐ ☐ ☐ ☐	4.16 4.18	4.2.4 6.2.2	4.18 (4.18) <5.2>	820.25
4. Are written job descriptions available?	☐ ☐ ☐ ☐ ☐	4.18	6.2.2	4.18 (4.18) <5.2>	820.20 820.25
5. Is there sufficient assurance that consultants are qualified?	☐ ☐ ☐ ☐ ☐			6.2.2 <5.2.3>	820.25 820.50
6. Are records kept of subjects on which the consultant advised?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4	<5.2.3>	820.25 820.50
7. Does there appear to be a sufficient number of personnel to address all of the functions?	☐ ☐ ☐ ☐ ☐	4.1	6.1	4.1 (4.1) <4.1.5>	820.20 820.25

Total Number of Boxes Checked for Section K 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
L. Validation					
1. Have the laboratory test methods been validated?	□ □ □ □ □	4.11	7.5.2 7.6	4.11 (4.11) <5.4>	820.72 820.80
2. Have all the manufacturing/packaging/inspection equipment/processes been validated to address the following:		4.9 4.11	7.5.2 7.6	4.9 4.11 (4.9) (4.11)	820.70 820.75
a. Demonstrate that the product-specification acceptance requirements can be consistently satisfied?	□ □ □ □ □				
b. Have the operating limits/settings on the equipment been qualified as being capable of achieving the desired results?	□ □ □ □ □				
c. Are the operating limits from the validation reflected in an operating procedure for employees to follow?	□ □ □ □ □				
d. Was the validation achieved without equipment failures, interruptions, or significant down time?	□ □ □ □ □				
e. Was the validation long enough in duration to simulate a typical batch size? On continuous processes, was the validation long enough to encompass power fluctuations, employee shift changes, and other factors that occur during a 24-hour period?	□ □ □ □ □				
3. If reconciliation of labeling is not performed due to 100% inspection and the inspection is automated, has the inspection process been validated?	□ □ □ □ □				820.70 820.75 820.120
4. Have support systems (e.g., compressed air, vacuum, water) been validated (certified)?	□ □ □ □ □		7.5.2	4.9 (4.9) <5.3>	820.70 820.75
5. Have the environmental-control systems been validated (certified)?	□ □ □ □ □		7.5.2	4.9 (4.9) <5.3>	820.70 820.75
6. Have all cleaning procedures been validated?	□ □ □ □ □		7.5.2	4.9 (4.9) <5.3>	820.70 820.75
7. In cases of computer systems for control of processes, data collection, etc., have the systems been validated, and do they include the following:			7.5.2	4.9 (4.9) <5.3>	820.70 820.75
a. Hardware validation?	□ □ □ □ □				
b. Software validation?	□ □ □ □ □				
c. Qualification of the equipment environment?	□ □ □ □ □				
d. Distances between central processing units and peripheral devices validated?	□ □ □ □ □				

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	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
L. Validation (continued)					
e. Validation of signal conversion, if applicable?	☐ ☐ ☐ ☐ ☐				
f. Security from alteration, or use of systems by unauthorized personnel?	☐ ☐ ☐ ☐ ☐				
g. Error-detection features validated?	☐ ☐ ☐ ☐ ☐				
h. Calibration program derived?	☐ ☐ ☐ ☐ ☐				
i. Maintenance programs for computer derived?	☐ ☐ ☐ ☐ ☐				
j. Check of alarm systems?	☐ ☐ ☐ ☐ ☐				
k. Storage facilities from environmental/security perspectives?	☐ ☐ ☐ ☐ ☐				
8. Do all the validation packages include the following:		4.9 4.16	4.2.4 7.5.2		820.70 820.75
a. Detailed description of the item/system (including flow diagrams)?	☐ ☐ ☐ ☐ ☐				
b. Intended function of the system?	☐ ☐ ☐ ☐ ☐				
c. Installation qualification information?	☐ ☐ ☐ ☐ ☐				
d. Operational qualification information?	☐ ☐ ☐ ☐ ☐				
e. Preapproved validation protocol?	☐ ☐ ☐ ☐ ☐				
f. Explanation of any deviations made to the original signed-off protocol?	☐ ☐ ☐ ☐ ☐				
g. Validation results?	☐ ☐ ☐ ☐ ☐				
h. Conclusions/recommendations?	☐ ☐ ☐ ☐ ☐				
i. Quality-assurance approval of validation?	☐ ☐ ☐ ☐ ☐				
9. Is there a formal change-control system that addresses change to validated systems/test methods and includes quality-assurance review/approval?	☐ ☐ ☐ ☐ ☐	4.5	4.2.3 7.5.2	4.5 (4.5)	820.40 820.70 820.75
10. Does there appear to be a sufficient number of personnel available to address all activities?	☐ ☐ ☐ ☐ ☐	4.1	6.1	4.1 (4.1) <4.1.5>	820.20 820.25

Total Number of Boxes Checked for Section L 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
M. Facility Engineering and Maintenance					
1. Are the facilities acceptable for the nature of the item being produced?	□ □ □ □ □	4.9	7.5.1	4.9 (4.9) <5.3>	820.70
2. Are the sanitation and maintenance procedures for the manufacturing and ventilation equipment being followed?	□ □ □ □ □		7.5.1	<5.3>	820.70 820.75 820.186
3. For equipment utilized by engineering and maintenance personnel, are there adequate written calibration procedures? Is there a record of the calibrations that are being performed?	□ □ □ □ □	4.11	7.6	4.11 (4.11) <5.3> <5.5>	820.70 820.72
4. Are the environmental systems adequate to control air pressure, humidity, temperature, microorganisms, and particulate matter?	□ □ □ □ □	4.9	7.5.1	4.9 (4.9) <5.3>	820.70 820.75
5. Are there procedures and logs to assure sanitation and pest control?	□ □ □ □ □			<5.3>	820.20 820.70
6. Are the adjacent exterior grounds manicured?	□ □ □ □ □			<5.3>	820.20 820.70
7. Is there an adequate supply of potable water that meets the public health service drinking-water standards?	□ □ □ □ □			<5.1> <5.3>	820.20 820.70
8. Is the lighting in all areas adequate?	□ □ □ □ □			<5.3>	820.20 820.70
9. Are adequately constructed waste containers located in appropriate areas?	□ □ □ □ □			<5.3>	820.70 820.140
10. Is there an adequate sanitation program for the water system?	□ □ □ □ □			<5.3>	820.70
11. Are there designated areas for eating, drinking, and smoking?	□ □ □ □ □			<5.1> <5.3>	820.70
12. Are the environmental-control systems periodically inspected, and are those inspections documented?	□ □ □ □ □	4.9	7.5.1	4.9 (4.9) <5.3>	820.70 820.75
13. Is there a formal maintenance schedule of manufacturing equipment?	□ □ □ □ □			4.9 (4.9) <5.5>	820.70
14. Are periodic inspections made and documented to assure that the maintenance of manufacturing equipment is performed according to established schedules?	□ □ □ □ □			4.9 (4.9) <5.3> <5.5>	820.70

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
M. Facility Engineering and Maintenance (continued)					
15. Are tools, gauges, and test equipment used by engineering and maintenance personnel		4.11	7.6	4.11 (4.11) <5.3> <5.5>	820.72
a. Identified to reflect the date calibrated?	☐ ☐ ☐ ☐ ☐				
b. Identified to reflect the date due for the next calibration?	☐ ☐ ☐ ☐ ☐				
c. Marked with the identification of the person responsible for such calibration?	☐ ☐ ☐ ☐ ☐				
16. Are adequate facilities used for storage of tools, gauges, and test equipment?	☐ ☐ ☐ ☐ ☐	4.11	7.6	4.11 (4.11) <5.3> <5.5>	820.72
17. Are acceptable calibration standards employed?	☐ ☐ ☐ ☐ ☐	4.11	7.6	4.11 (4.11) <5.3> <5.5>	820.72
18. Are there positive pressure differentials with all doors leading into less clean areas?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9) <5.3>	820.70 820.75
19. Are the positive atmospheric controls calibrated and monitored?	☐ ☐ ☐ ☐ ☐	4.9	7.5.2	4.9 (4.9) <5.3>	820.70 820.75
20. Are there established air-controlled environments, and are they operating within limits?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9) <5.3>	820.70 820.75
21. Are facility and equipment drawings and blueprints adequately controlled?	☐ ☐ ☐ ☐ ☐	4.5	4.2.3 7.5.1	4.5 (4.5)	820.40
22. Do pipes indicate contents and direction of flow?	☐ ☐ ☐ ☐ ☐		7.5.1		820.70
23. Does there appear to be a sufficient number of personnel to address the activities?	☐ ☐ ☐ ☐ ☐	4.1	6.1	4.1 (4.1) <4.1.5>	820.20 820.25

Total Number of Boxes Checked for Section M 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
N. Complaint Handling					
1. Is there a procedure for receiving, reviewing, and evaluating complaints by a formally designated unit?	☐ ☐ ☐ ☐ ☐	4.14	8.5.2 8.5.3	4.14 (4.14) <4.8>	820.198
2. Are the complaints processed per procedure in a uniform and timely manner?	☐ ☐ ☐ ☐ ☐	4.14	8.5.2 8.5.3	4.14 (4.14) <4.8>	820.198
3. Are nonformal received complaints documented?	☐ ☐ ☐ ☐ ☐	4.14 4.16	4.2.4 8.5.2 8.5.3	4.14 (4.14) <4.8>	820.198
4. Do all complaint records contain the following:		4.14 4.16	4.2.4 8.5.2 8.5.3	4.14 (4.14) <4.8>	820.198
a. Name of device?	☐ ☐ ☐ ☐ ☐				
b. Date complaint was received?	☐ ☐ ☐ ☐ ☐				
c. Product identification and control numbers?	☐ ☐ ☐ ☐ ☐				
d. Name, address, and phone number of complainant?	☐ ☐ ☐ ☐ ☐				
e. Nature and details of complaint?	☐ ☐ ☐ ☐ ☐				
f. Reply to complainant?	☐ ☐ ☐ ☐ ☐				
5. Are complaints evaluated to determine whether an investigation is necessary?	☐ ☐ ☐ ☐ ☐	4.14	8.5.2 8.5.3	4.14 (4.14) <4.8> <4.10> <4.11>	820.198
6. If no investigation is made, is the reason why and the person making such decision documented?	☐ ☐ ☐ ☐ ☐	4.14 4.16	4.2.4 8.5.2 8.5.3	4.14 (4.14) <4.8> <4.10> <4.11>	820.198
7. Do records of investigation include (in addition to items in question #4):		4.14 4.16	4.2.4 8.5.2 8.5.3	4.14 (4.14) <4.10> <4.11>	820.198
a. Documented request for return of product/sample?	☐ ☐ ☐ ☐ ☐				
b. Documented receipt of sample?	☐ ☐ ☐ ☐ ☐				
c. Determination of whether product failed to meet specifications?	☐ ☐ ☐ ☐ ☐				
d. Dates/results of investigation?	☐ ☐ ☐ ☐ ☐				
e. Corrective/preventive actions taken?	☐ ☐ ☐ ☐ ☐				
f. Technical references (where appropriate)?	☐ ☐ ☐ ☐ ☐				

Total Number of Boxes Checked for Section N 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating 3 2 1 0 NA	US 21 CFR Section 803.17 Section 803.18 Section 806.10 Section 821.25
O. Medical Device Tracking, Reporting, and Recalls		
1. Is the firm aware of its obligation to notify FDA is it goes out of business, transfers the product to a purchaser, or discontinues manufacture so that tracking of the device can continue?	□ □ □ □ □	821.25
2. Is there a tracking procedure that addresses the following:		821.25
a. Ability to retrieve from all internal and distributor locations devices that have not been distributed within a 3-working-day request time frame?	□ □ □ □ □	
b. Ability to retrieve the following data within a 10-working-day request time frame?	□ □ □ □ □	
i. The lot number, batch number, or serial number of the device, or other identifier necessary to track the device?	□ □ □ □ □	
ii. The name, mailing address, telephone number, and social security number (if applicable) of the patient receiving the device?	□ □ □ □ □	
iii. The date provided to the patient?	□ □ □ □ □	
iv. The name, mailing address, and telephone number of the explanting physician?	□ □ □ □ □	
3. Are tracking records retained for as long as the device is in use or in distribution for use?	□ □ □ □ □	821.25
4. Does the company's procedures include a requirement to perform audits of each product tracked at not less than 6-month intervals for the first 3 years of distribution and at least once per year thereafter?	□ □ □ □ □	821.25
5. Does the firm have a written MDR (Medical Device Reporting) procedure that address the following?		803.17 803.18
a. Timely and effective identification, communication, and evaluation of events that may potentially be reportable?	□ □ □ □ □	
b. A review process for determining whether the event is reportable?	□ □ □ □ □	
c. Timely transmission of reportable events to the FDA?	□ □ □ □ □	
d. Documentation and record keeping for the information that was evaluated to determine if an event was reportable?	□ □ □ □ □	
e. All associated information submitted to the FDA?	□ □ □ □ □	
6. Does the firm establish and maintain MDR event files for the following?		803.17 803.18
a. Information from any source that describes a device-related death, serious injury, or malfunction?	□ □ □ □ □	
b. The firm's evaluation of the information, including decisions to submit or not submit?	□ □ □ □ □	
c. Supporting documentation, such as failure analysis, lab reports, etc.?	□ □ □ □ □	
d. Decisions not to submit for a device-related death, serious injury, or malfunction?	□ □ □ □ □	
7. Does the firm retain the MDR files for 2 years or the life of the device, whichever is greater?	□ □ □ □ □	803.18
8. Is there a procedure that requires all correction and removals be reported to the appropriate FDA District Office within 10 days of initiating the action?	□ □ □ □ □	806.10
9. Based on review of files, has the 10-day requirement been complied with?	□ □ □ □ □	806.10
10. Do the files contain evidence that the following have been provided to the FDA?		806.10
a. The 7-digit registration number of the entity responsible for submission of the report?	□ □ □ □ □	
b. The month, day, and year that the report was made?	□ □ □ □ □	
c. A sequential numbering system for MDRs (e.g., 001, 002)?	□ □ □ □ □	
d. Name, address, and telephone number of manufacture?	□ □ □ □ □	

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	US 21 CFR
	3 2 1 0 NA	Section 803.17 Section 803.18 Section 806.10 Section 821.25
O. Medical Device Tracking, Reporting, and Recalls (continued)		
e. Brand name, classification name, or usual name of the device?	☐ ☐ ☐ ☐ ☐	
f. Intended use of the device?	☐ ☐ ☐ ☐ ☐	
g. Marketing status of the device?	☐ ☐ ☐ ☐ ☐	
h. Model, catalog, or code number of the device?	☐ ☐ ☐ ☐ ☐	
i. Manufacturing lot or serial number of the device?	☐ ☐ ☐ ☐ ☐	
j. Description of events leading to correction and removal?	☐ ☐ ☐ ☐ ☐	
k. Listing of illnesses or injuries that have occurred?	☐ ☐ ☐ ☐ ☐	
l. Total number of devices manufactured or distributed?	☐ ☐ ☐ ☐ ☐	
m. Date of manufacture?	☐ ☐ ☐ ☐ ☐	
n. Date of distribution?	☐ ☐ ☐ ☐ ☐	
o. Expiration date or expected device life?	☐ ☐ ☐ ☐ ☐	
p. Names, addresses, and telephone numbers of distributors?	☐ ☐ ☐ ☐ ☐	
q. Copies of all communications?	☐ ☐ ☐ ☐ ☐	

Total Number of Boxes Checked for Section O 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
P. Quality Systems Management System and Responsibility					
1. Is there a formal statement of the quality policy by the management of the company, and does its communication to the organization include the importance of meeting statutory as well as regulatory requirements?	☐ ☐ ☐ ☐ ☐	4.1	5.1 5.3 5.4.1	4.1 (4.1) <4.2>	820.20
2. Is there a "quality system" that addresses the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management?	☐ ☐ ☐ ☐ ☐	4.1 4.2	4.1 5.5.1	4.1 4.2 (4.1) (4.2) <4.2>	820.5 820.20
3. Is there a "Quality Manual" that addresses the "quality system"?	☐ ☐ ☐ ☐ ☐	4.1 4.2	4.2.1 4.2.2	4.1 4.2 (4.1) (4.2) <4.2>	
4. Are there periodic management reviews of the quality system and are the following inputs included?:		4.1 4.16	4.1 4.2.4 5.6.1 5.6.2 8.5.1	4.1 4.16 (4.1) (4.16) <4.14>	820.20
a. Results of audits?	☐ ☐ ☐ ☐ ☐				
b. Customer feedback?	☐ ☐ ☐ ☐ ☐				
c. Process performance and product conformity?	☐ ☐ ☐ ☐ ☐				
d. Status of corrective and preventive actions?	☐ ☐ ☐ ☐ ☐				
e. Follow-up actions from previous management reviews?	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐				
f. Changes that could affect the quality-management system?	☐ ☐ ☐ ☐ ☐				
g. Recommendations for improvement?	☐ ☐ ☐ ☐ ☐				
5. Does the organization analyze appropriate data to demonstrate the suitability and effectiveness of the quality-management system in regards to the following:			8.4	<4.14>	
a. Customer satisfaction?	☐ ☐ ☐ ☐ ☐				
b. Conformity to product requirements?	☐ ☐ ☐ ☐ ☐				
c. Trends of processes and products, including opportunities for preventive action?	☐ ☐ ☐ ☐ ☐				
d. Suppliers?	☐ ☐ ☐ ☐ ☐				
6. Does top management provide communication within the organization regarding the effectiveness of the quality-management system?	☐ ☐ ☐ ☐ ☐		5.5.3	<4.14>	
7. Is the individual responsible for the quality-assurance program (management representative) not directly responsible for the performance of a manufacturing operation?	☐ ☐ ☐ ☐ ☐	4.1	4.1 5.5.2	4.1 (4.1) <4.1>	820.20

INTERNAL DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Total Number of Boxes Checked for Section P 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

Audited by _____

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Scope: This checklist should be used to audit the internal facilities of a drug manufacturer or developer. Internal facilities that perform their own supply functions, such as plastic molding, printing of materials, and so on, should utilize the appropriate "Supplier" audit checklist as an adjunct to the internal evaluation process.

Note: In the United States there are additional regulations that address the development of drug products. The two sets of regulations are entitled Good Clinical Practices (GCP) and Good Laboratory Practices (GLP). They are significant enough in scope and depth to warrant separate audit manuals (with checklists), which have been published separately by Interpharm Press.

Design control is addressed in ISO 13485, but the document is specific for medical devices, not drug products.

The European Community (EC) GMPs for drug products also do not address design control.

As a result of the aforementioned situations, the Development and Design Control section of this checklist is limited in scope to the ISO 9001:1994 and ISO 9001:2000 perspectives. Please refer to the GLP and GCP audit manuals from Interpharm Press to assure proper auditing of United States drug-development requirements.

This checklist covers the following areas:

A. Development and Design Control
B. Contract Review
C. Purchasing
D. Receiving/In-Process-Material Handling and Storage
E. Production/Packaging/In-Process Control
F. Final Inspection
G. Final-Product Handling, Storage, Distribution, Installation, and Servicing
H. Laboratories and Calibration
I. Computer Systems, Documentation Controls, and Quality Records
J. Internal Audits
K. Training
L. Validation
M. Facility Engineering and Maintenance
N. Complaint Handling
O. Quality Systems Management And Responsibilities
P. EC GMP 1: Manufacture of Sterile Medicinal Products

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

The questions in this checklist include references to:

1. The United States Code of Federal Regulations 21 CFR, Part 211, Current Good Manufacturing Practice (CGMP) for Finished Pharmaceuticals
2. The United States Code of Federal Regulations 21 CFR, Parts 1301–1307, Requirements for Controlled Drug Substances
   Note: References in the checklist column are indicated with arrow brackets < >.
3. The United States Code of Federal Regulations 21 CFR, Part 11 — Electronic Records; Electronic Signatures. These questions are located in the Computer Systems, Documentation Controls, and Quality Records section of the checklist
   Note: References in the checklist column are indicated with squared brackets [].
4. International Organization for Standardization (ISO) ISO 9001:1994, Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation and Servicing, and ISO 9001:2000, Quality Management Systems—Requirements
5. International Organization for Standardization (ISO) 17025:1999, General Requirements for the Competence of Testing and Calibration Laboratories
   Note: The EC has approved ISO 17025 as a replacement for EN 45001, General Criteria for the Operation of Testing Laboratories.
6. The European Community (EC) Guide to Good Manufacturing Practices (GMP) for Medicinal Products, including Annexes 1 and 16.
7. International Organization for Standardization (ISO) 10011–1:1990, 2:1991, and 3:1991, Guidelines for Auditing Quality Systems; Auditing; Qualification Criteria for Quality System; and Management of Audit Programmes (American ISO equivalent, ANSI/ASQC Q10011–1, 2 and 3).
   Note: References to this standard are indicated under each appropriate question in the checklist.

Because internal facility audits may be performed by more than one person, signature spaces are provided at the end of each section to provide a record of each individual auditor's activities.

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Date(s) of Audit _____

Facility Location Name _____

Address _____

Audit Leader Name _____

Title _____

Audit Team Members Name _____

Function on Team _____

Name _____

Function on Team _____

Name _____

Function on Team _____

Name _____

Function on Team _____

Scope of Audit _____

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Applicable Regulations/Standards _____

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Opening Meeting Date _____

Attendees _____

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INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Closing (Wrap-up) Meeting Date _____

Attendees _____

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Audit Report Date Issued _____

Date Response Received _____

Date Response and Action Plan Approved _____

Date Actions Completed _____

Date Completed Actions Verified as Completed _____

Date Completed Actions Verified as Effective _____

Date Closed Out _____

Future Follow-up Items _____

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INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

QUALITY RATING SYSTEM

Rating	*Meaning*	*Interpretation*
3	Excellent	Item/area/system/knowledge is superior
2	Adequate	Item/area/system/knowledge meets basic minimum requirements.
1	Deficient	Item/area/system/knowledge is weak and not up to acceptable standards.
0	Unsatisfactory	Item/area/system/knowledge is missing or of a nature to warrant serious quality/compliance concerns.
NA	Not Applicable	Question is not applicable to type of operation, or item unable to be addressed during the audit.

Comment: Some users of the checklist may find the responses to some questions difficult to quantify on a 0–3 scale and may prefer to use a simple "yes" or "no" approach. In such cases, a "yes" should be assigned a "2" value, and a "no" should be assigned a "0" value.

CHECKLIST RESULTS AND RATING

	Number of Occurrences			
Section	**3s**	**2s**	**1s**	**0s**
A. Development and Design Control				
B. Contract Review				
C. Purchasing				
D. Received/In-Process-Material Handling and Storage				
E. Production/Packaging/In-Process Control				
F. Final Inspection				
G. Final-Product Handling, Storage, Distribution, Installation, and Servicing				
H. Laboratories and Calibration				
I. Computer Systems, Documentation Controls, and Quality Records				
J. Internal Audits				
K. Training				
L. Validation				
M. Facility Engineering and Maintenance				
N. Complaint Handling				
O. Quality-Systems Management and Responsibility				
P. EC GMP Annex 1: Sterile Products				
Totals				

Audit Findings Summary

Number of questions rated excellent ( ) Times 3 = ( )
Number of questions rated adequate ( ) Times 2 = ( )
Number of questions rated deficient ( ) Times 1 = ( )
Number of questions rated unsatisfactory (_____) Times 0 = (_____)

Total Number of Questions Answered = (_____) Rating Total = (_____)

"Rating Total" divided by "Number of Questions Answered" = _____ Audit Rating

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

I. Strengths

1. _____
2. _____
3. _____
4. _____
5. _____

II. Weaknesses

1. _____
2. _____
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III. Recommendations

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INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
A. Development and Design Control						
1. Is there a written plan under revision control that identifies each activity required, the personnel responsible, and their technical interfaces?	☐ ☐ ☐ ☐ ☐	4.2 4.4.1 4.4.2 4.4.3	7.3.1			
2. In the design of items, is appropriate input obtained and documented to assure proper development and approval?	☐ ☐ ☐ ☐ ☐	4.4.4	7.2.1 7.3.2			
3. Is the design output documented and expressed in terms that can be verified against the design inputs?	☐ ☐ ☐ ☐ ☐	4.4.5	7.3.3			
4. Are there design reviews after each phase?	☐ ☐ ☐ ☐ ☐	4.4.6	7.3.4			
5. Does the design review address each of the following items:		4.4.6	7.3.4			
a. Comparison of customer needs with technical specifications for materials, products, and processes?	☐ ☐ ☐ ☐ ☐					
b. Validation of the design through prototype tests?	☐ ☐ ☐ ☐ ☐					
c. Ability to perform under expected conditions of use and environments?	☐ ☐ ☐ ☐ ☐					
d. Considerations of unintended uses and misuses?	☐ ☐ ☐ ☐ ☐					
e. Safety and environmental compatibility?	☐ ☐ ☐ ☐ ☐					
f. Compliance with regulatory requirements, national and international standards, and corporate practices?	☐ ☐ ☐ ☐ ☐					
g. Comparisons with competitive designs?	☐ ☐ ☐ ☐ ☐					
h. Comparison with similar designs, especially analysis of internal and external problem history, to avoid repeating problems?	☐ ☐ ☐ ☐ ☐					
i. Reliability, serviceability, and maintainability?	☐ ☐ ☐ ☐ ☐					
j. Permissible tolerances and comparison with process capabilities?	☐ ☐ ☐ ☐ ☐					
k. Product-acceptance/rejection criteria?	☐ ☐ ☐ ☐ ☐					
l. Installability, ease of assembly, storage needs, shelf life, and disposability?	☐ ☐ ☐ ☐ ☐					
m. Benign failure and fail-safe characteristics?	☐ ☐ ☐ ☐ ☐					
n. Failure modes and effects analyses, and fault tree analysis?	☐ ☐ ☐ ☐ ☐					
o. Ability to diagnose and correct problems?	☐ ☐ ☐ ☐ ☐					
p. Manufacturability of the design, including special process needs, mechanization, automation, assembly, and installation of components?	☐ ☐ ☐ ☐ ☐					

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
A. Development and Design Control (continued)						
q. Capability to inspect and test the design, including special inspection and test requirements?	☐ ☐ ☐ ☐ ☐					
r. Specification of materials, components, and sub-assemblies, including approved suppliers?	☐ ☐ ☐ ☐ ☐					
s. Packaging, handling, storage, and shelf-life requirements?	☐ ☐ ☐ ☐ ☐					
t. Safety factors relating to incoming and outgoing items?	☐ ☐ ☐ ☐ ☐					
6. Is there a formal design-verification procedure (including clinical-investigation information) to confirm that the formalized, desired design output is adequate for its intended use?	☐ ☐ ☐ ☐ ☐	4.4.7	7.3.5			
7. Is there a procedure to assure the design of components is correctly translated into production documents?	☐ ☐ ☐ ☐ ☐	4.4.7	7.3.5			
8. Is there a design change-control procedure, and is it being followed?	☐ ☐ ☐ ☐ ☐	4.4.9 4.5.2	7.3.7			
9. Is there a market-readiness review before launch that addresses the following:						
a. Availability and adequacy of installation, operation, maintenance, and repair manuals?	☐ ☐ ☐ ☐ ☐					
b. Existence of an adequate distribution and customer-service organization?	☐ ☐ ☐ ☐ ☐					
c. Training of field personnel?	☐ ☐ ☐ ☐ ☐					
d. Availability of spare parts?	☐ ☐ ☐ ☐ ☐					
10. Is there a Design History File for each design that demonstrates it was developed in accord with all requirements?	☐ ☐ ☐ ☐ ☐	4.4 4.16	4.2.4			
11. Is there a sufficient number of people to address all activities?	☐ ☐ ☐ ☐ ☐	4.1	6.1			

Total Number of Boxes Checked for Section A 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
B. Contract Review						
1. Are the requirements, including specifications, acceptance criteria, and associated release responsibilities, adequately detailed in a contract?	□ □ □ □ □	4.3	5.2 7.2.1	7.1 7.11	4.4.1	
2. Does the contract, or other document, specify how amendments are made and communicated to affected functions?	□ □ □ □ □	4.3	7.2.2	7.1	4.4.1 4.4.4 4.4.5	
3. Is the contract formally agreed to before execution?	□ □ □ □ □	4.3	5.2 7.2	7.1	4.4.1	
4. Are the contracts periodically reviewed for adequacy?	□ □ □ □ □	4.3	7.2.2		4.4.2	
5. Are records of periodic reviews maintained for a specified period?	□ □ □ □ □	4.3 4.16	4.2.4 7.2.2		4.4.2	
6. For standard (noncustom) items, is there a product/service catalog/listing that is revision controlled to assure that the content is current and correct?	□ □ □ □ □	4.3	5.2 7.2.2 7.2.3			
7. For standard (noncustom) items, does the catalog/listing provide enough information to assure the purchaser will receive what is expected?	□ □ □ □ □	4.3	5.2 7.2.1 7.2.3			
8. Is there a procedure established and being followed that describes how verbal and formal orders are to be processed?	□ □ □ □ □	4.3	7.2.3		4.4.1	
9. Is there a procedure for resolving processed-order problems?	□ □ □ □ □	4.3	7.2.3		4.4.2 4.7 4.8	
10. Are subcontract intentions approved by the customer first?	□ □ □ □ □			7.8	4.5	

Total Number of Boxes Checked for Section B 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
C. Purchasing						
1. Is there a listing of qualified suppliers?	☐ ☐ ☐ ☐ ☐	4.6.2	7.4.1	1.2 5.26 5.40	4.6.1	211.84
2. Is there a procedure for how suppliers get qualified? Does it include, where appropriate, supplier audits?	☐ ☐ ☐ ☐ ☐	4.6.2	7.4.1	5.25 5.40	4.6.4	
3. Are purchasing documents reviewed for accuracy and completeness before release to the supplier?	☐ ☐ ☐ ☐ ☐	4.6.3	7.4.2	5.26 5.40	4.6.3	
4. Is there a clear agreement between the supplier and purchaser on the requirements of the purchase and how such conformance will be verified?	☐ ☐ ☐ ☐ ☐	4.3 4.6.3	7.4.2	5.26 5.40	4.6.3	
5. Are there agreements with suppliers that commit them to notification of proposed changes on a component?	☐ ☐ ☐ ☐ ☐	4.3 4.6.1	7.4.2			
6. Does there appear to be a sufficient number of personnel to address all the activities?	☐ ☐ ☐ ☐ ☐	4.1	6.1	2.1	4.1.5	211.25

Total Number of Boxes Checked for Section C 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
D. Received/In-Process-Material Handling and Storage						
1. Are receiving bays designed to avoid intrusion from weather, dust, insects, etc.?	□ □ □ □ □	4.15.2	7.5.5	3.20	5.8	211.80
2. Does the receiving quality-control function check incoming shipments against the requirements of the purchase order, specifications and applicable drawings prior to release to manufacturing?	□ □ □ □ □	4.10.1	7.1 8.1	1.4 4.11 4.19 4.20 5.3 5.4 5.5 5.27 5.30 5.40	4.6.2	211.84
3. Where appropriate, are material-weight checks made, or counts verified, upon receipt?	□ □ □ □ □	4.10.1	7.1 8.1	3.13 4.20 5.32 5.33	4.6.2	211.84 211.184
4. Are records of receiving activities properly stored?	□ □ □ □ □	4.16	4.2.4	4.19 4.20 4.21	4.6.2	211.184
5. Are inspected items properly segregated from the material awaiting inspection?	□ □ □ □ □	4.10.1	7.1 8.1	3.18 3.21 4.21 5.5	4.6.2 5.8	211.42
6. Is there a procedure to prevent acceptance of material from unqualified suppliers?	□ □ □ □ □	4.6.4	7.43	5.26	4.6.1 4.6.2	
7. Are the sampling plans employed by quality control sufficient?	□ □ □ □ □	4.20	8.1	4.22	4.6.1 5.7	211.84
8. If multiple shipments of the same lot of the same item are received at various points in time, is each one sampled, tested, and released independently?	□ □ □ □ □	4.10.1	7.1 8.1	5.28	4.6.1	211.84
9. If a received shipment contains more than one lot number for the same item, is each lot tested and released separately?	□ □ □ □ □	4.10	7.1	5.28	4.6.1	211.84
10. Is the sampling of received materials performed in a separate area or with proper controls?	□ □ □ □ □	4.15.3	8.1	3.14 3.22	4.6.1	211.80 211.84
11. Is inspected material adequately identified as accepted or rejected?	□ □ □ □ □	4.10.1 4.10.2 4.12 4.13	7.1 7.5.3 8.1 8.3	3.21 4.21 5.13 5.29	4.6.2 5.8	211.80
12. Do receiving inspection records indicate acceptance or rejection of incoming material?	□ □ □ □ □	4.10.2 4.13	7.4.3 7.5.3 8.2.4	5.13 5.29	4.6.2	211.84 211.184

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
D. Received/In-Process-Material Handling and Storage (continued)						
13. Is rejected material adequately controlled?	□ □ □ □ □	4.10.1 4.10.2 4.12 4.13	7.4.3 7.5.3 8.2.4 8.3	3.23 5.61	4.6.2 5.8	211.80 211.89
14. Do receiving inspection records reflect the reasons for rejection?	□ □ □ □ □	4.13 4.10.2	7.4.3 7.5.3 8.2.4 8.3	4.19 4.20 5.31	4.6.2	211.184
15. Is the cause for rejection of material determined, and are corrective/preventive actions taken?	□ □ □ □ □	4.13 4.14	7.4.3 7.5.3 8.2.4 8.3 8.5.2 8.5.3		4.6.2 4.9 4.10 4.11	211.84
16. Are component control numbers, material status, and other identifications on the storage containers easily viewable?	□ □ □ □ □	4.8	7.5.3	5.29 5.34	4.9	211.80
17. Is there an adequate procedure for the handling and disposition of returned goods from customers or distributors?	□ □ □ □ □	4.14	8.3	5.65		211.204
18. Is access to stockrooms and materials-storage areas restricted to authorized personnel?	□ □ □ □ □	4.15.3	7.5.5	3.5	4.6.1 5.8	211.122
19. Are materials handled, identified, and stored in a manner that will prevent damage, contamination, mix-up, and/or loss?	□ □ □ □ □	4.8 4.10.1 4.15.3 4.15.2	7.5.3	3.1 3.2 3.3 3.4 3.13 5.7 5.11 5.12 5.29	4.6.1 5.8	211.80
20. Are accountability records kept to permit traceability?	□ □ □ □ □	4.8 4.10 4.16	4.2.4 7.5.3		5.8	211.184
21. Are stocks reinspected and tested at intervals?	□ □ □ □ □	4.15.3	7.5.5	4.11 5.7 5.31 5.43	4.6.1	211.87
22. Are stocks rotated and, if not, is there a justifiable reason?	□ □ □ □ □	4.15	7.5.5	5.7		211.86 211.150
23. Is there a distinct and adequately sized label room?	□ □ □ □ □		7.5.5	5.41		211.42 211.122

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
D. Received/In-Process-Material Handling and Storage (continued)						
24. Is the label room designed to avoid mix-ups?	□ □ □ □ □			5.41		211.42 211.122
25. Is there a sufficient accountability system in the label room for labels?	□ □ □ □ □	4.15	7.55	5.40 5.41 5.42		211.125
26. Is there a reconciliation of labeling issued, used, and returned? *Note: Reconciliation may be waived for art or roll labeling if a 100% inspection is performed during or after completion of finishing operations.*	□ □ □ □ □			5.40 5.41 5.42		211.122 211.125
27. Is gang-print labeling prohibited unless adequately differentiated by size, shape, or color to assure against possible mix-ups? How about ability to detect such mix-ups?	□ □ □ □ □					211.122
28. Are there specified restrictions on authority for access to labels and other labeling?	□ □ □ □ □			3.25 5.41		211.122
29. Are labels proofread for accuracy before being released to inventory?	□ □ □ □ □			4.19 4.21 5.41		211.122
30. Are obsolete and outdated printed materials destroyed?	□ □ □ □ □			5.43		211.122
31. Is there an adequate procedure governing the return and salvage of products?	□ □ □ □ □			5.61 5.62 5.63 5.64 5.65		211.208
32. Are the materials-storage and -handling procedures documented?	□ □ □ □ □	4.15.1		4.19 4.24		211.142
33. Does there appear to be a sufficient number of personnel to address all activities?	□ □ □ □ □	4.1	6.1 6.2.1	2.1		211.25
Additional questions for controlled drugs						
34. Are there secure facilities and approved procedures for storage and movement of controlled drugs?	□ □ □ □ □					211.42
35. Are noncontrolled drugs stored with controlled drugs? If yes, has formal permission to be obtained from the regional director of the Drug Enforcement Administration (DEA)?	□ □ □ □ □					<1301.72>
36. Is an inventory taken at least every 2 years?	□ □ □ □ □					<1304.11>
37. Do the inventory records contain the name of the substance and the total quantity of the substance in metric unit weights?	□ □ □ □ □					<1304.11>

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
D. Received/In-Process-Material Handling and Storage (continued)						
38. For items in process at the time of inventory, does the following documentation exist:						<1304.11>
a. The name of substance?	☐ ☐ ☐ ☐ ☐					
b. The quantity of substance at each stage of manufacturing?	☐ ☐ ☐ ☐ ☐					
c. The physical form that the substance is to take upon completion of the processing (e.g., solution, granules)?	☐ ☐ ☐ ☐ ☐					
d. The batch number in process?	☐ ☐ ☐ ☐ ☐					
39. Do the inventory records include						<1304.11>
a. The names and quantities of materials held for quality purposes, disposal, or extemporaneous compounding?	☐ ☐ ☐ ☐ ☐					
b. The reasons for which substances are being held?	☐ ☐ ☐ ☐ ☐					
40. With regard to hallucinogenic substances, are amounts in excess of 150 grams for laboratory use recorded in the inventory system?	☐ ☐ ☐ ☐ ☐					<1304.11>
41. Are the disposals of controlled substances requested via the regional administrator of the DEA prior to disposal?	☐ ☐ ☐ ☐ ☐					<1307.21>
42. Are there effective controls to guard against theft/diversion of received controlled substances?	☐ ☐ ☐ ☐ ☐					<1301.71>
43. Do the records include the name, address, and registration number of the person from whom the substance was received?	☐ ☐ ☐ ☐ ☐					<1304.22>
44. Are the dates on documents specific as to when they were received? Are these dates referenced on all associated invoices or packing slips?	☐ ☐ ☐ ☐ ☐					<1304.21>

Total Number of Boxes Checked for Section D 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
E. Production/Packaging/In-Process Control						
1. Do the production employees appear to be neat, clean, suitably attired, organized, and operating efficiently?	□ □ □ □ □	4.19 4.18	6.2.2 7.5.1	2.16 2.17 2.18 2.19 2.20 3.5 5.1		211.25 211.28
2. Are there written procedures for production and process control?	□ □ □ □ □	4.9	4.2.3 7.5.1 7.5.2	4.14 4.15 4.26 4.27 5.2		211.100
3. Are the in-process procedures adequate for control of fabrication and services?	□ □ □ □ □	4.9	4.2.3 7.5.1 7.5.2	4.15 4.16 4.27 5.2		211.110
4. Are the written procedures being followed?	□ □ □ □ □	4.9	4.2.3 7.5.1	5.2		211.100
5. Does the production equipment appear to be appropriately designed, constructed, and maintained?	□ □ □ □ □	4.9	7.5.1 7.5.2	3.34 3.36 3.38 3.39		211.63 211.65
6. Is defective equipment labeled or removed?	□ □ □ □ □			3.44		
7. Are utensils cleaned to prevent contamination between different product usages?	□ □ □ □ □	4.9	7.5.1	2.18 3.36 3.37 3.39 5.18 5.19 5.20		211.67
8. Are production areas sufficient in size, construction, and location to accommodate the needs of the intended operation, including environmental requirements?	□ □ □ □ □	4.9	7.5.1	1.3 3.1 3.3 3.4 3.6 3.7 3.8 3.9 3.10 3.11 3.12 3.15 3.16		211.42

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
E. Production/Packaging/In-Process Control (continued)						
9. Are appropriate exhaust and vacuum systems employed in operations to minimize air contamination?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	3.1 3.3 3.6 3.10 3.12 3.14 3.15		211.46
10. Are equipment-cleaning/use logs and schedules being maintained?	☐ ☐ ☐ ☐ ☐	4.9 4.16	4.2.4 7.5.1	4.17 4.28 4.29		211.182
11. Are production records properly assembled and sufficient in the following content:		4.8 4.9 4.16	4.2.4 7.5.1 7.5.2 7.5.3	4.14 4.15 4.16 4.17 4.18 4.26 4.27 5.8		211.186 211.188
a. Is each prepared, dated and signed in full signature by one person and independently checked, dated, and signed by a second person?	☐ ☐ ☐ ☐ ☐					
b. Are the name, strength, and description of the dosage form included?	☐ ☐ ☐ ☐ ☐					
c. Are the name, weight, and measure of each active ingredient, and the total weight indicated?	☐ ☐ ☐ ☐ ☐					
d. Is a complete list of components provided?	☐ ☐ ☐ ☐ ☐					
e. Is an accurate statement of the correct measure or weight of each component made? Is the same weighing system used for each component?	☐ ☐ ☐ ☐ ☐					
f. Are statements made concerning any calculated excess of components?	☐ ☐ ☐ ☐ ☐					
g. Is the theoretical weight or measure at appropriate phases of production indicated?	☐ ☐ ☐ ☐ ☐					
h. Is there a description of the drug containers, closures, and packaging materials, including a specimen or copy of each label and other labeling?	☐ ☐ ☐ ☐ ☐					
i. Are there complete manufacturing and control instructions that include any special notations or precautions that are needed?	☐ ☐ ☐ ☐ ☐					
j. Is there documentation that each significant step in the manufacture, packaging or holding was accomplished, including:						211.134 211.192
i. Dates?	☐ ☐ ☐ ☐ ☐					
ii. Identity of major equipment and lines used?	☐ ☐ ☐ ☐ ☐					
iii. Identification of each batch of component used?	☐ ☐ ☐ ☐ ☐					
iv. Weights and measures of components used?	☐ ☐ ☐ ☐ ☐					
v. In-process laboratory control results?	☐ ☐ ☐ ☐ ☐					

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
E. Production/Packaging/In-Process Control (continued)						
vi. Inspection of the packaging and labeling area before and after use?	□ □ □ □ □					
vii. Any investigations made in accordance with 21 CFR 211.192, as well as examinations made in accordance with 21 CFR 211.134?	□ □ □ □ □					
k. Where environmental conditions can cause a product not to satisfy requirements, are such environmental conditions monitored and recorded for traceability on a per-lot/batch basis?	□ □ □ □ □					
12. Are line-clearance procedures employed to prevent packaging and labeling mix-ups?	□ □ □ □ □	4.8 4.9	4.2.3 7.5.1	5.34 5.35 5.45 5.57		211.130
13. Are there separate air-handling systems for the manufacture, processing, and packaging of highly sensitive items, like penicillin?	□ □ □ □ □			3.3 3.6		211.46
14. Are there acceptable written procedures for reprocessing batches?	□ □ □ □ □	4.9 4.13.1	4.2.3 7.5.1 7.5.2 8.3	4.17 4.18 5.55 5.62 5.63		211.115
15. Are the batch records and process "limits" information kept at the workstations during the entire operation? Are the directions strictly followed?	□ □ □ □ □	4.9 4.16	4.2.4 7.5.1	4.8		211.100
16. Are critical steps performed by a competent individual, checked by a second individual, and recorded in the batch record?	□ □ □ □ □					211.103
17. Have time limitations on the holding of processing and in-process items been established, and are they being adhered to?	□ □ □ □ □	4.9 4.16	4.2.4 7.5.1 7.5.2	4.15 4.17 4.18		211.111
18. Are changes to the issued batch records approved prior to the start of work and documented on the batch records?	□ □ □ □ □	4.4 4.5.2 4.5.3 4.9 4.16	4.2.3 4.2.4 7.5.1	5.15		211.100
19. Are proper gowning techniques and coverings employed?	□ □ □ □ □	4.9	7.5.1	2.16		211.28
20. Do the production employees use acceptable techniques?	□ □ □ □ □	4.9 4.18	7.5.1	2.8 2.9 2.10 2.12		211.25 211.101

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
E. Production/Packaging/In-Process Control (continued)						
21. Are bagged or boxed components stored off the floor?	☐ ☐ ☐ ☐ ☐					211.80
22. Are lubricants and coolants controlled properly so that they cannot come into contact with product containers, closures, in-process materials, or finished products?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	5.18		211.65
23. Is issued labeling examined for identity, correct expiration date, control number, storage conditions, handling instructions, and additional processing instructions?	☐ ☐ ☐ ☐ ☐			5.42 5.47 5.50		211.122 211.125
24. Is the aforementioned labeling inspection documented to include the date and person performing the inspection? Is the inspection included in the history record?	☐ ☐ ☐ ☐ ☐			5.52 5.53 5.54		211.122 211.125 211.130
25. Are packaging lines spatially or physically separated in a manner designed to prevent mix-ups?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	1.3 3.1 3.7 3.8 5.44 5.45 5.46 5.51 5.57		211.42
26. Do all components, in-process and final-product items reflect the inspection/testing "status"?	☐ ☐ ☐ ☐ ☐	4.8 4.10.2 4.10.3 4.12 4.13	7.5.1 7.5.3	5.13 5.31 5.34 5.43 5.61		211.42 211.80 211.82 211.84 211.122
27. Are filled containers, or other unlabeled product, that are set aside and held for subsequent labeling stored and identified properly to prevent mix-ups? (This identification must include the names, strengths, quantities of contents, and lot or control numbers of the containers/products.)	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	1.3 3.1 3.7 3.8 5.12 5.13 5.44 5.57 5.49 5.54		211.130
28. Are in-process materials "held" pending inspection/testing results?	☐ ☐ ☐ ☐ ☐	4.10.3 4.12	7.5.3 8.2.4	1.2 5.58 5.59 6.1 6.2 6.3 6.4		211.22 211.84

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
E. Production/Packaging/In-Process Control (continued)						
29. Are charts used for monitoring time, temperature, pressure, etc., and are they properly filed?	□ □ □ □ □	4.9 4.16	4.2.4 7.5.1	5.38		211.111
30. Is there a procedure to inspect manufacturing and control systems periodically, and are the inspections documented?	□ □ □ □ □	4.9 4.16	4.2.4 7.5.1	9.1		211.58
31. When nonemployees such as visitors are in the area, are they observed by the designated responsible person?	□ □ □ □ □			2.11		211.28
32. Does there appear to be a sufficient number of personnel to address all of the activities?	□ □ □ □ □	4.1	6.1 6.2.1	2.1		211.25
Additional questions for sterile products						
33. Is there a maximum allowable number of personnel in clean rooms?	□ □ □ □ □			*13		
34. When maintenance workers or visitors are permitted in the area, are they instructed and supervised?	□ □ □ □ □			*14		
35. Are personnel monitored for shedding of contaminants?	□ □ □ □ □			*16		
36. Are wristwatches, makeup, and jewelry prohibited in the clean areas?	□ □ □ □ □			*18		
37. Do gowning procedures				*17 *19		
a. Address washing before entering clean areas?	□ □ □ □ □					
b. Indicate the type of gowning depending on the class area?	□ □ □ □ □					
38. Are personnel engaged in the processing of animal-tissue materials or cultures of micro organisms restricted from sterile-product areas?	□ □ □ □ □			*15		
39. Does the processing of materials address the following:				*11 *12 *43 *44 *50 *51 *52 *53		
a. Time limits between washing, drying, and sterilization?	□ □ □ □ □					
b. Time limits between preparation, start of solution, and sterilization or filtration?	□ □ □ □ □					
c. Bioburden monitoring and depyrogenation?	□ □ □ □ □					
d. Passing solutions and noncombustible gases through a microorganism retaining filter?	□ □ □ □ □					
e. Preparation of components and products in the right level of environment?	□ □ □ □ □					

* ANNEX 1

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
E. Production/Packaging/In-Process Control (continued)						
40. When sterilization cannot be used and filtration is the only option, is the following addressed?				*82 *83 *84 *85 *86 *87		
a. Use of 0.22 micron, non fibre shedding filter or less?	☐ ☐ ☐ ☐ ☐					
b. Use of heat treatment if product tolerable?	☐ ☐ ☐ ☐ ☐					
c. Use of a second filtration process?	☐ ☐ ☐ ☐ ☐					
d. Bubble point, diffusive flow or pressure hold test to assure filter integrity?	☐ ☐ ☐ ☐ ☐					
e. Length of time a filter can be used (e.g., one day)?	☐ ☐ ☐ ☐ ☐					
41. Are containers closed by fusion (e.g., ampules) 100% tested for integrity?	☐ ☐ ☐ ☐ ☐			*89		
42. Are containers sealed under vacuum tested for maintenance of vacuum for an appropriate length of time?	☐ ☐ ☐ ☐ ☐			*88		
43. Are containers visually inspected for contamination and if inspected electronically, is the process validated?	☐ ☐ ☐ ☐ ☐			*88		
Additional questions for controlled drugs						
44. Are all in-process items returned to the controlled-drug storage areas at the termination of the process or work day? If not, are the materials securely locked to prevent access?	☐ ☐ ☐ ☐ ☐					<1301.73>
45. Are manufacturing areas for controlled substances clearly defined, and is access limited?	☐ ☐ ☐ ☐ ☐					<1301.73>
46. Are the limited-access areas under the surveillance of a designated individual and is the designation provided in writing?	☐ ☐ ☐ ☐ ☐					<1301.73>

Total Number of Boxes Checked for Section E 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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* ANNEX 1

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
F. Final Inspection						
1. Is there a final inspection performed by quality control on a batch-by-batch basis?	□ □ □ □ □	4.10.3 4.10.4	8.2.4	1.4 2.6 4.24 5.59 6.3		211.22
2. Does quality control procedures to assure that production records are reviewed prior to release?	□ □ □ □ □	4.10.4 4.16	4.2.4 8.2.4	5.58 5.59 6.3		211.22
3. Does quality assurance approve/reject product manufactured, processed, packaged, or held under contract by another company?	□ □ □ □ □	4.6.2 4.6.4 4.7	7.4.1 7.4.3 7.5.4	7.7		211.22
4. Is there a thorough investigation of any discrepancies found during the final review of the production documents?	□ □ □ □ □	4.13 4.13.1	8.3	4.7 5.15 5.55 6.3 6.4	4.10	211.192
5. Is the product checked for correct expiration dating?	□ □ □ □ □	4.8	7.5.3	5.8 5.50 6.2 6.3		211.137
6. Are records of inspection and test data maintained? Do they include the identity of the person performing the inspection or test?	□ □ □ □ □	4.10.5 4.16	4.2.4 7.5.3 8.2.4	6.7 6.8 6.9 6.10 6.16 6.17	4.12	211.165
7. Are inspection and test activities performed by independent personnel?	□ □ □ □ □	4.1.2.1 4.10	5.5.1	2.3 2.4 2.6		
8. Are valid sampling plans used?	□ □ □ □ □	4.20	8.1	6.11 6.12	5.4.4 5.4.5 5.7	211.165
9. Do the sampling procedures specify the manner in which the samples are to be obtained and by whom?	□ □ □ □ □	4.20	8.1	6.13	5.7	211.165
10. Is there a classification of defects?	□ □ □ □ □	4.10.5	7.1 8.1	4.13		211.165
11. Are reserve samples of finished products maintained?	□ □ □ □ □			6.14		211.170
12. Is there an adequate, ongoing marketed-product stability program?	□ □ □ □ □					211.166

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
F. Final Inspection (continued)						
13. Have the accuracy, sensitivity, specificity, and reproducibility of test methods been demonstrated via validation?	□ □ □ □ □	4.11	7.6	6.15	5.4	211.165
14. In cases of finished-product rejections that result in reprocessing, is another complete final inspection performed?	□ □ □ □ □	4.10.4 4.13.2	8.2.4 8.3	5.64		211.115
15. In cases where a product does not meet performance specifications, is there a formal investigation, including regulatory-requirement considerations, with corrective/preventive actions taken?	□ □ □ □ □	4.13.2 4.14	8.3 8.5.2 8.5.3	5.39 5.62	4.9 4.10 4.11	211.192
16. Does there appear to be a sufficient number of personnel to address all of the activities?	□ □ □ □ □	4.1	6.1	2.1	4.1.5	211.25

Total Number of Boxes Checked for Section F 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
G. Final Product Handling, Storage, Distribution, Installation and Servicing						
1. Is a checklist used to verify shipping requirements?	☐ ☐ ☐ ☐ ☐					211.196
2. Is product configuration verified prior to shipments?	☐ ☐ ☐ ☐ ☐	4.15	7.55			211.150 211.196
3. Do packing and shipping records identify the individuals performing and inspecting the shipping operations?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4 7.5.5			211.25
4. Are adequate storage facilities available and in use to safeguard the quality of the product between final acceptance and shipping?	☐ ☐ ☐ ☐ ☐	4.15.3	7.5.5	3.18 3.19 3.23 5.58 5.60		211.42 211.142
5. Is a rotated-stock system employed to assure that oldest approved products are shipped first?	☐ ☐ ☐ ☐ ☐	4.15.1	7.5.5	5.7		211.150
6. Are the packing and shipping containers acceptable to protect the product?	☐ ☐ ☐ ☐ ☐	4.15.4	7.5.5			211.130
7. Is there a system to assure that only products approved for release are distributed?	☐ ☐ ☐ ☐ ☐	4.12 4.13 4.15.5	7.5.3 7.5.5 8.3	1.2 5.58 5.59		211.150 211.165
8. Do distribution records indicate the location of the following:		4.16	4.2.4	4.25 8.12		211.196
a. Name and address of the consignee?	☐ ☐ ☐ ☐ ☐					
b. Date shipped?	☐ ☐ ☐ ☐ ☐					
c. Name and quantity of the item?	☐ ☐ ☐ ☐ ☐					
d. Control numbers of the item?	☐ ☐ ☐ ☐ ☐					
9. Is there an adequate recall procedure?	☐ ☐ ☐ ☐ ☐			4.25 8.8 8.9 8.10 8.11 8.12 8.13 8.14 8.15		211.150 211.196
10. Does there appear to be a sufficient number of people available to address all of the activities?	☐ ☐ ☐ ☐ ☐	4.1	6.1	2.1		211.25
Additional questions for controlled drugs						
11. For each controlled substance in finished form in the inventory, does the labeling include the following:						<1304.11>
a. Name of the substance?	☐ ☐ ☐ ☐ ☐					
b. Dosage form (tablet, capsule, liquid, etc.)?	☐ ☐ ☐ ☐ ☐					

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
G. Final Product Handling, Storage, Distribution, Installation and Servicing (continued)						
c. Number of units or volume in each commercial container?	□ □ □ □ □					
d. Number of commercial containers of each form (four 100 tablet bottles, three 2 milliliter vials)?	□ □ □ □ □					
12. Before distributing a controlled substance, is a good-faith inquiry made either with the DEA or an appropriate state-controlled agency to determine that the recipient is registered to possess the controlled substance?	□ □ □ □ □					<1301.74>
13. Are registration certificates available and current for the authorization of handling controlled drug substances?	□ □ □ □ □					<1301.74>
14. Is there a system that will assure the disclosure of suspicious orders that are received (e.g., unusual size, deviating order patterns, or unusual frequency)?	□ □ □ □ □					<1301.74>
15. Are transit losses of controlled substances reported to the DEA?	□ □ □ □ □					<1301.74>
16. Are controlled substances listed on Schedules II–V distributed as complimentary samples without prior written request to the customer?	□ □ □ □ □					<1301.74>
17. In selecting common or contract carriers, is there an effort made to assure that adequate security is provided by those carriers?	□ □ □ □ □					<1301.74>
18. When storing controlled substances in a public warehouse, is there an investigation made to assure that adequate secure facilities are provided?	□ □ □ □ □					<1301.74>
19. When distributing controlled drug substances through agents, is there an investigation to assure that appropriate provisions are on the premises to prevent against theft or diversion?	□ □ □ □ □					<1301.74>
20. Prior to the initial distribution of etorphine hydrochloride or diprenorphine, is there an investigation to verify through the Drug Enforcement Administration that the recipient is authorized to handle the substance?	□ □ □ □ □					<1301.74>
21. Does each commercial container have printed on it the symbol designating the schedule on which the controlled substance is listed?	□ □ □ □ □					<1302.03>
22. Does the labeling of each controlled substance indicate the symbol for the schedule on which the controlled substance is listed?	□ □ □ □ □					<1302.03>

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Total Number of Boxes Checked for Section G 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

Audited by _____

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
H. Laboratories and Calibration						
Note: Questions in this section are applicable to any testing/inspection function regardless of where it occurs (e.g., QC, Mfg., Eng., etc.)						
1. Are the laboratories adequate?	☐ ☐ ☐ ☐ ☐	4.11	7.6	3.26 3.27 3.28 3.29 6.6	5.3 5.5	211.22 211.42
2. Do the facilities have adequate equipment to perform testing and inspection functions?	☐ ☐ ☐ ☐ ☐	4.11	7.6	1.4 6.5 6.6	5.3 5.5	211.63 211.22
3. Is there provision for removing or labeling defective equipment?	☐ ☐ ☐ ☐ ☐			3.44		
4. Are test procedures and results properly documented?	☐ ☐ ☐ ☐ ☐	4.10.1 4.10.2	7.1 7.5.3 8.1 8.2.4	3.1 3.2 3.3 3.40 6.7 6.8 6.9 6.16 6.17 6.18	5.4 5.5 5.10	211.160
5. Is there an index of testing documents?	☐ ☐ ☐ ☐ ☐	4.10.1 4.10.2	7.1 8.1		5.4	211.160
6. Are there specific procedures that address the identification, collection, handling, storage, treatment, and disposal of samples?	☐ ☐ ☐ ☐ ☐	4.2 4.10		6.11 6.12 6.13 6.14	5.4 5.7	211.110 211.160 211.170
7. Are raw-material file samples maintained for future reference?	☐ ☐ ☐ ☐ ☐			1.4 6.12 6.13 6.14	5.6 5.7	211.170
8. Are the laboratory reagents and other chemical supplies identified, properly stored, and expiration dated?	☐ ☐ ☐ ☐ ☐			6.19 6.20 6.21	5.3 5.4 5.5 5.6	211.165
9. Are the laboratory instruments requiring calibration:		4.11	7.6 8.1	3.41	5.3 5.4 5.5 5.6	211.160
a. Maintained according to the calibration procedures?	☐ ☐ ☐ ☐ ☐					
b. Identified to reflect date due for net calibration?	☐ ☐ ☐ ☐ ☐					
c. Stored properly?	☐ ☐ ☐ ☐ ☐					
d. Calibrated to traceable standards?	☐ ☐ ☐ ☐ ☐					

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
H. Laboratories and Calibration (continued)						
10. Are animals used in the testing of components, in-process materials, and final product maintained and controlled in a proper manner?	□ □ □ □ □			3.33 6.22		211.173
11. Where animals are used for testing, are adequate histories maintained?	□ □ □ □ □			6.22		211.173
12. Does there appear to be a sufficient number of personnel to address all of the activities?	□ □ □ □ □	4.1	6.1	2.1	4.1.5	211.25

Total Number of Boxes Checked for Section H 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
I. Computer Systems, Documentation Controls, And Quality Records						
1. Are adequate controls in effect to assure that current drawings, change notices, and specifications are available at the place of the operations?	☐ ☐ ☐ ☐ ☐	4.5.1 4.5.2	4.2.3	4.2 4.5	4.3.1	211.100
2. Are the documents up-to-date, and are unneeded/obsolete documents removed from use?	☐ ☐ ☐ ☐ ☐	4.5.1 4.5.2	4.2.3	4.5	4.3.2	211.100
3. Is at least one copy of each document, including obsolete documents, retained for at least the life of the product?	☐ ☐ ☐ ☐ ☐	4.5.2	4.2.3 7.2.1 7.3.2	4.8 6.8		211.100
4. Are the documents comprehensive in context?	☐ ☐ ☐ ☐ ☐	4.2 4.4.4	4.2.3 7.2.1 7.3.2	4.1 4.10 4.11 4.12 4.13 4.14 4.15 4.16	4.3.1	211.100
5. Do written procedures exist governing a document change-control system, and are they being followed?	☐ ☐ ☐ ☐ ☐	4.5	4.2.3	4.3 4.5 4.7 5.15	4.3.3	211.100
6. Are production records retained for appropriate time periods?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4	6.8		211.180
7. Is there documentation for each product that includes:		4.2		4.10 4.11 4.12 4.13 4.14 4.15 4.16		211.186
a. Production specifications?	☐ ☐ ☐ ☐ ☐					
b. Product drawings?	☐ ☐ ☐ ☐ ☐					
c. Product composition?	☐ ☐ ☐ ☐ ☐					
d. Product formulation?	☐ ☐ ☐ ☐ ☐					
e. Compendial references?	☐ ☐ ☐ ☐ ☐					
f. Component specifications?	☐ ☐ ☐ ☐ ☐					
g. Production-process specifications?	☐ ☐ ☐ ☐ ☐					
h. Production equipment?	☐ ☐ ☐ ☐ ☐					
i. Special precautions?	☐ ☐ ☐ ☐ ☐					
j. Production methods?	☐ ☐ ☐ ☐ ☐					
k. Cleaning methods?	☐ ☐ ☐ ☐ ☐					
l. Production procedures?	☐ ☐ ☐ ☐ ☐					
m. Production environmental specifications?	☐ ☐ ☐ ☐ ☐					
n. Quality-assurance procedures?	☐ ☐ ☐ ☐ ☐					
o. Quality-assurance specifications?	☐ ☐ ☐ ☐ ☐					
p. Quality-assurance checks performed?	☐ ☐ ☐ ☐ ☐					
q. Expected yields?	☐ ☐ ☐ ☐ ☐					

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
I. Computer Systems, Documentation Controls, And Quality Records (continued)						
r. Quality-assurance apparatus used?	☐☐☐☐☐					
s. Packaging and labeling specifications?	☐☐☐☐☐					
t. Packaging and labeling methods?	☐☐☐☐☐					
u. Packaging and labeling procedures?	☐☐☐☐☐					
v. Copies of labels, labeling, and associated labeling procedures?	☐☐☐☐☐					
w. Storage conditions?	☐☐☐☐☐					
x. Shelf-life information?	☐☐☐☐☐					
8. Does a product "history record" exist for each batch of product, and does it include the following:		4.9 4.16	4.2.4 7.5.1 7.5.2	4.17 4.18 4.23 4.26		211.188
a. Date and times of manufacture?	☐☐☐☐☐					
b. Identity of equipment used?	☐☐☐☐☐					
c. Quantity released?	☐☐☐☐☐					
d. Control number used?	☐☐☐☐☐					
e. Specific label used?	☐☐☐☐☐					
f. Control number of each component used in the manufacture of the item?	☐☐☐☐☐					
g. Weights and measure units of each component used?	☐☐☐☐☐					
h. Acceptance record of the components?	☐☐☐☐☐					
i. Inspection/test results, dates and signatures of individuals performing the inspection?	☐☐☐☐☐					
j. Line-clearance sign-off?	☐☐☐☐☐					
k. Complete labeling records?	☐☐☐☐☐					
l. Sampling performed?	☐☐☐☐☐					
m. Identification of persons performing and supervising significant steps?	☐☐☐☐☐					
n. Product yield versus theoretical yield?	☐☐☐☐☐					
o. Any deviations/investigations?	☐☐☐☐☐					
9. Are records of activities properly generated and maintained to provide evidence of conformity to requirements?	☐☐☐☐☐	4.16	4.2.4	4.4 4.8 4.9	4.12 5.10	211.180
10. Are the records legible, readily identifiable, and easily retrievable?	☐☐☐☐☐	4.16	4.2.4	4.6 4.9	4.12	211.180
11. Is there a procedure that describes how to make changes to entry errors?	☐☐☐☐☐	4.16	4.2.4	4.7	4.12	
12. Is there an established retention schedule for quality records, and does it include the controls for identification, storage, and protection?	☐☐☐☐☐	4.16	4.2.4	4.8 4.9	4.12	211.180

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
I. Computer Systems, Documentation Controls, And Quality Records (continued)						
13. Does there appear to be a sufficient number of personnel to address all of the activities?	☐ ☐ ☐ ☐ ☐	4.1	6.1	2.1	4.1.5	211.25
Additional questions for controlled drugs						
14. Are records maintained for each controlled substance, and do the following:						<1304.22>
a. Name of the substance?	☐ ☐ ☐ ☐ ☐					
b. Quantity manufactured in bulk form?	☐ ☐ ☐ ☐ ☐					
c. Date, quantity, and lot number of each batch manufactured?	☐ ☐ ☐ ☐ ☐					
d. Quantity used in manufacturing the finished product?	☐ ☐ ☐ ☐ ☐					
e. Quantity used in manufacturing?	☐ ☐ ☐ ☐ ☐					
f. Finished-product dosage form, including strength?	☐ ☐ ☐ ☐ ☐					
g. Number of units manufactured?	☐ ☐ ☐ ☐ ☐					
h. Quantity used in quality-control activities?	☐ ☐ ☐ ☐ ☐					
i. Quantity lost during manufacturing and the cause?	☐ ☐ ☐ ☐ ☐					
j. Total quantity of the substance contained in the finished product?	☐ ☐ ☐ ☐ ☐					
k. Theoretical and actual yields?	☐ ☐ ☐ ☐ ☐					
l. Other information necessary to account for all controlled substances used?	☐ ☐ ☐ ☐ ☐					

Note: Complete the following checklist questions if the computer system creates, modifies, maintains, stores, archives, retrieves, transmits, records, or documents data, or the computer system produces or stores data, records, or documents used in FDA submissions.

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP [Part 11]
	3 2 1 0 NA					
15. Does the computer system have the ability to detect invalid or altered records?	☐ ☐ ☐ ☐ ☐			4.9		[11.10a]
16. Can accurate and complete records (including metadata) be generated in human-readable and electronic forms, such as screen display or printout, or copied to a media for review?	☐ ☐ ☐ ☐ ☐			4.9		[11.10b]
17. Does a retrieval mechanism exist to ensure the records (including the metadata) are available throughout the entire record-retention period?	☐ ☐ ☐ ☐ ☐			4.9		[11.10c]
18. Are controls, such as password AND user identification, in place to limit access to the computer system?	☐ ☐ ☐ ☐ ☐			4.9		[11.10d]

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP [Part 11]
I. Computer Systems, Documentation Controls, And Quality Records (continued)						
19. Does the computer system generate secure computer-generated audit-trail information?	□ □ □ □ □			4.9		[11.10e]
20. Does the audit trail capture operator entries or actions that create, modify, or delete a record?	□ □ □ □ □			4.9		[11.10e]
21. Does the audit trail have User ID, time, and date stamps?	□ □ □ □ □			4.9		[11.10e]
22. Is the original data still accessible, and not obscured for records that have been changed?	□ □ □ □ □			4.9		[11.10e]
23. Are electronic audit trails kept as long as the respective record?	□ □ □ □ □			4.9		[11.10e]
24. Are electronic audit trails available for FDA review and copying?	□ □ □ □ □			4.9		[11.10e]
25. Does the computer system (or systems) force the sequence of process steps or events during operations (as applicable)?	□ □ □ □ □			4.9		[11.10f]
26. Does the computer system (or systems) control these sequences?	□ □ □ □ □			4.9		[11.10f]
27. Are there system checks, including authorization, level of access, and privileges, for access to the computer system (or systems)?	□ □ □ □ □			4.9		[11.10g]
28. Are there system checks to verify input-device identification (as applicable)?	□ □ □ □ □			4.9		[11.10h]
29. Is access to the system and records controlled by a designated security unit (i.e., closed system)?	□ □ □ □ □			4.9		[11.30]
30. For an OPEN system, is document encryption (or alternative) used to protect confidentiality of the electronic records during transfer?	□ □ □ □ □			4.9		[11.30]
31. For an OPEN system, are digital signatures (or alternative) used to protect the authenticity, confidentiality, and integrity of the electronic records of the systems?	□ □ □ □ □			4.9		[11.30]
If the computer system uses electronic signatures, continue with the following questions.						
32. Is the electronic signature indicated on screen displays, printouts, and other human-readable formats?	□ □ □ □ □			4.9		[11.50]
33. Does the electronic signature contain the printed name of the signer, date and time of the signing, and the meaning (review, approval, authorship) of the signature?	□ □ □ □ □			4.9		[11.50]

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP [Part 11]
I. Computer Systems, Documentation Controls, And Quality Records (continued)						
34. Is the electronic or handwritten signature linked to the associated record so that it may not be removed, copied, or transferred by ordinary means, or repudiated?	☐ ☐ ☐ ☐ ☐			4.9		[11.70]
35. Are the e-signatures unique to the user only?	☐ ☐ ☐ ☐ ☐			4.9		[11.100a]
36. Are there procedures/mechanisms to prevent user IDs from being reused, reissued or shared?	☐ ☐ ☐ ☐ ☐			4.9		[11.100b]
37. Do all nonbiometric signatures contain at a minimum, 2 components, such as a user ID and password?	☐ ☐ ☐ ☐ ☐			4.9		[11.200a]
38. Does the computer system enforce the 2 components for a single e-signature event?	☐ ☐ ☐ ☐ ☐			4.9		[11.200a]
39. Does the computer system have a mechanism to terminate an extended idle session during a continuous session when an individual could execute a series of e-signatures?	☐ ☐ ☐ ☐ ☐			4.9		[11.200a]
40. Does the computer-system design prevent another individual from altering a signed record, thus leaving the original individuals e-signature intact?	☐ ☐ ☐ ☐ ☐			4.9		[11.200a]
41. Is the password encrypted?	☐ ☐ ☐ ☐ ☐			4.9		[11.200a]
42. Does the system force the user to reset passwords after the initial administration setting?	☐ ☐ ☐ ☐ ☐			4.9		[11.200a]
43. Does the biometric signature capture an individual's unique physical feature or action? (as applicable)	☐ ☐ ☐ ☐ ☐			4.9		[11.200b]
44. Is there a control system/procedure/computer system design to ensure that passwords and/or ID tokens are aged or not reissued?	☐ ☐ ☐ ☐ ☐			4.9		[11.300b]
45. Is there a control system/procedure that ensures the ID/password combinations are unique, and revised periodically (e.g., every 90 days)?	☐ ☐ ☐ ☐ ☐			49		[11.300b]
46. Does the computer-system design include detection procedures/alarms to detect and report attempted security breaches?	☐ ☐ ☐ ☐ ☐			4.9		[11.300d]
47. Is there a procedure(s) to back up and restore, archive, and retrieve data/records from the computer system?	☐ ☐ ☐ ☐ ☐			4.9		[11.10c]
48. Is there a procedure(s) for computer-system security? Does it include user access and responsibility?	☐ ☐ ☐ ☐ ☐			4.9		[11.10d]
49. Is there documented evidence of appropriate qualifications and training of system developers, users (supplier based), and maintenance personnel?	☐ ☐ ☐ ☐ ☐			4.9		[11.10I]

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP [Part 11]
I. Computer Systems, Documentation Controls, And Quality Records (continued)						
50. Is there a procedure(s) in place governing access to and use of documents containing sensitive information (e.g., password maintenance)?	□ □ □ □ □			4.9		[11.10k]
51. Is there a procedure(s) for change control of computer-system documentation, including audit trail?	□ □ □ □ □			4.9		[11.10k]
52. Is there a procedure(s) to verify and document individual identity prior to issuing an electronic signature (supplier based)?	□ □ □ □ □			4.9		[11.100b]
53. Is there a procedure to limit use of electronic signatures to the genuine owner only (supplier based)?	□ □ □ □ □			4.9		[11.200b]
54. Is there a procedure(s) to periodically check the ID code and password issuance (supplier based)?	□ □ □ □ □			4.9		[11.300a]

Total Number of Boxes Checked for Section I 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
J. Internal Audits						
1. Is there a formal procedure for performing internal audits? ISO 10011–3, Part 4.6.3	□ □ □ □ □	4.1 4.17	5.5.1 5.6.1 8.2.2 8.5.1	1.2 9.2 9.3	4.13	
2. Are audits performed by individuals not having direct responsibility for that which is being audited? ISO 10011–1, Part 4.2.1.4 ISO 10011–3, Part 4.1	□ □ □ □ □	4.17	8.2.2	1.2 9.2	4.13	
3. If the audit team includes experts with specialized background, auditor trainees, or observers, are they indicated as such in the audit report and not listed as auditors? ISO 10011–1, Part 4.2.1.1	□ □ □ □ □	4.17	8.2.2	1.2 9.2	4.13	
4. Does the frequency of audits take into consideration significant changes in management, organization, techniques, or technologies that could affect the results of previous audits? ISO 10011–1, Part 5.1.2	□ □ □ □ □	4.17	5.6.2 8.2.2	1.2 9.1	4.13	
5. Is there an audit plan that includes the following:		4.17	8.2.2 8.2.3	1.2 9.1	4.13	
a. Objective and scope of audit?	□ □ □ □ □					
b. Identification of intended reference standards/regulations to be used?	□ □ □ □ □					
c. Identification of audit team members?	□ □ □ □ □					
d. Date and place of the audit?	□ □ □ □ □					
e. Agenda of items to be audited?	□ □ □ □ □					
f. Identification of the individuals having direct responsibility for the areas to be audited?	□ □ □ □ □					
g. Expected time and duration for each audit activity?	□ □ □ □ □					
h. An opening and closing meeting?	□ □ □ □ □					
ISO 10011–1, Part 5.2.1 ISO 10011–3, Part 4.2						
6. Is there a closing meeting where audit results are presented and discussed? ISO 10011–1, Part 5.2.1 ISO 10011–1, Part 5.3.3	□ □ □ □ □	4.1 4.17	5.6.2 8.2.2	1.2 9.3	4.13	
7. Is there a formal audit report, with a distribution list that contains all audit observations and the specific requirements of the standard, regulation, or other document against which the observation was made? ISO 10011–1, Part 5.2.1 ISO 10011–1, Part 5.3.2.2 ISO 10011–3, Part 4.2 ISO 10011–3, Part 4.6.4	□ □ □ □ □	4.1 4.16 4.17	4.2.4 5.6.2 8.2.2	1.2 9.3	4.13	

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
J. Internal Audits						
8. Are documented corrective and preventive actions taken on noted audit deficiencies? ISO 10011–1, Part 7.0 ISO 10011–3, Part 4.6.5	□ □ □ □ □	4.1 4.14 4.16 4.17	4.2.4 5.5.1 5.6.2 8.2.2 8.5.2 8.5.3	1.2 9.3	4.9 4.10 4.11 4.13	
9. Do auditors have the required education, training, and experience? ISO 10011–2, Part 4.0 ISO 10011–2, Part 5.0 ISO 10011–2, Part 6.0 ISO 10011–3, Part 4.3.1 ISO 10011–3, Part 4.5.3	□ □ □ □ □	4.1 4.17 4.18	8.2.2			
10. Does there appear to be a sufficient number of personnel to accomplish audit-program objectives? ISO 10011–3, Part 4.6.2	□ □ □ □ □	4.1	6.1	2.1	4.1.5	

Total Number of Boxes Checked for Section J 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
K. Training						
1. Is there a training procedure for new employees that includes good manufacturing practices (GMPs)?	□ □ □ □ □	4.18	6.2.2	2.8 2.9 2.10 2.11 2.12	5.2	211.25
2. Is there a refresher training program that includes GMPs?	□ □ □ □ □			2.8 2.9 2.10 2.11 2.12	5.2	211.25
3. Are all employees made aware of defects that may occur from improper performance of their respective jobs?	□ □ □ □ □	4.1 4.18	6.1 6.2.2	2.8 2.9 2.10 2.11 2.12	5.2	211.25
4. Is the training of employees properly documented?	□ □ □ □ □	4.16 4.18	4.2.4 6.2.2	2.8 2.9	5.2	211.25
5. Are written job descriptions available?	□ □ □ □ □	4.18	6.2.2	2.2 2.4 2.5 2.6 2.7	5.2	211.25
6. Is there sufficient assurance that consultants are qualified?	□ □ □ □ □	6.2.2			5.2.3	211.34
7. Are records kept of subjects on which the consultant advised?	□ □ □ □ □	4.16	4.2.4		5.2.3	211.34
8. Does there appear to be a sufficient number of personnel to address all of the functions?	□ □ □ □ □	4.1	6.1	2.1	4.1.5	211.25

Total Number of Boxes Checked for Section K 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
L. Validation						
1. Have the laboratory test methods been validated?	□ □ □ □ □	4.11	7.5.2 7.6	1.4 6.15 *91 **37	5.4	211.165 211.194
2. Is there a Validation Master Plan (VMP) that contains the following:				**4		
a. Validation policy?	□ □ □ □ □					
b. Organizational structure of validation activities?	□ □ □ □ □					
c. Summary of facilities, systems equipment, and processes to be validated?	□ □ □ □ □					
d. Documentation format for protocols and reports?	□ □ □ □ □					
e. Planning and scheduling?	□ □ □ □ □					
f. Change control?	□ □ □ □ □					
g. Reference to existing documents?	□ □ □ □ □					
3. Have all the manufacturing/packaging/inspection processes been validated to address the following:		4.9 4.11	7.5.2 7.6	5.21 5.22 5.23 5.24	*19	211.63 211.67 211.68 211.100 211.110 211.113
a. Demonstrate that the product-specification acceptance requirements can be consistently satisfied?	□ □ □ □ □					
b. Have the operating limits/settings on the equipment been qualified as being capable of achieving the desired results?	□ □ □ □ □					
c. Are the operating limits from the validation reflected in an operating procedure for employees to follow?	□ □ □ □ □					
d. Was the validation achieved without equipment failures, interruptions, or significant down time?	□ □ □ □ □					
e. Was the validation long enough in duration to simulate a typical batch size? On continuous processes, was the validation long enough to encompass power fluctuations, employee shift changes, and other factors that occur during a 24-hour period?	□ □ □ □ □					
4. If reconciliation of labeling is not performed due to 100% inspection and the inspection is automated, has the inspection process been validated?	□ □ □ □ □			5.52		211.122 211.125
5. Have support systems (e.g., compressed air, vacuum, water) been validated (certified)?	□ □ □ □ □		7.5.2	5.18 5.19 5.20 *36 **1	5.3	211.110

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INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
L. Validation (continued)						
6. Have the environmental-control systems been validated (certified)?	☐ ☐ ☐ ☐ ☐		7.5.2	5.18 5.19 5.20 **1	5.3	211.46
7. Have aseptic fill processes been validated with media fills, 3 consecutive product runs, and repeated twice per year?	☐ ☐ ☐ ☐ ☐		7.5.2	5.22 *8, *10, *36, *42, *55, *58 *69, *73, *81, *88 **1		211.113
8. Have all cleaning procedures been validated?	☐ ☐ ☐ ☐ ☐		7.5.2	5.19 **36, **38, **39, **40 **41, **42	5.3	211.67
9. In cases of computer systems for control of processes, data collection, etc., have the systems been validated, and do they include the following:			7.5.2	4.9	5.3	211.68 [11.10a]
a. Hardware validation?	☐ ☐ ☐ ☐ ☐					
b. Software validation?	☐ ☐ ☐ ☐ ☐					
c. Qualification of the equipment environment?	☐ ☐ ☐ ☐ ☐					
d. Distances between central processing units and peripheral devices validated?	☐ ☐ ☐ ☐ ☐					
e. Validation of signal conversion, if applicable?	☐ ☐ ☐ ☐ ☐					
f. Security from alteration, or use of systems by unauthorized personnel?	☐ ☐ ☐ ☐ ☐					
g. Error-detection features validated?	☐ ☐ ☐ ☐ ☐					
h. Calibration program derived?	☐ ☐ ☐ ☐ ☐					
i. Maintenance programs for computer derived?	☐ ☐ ☐ ☐ ☐					
j. Check of alarm systems?	☐ ☐ ☐ ☐ ☐					
k. Storage facilities from environmental/security perspectives?	☐ ☐ ☐ ☐ ☐					
10. Do all the validation packages include the following:		4.9 4.16	4.2.4 7.5.2	5.21 5.22 5.23 5.24 **6, **7, **8,**11, **12, **13, **14, **15, **16, **17, **18		211.63 211.67 211.68 211.100 211.110 211.113 [11.10a]
a. Detailed description of the item/system (including flow diagrams)?	☐ ☐ ☐ ☐ ☐					
b. Intended function of the system?	☐ ☐ ☐ ☐ ☐					
c. Installation-qualification information?	☐ ☐ ☐ ☐ ☐					
d. Operational-qualification information?	☐ ☐ ☐ ☐ ☐					
e. Preapproved validation protocol?	☐ ☐ ☐ ☐ ☐					
f. Performance qualification?	☐ ☐ ☐ ☐ ☐					

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INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
L. Validation (continued)						
g. Explanation of any deviations made to the original signed-off protocol?	☐ ☐ ☐ ☐ ☐					
h. Validation results?	☐ ☐ ☐ ☐ ☐					
i. Conclusions/recommendations?	☐ ☐ ☐ ☐ ☐					
j. Quality-assurance approval of validation before lot release?	☐ ☐ ☐ ☐ ☐					
11. Is there a formal change-control system that addresses change to validated systems/test methods and includes quality-assurance review/approval?	☐ ☐ ☐ ☐ ☐	4.5	4.2.3 7.5.2	5.23		211.22 211.100 [11.10a]
12. Does there appear to be a sufficient number of personnel available to address all activities?	☐ ☐ ☐ ☐ ☐	4.1	6.1	2.1	4.1.5	211.25
Additional questions for sterile products						
13. Is the system for closing the containers validated?	☐ ☐ ☐ ☐ ☐			*88		
14. Do sterilization processes address the following:				*55		
a. Validation of achieving desired sterilizing conditions in all parts of each type of load?	☐ ☐ ☐ ☐ ☐			*56 *57 *58		
b. Assurance that cooling cycles are adequate?	☐ ☐ ☐ ☐ ☐					
c. At least annual verification of validity of process?	☐ ☐ ☐ ☐ ☐					
d. Validation of loading configurations?	☐ ☐ ☐ ☐ ☐					
15. For ethylene oxide sterilization, are the conditions and times validated to permit proper degassing?	☐ ☐ ☐ ☐ ☐			*81		

Total Number of Boxes Checked for Section L 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
M. Facility Engineering and Maintenance						
1. Are the facilities acceptable for a drug product, and clean areas classified by levels?	□ □ □ □ □	4.9	7.5.1	3.1 3.4 3.9 3.32 3.33 *1 *2 *3	5.3	211.42
2. Are the sanitation and maintenance procedures for the manufacturing and ventilation equipment being followed?	□ □ □ □ □		7.5.1	3.2 3.43	5.3	211.56 211.67
3. Is there a review to assure that the maintenance procedure will not present a product-quality risk?	□ □ □ □ □			3.35		
4. For equipment utilized by engineering and maintenance personnel, are there adequate written calibration procedures? Is there a record of the calibrations that are being performed?	□ □ □ □ □	4.11	7.6	3.32 3.40 3.41	5.3 5.5	211.160
5. Are the environmental systems adequate and monitored to control air pressure, humidity, temperature, microorganisms, air flow, and particulate matter?	□ □ □ □ □	4.9	7.5.1	3.3 3.12 *4 *5	5.3	211.42 211.46
6. Are there procedures and logs to assure sanitation and pest control?	□ □ □ □ □				5.3	211.56
7. Are the adjacent exterior grounds manicured?	□ □ □ □ □				5.3	211.56
8. Is there an adequate supply of potable water that meets the public health service drinking-water standards?	□ □ □ □ □			3.30 3.31	5.1 5.3	211.48
9. Are adequate washing facilities with hot/cold water, soap, clean toilets, and air dryers or single-service towels provided?	□ □ □ □ □			3.30 3.31	5.1 5.3	211.52
10. Is the lighting in all areas adequate?	□ □ □ □ □			3.3 3.16	5.3	211.44
11. Are adequately constructed waste containers located in appropriate areas?	□ □ □ □ □			5.61	5.3	211.50
12. Are drains to sewers designed with an air break to prevent back siphonage?	□ □ □ □ □			3.11		211.48
13. Is there an adequate disposal-collection system?	□ □ □ □ □				5.3	211.50
14. Is there an adequate sanitation program for the water system?	□ □ □ □ □			3.43	5.3	211.56 211.67

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INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
M. Facility Engineering and Maintenance (continued)						
15. Are there designated areas for eating, drinking, and smoking?	□ □ □ □ □			3.30	5.1 5.3	211.42
16. Is there an acceptable separate gowning area?	□ □ □ □ □	4.9	7.5.1	3.31		211.42
17. Are the environmental-control systems periodically inspected, and are those inspections documented?	□ □ □ □ □	4.9	7.5.1	3.2 3.3 5.20	5.3	211.42 211.46
18. Is there a formal maintenance schedule of manufacturing equipment? Is it kept visibly near each piece of equipment?	□ □ □ □ □			3.34 3.35 5.20	5.5	211.42 211.56 211.67
19. Are periodic inspections made and documented to assure that the maintenance of manufacturing equipment is performed according to established schedules?	□ □ □ □ □			3.34 3.35 5.20	5.3 5.5	211.42 211.56 211.67 211.82
20. Are tools, gauges, and test equipment used by engineering and maintenance personnel:		4.11	7.6	3.41	5.3 5.5	211.160
a. Identified to reflect the date calibrated?	□ □ □ □ □					
b. Identified to reflect the date due for the next calibration?	□ □ □ □ □					
c. Marked with the identification of the person responsible for such calibration?	□ □ □ □ □					
21. Are adequate facilities used for storage of tools, gauges, and test equipment?	□ □ □ □ □	4.11	7.6	1.3 3.36	5.3 5.5	211.160
22. Are acceptable calibration standards employed?	□ □ □ □ □	4.11	7.6	3.41	5.3 5.5	211.160
23. Are there positive pressure differentials with all doors leading into less clean areas?	□ □ □ □ □	4.9	7.5.1	3.7 5.19 5.20	5.3	211.42
24. Are the positive atmospheric controls calibrated and monitored?	□ □ □ □ □	4.9	7.5.1	5.20	5.3	211.42 211.58
25. Are there established air-controlled environments, and are they operating within limits?	□ □ □ □ □	4.9	7.5.1	3.6 3.7 5.20	5.3	211.42 211.58
26. Are facility and equipment drawings and blueprints adequately controlled?	□ □ □ □ □	4.5	4.2.3 7.5.1			211.100
27. Do pipes indicate contents and direction of flow?	□ □ □ □ □		7.5.1	3.42		211.42
28. Does there appear to be a sufficient number of personnel to address the activities?	□ □ □ □ □	4.1	6.1	2.1	4.1.5	211.25

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
M. Facility Engineering and Maintenance (continued)						
Additional questions for sterile products						
29. Are isolators monitored for leaks?	☐ ☐ ☐ ☐ ☐			*9		
30. Do the premises and equipment address the following:				*22		
a. Smooth, impervious, and unbroken surfaces?	☐ ☐ ☐ ☐ ☐			*23		
b. No uncleanable recesses?	☐ ☐ ☐ ☐ ☐			*24		
c. False ceilings sealed?	☐ ☐ ☐ ☐ ☐			*25		
d. No sinks or drains in grade A/B areas used for aseptic manufacture?	☐ ☐ ☐ ☐ ☐			*27 *28 *29		
e. Other areas have air breaks between the machine or sink and the drains?	☐ ☐ ☐ ☐ ☐			*30 *31		
f. Air locks at appropriate grade levels?	☐ ☐ ☐ ☐ ☐			*32 *33		
g. Entrance and exit doors to air locks that do not open at the same time?	☐ ☐ ☐ ☐ ☐			*34 *35		
h. Warning systems to indicate air-control failures?	☐ ☐ ☐ ☐ ☐			*37		
i. No conveyor belts traveling between Grade A and B areas unless continually sterilized?	☐ ☐ ☐ ☐ ☐			*38 *39		
j. Designs so that service to the area can be performed outside of it?	☐ ☐ ☐ ☐ ☐					
k. Planning and tracking of maintenance operations to assure against contamination before or after activities are performed?	☐ ☐ ☐ ☐ ☐					
l. Water treatment, distribution, and storage facilities that assure against microbial growth?	☐ ☐ ☐ ☐ ☐					
m. Sanitization of areas, equipment, etc. using approved agents and methods?	☐ ☐ ☐ ☐ ☐					
n. Monitoring of sanitization effectiveness?	☐ ☐ ☐ ☐ ☐					
Additional questions for controlled drugs						
31. For schedule I and II materials:						<1301.72>
a. For small quantities, is there a safe or steel cabinet that provides:						
i. 30 man-minutes against surreptitious entry?	☐ ☐ ☐ ☐ ☐					
ii. 10 man-minutes against forced entry?	☐ ☐ ☐ ☐ ☐					
iii. 20 man-hours against lock manipulation?	☐ ☐ ☐ ☐ ☐					
iv. 20 man-hours against radiological techniques?	☐ ☐ ☐ ☐ ☐					
v. If safe weighs less than 750 lbs., is it bolted securely so that it cannot be removed?	☐ ☐ ☐ ☐ ☐					
vii. An alarm system that transmits to local or state police, or a 24-hour central station operated by the company?	☐ ☐ ☐ ☐ ☐					

* ANNEX 1

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
M. Facility Engineering and Maintenance (continued)						
b. For larger quantities, a vault that provides						
i. Wall or perimeter line that transmits to a central-station protection company, local or state police agency, or a 24-hour control station operated by the registrant?	☐ ☐ ☐ ☐ ☐					
ii. Contact switch on the door of the vault, connected to the alarm system?	☐ ☐ ☐ ☐ ☐					
iii. One of the following to detect entry:						
– Complete electronic lacing of the walls?	☐ ☐ ☐ ☐ ☐					
– Ultrasonic equipment within the vault?	☐ ☐ ☐ ☐ ☐					
– A sound-accumulation system?	☐ ☐ ☐ ☐ ☐					
iv. Walls, floors, and ceilings constructed of at least 8 inches of reinforced concrete, reinforced vertically and horizontally with 0.5-inch steel rods tied 6 inches on the center?	☐ ☐ ☐ ☐ ☐					
v. A door and frame unit that provides:						
– 30 man-minutes against surreptitious entry?	☐ ☐ ☐ ☐ ☐					
– 10 man-minutes against forced entry?	☐ ☐ ☐ ☐ ☐					
– 20 man-hours against lock manipulation?	☐ ☐ ☐ ☐ ☐					
– 20 man-hours against radiological techniques?	☐ ☐ ☐ ☐ ☐					
vi. A "day gate" that is self-closing and self-locking during the hours of operation in which the vault doors open?	☐ ☐ ☐ ☐ ☐					
32. For Schedules III, IV, and V, are one of the following employed for storage:						<1301.72>
a. A safe or steel cabinet as described in question 31.a?	☐ ☐ ☐ ☐ ☐					
b. A vault as described in question 31.b?	☐ ☐ ☐ ☐ ☐					
c. A building with perimeter security that limits access during working hours?	☐ ☐ ☐ ☐ ☐					
i. A building that provides security after working hours with an alarm as described in question 31.a.vi?	☐ ☐ ☐ ☐ ☐					
ii. A building equipped with self-closing/locking doors with sealed or welded hinges to prevent removal?	☐ ☐ ☐ ☐ ☐					
iii. Are there locks on doors with limited access to a limited number of employees?	☐ ☐ ☐ ☐ ☐					

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
	3 2 1 0 NA					
M. Facility Engineering and Maintenance (continued)						
d. A cage located within a building on the premises that:						
i. Has walls with not less than 10-gauge steel fabric mounted on steel posts?	☐ ☐ ☐ ☐ ☐					
ii. Has posts at least 1 inch in diameter?	☐ ☐ ☐ ☐ ☐					
iii. Has posts set in concrete or with lag bolts that are pinned or braised?	☐ ☐ ☐ ☐ ☐					
iv. Has posts that are not more than 10 feet apart with horizontal 1.5-inch reinforcements every 60 inches?	☐ ☐ ☐ ☐ ☐					
v. Has mesh construction of not more than 2.5 inches across the square?	☐ ☐ ☐ ☐ ☐					
vi. Has a ceiling of the same construction that is securely attached to the structural ceiling of the building?	☐ ☐ ☐ ☐ ☐					
vii. Has a door constructed of 10-gauge steel fabric on a metal frame in a metal flange?	☐ ☐ ☐ ☐ ☐					
viii. Is equipped with alarms as described in question 31.a.vi?	☐ ☐ ☐ ☐ ☐					

Total Number of Boxes Checked for Section M 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
N. Complaint Handling						
1. Is there a written procedure for handling written and oral complaints?	☐ ☐ ☐ ☐ ☐	4.14	8.5.2 8.5.3	8.2 8.3	4.8	211.198
2. Are complaints processed in a uniform and timely manner?	☐ ☐ ☐ ☐ ☐	4.14	8.5.2 8.5.3	8.2 8.3	4.8	211.198
3. Does the complaint record indicate the following:		4.14 4.16	4.2.4 8.5.2 8.5.3	8.2 8.3	4.8	211.198
a. Date of complaint?	☐ ☐ ☐ ☐ ☐					
b. Name and strength of the product?	☐ ☐ ☐ ☐ ☐					
c. Lot number?	☐ ☐ ☐ ☐ ☐					
d. Name of complainant?	☐ ☐ ☐ ☐ ☐					
e. Nature of complaint?	☐ ☐ ☐ ☐ ☐					
f. Reply to complainant?	☐ ☐ ☐ ☐ ☐					
4. Are complaints reviewed promptly to determine if the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the US Food and Drug Administration (FDA)?	☐ ☐ ☐ ☐ ☐			8.6 8.7		211.198
5. Are complaints reviewed to determine if an investigation is necessary?	☐ ☐ ☐ ☐ ☐	4.14	8.5.2 8.5.3	8.6	4.8 4.10 4.11	211.198
6. If no investigation is deemed necessary, is the rationale for that decision documented and signed by the individual making it?	☐ ☐ ☐ ☐ ☐	4.14 4.16	4.2.4 8.5.2 8.5.3		4.8 4.10 4.11	211.198
7. If an investigation is performed, is it performed by the quality-control unit, and does the complaint record include (in addition to items in question #3):		4.14 4.16	4.2.4 8.5.2 8.5.3	8.2 8.3 8.4	4.10 4.11	211.198
a. Documented request for returned product/sample?	☐ ☐ ☐ ☐ ☐					
b. Determination of whether the product failed to meet specifications?	☐ ☐ ☐ ☐ ☐					
c. Dates and results of investigation?	☐ ☐ ☐ ☐ ☐					
d. Corrective/preventive actions taken?	☐ ☐ ☐ ☐ ☐					

Total Number of Boxes Checked for Section N 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
O. Quality-Management Systems and Responsibilities						
1. Is there a formal quality policy by the management of the company, and does its communication to the organization include the importance of meeting statutory as well as regulatory requirements?	☐ ☐ ☐ ☐ ☐	4.1	5.1 5.3 5.4.1		4.2	
2. Is there a "quality system" that addresses the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management?	☐ ☐ ☐ ☐ ☐	4.1 4.2	4.1 5.5.1	1.2 1.3 1.4 2.3	4.2	211.22
3. Is there a "Quality Manual" that addresses the "quality system"?	☐ ☐ ☐ ☐ ☐	4.1 4.2	4.2.1 4.2.2		4.2	
4. Are there periodic management reviews of the quality system and are the following inputs included:		4.1 4.16	4.1 4.2.4 5.6.1 5.6.2 8.5.1		4.14	
a. Results of audits?	☐ ☐ ☐ ☐ ☐					
b. Customer feedback?	☐ ☐ ☐ ☐ ☐					
c. Process performance and product conformity?	☐ ☐ ☐ ☐ ☐					
d. Status of corrective and preventive action?	☐ ☐ ☐ ☐ ☐					
e. Follow-up actions from previous management reviews?	☐ ☐ ☐ ☐ ☐					
f. Changes that could affect the quality-management system?	☐ ☐ ☐ ☐ ☐					
g. Recommendations for improvement?	☐ ☐ ☐ ☐ ☐					
5. Does the organization analyze appropriate data to demonstrate the suitability and effectiveness of the quality-management system in regards to the following:			8.4		4.14	
a. Customer satisfaction?	☐ ☐ ☐ ☐ ☐					
b. Conformity to product requirements?	☐ ☐ ☐ ☐ ☐					
c. Trends of processes and products, including opportunities for preventive action?	☐ ☐ ☐ ☐ ☐					
d. Suppliers?	☐ ☐ ☐ ☐ ☐					
6. Does top management provide communication within the organization regarding the effectiveness of the quality-management system?	☐ ☐ ☐ ☐ ☐		5.5.3		4.14	
7. Is the individual responsible for the quality-assurance program (management representative) not directly responsible for the performance of a manufacturing operation?	☐ ☐ ☐ ☐ ☐	4.1	4.1 5.5.2	2.3 2.4 2.6 2.7	4.1	
8. Does quality assurance have the authority to approve/reject plant, equipment, process, and procedural changes?	☐ ☐ ☐ ☐ ☐	4.5	7.4.1 7.4.3 7.5.4	2.6 2.7 4.3 6.18		211.22

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	USGMP Part 211 <Part 1301> [Part 11]
O. Quality-Management Systems and Responsibilities						
9. Are personnel in contact with drugs given physical inspections or periodic health checks?	□ □ □ □ □			2.14		211.28
10. Is there a procedure for exclusion of ill personnel or personnel who have open lesions, from product-contact jobs?	□ □ □ □ □			2.15		211.28

Total Number of Boxes Checked for Section O 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating 3 2 1 0 NA	Section
P. EC GMP ANNEX 1: Manufacture of Sterile Medicinal Products		
Facilities, Equipment and Processes	☐ ☐ ☐ ☐ ☐	
1. Are the clean areas for manufacturing divided into grades A, B, C, or D as defined in Annex 1?	☐ ☐ ☐ ☐ ☐	1, 2, 3
2. Are clean areas monitored for particulate and microbial contamination, humidity, temperature, and air flow?	☐ ☐ ☐ ☐ ☐	4, 5, 45
3. Are isolators monitored for leaks?	☐ ☐ ☐ ☐ ☐	9
4. For blow/fill/seal equipment, is an air shower part of the design, and does it meet grade A, B, C, or D as required?	☐ ☐ ☐ ☐ ☐	10
5. For aseptic/terminally sterilized items, are the components/products prepared in the right grade environment?	☐ ☐ ☐ ☐ ☐	11, 12
6. Do the premises and equipment address the following:		22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39
a. Exposed surfaces are smooth, impervious and unbroken?	☐ ☐ ☐ ☐ ☐	
b. No uncleanable recesses, ledges, shelves, pipes and equipment?	☐ ☐ ☐ ☐ ☐	
c. False ceilings sealed?	☐ ☐ ☐ ☐ ☐	
d. Sinks and drains prohibited in aseptic manufacturing areas?	☐ ☐ ☐ ☐ ☐	
e. Change rooms that act as air locks with doors that do not open simultaneously?	☐ ☐ ☐ ☐ ☐	
f. Positive pressure differentials?	☐ ☐ ☐ ☐ ☐	
g. Conveyor belts that do not pass through a processing area of lower air cleanliness unless continually sterilized?	☐ ☐ ☐ ☐ ☐	
h. An adequate continuous loop water system?	☐ ☐ ☐ ☐ ☐	
i. Validation of equipment?	☐ ☐ ☐ ☐ ☐	
7. Does processing of materials address the following:		42, 43, 44, 50, 51, 52, 53
a. Validation of aseptic processes via use of a media fill?	☐ ☐ ☐ ☐ ☐	
b. 3 consecutive validation runs on each shift?	☐ ☐ ☐ ☐ ☐	
c. Repeated at least twice per year?	☐ ☐ ☐ ☐ ☐	
d. Time limits between washing, drying, and sterilization?	☐ ☐ ☐ ☐ ☐	
e. Time limits between preparation, start of solution, and its sterilization or filtration?	☐ ☐ ☐ ☐ ☐	
f. Bioburden monitoring and absence of pyrogens assured?	☐ ☐ ☐ ☐ ☐	
g. Passing of solutions and noncombustible gases through a microorganism-retaining filter?	☐ ☐ ☐ ☐ ☐	
8. Do sterilization processes address the following?		55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81
a. Validation of achieving desired sterilizing conditions in all parts of each type of load?	☐ ☐ ☐ ☐ ☐	
b. Assurance that cooling cycles are adequate?	☐ ☐ ☐ ☐ ☐	
c. At least annual verification of validity of process?	☐ ☐ ☐ ☐ ☐	
d. Validation of loading configurations?	☐ ☐ ☐ ☐ ☐	
e. Use of biological/dosimeter indicators?	☐ ☐ ☐ ☐ ☐	
f. A clear means of differentiating between sterilized and nonsterilized lots?	☐ ☐ ☐ ☐ ☐	
g. Appropriate records/charts of each sterilizer run (e.g., time, temperature, pressure, etc.)?	☐ ☐ ☐ ☐ ☐	
h. Monitoring of drain temperatures in the sterilizer run?	☐ ☐ ☐ ☐ ☐	
i. Air used in the process is HEPA filtered?	☐ ☐ ☐ ☐ ☐	
j. Validated conditions and times to permit proper degassing from ethylene oxide use?	☐ ☐ ☐ ☐ ☐	

INTERNAL DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating 3 2 1 0 NA	Section
P. EC GMP ANNEX 1: Manufacture of Sterile Medicinal Products		
9. Does filtration of products which cannot be sterilized in their final container address the following?		82, 83, 84,
a. Filtration through a filter pore size of 0.22 micron or less?	☐ ☐ ☐ ☐ ☐	85, 86, 87
b. Non fibre shedding filters?	☐ ☐ ☐ ☐ ☐	
c. Bubble point, diffusive flow or pressure hold testing for filter assembly integrity before and after use?	☐ ☐ ☐ ☐ ☐	
d. Length of filter use validated?	☐ ☐ ☐ ☐ ☐	
e. Compatibility of filter with product qualified?	☐ ☐ ☐ ☐ ☐	
Container/closure systems	☐ ☐ ☐ ☐ ☐	
10. Is the system for closing the container validated?	☐ ☐ ☐ ☐ ☐	88
11. Are containers closed by fusion (e.g., ampoles) 100% integrity tested?	☐ ☐ ☐ ☐ ☐	88
12. Are containers sealed under vacuum tested for maintenance of vacuum for an appropriate length of time?	☐ ☐ ☐ ☐ ☐	89
13. Are containers visually inspected for contamination and, if inspected electronically, is the process validated?	☐ ☐ ☐ ☐ ☐	90
Quality control	☐ ☐ ☐ ☐ ☐	
14. Are sterility tests performed on final product, and are the tests qualified for each product?	☐ ☐ ☐ ☐ ☐	91
15. Are sterility test samples taken in a manner representative of the entire batch?	☐ ☐ ☐ ☐ ☐	93
Personnel	☐ ☐ ☐ ☐ ☐	
16. Is there a maximum number of personnel allowed in clean areas performing activities?	☐ ☐ ☐ ☐ ☐	13
17. When outside staff (maintenance, service, visitors) are brought in, is there a procedure being followed that assures such personnel are properly instructed and supervised?	☐ ☐ ☐ ☐ ☐	14
18. Are personnel engaged in processing of animal-tissue materials or cultures of microorganisms restricted from sterile-product areas?	☐ ☐ ☐ ☐ ☐	15
19. Are personnel monitored for shedding of contaminants?	☐ ☐ ☐ ☐ ☐	16.
20. Are there specific procedures for changing clothes and washing before entering clean areas?	☐ ☐ ☐ ☐ ☐	17
21. Are wristwatches, makeup, and jewelry prohibited in clean areas?	☐ ☐ ☐ ☐ ☐	18
22. Is the type of gowning specified for the level of clean room?	☐ ☐ ☐ ☐ ☐	19

Total Number of Boxes Checked for Section P 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Scope: This checklist should be utilized to evaluate a source that develops or manufactures medical device products/assemblies on a contract basis for another company.

In the case of software-development contractors, the "Contract Software-Developer Audit Checklist" should be used.

This checklist covers the following areas:

A. Contract Review
B. Development and Design Control
C. Purchasing
D. Receiving/In-Process-Material Handling and Storage
E. Production/Packaging/In-Process Control
F. Final Inspection
G. Final-Product Handling, Storage, Distribution, Installation, and Servicing
H. Laboratories and Calibration
I. Computer Systems, Documentation Controls, and Quality Records
J. Internal Audits
K. Training
L. Validation
M. Facility Engineering and Maintenance
N. Complaint Handling
O. Medical Device Tracking, Reporting, and Recalls
P. Quality-Management Systems and Responsibility
Q. Other Considerations

The questions in this checklist include references to:

1. The United States Code of Federal Regulations 21 CFR, Part 820—Quality System Regulation (QSReg.), Current Good Manufacturing Practice (CGMP) Requirements for Medical Devices
2. The United States Code of Federal Regulations 21 CFR, Part 11—Electronic Records; Electronic Signatures. These questions are located in the Computer Systems, Documentation Controls, and Records section of the checklist.
   Note: References in the checklist column are indicated with squared brackets [].

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

3. The United States Code of Federal Regulations 21 CFR, Sections 803.17 and 803.18 for Medical Device Reporting
4. The United States Code of Federal Regulations 21 CFR, Section 806.10 for Corrections and Removals (Recalls)
5. The United States Code of Federal Regulations 21 CFR, Section 821.25 for Medical Device Tracking
6. International Organization for Standardization (ISO) ISO 9001:1994, Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation and Servicing, and ISO 9001:2000, Quality Management Systems—Requirements
7. International Organization for Standardization (ISO) documents ISO 13485:1996, Quality Systems—Medical Devices—Particular Requirements for the Application of ISO 9001, and ISO 13488:1996, Quality Systems—Medical Devices—Particular Requirements for the Application of ISO 9002.
   Note: References to ISO 13488 are indicated in the checklist by parenthesis ( ).
8. International Organization for Standardization (ISO) 10011–1:1990, 2:1991, and 3:1991; Guidelines for Auditing Quality Systems: Auditing; Qualification Criteria for Quality System; and Management of Audit Programmes (American ISO equivalent, ANSI/ASQC Q10011–1, 2, and 3)
   Note: References to this standard are indicated under each appropriate question in the checklist.
9. International Organization for Standardization (ISO) 17025:1999, General Requirements for the Competence of Testing and Calibration Laboratories
   Note: References to ISO 17025 are indicated in the checklist by arrow brackets < >.

Because audits may be performed by more than one person, signature spaces are provided at the end of each section to provide a record of each individual auditor's activities.

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Date(s) of Audit _____

Facility Location Company Name _____

Address _____

City _____ State _____ Zip _____

Telephone _____ Fax _____

E-mail _____

Is the company a division or subsidiary of another corporation?

If yes, describe relationships _____

_____

Audit Leader Name _____

Title _____

Audit Team Members Name _____

Function on Team _____

Name _____

Function on Team _____

Name _____

Function on Team _____

Name _____

Function on Team _____

Nature of Audit

1. Prospective Source _____ Current Source _____

2. Problem-Instigated Audit* _____ Routine Audit _____

*Nature of Problem _____

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Items currently manufactured for our company:

1. _____

2. _____

3. _____

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Items being considered to be manufactured for our company:

1. _____
2. _____
3. _____

How is a lot/batch defined?

_____

_____

What is the lot/batch-numbering system?

_____

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How many shifts are there? _____

Approximate number of employees at facility? _____

Approximate square footage of facility (including warehouse)? _____

Has a regulatory agency inspected the facility? If yes, provide dates and results:

_____

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Is the facility of company ISO 9000 Certified? If yes, describe: _____

If yes, who is the notified body? _____

Primary Individuals Contacted

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Closing (Wrap-up) Meeting Date _____

Attendees _____

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Audit Report Date Issued _____

Date Response Received _____

Date Response and Action Plan Approved _____

Date Actions Completed _____

Date Completed Actions Verified as Completed _____

Date Completed Actions Verified as Effective _____

Date Closed Out _____

Future Follow-up Items _____

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CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

QUALITY RATING SYSTEM

Rating	*Meaning*	*Interpretation*
3	Excellent	Item/area/system/knowledge is superior
2	Adequate	Item/area/system/knowledge meets basic minimum requirements.
1	Deficient	Item/area/system/knowledge is weak and not up to acceptable standards.
0	Unsatisfactory	Item/area/system/knowledge is missing or of a nature to warrant serious quality/compliance concerns.
NA	Not Applicable	Question is not applicable to type of operation, or item unable to be addressed during the audit.

Comment: Some users of the checklist may find the responses to some questions difficult to quantify on a 0–3 scale and may prefer to use a simple "yes" or "no" approach. In such cases, a "yes" should be assigned a "2" value, and a "no" should be assigned a "0" value.

CHECKLIST RESULTS AND RATING

	Number of Occurrences			
Section	**3s**	**2s**	**1s**	**0s**
A. Contract Review				
B. Development and Design Control				
C. Purchasing				
D. Received/In-Process-Material Handling and Storage				
E. Production/Packaging/In-Process Control				
F. Final Inspection				
G. Final-Product Handling, Storage, Distribution, Installation, and Servicing				
H. Laboratories and Calibration				
I. Computer Systems, Documentation Controls, and Quality Records				
J. Internal Audits				
K. Training				
L. Validation				
M. Facility Engineering and Maintenance				
N. Complaint Handling				
O. Medical Device Tracking, Reporting, and Recalls				
P. Quality-Systems Management and Responsibility				
Q. Other Considerations				
Totals				

Audit Findings Summary

Number of questions rated excellent ( ) Times 3 = ( )
Number of questions rated adequate ( ) Times 2 = ( )
Number of questions rated deficient ( ) Times 1 = ( )
Number of questions rated unsatisfactory (____) Times 0 = (____)

Total Number of Questions Answered = (____) Rating Total = (____)

"Rating Total" divided by "Number of Questions Answered" = _____ Audit Rating

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

I. Strengths

1. _____
2. _____
3. _____
4. _____
5. _____

II. Weaknesses

1. _____
2. _____
3. _____
4. _____
5. _____

III. Recommendations

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CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
A. Contract Review					
1. Are the requirements and expectations of both parties, including specifications and acceptance criteria, adequately detailed in a contract? Examples:		4.3	5.2 7.2.1	7 <4.4.1>	
a. Who has responsibility and authority for supplier selection and purchasing of components?	☐ ☐ ☐ ☐ ☐				
b. Who will perform reliability or stability studies?	☐ ☐ ☐ ☐ ☐				
c Who will perform final-product testing?	☐ ☐ ☐ ☐ ☐				
d. Who will release product to market?	☐ ☐ ☐ ☐ ☐				
e. Will batch records be required to be sent for review before release?	☐ ☐ ☐ ☐ ☐				
f. Who will store/distribute product?	☐ ☐ ☐ ☐ ☐				
g. Who will accommodate regulatory inspections? If contractor, will we be notified/involved?	☐ ☐ ☐ ☐ ☐				
h. Who will receive/process/respond to product complaints?	☐ ☐ ☐ ☐ ☐				
i. Who will be responsible for recall procedures?	☐ ☐ ☐ ☐ ☐				
j. Who will be responsible for "installation" of devices?	☐ ☐ ☐ ☐ ☐				
k. Who will be responsible for "servicing" installations?	☐ ☐ ☐ ☐ ☐				
l. Who will receive/disposition returned goods?	☐ ☐ ☐ ☐ ☐				
m. Who will be responsible for the issuance and change control of:	☐ ☐ ☐ ☐ ☐				
i. Component, in-process, final product specifications?	☐ ☐ ☐ ☐ ☐				
ii. Labeling?	☐ ☐ ☐ ☐ ☐				
iii. Lot number system?	☐ ☐ ☐ ☐ ☐				
iv. Batch record formats?	☐ ☐ ☐ ☐ ☐				
v. Manufacturing instructions?	☐ ☐ ☐ ☐ ☐				
vi. Bills of materials?	☐ ☐ ☐ ☐ ☐				
vii. Test methods?	☐ ☐ ☐ ☐ ☐				
viii. Procedures?	☐ ☐ ☐ ☐ ☐				
ix. Sampling plans?	☐ ☐ ☐ ☐ ☐				
x. Sampling methods?	☐ ☐ ☐ ☐ ☐				
xi. Design requirements?	☐ ☐ ☐ ☐ ☐				
n. Who will write validation protocols, perform testing, review and maintain packages?	☐ ☐ ☐ ☐ ☐				
2. Where appropriate, are customer documents translated into the firm's internal documentation? If so, is the system of control adequate to assure that current editions will be utilized in manufacturing the items?	☐ ☐ ☐ ☐ ☐	4.3	7.22	4 4.3 (4.3) <4.4.5>	

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
A. Contract Review (continued)					
3. Does the contract, or other document, specify how amendments are made and communicated to affected functions?	□ □ □ □ □	4.3	7.2.2	4.3 (4.3) <4.4.1> <4.4.4> <4.4.5>	
4. Are the contracts periodically reviewed for adequacy?	□ □ □ □ □	4.3	7.2.2	4.3 (4.3) <4.4.2>	
5. Are records of these periodic reviews maintained for a specified period of time?	□ □ □ □ □	4.3 4.16	4.2.4 7.2.2	4.3 (4.3) <4.4.2>	
6. Is there are a procedure established and being followed that describes how verbal and formal orders are to be processed?	□ □ □ □ □	4.3	7.2.3	4.3 (4.3) <4.4.1>	
7. Is there a procedure for resolving processed-order problems?	□ □ □ □ □	4.3	7.2.3	4.3 (4.3) <4.4.2> <4.7> <4.8>	
8. Are subcontract intentions approved by the customer first?	□ □ □ □ □			<4.5>	

Total Number of Boxes Checked for Section A 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
B. Development and Design Control					
1. For projects relating to new or modified products, services, or processes, is there a written plan that identifies each activity required and the person responsible?	☐ ☐ ☐ ☐ ☐	4.4.1 4.4.2	7.3.1	4.4.1 4.4.2	820.30
2. Do the plans address and define the following:		4.4.1 4.4.2	7.3.1	4.4.1 4.4.2	820.30
a. Purpose/scope of project?	☐ ☐ ☐ ☐ ☐				
b. Strategy for development?	☐ ☐ ☐ ☐ ☐				
c. Configuration management?	☐ ☐ ☐ ☐ ☐				
d. Verification strategy?	☐ ☐ ☐ ☐ ☐				
e. Validation strategy?	☐ ☐ ☐ ☐ ☐				
f. Design standards, methodologies, practices, and conventions to be followed?	☐ ☐ ☐ ☐ ☐				
g. Design tools to be used?	☐ ☐ ☐ ☐ ☐				
h. Document control, approval, and distribution?	☐ ☐ ☐ ☐ ☐				
i. Training strategy?	☐ ☐ ☐ ☐ ☐				
j. Deliverables at each phase of development?	☐ ☐ ☐ ☐ ☐				
k. Acceptance criteria for moving into next phase?	☐ ☐ ☐ ☐ ☐				
l. Interfaces of groups and their responsibilities?	☐ ☐ ☐ ☐ ☐				
Examples: – Marketing—Customer requirements – Engineering—Design requirements – Regulatory—Premarket approval – Purchasing—Supplier requirements – Manufacturing—Pilot runs – Quality Assurance—Testing/design reviews					
3. Are all design and development plans approved and under revision control?	☐ ☐ ☐ ☐ ☐	4.4.1 4.4.2 4.4.9	7.3.1 7.3.7	4.4.1 4.4.2	820.30
4. Is there a project-development schedule under revision control that identifies tasks, responsibilities, time required, and interrelationships/dependencies between tasks?	☐ ☐ ☐ ☐ ☐	4.4.1 4.4.2	7.3.1	4.2 4.4.1	820.30
5. Is appropriate design input obtained to assure the needs of the user and patient (including safety)?	☐ ☐ ☐ ☐ ☐	4.4.4	7.2.1 7.3.2	4.4.4	820.30
6. Is the design output defined in terms that allow an adequate evaluation of conformance to design-input requirements?	☐ ☐ ☐ ☐ ☐	4.4.5	7.3.3	4.4.5	820.30
7. Is there a design review after each phase?	☐ ☐ ☐ ☐ ☐	4.4.6	7.3.4	4.4.6	820.30

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
B. Development and Design Control (continued)					
8. Does the design review address each of the following items:		4.4.6	7.3.4	4.4.6	820.30
a. Comparison of customer needs with technical specifications for materials, products, and processes?	☐ ☐ ☐ ☐ ☐				
b. Validation of the design through prototype tests?	☐ ☐ ☐ ☐ ☐				
c. Ability to perform under expected conditions of use and environments?	☐ ☐ ☐ ☐ ☐				
d. Considerations of unintended uses and misuses?	☐ ☐ ☐ ☐ ☐				
e. Safety and environmental compatibility?	☐ ☐ ☐ ☐ ☐				
f. Compliance with regulatory requirements, national and international standards, and corporate practices?	☐ ☐ ☐ ☐ ☐				
g. Comparisons with competitive designs?	☐ ☐ ☐ ☐ ☐				
h. Comparisons with similar designs, especially analysis of internal and external problem history, to avoid repeating problems?	☐ ☐ ☐ ☐ ☐				
i. Reliability, serviceability, and maintainability?	☐ ☐ ☐ ☐ ☐				
j. Permissible tolerances and comparison with process capabilities?	☐ ☐ ☐ ☐ ☐				
k. Product-acceptance/rejection criteria?	☐ ☐ ☐ ☐ ☐				
l. Installability, ease of assembly, storage needs, shelf life, and disposability?	☐ ☐ ☐ ☐ ☐				
m. Benign failure and fail-safe characteristics?	☐ ☐ ☐ ☐ ☐				
n. Failure modes and effects analyses, and fault tree analysis?	☐ ☐ ☐ ☐ ☐				
o. Ability to diagnose and correct problems?	☐ ☐ ☐ ☐ ☐				
p. Manufacturability of the design, including special process needs, mechanization, automation, assembly, and installation of components?	☐ ☐ ☐ ☐ ☐				
q. Capability to inspect and test the design, including special inspection and test requirements?	☐ ☐ ☐ ☐ ☐				
r. Specification of materials, components, and subassemblies, including approved suppliers?	☐ ☐ ☐ ☐ ☐				
s. Packaging, handling, storage, and shelf-life requirements?	☐ ☐ ☐ ☐ ☐				
t. Safety factors relating to incoming and outgoing items?	☐ ☐ ☐ ☐ ☐				
9. Is there a formal design-verification procedure (including clinical-investigation information) to confirm that the formalized, desired design output is adequate for its intended use?	☐ ☐ ☐ ☐ ☐	4.4.7	7.3.5	4.4.7	820.30

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
B. Development and Design Control (continued)					
10. Is there a design validation performed under defined operating conditions that demonstrates the device conformed to the defined user needs and intended uses?	☐ ☐ ☐ ☐ ☐	4.4.8	7.3.6	4.4.8	820.30
11. Is there a procedure to assure the design of components is correctly translated/transferred into production documents?	☐ ☐ ☐ ☐ ☐	4.4.7	7.3.5		820.30
12. Is there a design change-control procedure?	☐ ☐ ☐ ☐ ☐	4.4.9 4.5.2	7.3.7	4.4.9 4.5.2	820.30
13. Is there a market-readiness review before launch that addresses the following:					820.30
a. Availability and adequacy of installation, operation, maintenance, and repair manuals?	☐ ☐ ☐ ☐ ☐				
b. Existence of an adequate distribution and customer-service organization?	☐ ☐ ☐ ☐ ☐				
c. Training of field personnel?	☐ ☐ ☐ ☐ ☐				
d. Availability of spare parts?	☐ ☐ ☐ ☐ ☐				
14. Is there a Design History File (record) for each design that demonstrates it was developed in accord with all requirements?	☐ ☐ ☐ ☐ ☐	4.4 4.16	4.2.4	4.4 4.16	820.30
15. Is there a sufficient number of people to address all activities?	☐ ☐ ☐ ☐ ☐	4.1	6.1 6.2.1	4.1 <4.1.5>	820.20 820.25

Total Number of Boxes Checked for Section B 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
C. Purchasing					
1. Is there a listing of qualified suppliers?	□ □ □ □ □	4.6.2	7.4.1	4.6.2 (4.6.2) <4.6.1>	820.50
2. Is the methodology used to qualify the supplier documented? Does it include, where appropriate, supplier audits?	□ □ □ □ □	4.6.2	7.4.1	4.6.2 (4.6.2) <4.6.4>	820.50
3. Are purchasing documents reviewed for accuracy and completeness before release to the supplier?	□ □ □ □ □	4.6.3	7.4.2	4.6.3 (4.6.3) <4.6.3>	820.50
4. Is there a clear agreement between the supplier and purchaser on the requirements of the purchase and how such conformance will be verified?	□ □ □ □ □	4.3 4.6.3	7.4.2	4.3 4.6.3 <4.6.3>	820.50
5. Does there appear to be a sufficient number of personnel to address all the activities?	□ □ □ □ □	4.1	6.1	4.1 (4.1) <4.1.5>	820.20 820.25

Total Number of Boxes Checked for Section C 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
D. Received/In-Process-Material Handling and Storage					
1. Are receiving bays designed to avoid intrusion from weather, dust, insects, etc.?	☐ ☐ ☐ ☐ ☐	4.15.2	7.5.5	4.15.2 (4.15.2) <5.8>	820.140
2. Does the receiving quality-control function check incoming shipments against the requirements of the purchase order, specifications, and applicable drawings prior to release to manufacturing?	☐ ☐ ☐ ☐ ☐	4.10.1	7.1 8.1	4.10.1 <4.6.2>	820.80
3. Where appropriate, are material-weight checks made, or counts verified, upon receipt?	☐ ☐ ☐ ☐ ☐	4.10.1	7.1 8.1	4.10.1 <4.6.2>	820.80
4. Are records of receiving activities properly stored?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4	4.16 <4.6.2>	820.80 820.180
5. Are inspected items properly segregated from the material awaiting inspection?	☐ ☐ ☐ ☐ ☐	4.10.1	7.1 8.1	4.10.1 <4.6.2> <5.8>	820.60 820.86 820.140 820.150
6. Is there a procedure to prevent acceptance of material from unqualified suppliers?	☐ ☐ ☐ ☐ ☐	4.6.4	7.4.3	4.6.4 <4.6.1> <4.6.2>	820.50 820.80 820.86
7. Are the sampling plans employed by quality control sufficient?	☐ ☐ ☐ ☐ ☐	4.20	8.1	4.20 (4.20) <4.6.1> <5.7>	820.80 820.250
8. If multiple shipments of the same lot of the same item are received at various points in time, is each one sampled, tested, and released independently?	☐ ☐ ☐ ☐ ☐	4.10.1	7.1 8.1	4.10.1 (4.10.1) <4.6.1>	820.80 820.86 820.140
9. If a received shipment contains more than one lot number for the same item, is each lot tested and released separately?	☐ ☐ ☐ ☐ ☐	4.10	7.1	4.10 <4.6.1>	820.60 820.80 820.86 820.140
10. Is the sampling of received materials performed in a separate area or with proper controls?	☐ ☐ ☐ ☐ ☐	4.15.3	8.1	4.15.3 (4.15.3) <4.6.1>	820.86 820.140
11. Is inspected material adequately identified as accepted or rejected?	☐ ☐ ☐ ☐ ☐	4.10.1 4.10.2 4.12 4.13	7.1 7.5.3 8.1 8.3	4.10.1 4.12 4.13 (4.10.1) (4.12) (4.13) <4.6.2> <5.8>	820.60 820.86 820.90

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
D. Received/In-Process-Material Handling and Storage (continued)					
12. Do receiving inspection records indicate acceptance or rejection of incoming material?	□ □ □ □ □	4.13 4.10.2	7.4.3 7.5.3 8.2.4	4.10.2 4.13 (4.10.2) (4.13) <4.6.2>	820.60 820.80 820.86 820.90
13 Is rejected material adequately controlled?	□ □ □ □ □	4.10.1 4.10.2 4.12 4.13	7.4.3 7.5.3 8.2.4 8.3	4.12 4.13 (4.12) (4.13) <4.6.2> <5.8>	820.60 820.86 820.90 820.140
14. Do receiving inspection records reflect the reasons for rejection?	□ □ □ □ □	4.13 4.10.2	7.4.3 7.5.3 8.2.4 8.3	4.10.2 (4.10.2) 4.13 (4.13) <4.6.2>	820.80 820.90
15. Is the cause for rejection of material determined; are corrective and preventive actions initiated; and is follow-up pursued?	□ □ □ □ □	4.13 4.14	7.4.3 7.5.3 8.2.4 8.3 8.5.2 8.5.3	4.13 4.14 (4.13) (4.14) <4.6.2> <4.9> <4.10> <4.11>	820.90 820.100
16. Are component control numbers, material status, and other identifications on the storage containers easily viewable?	□ □ □ □ □	4.8	7.5.3	4.8 (4.8) <4.9>	820.60 820.86
17. Is there an adequate procedure for the handling and disposition of returned goods from customers or distributors?	□ □ □ □ □	4.14	8.3		820.60 820.80 820.86 820.140
18. Is access to stockrooms and materials-storage areas restricted to authorized personnel?	□ □ □ □ □	4.15.3	7.5.5	4.15.3 (4.15.3) <4.6.1> <5.8>	820.150
19. Are materials stored in a manner that will prevent damage, contamination, mix-up, and/or loss?	□ □ □ □ □	4.8 4.10.1 4.15.3	7.5.3	4.8 (4.8) <4.6.1> <5.8>	820.60 820.150

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
D. Received/In-Process-Material Handling and Storage (continued)					
20. Are accountability records kept to permit traceability?	□ □ □ □ □	4.8 4.10 4.16	4.2.4 7.5.3	4.8 4.10 4.16 (4.8) (4.10) (4.16) <5.8>	820.80 820.180
21. Are stocks reinspected and tested at intervals?	□ □ □ □ □	4.15.3	7.5.5	4.15.3 (4.15.3) <4.6.1>	820.150
22. Are stocks rotated and, if not, is there a justifiable reason?	□ □ □ □ □	4.15	7.5.5	4.15 (4.15)	820.150
23. Is the storage for labels distinct and in a proper area?	□ □ □ □ □				820.120 820.140 820.150
24. Is there a sufficient accountability system for labels?	□ □ □ □ □	4.15	7.5.5		820.120 820.140 820.150
25. Is there a reconciliation of labeling issued, used, and returned? *Note: Reconciliation may be waived for art or roll labeling if a 100% inspection is performed during or after completion of finishing operations.*	□ □ □ □ □				820.120 820.140 820.150
26. Is gang-print labeling prohibited unless adequately differentiated by size, shape, or color to assure against possible mix-ups? How about ability to detect such mix-ups?	□ □ □ □ □				820.120 820.140 820.150
27. Are there specified restrictions on authority for access to labels and other labeling?	□ □ □ □ □				820.120 820.150
28. Are labels proofread for accuracy before being released to inventory?	□ □ □ □ □				820.120
29. Are obsolete and outdated printed materials destroyed?	□ □ □ □ □				820.120 820.140 820.150
30. Is there an adequate procedure governing the return and salvage of products?	□ □ □ □ □			4.8 (4.8)	820.140
31. Does there appear to be a sufficient number of personnel to address all activities?	□ □ □ □ □	4.1	6.1 6.2.1	4.1 (4.1) <4.1.5>	820.20 820.25

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Total Number of Boxes Checked for Section D 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

Audited by _____

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
E. Production/Packaging/In-Process Control					
1. Do the production employees appear to be neat, clean, suitably attired, organized, and operating efficiently?	☐ ☐ ☐ ☐ ☐	4.9 4.18	6.2.2 7.5.1	4.9 4.18 (4.9) (4.18)	820.25 820.70
2. Are there written procedures for production and process control?	☐ ☐ ☐ ☐ ☐	4.9	4.2.3 7.5.1 7.5.2	4.9 (4.9)	820.70
3. Are the in-process procedures adequate for control of fabrication and services?	☐ ☐ ☐ ☐ ☐	4.9	4.2.3 7.5.1 7.5.2	4.9 (4.9)	820.70
4. Are the written procedures being followed?	☐ ☐ ☐ ☐ ☐	4.9	4.2.3 7.5.1	4.9 (4.9)	820.70
5. Does the production equipment appear to be appropriately designed, constructed, and maintained?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1 7.5.2	4.9 (4.9)	820.70 820.75
6. Are utensils cleaned to prevent contamination between different product usages?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	820.70
7. Are production areas sufficient in size, construction, and location to accommodate the needs of the intended operation, including environmental requirements?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	820.70
8. Are appropriate exhaust and vacuum systems employed in operations to minimize air contamination?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	820.70
9. Are equipment-cleaning/use logs and schedules being maintained?	☐ ☐ ☐ ☐ ☐	4.9 4.16	4.2.4 7.5.1	4.9 (4.9)	820.70
10. Are production records properly assembled and sufficient in the following content:		4.8 4.9 4.16	4.2.4 7.5.1 7.5.2 7.5.3	4.8 4.9 4.16 (4.8) (4.9) (4.16)	820.40 820.70 820.184
a. Is each prepared, dated, and signed in full signature by one person and independently checked, dated, and signed by a second person?	☐ ☐ ☐ ☐ ☐				
b. Are the name, strength, and description of the dosage form included?	☐ ☐ ☐ ☐ ☐				
c. Are the name, weight and measure of each active ingredient and the total weight indicated?	☐ ☐ ☐ ☐ ☐				
d. Is a complete list of components provided?	☐ ☐ ☐ ☐ ☐				
e. Is an accurate statement of the correct measure or weight of each component made? Is the same weighing system used for each component?	☐ ☐ ☐ ☐ ☐				

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
E. Production/Packaging/In-Process Control (continued)					
f. Are statements made concerning any calculated excess of components?	□ □ □ □ □				
g. Is the theoretical weight or measure at appropriate phases of production indicated?	□ □ □ □ □				
h. Is there a description of the drug containers, closures, and packaging materials, including a specimen or copy of each label and other labeling?	□ □ □ □ □				
i. Are there complete manufacturing and control instructions that include any special notations or precautions that are needed?	□ □ □ □ □				
j. Is there documentation that each significant step in the manufacture, packaging, or holding was accomplished, including:					
i. Dates?	□ □ □ □ □				
ii. Identity of major equipment and lines used?	□ □ □ □ □				
iii. Identification of each batch of component used?	□ □ □ □ □				
iv. Weights and measures of components used?	□ □ □ □ □				
v. In-process laboratory control results?	□ □ □ □ □				
vi. Inspection of the packaging and labeling area before and after use?	□ □ □ □ □				
k. Where environmental conditions can prevent a product from satisfying requirements, are such environmental conditions monitored and recorded for traceability on a per-lot/batch basis?	□ □ □ □ □				
11. Are line-clearance procedures employed to prevent packaging and labeling mix-ups?	□ □ □ □ □	4.8 4.9	4.2.3 7.5.1	4.8 4.9 (4.8) (4.9)	820.60 820.70 820.140
12. Are there acceptable written procedures for reprocessing batches?	□ □ □ □ □	4.9 4.13.1	4.2.3 7.5.1 7.5.2 8.3	4.9 4.13.1 (4.9) (4.13.1)	820.70 820.75 820.90
13. Are the batch records and process "limits" information kept at the workstations during the entire operation? Are the directions strictly followed?	□ □ □ □ □	4.9 4.16	4.2.4 7.5.1	4.9 4.16 (4.9) (4.16)	820.40 820.70
14. Have time limitations on the holding of processing and in-process items been established, and are they being adhered to?	□ □ □ □ □	4.9 4.16	4.2.4 7.5.1 7.5.2	4.9 4.16 (4.9) (4.16)	820.70 820.75

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
E. Production/Packaging/In-Process Control (continued)					
15. Are changes to the issued batch records approved prior to the start of work and documented on the batch records?	☐ ☐ ☐ ☐ ☐	4.4 4.5.2 4.5.3 4.9 4.16	4.2.3 4.2.4 7.5.1	4.4 4.5.2 4.5.3 4.9 4.16 (4.4) (4.5.2) (4.5.3) (4.9) (4.16)	820.40 820.70 820.75
16. Are proper gowning techniques and coverings employed?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	820.25 820.70
17. Do the production employees use acceptable techniques?	☐ ☐ ☐ ☐ ☐	4.9 4.18	7.5.1	4.9 4.18 (4.9) (4.18)	820.25 820.70 820.75
18. Are bagged or boxed components stored off the floor?	☐ ☐ ☐ ☐ ☐				820.140
19. Are lubricants and coolants controlled properly so that they cannot come into contact with product containers, closures, in-process materials, or finished products?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9	820.70 820.184
20. Is issued labeling examined for identity, correct expiration date, control number, storage conditions, handling instructions, and additional processing instructions?	☐ ☐ ☐ ☐ ☐				820.60 820.70 820.140 820.184
21. Is the aforementioned labeling inspection documented to include the date and person performing the inspection? Is the inspection included in the history record?	☐ ☐ ☐ ☐ ☐				820.70 820.120 820.130 820.184

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC BMP	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA					
E. Production/Packaging/In-Process Control (continued)						
22. Are packaging lines spatially or physically separated in a manner designed to prevent mix-ups?	□ □ □ □ □	4.9	7.5.1	1.3 3.1 3.7 3.8 5.44 5.45 5.46 5.26 5.51 5.57	4.9 (4.9)	820.60 820.70 820.120
23. Do all components, in-process, and final-product items reflect the inspection/testing "status"?	□ □ □ □ □	4.8 4.10.2 4.10.3 4.12	7.5.1 7.5.3	5.13 5.31 5.34 5.43 5.61	4.8 4.10.2 4.10.3 4.12 (4.8) (4.10.2) (4.10.3) (4.12)	820.86
24. Are filled containers, or other unlabeled product, set aside and held for subsequent labeling stored and identified properly to prevent mix-ups? (Such identification must include the names, strength, quantity of contents, and lot or control number of such containers/products.)	□ □ □ □ □	4.9	7.5.1	1.3 3.1 3.7 3.8 5.12 5.13 5.44 5.54 5.57	4.9 (4.9)	820.60 820.70 820.140 820.150
25. Are in-process materials "held" pending inspection/testing results?	□ □ □ □ □	4.10.3 4.12	7.5.3 8.2.4	1.2 5.58 5.59 6.1 6.2 6.3 6.4	4.10.3 (4.10.3) 4.12 (4.12)	820.20 820.80 820.86
26. Are charts used for monitoring time, temperature, pressure, etc., and are they filed properly?	□ □ □ □ □	4.9 4.16	4.2.4 7.5.1	5.38	4.9 4.16 (4.9) (4.16)	820.70 820.75 820.184
27. Is there a procedure to inspect manufacturing and control systems periodically, and are such inspections documented?	□ □ □ □ □	4.9 4.16	4.2.4 7.5.1	9.1	4.9 4.16 (4.9) (4.16)	820.70
28. When nonemployees such as visitors are in the area, are they observed by the designated responsible person?	□ □ □ □ □			2.11		820.25

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Total Number of Boxes Checked for Section E 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

Audited by _____

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
F. Final Inspection					
1. Is there a final inspection performed by quality control on a batch-by-batch basis?	☐ ☐ ☐ ☐ ☐	4.10.3 4.10.4	8.2.4	4.10.3 4.10.4 (4.10.3) (4.10.4)	820.80 820.86
2. Does quality control have written procedures to assure that production records are reviewed prior to release?	☐ ☐ ☐ ☐ ☐	4.10.4 4.16	4.2.4 8.2.4	4.10.4 4.16 (4.10.4) (4.16)	820.80 820.184
3. Is there an adequate ongoing marketed-product stability program?	☐ ☐ ☐ ☐ ☐				
4. Is there a thorough investigation of any discrepancies found during the final review of the production documents?	☐ ☐ ☐ ☐ ☐	4.13 4.13.1	8.3	4.13 (4.13) 4.13.1 (4.13.1) <4.10>	820.90 820.100 820.184
5. Is the product checked for correct expiration dating?	☐ ☐ ☐ ☐ ☐	4.8	7.5.3		820.60 820.80 820.184
6. Are records of inspection and test data maintained? Do they include the identity of the person performing the inspection or test?	☐ ☐ ☐ ☐ ☐	4.10.5 4.16	4.2.4 7.5.3 8.2.4	4.10.5 4.16 (4.10.5) (4.16) <4.12>	820.80
7. Are inspection and test activities carried out by personnel independent of those responsible for the work being performed?	☐ ☐ ☐ ☐ ☐	4.1.2.1 4.10	5.5.1	4.1 4.10 (4.1) (4.10)	820.5 820.20
8. Are valid sampling plans used?	☐ ☐ ☐ ☐ ☐	4.20	8.1	4.20 (4.20) <5.4.4> <5.4.5> <5.7>	820.250
9. Do the sampling procedures specify the manner in which the samples are to be obtained and by whom?	☐ ☐ ☐ ☐ ☐	4.20	8.1	4.20 (4.20) <5.7>	820.250
10. Is there a classification of defects?	☐ ☐ ☐ ☐ ☐	4.10.5	7.1 8.1	4.10.5 (4.10.5)	820.80 820.181
11. Are reserve samples of finished products maintained?	☐ ☐ ☐ ☐ ☐				820.198
12. Have the accuracy, sensitivity, specificity, and reproducibility of test methods been demonstrated via validation?	☐ ☐ ☐ ☐ ☐	4.11	7.6	4.11 (4.11) <5.4>	820.72 820.80

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	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
F. Final Inspection (continued)					
13. In cases of finished-product rejections that result in reprocessing, is another complete final inspection performed?	□ □ □ □ □	4.10.4 4.13.2	8.2.4 8.3	4.10.4 4.13.2 (4.10.4) (4.13.2)	820.70 820.80 820.90
14. In cases where a product does not meet performance specifications, is there a formal investigation, including regulatory-requirement considerations, with identification/follow-up of corrective/preventive actions to be taken?	□ □ □ □ □	4.13.2 4.14	8.3 8.5.2 8.5.3	4.13.2 4.14 (4.13.2) (4.14) <4.9> <4.10> <4.11>	820.90 820.100
15. Does there appear to be a sufficient number of personnel to address all of the activities?	□ □ □ □ □	4.1	6.1	4.1 (4.1) <4.1.5>	820.20 820.25

Total Number of Boxes Checked for Section F 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
G. Final-Product Handling, Storage, Distribution, Installation, and Servicing					
1. Is a checklist used to verify shipping requirements?	□ □ □ □ □				820.160
2. Is product configuration verified prior to shipments?	□ □ □ □ □	4.15	7.55		820.60 820.86 820.160
3. Do packing and shipping records identify the individuals performing and inspecting the shipping operations?	□ □ □ □ □	4.16	4.2.4 7.5.5		820.160
4. Are adequate storage facilities available and in use to safeguard the quality of the product between final acceptance and shipping?	□ □ □ □ □	4.15.3	7.5.5	4.15.3 (4.15.3)	820.86 820.140 820.150
5. Is a rotated-stock system employed to assure that oldest approved devices are shipped first?	□ □ □ □ □	4.15.1	7.5.5		820.150
6. Are the packing and shipping containers acceptable to protect the product?	□ □ □ □ □	4.15.4	7.5.5	4.15.4 (4.15.4)	820.130
7. Is there a system to assure that only products approved for release are distributed?	□ □ □ □ □	4.12 4.13 4.15.5	7.5.3 7.5.5 8.3	4.12 4.13 4.15.5 (4.12) (4.13) (4.15.5)	820.86 820.160
8. Do distribution records indicate the location of the following:		4.16	4.2.4		820.160
a. Name and address of the consignee?	□ □ □ □ □				
b. Date shipped?	□ □ □ □ □				
c. Name and quantity of the item?	□ □ □ □ □				
d. Control numbers of the item?	□ □ □ □ □				
9. Is there an adequate recall procedure?	□ □ □ □ □			4.8 4.14 (4.8) (4.14)	820.60 820.65 820.160 820.180 820.184
10. Are there an acceptable procedure and records verifying correct installation of devices?	□ □ □ □ □	4.8 4.9	7.5.1 7.5.3	4.8 4.9 (4.8) (4.9)	820.170
11. Is there an adequate backup system of spare parts, competent servicing, etc.?	□ □ □ □ □	4.19	7.5.1	4.19	820.200
12. Are installation and service instructions for use suitable for the intended reader?	□ □ □ □ □	4.19	7.5.1	4.19 (4.19)	820.170 820.200

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	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
G. Final-Product Handling, Storage, Distribution, Installation, and Servicing (continued)					
13. Are appropriate records of servicing maintained?	□ □ □ □ □	4.16	4.2.4 7.5.1 7.5.3	4.16 (4.16)	820.200
14. Are there sufficient controls and validation of field or field-service measurement and test equipment?	□ □ □ □ □	4.11 4.19	7.5.1 7.6	4.11 4.19 (4.11) (4.19)	820.72
15. Does there appear to be a sufficient number of people available to address all of the activities?	□ □ □ □ □	4.1	6.1	4.1 (4.1)	820.20 820.25

Total Number of Boxes Checked for Section G 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
H. Laboratories and Calibration					
1. Are the laboratories adequate?	□ □ □ □ □	4.11	7.6	4.11 (4.11) <5.3> <5.5>	820.20 820.72 820.80
2. Do the facilities have adequate equipment and associated controls for the performance of testing and inspection functions?	□ □ □ □ □	4.11	7.6	4.11 (4.11) <5.3> <5.5>	820.72
3. Are test procedures and results properly documented?	□ □ □ □ □	4.10.1 4.10.2	7.1 7.5.3 8.1 8.2.4	4.10.1 4.10.2 (4.10.1) (4.10.2) <5.4> <5.5> <5.10>	820.80 820.184
4. Is there an index of testing documents?	□ □ □ □ □	4.10.1 4.10.2	7.1 8.1	4.10.1 4.10.2 (4.10.1) (4.10.2) <5.4>	820.80
5. Are there specific procedures that address the identification, collection, handling, storage, treatment, and disposal of samples?	□ □ □ □ □	4.2 4.10		<5.4> <5.7>	
6. Are raw-material file samples maintained for future reference?	□ □ □ □ □			<5.6> <5.7>	
7. Are the laboratory reagents and other chemical supplies identified, properly stored, and expiration dated?	□ □ □ □ □			<5.3> <5.4> <5.5> <5.6>	
8. Are the instruments requiring calibration		4.11	7.6 8.1	4.11 (4.11) <5.3> <5.4> <5.5> <5.6>	820.72
a. Maintained according to the calibration procedures?	□ □ □ □ □				
b. Identified to reflect date due for net calibration?	□ □ □ □ □				
c. Stored properly?	□ □ □ □ □				
d. Calibrated to traceable standards?	□ □ □ □ □				
9. Does there appear to be a sufficient number of personnel to address all of the activities?	□ □ □ □ □	4.1	6.1	4.1 (4.1) <4.1.5>	820.20 820.25

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Total Number of Boxes Checked for Section H 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

Audited by _____

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
I. Computer Systems, Documentation Controls, and Records					
1. Are adequate controls in effect to assure that current drawings, change notices, and specifications are available at the place of the operations?	□ □ □ □ □	4.5.1 4.5.2	4.2.3	4.5.1 4.5.2 (4.5.1) (4.5.2) <4.3.1>	820.40
2. Are the documents up-to-date, and are unneeded/obsolete documents removed from use?	□ □ □ □ □	4.5.1 4.5.2	4.2.3	4.5.1 4.5.2 (4.5.1) (4.5.2) <4.3.2>	820.40
3. Is at least 1 copy of each document, including obsolete documents, retained for at least the life of the product?	□ □ □ □ □	4.5.2	4.2.3 7.2.1 7.3.2	4.5.2 (4.5.2)	820.40 820.180
4. Are the documents comprehensive in context?	□ □ □ □ □	4.2 4.4.4	4.2.3 7.2.1 7.3.2	4.2 4.4.4 (4.2) <4.3.1>	820.40
5. Do written procedures exist governing a document change-control system, and are they being followed?	□ □ □ □ □	4.5	4.2.3	4.5 (4.5) <4.3.3>	820.40
6. Are changes evaluated to determine if a regulatory submission is required?	□ □ □ □ □				820.40
7. Is there a list of "current" documents?	□ □ □ □ □				820.40
8. Are production records retained for appropriate time periods?	□ □ □ □ □	4.16	4.2.4	4.16 (4.16)	820.180
9. Is there a product "master record" for each product that includes:					820.181
a. Production specifications?	□ □ □ □ □				
b. Product drawings?	□ □ □ □ □				
c. Product composition?	□ □ □ □ □				
d. Product formulation?	□ □ □ □ □				
e. Compendial references?	□ □ □ □ □				
f. Component specifications?	□ □ □ □ □				
g. Production-process specifications?	□ □ □ □ □				
h. Production equipment?	□ □ □ □ □				
i. Special precautions?	□ □ □ □ □				
j. Production methods?	□ □ □ □ □				
k. Cleaning methods?	□ □ □ □ □				
l. Production procedures?	□ □ □ □ □				
m. Production environmental specifications?	□ □ □ □ □				

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	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
I. Computer Systems, Documentation Controls, and Records (continued)					
n. Quality-assurance procedures?	☐ ☐ ☐ ☐ ☐				
o. Quality-assurance specifications?	☐ ☐ ☐ ☐ ☐				
p. Quality-assurance checks performed?	☐ ☐ ☐ ☐ ☐				
q. Expected yields?	☐ ☐ ☐ ☐ ☐				
r. Quality-assurance apparatus used?	☐ ☐ ☐ ☐ ☐				
s. Packaging and labeling specifications?	☐ ☐ ☐ ☐ ☐				
t. Packaging and labeling methods?	☐ ☐ ☐ ☐ ☐				
u. Packaging and labeling procedures?	☐ ☐ ☐ ☐ ☐				
v. Full information on components, suppliers, and specifications?	☐ ☐ ☐ ☐ ☐				
w. Copies of critical component supplier agreements?	☐ ☐ ☐ ☐ ☐				
x. Copies of labels, labeling, and associated labeling procedures?	☐ ☐ ☐ ☐ ☐				
y. Storage conditions?	☐ ☐ ☐ ☐ ☐				
z. Shelf-life information?	☐ ☐ ☐ ☐ ☐				
10. Does a product "history record" exist for each batch of product and does it include the following		4.9 4.16	4.2.4 7.5.1 7.5.2	4.9 4.16	
a. Date and times of manufacture?	☐ ☐ ☐ ☐ ☐				
b. Identity of equipment used?	☐ ☐ ☐ ☐ ☐				
c. Quantity released for distribution?	☐ ☐ ☐ ☐ ☐				
d. Control number used?	☐ ☐ ☐ ☐ ☐				
e. Specific label used?	☐ ☐ ☐ ☐ ☐				
f. Control number of each component used in the manufacture of the item?	☐ ☐ ☐ ☐ ☐				
g. Weights and measure units of each component used?	☐ ☐ ☐ ☐ ☐				
h. Acceptance record of the components?	☐ ☐ ☐ ☐ ☐				
i. Inspections and test results, dates, and signatures of individuals performing the inspection?	☐ ☐ ☐ ☐ ☐				
j. Line clearance sign off?	☐ ☐ ☐ ☐ ☐				
k. Complete labeling control records?	☐ ☐ ☐ ☐ ☐				
l. Sampling performed?	☐ ☐ ☐ ☐ ☐				
m. Identification of persons performing and supervising significant steps?	☐ ☐ ☐ ☐ ☐				
n. Product yield versus theoretical yield?	☐ ☐ ☐ ☐ ☐				
o. Any deviations/investigations made?	☐ ☐ ☐ ☐ ☐				
11. Is there a Quality System Record (QSR) that is a listing of non-product-specific documents, organized by type (e.g., maintenance procedures, manufacturing procedures, environmental monitoring procedures)?	☐ ☐ ☐ ☐ ☐				820.186

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	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
I. Computer Systems, Documentation Controls, and Records (continued)					
12. Are records of activities properly generated and maintained to provide evidence of conformity to requirements?	□ □ □ □ □	4.16	4.2.4	4.16 (4.16) <4.12> <5.10>	820.180
13. Are the records legible, readily identifiable, and easily retrievable?	□ □ □ □ □	4.16	4.2.4	4.16 (4.16) <4.12>	
14. Is there a procedure that describes how to make changes to entry errors?	□ □ □ □ □	4.16	4.2.4	(4.16) <4.12>	
15. Is there an established retention schedule for quality records, and does it include the controls for identification, storage, and protection?	□ □ □ □ □	4.16	4.2.4	(4.16) <4.12>	
16. Does there appear to be a sufficient number of personnel to address all of the activities?	□ □ □ □ □	4.1	6.1	4.1 (4.1) <4.1.5>	820.20 820.25

Note: Complete the following checklist questions if the computer system creates, modifies, maintains, stores, archives, retrieves, transmits, records, or documents data, or the computer system produces or stores data, records, or documents used in FDA submissions.

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR [Part 11]
	3 2 1 0 NA				
17. Does the computer system have the ability to detect invalid or altered records?	□ □ □ □ □				[11.10a]
18. Can accurate and complete records (including metadata) be generated in human-readable and electronic forms, such as screen display or printout, or copied to a media for review?	□ □ □ □ □				[11.10b]
19. Does a retrieval mechanism exist to ensure the records (including the metadata) are available throughout the entire record-retention period?	□ □ □ □ □				[11.10c]
20. Are controls, such as password AND user identification, in place to limit access to the computer system?	□ □ □ □ □				[11.10d]
21. Does the computer system generate secure computer-generated audit-trail information?	□ □ □ □ □				[11.10e]
22. Does the audit trail capture operator entries or actions that create, modify, or delete a record?	□ □ □ □ □				[11.10e]
23. Does the audit trail have User ID, time, and date stamps?	□ □ □ □ □				[11.10e]

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	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR [Part 11]
	3 2 1 0 NA				
I. Computer Systems, Documentation Controls, and Records (continued)					
24. Is the original data still accessible, and not obscured for records that have been changed?	☐ ☐ ☐ ☐ ☐				[11.10e]
25. Are electronic audit trails kept as long as the respective record?	☐ ☐ ☐ ☐ ☐				[11.10e]
26. Are electronic audit trails available for FDA review and copying?	☐ ☐ ☐ ☐ ☐				[11.10e]
27. Does the computer system (or systems) force the sequence of process steps or events during operations (as applicable)?	☐ ☐ ☐ ☐ ☐				[11.10f]
28. Does the computer system (or systems) control such sequences?	☐ ☐ ☐ ☐ ☐				[11.10f]
29. Are there system checks including authorization, level of access, and privileges, for access to the computer system (or systems)?	☐ ☐ ☐ ☐ ☐				[11.10g]
30. Are there system checks to verify input-device identification (as applicable)?	☐ ☐ ☐ ☐ ☐				[11.10h]
31. Is access to the system and records controlled by a designated security unit (i.e., closed system)?	☐ ☐ ☐ ☐ ☐				[11.30]
32. For an OPEN system, is document encryption (or alternative) used to protect confidentiality of the electronic records during transfer?	☐ ☐ ☐ ☐ ☐				[11.30]
33. For an OPEN system, are digital signatures (or alternative) used to protect the authenticity, confidentiality, and integrity of the electronic records of the systems?	☐ ☐ ☐ ☐ ☐				[11.30]
If the computer system uses electronic signatures, continue with the following questions.					
34. Is the electronic signature indicated on screen displays, printouts, and other human-readable formats?	☐ ☐ ☐ ☐ ☐				[11.50]
35. Does the electronic signature contain the printed name of the signer, date and time of the signing, and the meaning (review, approval, authorship) of the signature?	☐ ☐ ☐ ☐ ☐				[11.50]
36. Is the electronic or handwritten signature linked to the associated records so that it may not be removed, copied, or transferred by ordinary means, or repudiated?	☐ ☐ ☐ ☐ ☐				[11.70]
37. Are the e-signatures unique to the user only?	☐ ☐ ☐ ☐ ☐				[11.100a]

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR [Part 11]
	3 2 1 0 NA				
I. Computer Systems, Documentation Controls, and Records (continued)					
38. Are there procedures/mechanisms to prevent user IDs from being reused, reissued, or shared?	□ □ □ □ □				[11.100b]
39. Do all nonbiometric signatures contain, at a minimum, 2 components, such as a user ID and password?	□ □ □ □ □				[11.200a]
40. Does the computer system enforce the 2 components for a single e-signature event?	□ □ □ □ □				[11.200a]
41. Does the computer system have a mechanism to terminate an extended idle session during a continuous session when an individual could execute a series of e-signatures?	□ □ □ □ □				[11.200a]
42. Does the computer-system design prevent another individual from altering a signed record, thus leaving the original individuals e-signature intact?	□ □ □ □ □				[11.200a]
43. Is the password encrypted?	□ □ □ □ □				[11.200a]
44. Does the system force the user to reset passwords after the initial administration setting?	□ □ □ □ □				[11.200a]
45. Does the biometric signature capture an individual's unique physical feature or action (as applicable)?	□ □ □ □ □				[11.200b]
46. Is there a control system/procedure/computer system design to ensure that passwords and/or ID tokens are aged or not reissued?	□ □ □ □ □				[11.300b]
47. Is there a control system/procedure that ensures the ID/password combinations are unique and revised periodically (e.g., every 90 days)?	□ □ □ □ □				[11.300b]
48. Does the computer-system design include detection procedures/alarms to detect and report attempted security breaches?	□ □ □ □ □				[11.300d]
49. Is there a procedure(s) to back up and restore, archive, and retrieve data/records from the computer system?	□ □ □ □ □				[11.10c]
50. Is there a procedure(s) for computer-system security? Does it include user access and responsibility?	□ □ □ □ □				[11.10d]
51. Is there documented evidence of appropriate qualifications and training of system developers, users (supplier based), and maintenance personnel?	□ □ □ □ □				[11.10I]
52. Is there a procedure(s) in place governing access to and use of documents containing sensitive information (e.g., password maintenance)?	□ □ □ □ □				[11.10k]

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR [Part 11]
I. Computer Systems, Documentation Controls, and Records (continued)					
53. Is there a procedure(s) for change control of computer-system documentation, including audit trail?	☐ ☐ ☐ ☐ ☐				[11.10k]
54. Is there a procedure(s) to verify and document individual identity prior to issuing an electronic signature (supplier based)?	☐ ☐ ☐ ☐ ☐				[11.100b]
55. Is there a procedure to limit use of electronic signatures to the genuine owner only (supplier based)?	☐ ☐ ☐ ☐ ☐				[11.200b]
56. Is there a procedure(s) to periodically check the ID code and password issuance (supplier based)?	☐ ☐ ☐ ☐ ☐				[11.300a]

Total Number of Boxes Checked for Section I 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
J. Internal Audits					
1. Is there a formal procedure for performing internal audits? ISO 10011–3, Part 4.6.3	☐ ☐ ☐ ☐ ☐	4.1 4.17	5.5.1 5.6.1 8.2.2 8.5.1	4.1 4.17 (4.1) (4.17) <4.13>	820.20 820.22
2. Are audits performed by individuals not having direct responsibility for that which is being audited? ISO 10011–1, Part 4.2.1.4 ISO 10011–3, Part 4.1	☐ ☐ ☐ ☐ ☐	4.17	8.2.2	4.17 (4.17) <4.13>	820.22
3. If the audit team includes experts with specialized background, auditor trainees or observers, are they indicated as such in the audit report and not listed as auditors? ISO 10011–1, Part 4.2.1.1	☐ ☐ ☐ ☐ ☐	4.17	8.2.2	4.17 (4.17) <4.13>	
4. Does the frequency of audit take into consideration significant changes in management, organization, techniques, or technologies that could affect the results of previous audits? ISO 10011–1, Part 5.1.2	☐ ☐ ☐ ☐ ☐	4.17	5.6.2 8.2.2	4.17 (4.17) <4.13>	
5. Is there an audit plan that includes the following:		4.17	8.2.2 8.2.3	4.17 (4.17) <4.13>	
a. Objective and scope of audit?	☐ ☐ ☐ ☐ ☐				
b. Identification of intended reference standards/regulations to be used on the audit?	☐ ☐ ☐ ☐ ☐				
c. Identification of audit team members?	☐ ☐ ☐ ☐ ☐				
d. Date and place of audit?	☐ ☐ ☐ ☐ ☐				
e. Agenda of items to be audited?	☐ ☐ ☐ ☐ ☐				
f. Identification of the individuals having direct responsibility for the areas to be audited?	☐ ☐ ☐ ☐ ☐				
g. Expected time and duration for each audit activity?	☐ ☐ ☐ ☐ ☐				
h. An opening and closing meeting?	☐ ☐ ☐ ☐ ☐				
ISO 10011–1, Part 5.2.1 ISO 10011–3, Part 4.2					
6. Is there a closing meeting where audit results are presented and discussed? ISO 10011–1, Part 5.2.1 ISO 10011–1, Part 5.3.3	☐ ☐ ☐ ☐ ☐	4.1 4.17	5.6.2 8.2.2	4.1 4.17 (4.1) (4.17) <4.13>	820.20 820.22

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
J. Internal Audits (continued)					
7. Is there a formal audit report, with a distribution list, that contains all audit observations and the specific requirements of the standard, regulation, or other document against which the observation was made? ISO 10011–1, Part 5.2.1 ISO 10011–1, Part 5.3.2.2 ISO 10011–3, Part 4.2 ISO 10011–3, Part 4.6.4	□ □ □ □ □	4.1 4.16 4.17	4.2.4 5.6.2 8.2.2	4.1 4.17 (4.1) (4.17) <4.13>	820.20 820.22
8. Are documented corrective and preventive actions taken on noted audit deficiencies? ISO 10011–1, Part 7.0 ISO 10011–3, Part 4.6.5	□ □ □ □ □	4.1 4.14 4.16 4.17	4.2.4 5.5.1 5.6.2 8.2.2 8.5.2 8.5.3	4.1 4.14 4.16 4.17 (4.1) (4.14) (4.16) (4.17) <4.9> <4.10> <4.11> <4.13>	820.20 820.22 820.100
9. Do auditors have the required education, training, and experience? ISO 10011–2, Part 4.0 ISO 10011–2, Part 5.0 ISO 10011–2, Part 6.0 ISO 10011–3, Part 4.3.1 ISO 10011–3, Part 4.5.3	□ □ □ □ □	4.1 4.17 4.18	8.2.2	4.1 4.17 4.18 (4.1) (4.17) (4.18) <4.13> <5.2>	820.20 820.22
10. Does there appear to be a sufficient number of personnel to accomplish audit-program objectives? ISO 10011–3, Part 4.6.2	□ □ □ □ □	4.1	6.1	4.1 (4.1) <4.15>	820.20 820.25

Total Number of Boxes Checked for Section J 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
K. Training					
1. Is there a training procedure for new employees that includes good manufacturing practices (GMPs)?	□ □ □ □ □	4.18	6.2.2	4.18 (4.18) <5.2>	820.25
2. Are all employees made aware of defects that may occur from improper performance of their respective jobs?	□ □ □ □ □	4.1 4.18	6.1 6.2.2	4.1 4.18 (4.1) (4.18) <5.2>	820.25
3. Is the training of employees properly documented?	□ □ □ □ □	4.16 4.18	4.2.4 6.2.2	4.18 (4.18) <5.2>	820.25
4. Are written job descriptions available?	□ □ □ □ □	4.18	6.2.2	4.18 (4.18) <5.2>	820.20 820.25
5. Is there sufficient assurance that consultants are qualified?	□ □ □ □ □		6.22	<5.2.3>	820.25 820.50
6. Are records kept of subjects on which the consultant advised?	□ □ □ □ □	4.16	4.2.4	<5.2.3>	820.25 820.50
7. Does there appear to be a sufficient number of personnel to address all of the functions?	□ □ □ □ □	4.1	6.1	4.1 (4.1) <4.1.5>	820.20 820.25

Total Number of Boxes Checked for Section K 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
L. Validation					
1. Have the laboratory test methods been validated?	☐ ☐ ☐ ☐ ☐	4.11	7.5.2 7.6	4.11 (4.11) <5.4>	820.72 820.80
2. Have all the manufacturing/packaging/inspection equipment/processes been validated to address the following:		4.9 4.11	7.5.2 7.6	4.9 4.11 (4.9) (4.11)	820.70 820.75
a. Demonstrate that the product-specification acceptance requirements can be consistently satisfied?	☐ ☐ ☐ ☐ ☐				
b. Have the operating limits/settings on the equipment been qualified as being capable of achieving the desired results?	☐ ☐ ☐ ☐ ☐				
c. Are the operating limits from the validation reflected in an operating procedure for employees to follow?	☐ ☐ ☐ ☐ ☐				
d. Was the validation achieved without equipment failures, interruptions, or significant down time?	☐ ☐ ☐ ☐ ☐				
e. Was the validation long enough in duration to simulate a typical batch size? On continuous processes, was the validation long enough to encompass power fluctuations, employee shift changes, and other factors that occur during a 24-hour period?	☐ ☐ ☐ ☐ ☐				
3. If reconciliation of labeling is not performed due to 100% inspection and the inspection is automated, has the inspection process been validated?	☐ ☐ ☐ ☐ ☐				820.70 820.75 820.120
4. Have support systems (e.g., as compressed air, vacuum, water) been validated (certified)?	☐ ☐ ☐ ☐ ☐		7.5.2	4.9 (4.9) <5.3>	820.70 820.75
5. Have the environmental-control systems been validated (certified)?	☐ ☐ ☐ ☐ ☐		7.5.2	4.9 (4.9) <5.3>	820.70 820.75
6. Have all cleaning procedures been validated?	☐ ☐ ☐ ☐ ☐		7.5.2	4.9 (4.9) <5.3>	820.70 820.75
7. In cases of computer systems for control of processes, data collection, etc., have the systems been validated, and do they include the following?			7.5.2	4.9 (4.9) <5.3>	820.70 820.75 [11.10a]
a. Hardware validation?	☐ ☐ ☐ ☐ ☐				
b. Software validation?	☐ ☐ ☐ ☐ ☐				
c. Qualification of the equipment environment?	☐ ☐ ☐ ☐ ☐				

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
L. Validation (continued)					
d. Distances between central processing units and peripheral devices validated?	☐ ☐ ☐ ☐ ☐				
e. Validation of signal conversion, if applicable?	☐ ☐ ☐ ☐ ☐				
f. Security from alteration or use of systems by unauthorized personnel?	☐ ☐ ☐ ☐ ☐				
g. Error-detection features validated?	☐ ☐ ☐ ☐ ☐				
h. Calibration program derived?	☐ ☐ ☐ ☐ ☐				
i. Maintenance programs for computer derived?	☐ ☐ ☐ ☐ ☐				
j. Check of alarm systems?	☐ ☐ ☐ ☐ ☐				
k. Storage facilities from environmental/security perspectives?	☐ ☐ ☐ ☐ ☐				
8. Do all the validation packages include the following:		4.9 4.16	4.2.4 7.5.2		820.70 820.75 [11.10a]
a. Detailed description of the item/system (including flow diagrams)?	☐ ☐ ☐ ☐ ☐				
b. Intended function of the system?	☐ ☐ ☐ ☐ ☐				
c. Installation-qualification information?	☐ ☐ ☐ ☐ ☐				
d. Operational-qualification information?	☐ ☐ ☐ ☐ ☐				
e. Preapproved validation protocol?	☐ ☐ ☐ ☐ ☐				
f. Explanation of any deviations made to the original signed-off protocol?	☐ ☐ ☐ ☐ ☐				
g. Validation results?	☐ ☐ ☐ ☐ ☐				
h. Conclusions/recommendations?	☐ ☐ ☐ ☐ ☐				
i. Quality-assurance approval of validation?	☐ ☐ ☐ ☐ ☐				
9. Is there a formal change-control system that addresses change to validated systems/test methods and includes quality-assurance review/approval?	☐ ☐ ☐ ☐ ☐	4.5	4.2.3 7.5.2	4.5 (4.5)	820.40 820.70 820.75 [11.10a]
10. Does there appear to be a sufficient number of personnel available to address all activities?	☐ ☐ ☐ ☐ ☐	4.1	6.1	4.1 (4.1) <4.1.5>	820.20 820.25

Total Number of Boxes Checked for Section L 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
M. Facility Engineering and Maintenance					
1. Are the facilities acceptable for the nature of the item being produced?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9) <5.3>	820.70
2. Are the sanitation and maintenance procedures for the manufacturing and ventilation equipment being followed?	☐ ☐ ☐ ☐ ☐		7.5.1	<5.3>	820.70 820.75 820.186
3. For equipment utilized by engineering and maintenance personnel, are there adequate written calibration procedures? Is there a record of the calibrations that are being performed?	☐ ☐ ☐ ☐ ☐	4.11	7.6	4.11 (4.11) <5.3> <5.5>	820.70 820.72
4. Are the environmental systems adequate to control air pressure, humidity, temperature, microorganisms, and particulate matter?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9) <5.3>	820.70 820.75
5. Are there procedures and logs to assure sanitation and pest control?	☐ ☐ ☐ ☐ ☐			<5.3>	820.20 820.70
6. Are the adjacent exterior grounds manicured?	☐ ☐ ☐ ☐ ☐			<5.3>	820.20 820.70
7. Is there an adequate supply of potable water that meets the public health service drinking-water standards?	☐ ☐ ☐ ☐ ☐			<5.1> <5.3>	820.20 820.70
8. Are adequate washing facilities with hot/cold water, soap, clean toilets, and air dryers or single-service towels provided?	☐ ☐ ☐ ☐ ☐			<5.1> <5.3>	820.20 820.70
9. Is the lighting in all areas adequate?	☐ ☐ ☐ ☐ ☐			<5.3>	820.20 820.70
10. Are adequately constructed waste containers located in appropriate areas?	☐ ☐ ☐ ☐ ☐			<5.3>	820.70 820.140
11. Is there an adequate sanitation program for the water system?	☐ ☐ ☐ ☐ ☐			<5.3>	820.70
12. Are there designated areas for eating, drinking, and smoking?	☐ ☐ ☐ ☐ ☐			<5.1> <5.3>	820.70
13. Are the environmental-control systems periodically inspected, and are those inspections documented?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9) <5.3>	820.70 820.75
14. Is there a formal maintenance schedule of manufacturing equipment?	☐ ☐ ☐ ☐ ☐			4.9 (4.9) <5.5>	820.70
15. Are periodic inspections made and documented to assure that the maintenance of manufacturing equipment is performed according to established schedules?	☐ ☐ ☐ ☐ ☐			4.9 (4.9) <5.3> <5.5>	820.70

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
M. Facility Engineering and Maintenance (continued)					
16. Are tools, gauges, and test equipment used by engineering and maintenance personnel:		4.11	7.6	4.11 (4.11) <5.3> <5.5>	820.72
a. Identified to reflect the date calibrated?	□ □ □ □ □				
b. Identified to reflect the date due for the next calibration?	□ □ □ □ □				
c. Marked with the identification of the person responsible for such calibration?	□ □ □ □ □				
17. Are adequate facilities used for storage of tools, gauges, and test equipment?	□ □ □ □ □	4.11	7.6	4.11 (4.11) <5.3> <5.5>	820.72
18. Are acceptable calibration standards employed?	□ □ □ □ □	4.11	7.6	4.11 (4.11) <5.3> <5.5>	820.72
19. Are there positive pressure differentials with all doors leading into less clean areas?	□ □ □ □ □	4.9	7.5.1	4.9 (4.9) <5.3>	820.70 820.75
20. Are the positive atmospheric controls calibrated and monitored?	□ □ □ □ □	4.9	7.5.2	4.9 (4.9) <5.3>	820.70 820.75
21. Are there established air-controlled environments, and are they operating within limits?	□ □ □ □ □	4.9	7.5.1	4.9 (4.9) <5.3>	820.70 820.75
22. Are facility and equipment drawings and blueprints adequately controlled?	□ □ □ □ □	4.5	4.2.3 7.5.1	4.5 (4.5)	820.40
23. Do pipes indicate contents and direction of flow?	□ □ □ □ □		7.5.1		820.70
24. Does there appear to be a sufficient number of personnel to address the activities?	□ □ □ □ □	4.1	6.1	4.1 (4.1) <4.1.5>	820.20

Total Number of Boxes Checked for Section M 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
N. Complaint Handling					
1. Is there a procedure for receiving, reviewing, and evaluating complaints by a formally designated unit?	☐ ☐ ☐ ☐ ☐	4.14	8.5.2 8.5.3	4.14 (4.14) <4.8>	820.198
2. Are the complaints processed per procedure in a uniform and timely manner?	☐ ☐ ☐ ☐ ☐	4.14	8.5.2 8.5.3	4.14 (4.14) <4.8>	820.198
3. Are nonformal received complaints documented?	☐ ☐ ☐ ☐ ☐	4.14 4.16	4.2.4 8.5.2 8.5.3	4.14 (4.14) <4.8>	820.198
4. Do all complaint records contain the following:		4.14 4.16	4.2.4 8.5.2 8.5.3	4.14 (4.14) <4.8>	820.198
a. Name of device?	☐ ☐ ☐ ☐ ☐				
b. Date complaint was received?	☐ ☐ ☐ ☐ ☐				
c. Product-identification and control numbers?	☐ ☐ ☐ ☐ ☐				
d. Name, address, and phone number of complainant?	☐ ☐ ☐ ☐ ☐				
e. Nature and details of complaint?	☐ ☐ ☐ ☐ ☐				
f. Reply to complainant?	☐ ☐ ☐ ☐ ☐				
5. Are complaints evaluated to determine whether an investigation is necessary?	☐ ☐ ☐ ☐ ☐	4.14	8.5.2 8.5.3	4.14 (4.14) <4.8> <4.10> <4.11>	820.198
6. If no investigation is made, is the reason for that decision and the person making it documented?	☐ ☐ ☐ ☐ ☐	4.14 4.16	4.2.4 8.5.2 8.5.3	4.14 (4.14) <4.8> <4.10> <4.11>	820.198
7. Do records of investigation include (in addition to items in question #4):		4.14 4.16	4.2.4 8.5.2 8.5.3	4.14 (4.14) <4.10> <4.11>	820.198
a. Documented request for return of product/sample?	☐ ☐ ☐ ☐ ☐				
b. Documented receipt of sample?	☐ ☐ ☐ ☐ ☐				
c. Determination of whether product failed to meet specifications?	☐ ☐ ☐ ☐ ☐				
d. Dates/results of investigation?	☐ ☐ ☐ ☐ ☐				
e. Corrective/preventive actions taken?	☐ ☐ ☐ ☐ ☐				
f. Technical references (where appropriate)?	☐ ☐ ☐ ☐ ☐				

Total Number of Boxes Checked for Section N 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating 3 2 1 0 NA	US 21 CFR Section
O. Medical Device Tracking, Reporting, and Recalls		
1. Is the company aware of its obligation to notify FDA is it goes out of business, transfers the product to a purchaser, or discontinues manufacture so that tracking of the device can continue?	☐ ☐ ☐ ☐ ☐	821.25
2. Is there a tracking procedure that addresses the following:		821.25
a. Ability to retrieve from all internal and distributor locations devices that have not been distributed within a 3-working-day request time frame?	☐ ☐ ☐ ☐ ☐	
b. Ability to retrieve the following data within a 10-working-day request time frame?	☐ ☐ ☐ ☐ ☐	
i. The lot number, batch number, or serial number of the device, or other identifier necessary to track the device?	☐ ☐ ☐ ☐ ☐	
ii. The name, mailing address, telephone number, and social security number (if applicable) of the patient receiving the device?	☐ ☐ ☐ ☐ ☐	
iii. The date provided to the patient?	☐ ☐ ☐ ☐ ☐	
iv. The name, mailing address, and telephone number of the explanting physician?	☐ ☐ ☐ ☐ ☐	
3. Are tracking records retained for as long as the device is in use or in distribution for use?	☐ ☐ ☐ ☐ ☐	821.25
4. Does the company's procedures include a requirement to perform audits of each product tracked at not less than 6-month intervals for the first 3 years of distribution and at least once per year thereafter?	☐ ☐ ☐ ☐ ☐	821.25
5. Does the company have a written MDR (Medical Device Reporting) procedure that address the following?		803.17 803.18
a. Timely and effective identification, communication, and evaluation of events that may potentially be reportable?	☐ ☐ ☐ ☐ ☐	
b. A review process for determining whether the event is reportable?	☐ ☐ ☐ ☐ ☐	
c. Timely transmission of reportable events to the FDA?	☐ ☐ ☐ ☐ ☐	
d. Documentation and record keeping for the information that was evaluated to determine if an event was reportable?	☐ ☐ ☐ ☐ ☐	
e. All associated information submitted to the FDA?	☐ ☐ ☐ ☐ ☐	
6. Does the company establish and maintain MDR event files for the following?		803.17 803.18
a. Information from any source that describes a device-related death, serious injury, or malfunction?	☐ ☐ ☐ ☐ ☐	
b. The company's evaluation of the information, including decisions to submit or not submit?	☐ ☐ ☐ ☐ ☐	
c. Supporting documentation, such as failure analysis, lab reports, etc.?	☐ ☐ ☐ ☐ ☐	
d. Decisions not to submit for a device-related death, serous injury, or malfunction?	☐ ☐ ☐ ☐ ☐	
7. Does the company retain the MDR files for 2 years or the life of the device, whichever is greater?	☐ ☐ ☐ ☐ ☐	803.18
8. Is there a procedure that requires all correction and removals be reported to the appropriate FDA District Office within 10 days of initiating the action?	☐ ☐ ☐ ☐ ☐	806.10
9. Based on review of files, has the 10-day requirement been complied with?	☐ ☐ ☐ ☐ ☐	806.10
10. Do the files contain evidence that the following have been provided to the FDA?		806.10
a. The 7-digit registration number of the entity responsible for submission of the report?	☐ ☐ ☐ ☐ ☐	
b. The month, day, and year that the report was made?	☐ ☐ ☐ ☐ ☐	
c. A sequential numbering system for MDRs (e.g., 001, 002)?	☐ ☐ ☐ ☐ ☐	
d. Name, address, and telephone number of manufacture?	☐ ☐ ☐ ☐ ☐	
e. Brand name, classification name, or usual name of the device?	☐ ☐ ☐ ☐ ☐	

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating 3 2 1 0 NA	US 21 CFR Section
O. Medical Device Tracking, Reporting, and Recalls (continued)		
f. Intended use of the device?	☐ ☐ ☐ ☐ ☐	
g. Marketing status of the device?	☐ ☐ ☐ ☐ ☐	
h. Model, catalog, or code number of the device?	☐ ☐ ☐ ☐ ☐	
i. Manufacturing lot or serial number of the device?	☐ ☐ ☐ ☐ ☐	
j. Description of events leading to correction and removal?	☐ ☐ ☐ ☐ ☐	
k. Listing of illnesses or injuries that have occurred?	☐ ☐ ☐ ☐ ☐	
l. Total number of devices manufactured or distributed?	☐ ☐ ☐ ☐ ☐	
m. Date of manufacture?	☐ ☐ ☐ ☐ ☐	
n. Date of distribution?	☐ ☐ ☐ ☐ ☐	
o. Expiration date or expected device life?	☐ ☐ ☐ ☐ ☐	
p. Names, addresses, and telephone numbers of distributors?	☐ ☐ ☐ ☐ ☐	
q. Copies of all communications?	☐ ☐ ☐ ☐ ☐	

Total Number of Boxes Checked for Section O 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820
	3 2 1 0 NA				
P. Quality-Systems Management Systems and Responsibility					
1. Is there a formal statement of the quality policy by the management of the company, and does its communication to the organization include the importance of meeting statutory as well as regulatory requirements?	☐ ☐ ☐ ☐ ☐	4.1	5.1 5.3 5.4.1	4.1 (4.1) <4.2>	820.20
2. Is there a "quality system" that addresses the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management?	☐ ☐ ☐ ☐ ☐	4.1 4.2	4.1 5.5.1	4.1 4.2 (4.1) (4.2) <4.2>	820.5 820.20
3. Is there a "Quality Manual" that addresses the "quality system"?	☐ ☐ ☐ ☐ ☐	4.1 4.2	4.2.1 4.2.2	4.1 4.2 (4.1) (4.2) <4.2>	
4. Are there periodic management reviews of the quality system and are the following inputs included?:		4.1 4.16	4.1 4.2.4 5.6.1 5.6.2 8.5.1	4.1 4.16 (4.1) (4.16) <4.14>	820.20
a. Results of audits?	☐ ☐ ☐ ☐ ☐				
b. Customer feedback?	☐ ☐ ☐ ☐ ☐				
c. Process performance and product conformity?	☐ ☐ ☐ ☐ ☐				
d. Status of corrective and preventive actions?	☐ ☐ ☐ ☐ ☐				
e. Follow-up actions from previous management reviews?	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐				
f. Changes that could affect the quality-management system?	☐ ☐ ☐ ☐ ☐				
g. Recommendations for improvement?	☐ ☐ ☐ ☐ ☐				
5. Does the organization analyze appropriate data to demonstrate the suitability and effectiveness of the quality-management system in regards to the following:			8.4	<4.14>	
a. Customer satisfaction?	☐ ☐ ☐ ☐ ☐				
b. Conformity to product requirements?	☐ ☐ ☐ ☐ ☐				
c. Trends of processes and products, including opportunities for preventive action?	☐ ☐ ☐ ☐ ☐				
d. Suppliers?	☐ ☐ ☐ ☐ ☐				
6. Does top management provide communication within the organization regarding the effectiveness of the quality-management system?	☐ ☐ ☐ ☐ ☐		5.5.3	<4.14>	
7. Is the individual responsible for the quality-assurance program (management representative) not directly responsible for the performance of a manufacturing operation?	☐ ☐ ☐ ☐ ☐	4.1	4.1 5.5.2	4.1 (4.1) <4.1>	820.20

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Total Number of Boxes Checked for Section P 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

Audited by _____

CONTRACT DEVICE MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US 21 CFR QSReg. Part 820 [Part 11]
	3 2 1 0 NA				
Q. Other Considerations					
1. Does there appear to be a desirable administrative attitude toward our requirements?	□ □ □ □ □	4.2 4.3	5.2	4.2 4.3 (4.2) (4.3) <4.7>	
2. Does there appear to be sufficient, technically competent engineering, production, and quality-control support for the product intended?	□ □ □ □ □	4.2 4.3	5.2 6.2.2 6.3	4.2 4.3 (4.2) (4.3) <4.1.5> <5.2.1>	820.20
3. Does there appear to be an acceptable, functioning quality-control department that is capable of making decisions without fear of political repercussions?	□ □ □ □ □	4.1.2	6.4	4.1 (4.1) <4.1.5>	820.5 820.30
4. Does there appear to be a good cooperative team approach among the departments in regard to solving quality problems?	□ □ □ □ □		6.4		
5. Does the facility appear to be operating in such manner that a shutdown or a sale of the operation is not imminent?	□ □ □ □ □	4.2 4.3	5.2		

Total Number of Boxes Checked for Section Q 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Scope: This checklist should be used to audit a source that manufactures or develops finished drug dosage forms on a contract basis for another company. Sources that develop or manufacture bulk drugs should be evaluated with the "Chemical-Supplier Audit Checklist."

Note: In the United States, there are additional regulations that address the development of drug products. The two sets of regulations are entitled Good Clinical Practices (GCPs) and Good Laboratory Practices (GLPs). They are significant enough in scope and depth to warrant separate audit manuals (with checklists) and have been published separately by Interpharm Press.

Design control is addressed in ISO 13485, but the document is specific for medical devices, not drug products.

The European Community (EC) GMPs for drug products also do not address design control.

As a result of the aforementioned situations, the Development and Design Control section of this checklist is limited in scope to the ISO 9001:1994 and ISO 9001:2000 perspectives. Please refer to the GLP and GCP audit manuals from Interpharm Press to assure proper auditing of United States drug-development requirements.

This checklist covers the following areas:

A. Contract Review
B. Development and Design Control
C. Purchasing
D. Receiving/In-Process-Material Handling and Storage
E. Production/Packaging/In-Process Control
F. Final Inspection
G. Final-Product Handling, Storage, Distribution, Installation, and Servicing
H. Laboratories and Calibration
I. Computer Systems, Documentation Controls, and Quality Records
J. Internal Audits
K. Training
L. Validation
M. Facility Engineering and Maintenance
N. Complaint Handling
O. Quality-Management Systems and Responsibilities
P. EC GMP Annex 1: Sterile Products
Q. Other Considerations

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

The questions in this checklist include references to:

1. The United States Code of Federal Regulations 21 CFR, Part 211, Current Good Manufacturing Practice (CGMP) for Finished Pharmaceuticals
2. The United States Code of Federal Regulations 21 CFR, Parts 1301–1307, Requirements for Controlled Drug Substances
   Note: References in the checklist column are indicated with arrow brackets < >.
3. The United States Code of Federal Regulations 21 CFR, Part 11—Electronic Records; Electronic Signatures. These questions are located in the Computer Systems, Documentation Controls, and Records section of the checklist
   Note: References in the checklist column are indicated with squared brackets [].
4. International Organization for Standardization (ISO) ISO 9001:1994, Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation and Servicing, and ISO 9001:2000, Quality Management System—Requirements
5. International Organization for Standardization (ISO) 17025:1999, General Requirements for the Competence of Testing and Calibration Laboratories
   Note: The European Community (EC) has approved ISO 17025 as a replacement for EN 45001, General Criteria for the Operation of Testing Laboratories
6. The European Community (EC) Guide to Good Manufacturing Practices (GMP) for Medicinal Products, including Annexes 1 and 16
7. International Organization for Standardization (ISO) 10011–1:1990, 2:1991, and 3:1991; Guidelines for Auditing Quality Systems: Auditing; Qualification Criteria for Quality System; and Management of Audit Programmes (American ISO equivalent, ANSI/ASQC Q10011–1, 2, and 3)
   Note: References to this standard are indicated under each appropriate question in the checklist.

Because audits may be performed by more than one person, signature spaces are provided at the end of each section to provide a record of each individual auditor's activities.

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Date(s) of Audit _____

Facility Location Company Name _____

Address _____

City _____ State _____ Zip _____

Telephone _____ Fax _____

E-mail _____

Is the company a division or subsidiary of another corporation?

If yes, describe the reporting relationship _____

_____

Audit Leader Name _____

Title _____

Audit Team Members Name _____

Function on Team _____

Name _____

Function on Team _____

Name _____

Function on Team _____

Name _____

Function on Team _____

Nature of Audit

1. Prospective Source _____ Current Source _____

2. Problem-Instigated Audit* _____ Routine Audit _____

*Nature of Problem _____

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CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Items currently manufactured for our company:

1. _____
2. _____
3. _____

Items under consideration to be manufactured/developed for our company:

1. _____
2. _____
3. _____

How is a lot/batch defined?

_____

_____

_____

What is the lot/batch-numbering system?

_____

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How many shifts are there? _____

Approximate number of employees at facility? _____

Approximate square footage of facility (including warehouse)? _____

Has a regulatory agency inspected the facility? If yes, provide dates and results:

_____

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_____

Is the facility of company ISO-9000 Certified? If yes, describe: _____

If yes, who is the notified body? _____

Are there Plant Master Files of Drug Master Files available for use as reference documents on United States NDA/ANDA/510k submissions? _____

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Primary Individuals Contacted

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Opening Meeting Date _____

Attendees _____

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Closing (Wrap-up) Meeting Date _____

Attendees _____

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CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Audit Report Date Issued _____

Date Response Received _____

Date Response and Action Plan Approved _____

Date Actions Completed _____

Date Completed Actions Verified as Completed _____

Date Completed Actions Verified as Effective _____

Date Closed Out _____

Future Follow-up Items _____

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CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

QUALITY RATING SYSTEM

Rating	*Meaning*	*Interpretation*
3	Excellent	Item/area/system/knowledge is superior
2	Adequate	Item/area/system/knowledge meets basic minimum requirements.
1	Deficient	Item/area/system/knowledge is weak and not up to acceptable standards.
0	Unsatisfactory	Item/area/system/knowledge is missing or of a nature to warrant serious quality/compliance concerns.
NA	Not Applicable	Question is not applicable to type of operation, or item unable to be addressed during the audit.

Comment: Some users of the checklist may find the responses to some questions difficult to quantify on a 0–3 scale and may prefer to use a simple "yes" or "no" approach. In such cases, a "yes" should be assigned a "2" value, and a "no" should be assigned a "0" value.

CHECKLIST RESULTS AND RATING

	Number of Occurrences			
Section	**3s**	**2s**	**1s**	**0s**
A. Contract Review				
B. Development and Design Control				
C. Purchasing				
D. Received/In-Process-Material Handling and Storage				
E. Production/Packaging/In-Process Control				
F. Final Inspection				
G. Final-Product Handling, Storage, Distribution, Installation, and Servicing				
H. Laboratories and Calibration				
I. Computer Systems, Documentation Controls, and Quality Records				
J. Internal Audits				
K. Training				
L. Validation				
M. Facility Engineering and Maintenance				
N. Complaint Handling				
O. Quality-Systems Management and Responsibility				
P. EC GMP Annex 1: Sterile Products				
Q. Other Considerations				
Totals				

Audit Findings Summary

Number of questions rated excellent ( ) Times 3 = ( )
Number of questions rated adequate ( ) Times 2 = ( )
Number of questions rated deficient ( ) Times 1 = ( )
Number of questions rated unsatisfactory (_____) Times 0 = (_____)

Total Number of Questions Answered = (_____) Rating Total = (_____)

"Rating Total" divided by "Number of Questions Answered" = _____ Audit Rating

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

I. Strengths

1. _____
2. _____
3. _____
4. _____
5. _____

II. Weaknesses

1. _____
2. _____
3. _____
4. _____
5. _____

III. Recommendations

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CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1304> [Part 11]
A. Contract Review						
1. Are the requirements, including specifications and acceptance criteria, adequately detailed in a contract? Examples:		4.3	5.2 7.2.1	7.1 7.11	4.4.1	
a. Who has responsibility and authority for supplier selection and purchasing of components?	☐ ☐ ☐ ☐ ☐					
b. Who will perform reliability or stability studies?	☐ ☐ ☐ ☐ ☐					
c Who will perform final product testing?	☐ ☐ ☐ ☐ ☐					
d. Who will release product to market?	☐ ☐ ☐ ☐ ☐					
e. Will batch records be required to be sent for review before release?	☐ ☐ ☐ ☐ ☐					
f. Who will store/distribute product?	☐ ☐ ☐ ☐ ☐					
g. Who will accommodate regulatory inspections? If contractor, will we be notified/involved?	☐ ☐ ☐ ☐ ☐					
h. Who will receive/process/respond to product complaints?	☐ ☐ ☐ ☐ ☐					
i. Who will be responsible for recall procedures?	☐ ☐ ☐ ☐ ☐					
j. Who will be responsible for “installation” of devices?	☐ ☐ ☐ ☐ ☐					
k. Who will be responsible for “servicing” installations?	☐ ☐ ☐ ☐ ☐					
l. Who will receive/disposition returned goods?	☐ ☐ ☐ ☐ ☐					
m. Who will be responsible for the issuance and change control of:						
i. Component, in-process, final product specifications?	☐ ☐ ☐ ☐ ☐					
ii. Labeling?	☐ ☐ ☐ ☐ ☐					
iii. Lot-number system?	☐ ☐ ☐ ☐ ☐					
iv. Batch-record formats?	☐ ☐ ☐ ☐ ☐					
v. Manufacturing instructions?	☐ ☐ ☐ ☐ ☐					
vi. Bills of materials?	☐ ☐ ☐ ☐ ☐					
vii. Test methods?	☐ ☐ ☐ ☐ ☐					
viii. Procedures?	☐ ☐ ☐ ☐ ☐					
ix Sampling plans?	☐ ☐ ☐ ☐ ☐					
x. Sampling methods?	☐ ☐ ☐ ☐ ☐					
xi. Design requirements?	☐ ☐ ☐ ☐ ☐					
n. Who will write validation protocols, perform testing, review and maintain packages?	☐ ☐ ☐ ☐ ☐					
2. Does the contract, or other document, specify how amendments are made and communicated to affected functions?	☐ ☐ ☐ ☐ ☐	4.3	7.2.2	7.1	4.4.1 4.4.4 4.4.5	

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1304> [Part 11]
A. Contract Review (continued)						
3. Where appropriate, are customer documents translated into the company's internal documentation? If so, is the system of control adequate to assure that current editions will be utilized in manufacturing the items?	☐ ☐ ☐ ☐ ☐	4.3	7.2.2	7.1	4.4.5	
4. Is the contract formally agreed to before execution?	☐ ☐ ☐ ☐ ☐	4.3	5.2 7.2	7.1	4.4.1	
5. Are the contracts periodically reviewed for adequacy?	☐ ☐ ☐ ☐ ☐	4.3	7.2.2		4.4.2	
6. Are records of these periodic reviews maintained for a specified period?	☐ ☐ ☐ ☐ ☐	4.3 4.16	4.2.4 7.2.2		4.4.2	
7. For standard (noncustom) items, is there a product/service catalog/list that is revision controlled to assure that the contents are current and correct?	☐ ☐ ☐ ☐ ☐	4.3	5.2 7.2.2 7.2.3			
8. For standard (noncustom) items, does the catalog/list provide enough information to assure the purchaser will receive what is expected?	☐ ☐ ☐ ☐ ☐	4.3	5.2 7.2.3			
9. Is there a procedure established and being followed that describes how verbal and formal orders are to be processed?	☐ ☐ ☐ ☐ ☐	4.3	7.2.3		4.4.1	
10. Is there a procedure for resolving processed-order problems?	☐ ☐ ☐ ☐ ☐	4.3	7.2.3		4.4.2 4.7 4.8	
11. Are subcontract intentions approved by the customer first?	☐ ☐ ☐ ☐ ☐			7.8	4.5	

Total Number of Boxes Checked for Section A 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
B. Development and Design Control						
1. Is there a written plan under revision control that identifies each activity required, the personnel responsible, and their technical interfaces?	☐ ☐ ☐ ☐ ☐	4.2 4.4.1 4.4.2 4.4.3	7.3.1			
2. In the design of items, is appropriate input obtained and documented to assure proper development and approval?	☐ ☐ ☐ ☐ ☐	4.4.4	7.2.1 7.3.2			
3. Is the design output documented and expressed in terms that can be verified against the design inputs?	☐ ☐ ☐ ☐ ☐	4.4.5	7.3.3			
4. Are there design reviews after each phase?	☐ ☐ ☐ ☐ ☐	4.4.6	7.3.4			
5. Does the design review address each of the following items:		4.4.6	7.3.4			
a. Comparison of customer needs with technical specifications for materials, products, and processes?	☐ ☐ ☐ ☐ ☐					
b. Validation of the design through prototype tests?	☐ ☐ ☐ ☐ ☐					
c. Ability to perform under expected conditions of use and environments?	☐ ☐ ☐ ☐ ☐					
d. Considerations of unintended uses and misuses?	☐ ☐ ☐ ☐ ☐					
e. Safety and environmental compatibility?	☐ ☐ ☐ ☐ ☐					
f. Compliance with regulatory requirements, national and international standards, and corporate practices?	☐ ☐ ☐ ☐ ☐					
g. Comparisons with competitive designs?	☐ ☐ ☐ ☐ ☐					
h. Comparison with similar designs, especially analysis of internal and external problem history, to avoid repeating problems?	☐ ☐ ☐ ☐ ☐					
i. Reliability, serviceability and maintainability?	☐ ☐ ☐ ☐ ☐					
j. Permissible tolerances and comparison with process capabilities?	☐ ☐ ☐ ☐ ☐					
k. Product acceptance/rejection criteria?	☐ ☐ ☐ ☐ ☐					
l. Installability, ease of assembly, storage needs, shelf life, and disposability?	☐ ☐ ☐ ☐ ☐					
m. Benign failure and fail-safe characteristics?	☐ ☐ ☐ ☐ ☐					
n. Failure modes and effects analyses, and fault tree analysis?	☐ ☐ ☐ ☐ ☐					
o. Ability to diagnose and correct problems?	☐ ☐ ☐ ☐ ☐					
p. Manufacturability of the design, including special process needs, mechanization, automation, assembly, and installation of components?	☐ ☐ ☐ ☐ ☐					

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
B. Development and Design Control (continued)						
q. Capability to inspect and test the design, including special inspection and test requirements?	☐ ☐ ☐ ☐ ☐					
r. Specification of materials, components, and subassemblies, including approved suppliers?	☐ ☐ ☐ ☐ ☐					
s. Packaging, handling, storage, and shelf-life requirements?	☐ ☐ ☐ ☐ ☐					
t. Safety factors relating to incoming and outgoing items?	☐ ☐ ☐ ☐ ☐					
6. Is there a formal design-verification procedure (including clinical-investigation information) to confirm that the formalized, desired design output is adequate for its intended use?	☐ ☐ ☐ ☐ ☐	4.4.7	7.3.5			
7. Is there a procedure to assure the design of components is correctly translated into production documents?	☐ ☐ ☐ ☐ ☐	4.4.7	7.3.5			
8. Is there a design change-control procedure, and is it being followed?	☐ ☐ ☐ ☐ ☐	4.4.9 4.5.2	7.3.7			
9. Is there a market-readiness review before launch that addresses the following:						
a. Availability and adequacy of installation, operation, maintenance, and repair manuals?	☐ ☐ ☐ ☐ ☐					
b. Existence of an adequate distribution and customer-service organization?	☐ ☐ ☐ ☐ ☐					
c. Training of field personnel?	☐ ☐ ☐ ☐ ☐					
d. Availability of spare parts?	☐ ☐ ☐ ☐ ☐					
10. Is there a Design History File (record) for each design that demonstrates it was developed in accord with all requirements?	☐ ☐ ☐ ☐ ☐	4.4 4.16	4.2.4			
11. Is there a sufficient number of people to address all activities?	☐ ☐ ☐ ☐ ☐	4.1	6.1			211.25

Total Number of Boxes Checked for Section B 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1304> [Part 11]
C. Purchasing						
1. Is there a list of qualified suppliers?	☐ ☐ ☐ ☐ ☐	4.6.2	7.4.1	1.2 5.26 5.40	4.6.1	211.84
2. Is there a procedure for how suppliers get qualified? Does it include, where appropriate, supplier audits?	☐ ☐ ☐ ☐ ☐	4.6.2	7.4.1	5.25 5.40	4.6.4	
3. Are purchasing documents reviewed for accuracy and completeness before release to the supplier?	☐ ☐ ☐ ☐ ☐	4.6.3	7.4.2	5.26 5.40	4.6.3	
4. Is there a clear agreement between the supplier and purchaser on the requirements of the purchase and how such conformance will be verified?	☐ ☐ ☐ ☐ ☐	4.3 4.6.3	7.4.2	5.25 5.40	4.6.3	
5. Are there agreements with suppliers that commit them to notification of proposed changes on a component?	☐ ☐ ☐ ☐ ☐	4.3 4.6.1	7.4.2			
6. Does there appear to be a sufficient number of personnel to address all the activities?	☐ ☐ ☐ ☐ ☐	4.1	6.1	2.1	4.1.5	211.25

Total Number of Boxes Checked for Section C 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
D. Received/In-Process Material Handling and Storage						
1. Are receiving bays designed to avoid intrusion from weather, dust, insects, etc.?	□ □ □ □ □	4.15.2	7.5.5	3.20	5.8	211.80
2. Does the receiving quality-control function check incoming shipments against the requirements of the purchase order, specifications, and applicable drawings prior to release to manufacturing?	□ □ □ □ □	4.10.1	7.1 8.1	1.4 4.11 4.19 4.20 5.3 5.4 5.5 5.27 5.30 5.40	4.6.2	211.84
3. Where appropriate, are material-weight checks made, or counts verified, upon receipt?	□ □ □ □ □	4.10.1	7.1 8.1	3.13	4.6.2	211.84 211.184
4. Are records of receiving activities properly stored?	□ □ □ □ □	4.16	4.2.4	4.19 4.20 4.21	4.6.2	211.184
5. Are inspected items properly segregated from the material awaiting inspection?	□ □ □ □ □	4.10.1	7.1 8.1	3.18 3.21 4.21 5.5	4.6.2 5.8	211.42
6. Is there a procedure to prevent acceptance of material from unqualified suppliers?	□ □ □ □ □	4.6.4	7.43	5.26	4.6.1 4.6.2	
7. Are the sampling plans employed by quality control sufficient?	□ □ □ □ □	4.20	8.1	4.22	4.6.1 5.7	211.84
8. If multiple shipments of the same lot of the same item are received at various points in time, is each one sampled, tested, and released independently?	□ □ □ □ □	4.10.1	7.1 8.1	5.28	4.6.1	211.84
9. If a received shipment contains more than one lot number for the same item, is each lot tested and released separately?	□ □ □ □ □	4.10	7.1	5.28	4.6.1	211.84
10. Is the sampling of received materials performed in a separate area or with proper controls?	□ □ □ □ □	4.15.3	8.1	3.14 3.22	4.6.1	211.80 211.84
11. Is inspected material adequately identified as accepted or rejected?	□ □ □ □ □	4.10.1 4.12 4.13	7.1 7.5.3 8.1 8.3	3.21 4.21 5.13 5.29	4.6.2 5.8	211.80
12. Do receiving inspection records indicate acceptance or rejection of incoming material?	□ □ □ □ □	4.10.2 4.13	7.4.3 7.5.3 8.2.4	5.13 5.29	4.6.2	211.84 211.184

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
D. Received/In-Process Material Handling and Storage (continued)						
13. Is rejected material adequately controlled?	☐ ☐ ☐ ☐ ☐	4.12 4.13	7.4.3 7.5.3 8.2.4 8.3	3.23 5.61	4.6.2 5.8	211.80 211.89
14. Do receiving inspection records reflect the reasons for rejection?	☐ ☐ ☐ ☐ ☐	4.13 4.10.2	7.4.3 7.5.3 8.2.4 8.3	4.19 4.20 5.31	4.6.2	211.184
15. Is the cause for rejection of material determined, and are corrective/preventive actions taken?	☐ ☐ ☐ ☐ ☐	4.13 4.14	7.4.3 7.5.3 8.2.4 8.3 8.5.2 8.5.3		4.6.2 4.9 4.10 4.11	211.84
16. Are component control numbers, material status, and other identifications on the storage containers easily viewable?	☐ ☐ ☐ ☐ ☐	4.8	7.5.3	5.29 5.34	4.9	211.80
17. Is there an adequate procedure for the handling and disposition of returned goods?	☐ ☐ ☐ ☐ ☐	4.14	8.3	5.65		211.204
18. Is access to stockrooms and materials-storage areas restricted to authorized personnel?	☐ ☐ ☐ ☐ ☐	4.15.3	7.5.5	3.5	4.6.1 5.8	211.122
19. Are materials handled, identified and stored in a manner that will prevent damage, contamination, mix-up, and/or loss?	☐ ☐ ☐ ☐ ☐	4.8 4.10.1 4.15.3 4.15.2	7.5.3	3.1 3.2 3.3 3.4 3.13 5.7 5.11 5.12 5.29	4.6.1 5.8	211.80
20. Are accountability records kept to permit traceability?	☐ ☐ ☐ ☐ ☐	4.8 4.10 4.16	4.2.4 7.5.3		5.8	211.184
21. Are stocks reinspected and tested at intervals?	☐ ☐ ☐ ☐ ☐	4.15.3	7.5.5	4.11 5.7 5.31 5.43	4.6.1	211.87
22. Are stocks rotated and, if not, is there a justifiable reason?	☐ ☐ ☐ ☐ ☐	4.15	7.5.5	5.7		211.86 211.150
23. Is there a distinct and adequately sized label room?	☐ ☐ ☐ ☐ ☐		7.5.5	5.41		211.42 211.122

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
	3 2 1 0 NA					
D. Received/In-Process Material Handling and Storage (continued)						
24. Is the label room designed to avoid mix-ups?	☐ ☐ ☐ ☐ ☐			5.41		211.42 211.122
25. Is there a sufficient accountability system in the label room for labels?	☐ ☐ ☐ ☐ ☐	4.15	7.55	5.40 5.41 5.42		211.125
26. Is there a reconciliation of labeling issued, used, and returned? *Note: Reconciliation may be waived for art or roll labeling if a 100% inspection is performed during or after completion of finishing operations.*	☐ ☐ ☐ ☐ ☐			5.40 5.41 5.42		211.122 211.125
27. Is gang-print labeling prohibited unless adequately differentiated by size, shape, or color to assure against possible mix-ups? How about ability to detect such mix-ups?	☐ ☐ ☐ ☐ ☐					211.122
28. Are there specified restrictions on authority for access to labels and other labeling?	☐ ☐ ☐ ☐ ☐			3.25 5.41		211.122
29. Are labels proofread for accuracy before being released to inventory?	☐ ☐ ☐ ☐ ☐			4.19 4.21 5.41		211.122
30. Are obsolete and outdated printed materials destroyed?	☐ ☐ ☐ ☐ ☐			5.43		211.122
31. Is there an adequate procedure governing the return and salvage of products?	☐ ☐ ☐ ☐ ☐			5.61 5.62 5.63 5.64 5.65		211.208
32. Are the material-storage and handling procedures documented?	☐ ☐ ☐ ☐ ☐	4.15.1		4.19 4.24		211.142
33. Does there appear to be a sufficient number of personnel to address all activities?	☐ ☐ ☐ ☐ ☐	4.1	6.1 6.2.1	2.1	4.1.5	211.25
Additional questions for controlled drugs						
34. Are there secure facilities and approved procedures for storage and movement of controlled drugs?	☐ ☐ ☐ ☐ ☐					211.42
35. Are noncontrolled drugs stored with controlled drugs? If yes, has formal permission be obtained from the regional director of the Drug Enforcement Administration (DEA)?	☐ ☐ ☐ ☐ ☐					<1301.72>
36. Is an inventory taken at least every 2 years?	☐ ☐ ☐ ☐ ☐					<1304.11>
37. Do the inventory records contain the name and quantity for each controlled substance?	☐ ☐ ☐ ☐ ☐					<1304.11>

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
D. Received/In-Process Material Handling and Storage (continued)						
38. For items in process at the time of inventory, does the following documentation exist:						<1304.11>
a. Name of substance?	☐ ☐ ☐ ☐ ☐					
b. Quantity of substance at each stage of manufacturing?	☐ ☐ ☐ ☐ ☐					
c. Physical form that the substance is to take upon completion of the processing (e.g., solution, granules)?	☐ ☐ ☐ ☐ ☐					
d. Batch number in process?	☐ ☐ ☐ ☐ ☐					
39. Do the inventory records include the following:						<1304.11>
a. Names and quantities of materials held for quality purposes, disposal, or extemporaneous compounding?	☐ ☐ ☐ ☐ ☐					
b. Reasons for which substances are being held?	☐ ☐ ☐ ☐ ☐					
40. With regard to hallucinogenic substances, are amounts in excess of 150 grams for laboratory use recorded in the inventory system?	☐ ☐ ☐ ☐ ☐					<1304.11>
41. Are the disposals of controlled substances requested via the regional administrator of the DEA prior to disposal?	☐ ☐ ☐ ☐ ☐					<1307.21>
42. Are there effective controls to guard against theft or diversion of controlled substances upon receipt?	☐ ☐ ☐ ☐ ☐					<1301.71>
43. Do the records include the name, address, and registration number of the person from whom the substance was received?	☐ ☐ ☐ ☐ ☐					<1304.22>
44. Do the dates on documents specify when they were received? Are these dates referenced on all associated invoices or packing slips?	☐ ☐ ☐ ☐ ☐					<1304.21>

Total Number of Boxes Checked for Section D 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
E. Production/Packaging/In-Process ControlReview						
1. Do the production employees appear to be neat, clean, suitably attired, organized, and operating efficiently?	□ □ □ □ □	4.9 4.18	6.2.2 7.5.2	2.16 2.17 2.18 2.19 2.20 3.5 5.1		211.25 211.28
2. Are there written procedures for production and process control?	□ □ □ □ □	4.9	4.2.3 7.5.1 7.5.2	4.14 4.15 4.26 4.27 5.2		211.100
3. Are the in-process procedures adequate for control of fabrication and services?	□ □ □ □ □	4.9	4.2.3 7.5.1 7.5.2	4.15 4.16 4.27 4.37 5.2		211.110
4. Are the written procedures being followed?	□ □ □ □ □	4.9	4.2.3 7.5.1	5.2		211.100
5. Does the production equipment appear to be appropriately designed, constructed, and maintained?	□ □ □ □ □	4.9	7.5.1 7.5.2	3.34 3.36 3.38 3.39		211.63 211.65
6. Is defective equipment labeled or removed?	□ □ □ □ □			3.44		
7. Are utensils cleaned to prevent contamination between different product usages?	□ □ □ □ □	4.9	7.5.1	2.18 3.36 3.37 3.39 5.18 5.19 5.20		211.67
8. Are production areas sufficient in size, construction, and location to accommodate the needs of the intended operation, including environmental requirements?	□ □ □ □ □	4.9	7.5.1	1.3 3.1 3.3 3.4 3.6 3.7 3.8 3.9 3.10 3.11 3.12 3.15 3.16		211.42

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
E. Production/Packaging/In-Process ControlReview (continued)						
9. Are appropriate exhaust and vacuum systems employed in operations to minimize air contamination?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	3.1 3.3 3.6 3.10 3.12 3.14 3.15		211.46
10. Are equipment-cleaning/use logs and schedules being maintained?	☐ ☐ ☐ ☐ ☐	4.9 4.16	4.2.4 7.5.1	4.17 4.28 4.29		211.182
11. Are production records properly assembled and sufficient in the following content:		4.8 4.9 4.16	4.2.4 7.5.1 7.5.2 7.5.3	4.14 4.15 4.16 4.17 4.18 4.26 4.27 5.8		211.186 211.188
a. Is each prepared, dated, and signed in full signature by 1 person and independently checked, dated, and signed by a second person?	☐ ☐ ☐ ☐ ☐					
b. Are the name, strength, and description of the dosage form included?	☐ ☐ ☐ ☐ ☐					
c. Are the name, weight, and measure of each active ingredient and the total weight indicated?	☐ ☐ ☐ ☐ ☐					
d. Is a complete list of components provided?	☐ ☐ ☐ ☐ ☐					
e. Is an accurate statement of the correct measure or weight of each component made? Is the same weighing system used for each component?	☐ ☐ ☐ ☐ ☐					
f. Are statements made concerning any calculated excess of components?	☐ ☐ ☐ ☐ ☐					
g. Is the theoretical weight or measure at appropriate phases of production indicated?	☐ ☐ ☐ ☐ ☐					
h. Is there a description of the drug containers, closures, and packaging materials, including a specimen or copy of each label and other labeling?	☐ ☐ ☐ ☐ ☐					
i. Are there complete manufacturing and control instructions that include any special notations or precautions that are needed?	☐ ☐ ☐ ☐ ☐					
j. Is there documentation that each significant step in the manufacture, packaging, or holding was accomplished, including the following:						211.134 211.192
1. Dates?	☐ ☐ ☐ ☐ ☐					
2. Identity of major equipment and lines used?	☐ ☐ ☐ ☐ ☐					
3. Identification of each batch of component used?	☐ ☐ ☐ ☐ ☐					
4. Weights and measures of components used?	☐ ☐ ☐ ☐ ☐					
5. In-process laboratory control results?	☐ ☐ ☐ ☐ ☐					

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
	3 2 1 0 NA					
E. Production/Packaging/In-Process ControlReview (continued)						
6. Inspection of the packaging and labeling area before and after use?	□ □ □ □ □					
7. Any investigations made in accordance with 21 CFR 211.192, as well as examinations made in accordance with 21 CFR 211.134?	□ □ □ □ □					
k. Where environmental conditions can prevent a product from satisfying requirements, are those environmental conditions monitored and recorded for traceability on a per-lot/batch basis?	□ □ □ □ □					
12. Are line-clearance procedures employed to prevent packaging and labeling mix-ups?	□ □ □ □ □	4.8 4.9	4.2.3 7.5.1	5.34 5.35 5.45 5.57		211.130
13. Are there separate air-handling systems for the manufacture, processing, and packaging of highly sensitive items; like penicillin?	□ □ □ □ □			3.3 3.6		211.46
14. Are there acceptable written procedures for reprocessing batches?	□ □ □ □ □	4.9 4.13.1	4.2.3 7.5.1 7.5.2 8.3	4.17 4.18 5.55 5.62 5.63		211.115
15. Are the batch records and process "limits" information kept at the workstations during the entire operation? Are the directions strictly followed?	□ □ □ □ □	4.9 4.16	4.2.4 7.5.1	4.8		211.100
16. Are critical steps performed by a competent individual, checked by a second individual, and recorded in the batch record?	□ □ □ □ □					211.103
17. Have time limitations on the holding of processing and in-process items been established, and are they being adhered to?	□ □ □ □ □	4.9 4.16	4.2.4 7.5.1 7.5.2	4.15 4.17 4.18		211.111
18. Are changes to the issued batch records approved prior to the start of work and documented on the batch records?	□ □ □ □ □	4.4 4.5.2 4.5.3 4.9 4.16	4.2.3 4.2.4 7.5.1	5.15		211.100
19. Are proper gowning techniques and coverings employed?	□ □ □ □ □	4.9	7.5.1	2.16		211.28
20. Do the production employees use acceptable techniques?	□ □ □ □ □	4.9 4.18	7.5.1	2.8 2.9 2.10 2.12		211.25 211.101

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
E. Production/Packaging/In-Process ControlReview (continued)						
21. Are bagged or boxed components stored off the floor?	☐ ☐ ☐ ☐ ☐					211.80
22. Are lubricants and coolants controlled properly so that they cannot come into contact with product containers, closures, in-process materials, or finished products?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	5.18		211.65
23. Is issued labeling examined for identity, correct expiration date, control number, storage conditions, handling instructions, and additional processing instructions?	☐ ☐ ☐ ☐ ☐			5.42 5.47 5.50		211.122 211.125
24. Is the aforementioned labeling inspection documented to include the date and person performing the inspection? Is the inspection included in the history record?	☐ ☐ ☐ ☐ ☐			5.52 5.53 5.54		211.122 211.125 211.130
25. Are packaging lines spatially or physically separated in a manner designed to prevent mix-ups?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	1.3 3.1 3.7 3.8 5.44 5.45 5.46 5.51 5.57		211.42
26. Do all components, in-process and final product items reflect the inspection/testing "status"?	☐ ☐ ☐ ☐ ☐	4.8 4.10.2 4.10.3 4.12 4.13	7.5.1 7.5.3	5.13 5.31 5.34 5.43 5.61		211.42 211.80 211.82 211.84 211.122
27. Are filled containers, or other unlabeled product, that are set aside and held for subsequent labeling stored and identified properly to prevent mix-ups? (This identification must include the names, strengths, quantities of contents, and lot or control number of the containers/products.)	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	1.3 3.1 3.7 3.8 5.12 5.13 5.44 5.49 5.54 5.57		211.130
28. Are in-process materials "held" pending inspection/testing results?	☐ ☐ ☐ ☐ ☐	4.10.3 4.12	7.5.3 8.2.4	1.2 5.58 5.59 6.1 6.2 6.3 6.4		211.22 211.84

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
	3 2 1 0 NA					
E. Production/Packaging/In-Process ControlReview (continued)						
29. Are charts used for monitoring time, temperature, pressure etc., and are they properly filed?	□ □ □ □ □	4.9 4.16	4.2.4 7.5.1	5.38		211.111
30. Is there a procedure to inspect manufacturing and control systems periodically, and are those inspections documented?	□ □ □ □ □	4.9 4.16	4.2.4 7.5.1	9.1		211.58
31. When nonemployees such as visitors are in the area, are they observed by the designated responsible person?	□ □ □ □ □			2.11		211.28
32. Does there appear to be a sufficient number of personnel to address all of the activities?	□ □ □ □ □	4.1	6.1 6.2.1	2.1		211.25
Additional questions for sterile products						
33. Is there a maximum allowable number of personnel in clean rooms?	□ □ □ □ □			*13		
34. When maintenance workers or visitors are permitted in the area, are they instructed and supervised?	□ □ □ □ □			*14		
35. Are personnel monitored for shedding of contaminants?	□ □ □ □ □			*16		
36. Are wristwatches, makeup, and jewelry prohibited in the clean areas?	□ □ □ □ □			*18		
37. Do gowning procedures:				*17		
a. Address washing before entering clean areas?	□ □ □ □ □			*19		
b. Indicate the type of gowning depending on the class area?	□ □ □ □ □					
38. Are personnel engaged in the processing of animal-tissue materials or cultures of microorganisms restricted from sterile-product areas?	□ □ □ □ □			*15		
39. Does the processing of materials address the following:				*11 *12		
a. Time limits between washing, drying, and sterilization?	□ □ □ □ □			*43 *44		
b. Time limits between preparation, start of solution, and sterilization or filtration?	□ □ □ □ □			*50 *51		
c. Bioburden monitoring and depyrogenation?	□ □ □ □ □			*52 *53		
d. Passing solutions and noncombustible gases through a microorganism-retaining filter?	□ □ □ □ □					
e. Preparation of components and products in the right level of environment?	□ □ □ □ □					

* ANNEX 1

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
E. Production/Packaging/In-Process ControlReview (continued)						
40. When sterilization cannot be used and filtration is the only option, is the following addressed?				*82 *83 *84 *85 *86 *87		
a. Use of 0.22-micron, nonfibre-shedding filter or less?	□ □ □ □ □					
b. Use of heat treatment if product tolerable?	□ □ □ □ □					
c. Use of a second filtration process?	□ □ □ □ □					
d. Bubble-point, diffusive-flow or pressure-hold test to assure filter integrity?	□ □ □ □ □					
e. Length of time a filter can be used? (e.g., 1 day)	□ □ □ □ □					
41. Are containers closed by fusion (e.g., ampules) 100% tested for integrity?	□ □ □ □ □			*88		
42. Are containers sealed under vacuum tested for maintenance of vacuum for an appropriate length of time?	□ □ □ □ □			*89		
43. Are containers visually inspected for contamination and, if inspected electronically, is the process validated?	□ □ □ □ □			*88		
Additional questions for controlled drugs						
44. Are all in-process items returned to the controlled-drug storage areas at the termination of the process or work day? If not, are the materials securely locked to prevent access?	□ □ □ □ □					<1301.73>
45. Are manufacturing areas for controlled substances clearly defined and limited in access?	□ □ □ □ □		7.5.1			<1301.73>
46. Are the limited-access areas under the surveillance of a designated individual and is such designation provided in writing?	□ □ □ □ □			5.16		<1301.73>

Total Number of Boxes Checked for Section E 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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* ANNEX 1

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
F. Final Inspection						
1. Is there a final inspection performed by quality control on a batch-by-batch basis?	☐ ☐ ☐ ☐ ☐	4.10.3 4.10.4	8.2.4	1.4 2.6 4.24 5.59 6.3		211.22
2. Does quality control have procedures to assure that production records are reviewed prior to release?	☐ ☐ ☐ ☐ ☐	4.10.4 4.16	4.2.4 8.2.4	5.58 5.59 6.3		211.22
3. Does quality assurance approve or reject product manufactured, processed, packaged, or held under contract by another company?	☐ ☐ ☐ ☐ ☐	4.6.2 4.6.4 4.7	7.4.1 7.4.3 7.5.4	7.7		211.22
4. Is there a thorough investigation of any discrepancies found during the final review of the production documents?	☐ ☐ ☐ ☐ ☐	4.13 4.13.1	8.3	4.7 5.15 5.55 6.3 6.4	4.10	211.192
5. Is the product checked for correct expiration dating?	☐ ☐ ☐ ☐ ☐	4.8	7.5.3	5.8 5.50 6.2 6.3		211.137
6. Are records of inspection and test data maintained? Do they include the identity of the person performing the inspection or test?	☐ ☐ ☐ ☐ ☐	4.10.5 4.16	4.2.4 7.5.3 8.2.4	6.7 6.8 6.9 6.10 6.16 6.17	4.12	211.165
7. Are inspections and test activities performed by independent personnel?	☐ ☐ ☐ ☐ ☐	4.1.2.1 4.10	5.5.1	2.3 2.4 2.6		
8. Are valid sampling plans used?	☐ ☐ ☐ ☐ ☐	4.20	8.1	6.11 6.12	5.4.4 5.4.5 5.7	211.165
9. Do the sampling procedures specify the manner in which the samples are to be obtained and by whom?	☐ ☐ ☐ ☐ ☐	4.20	8.1	6.13	5.7	211.165
10. Is there a classification of defects?	☐ ☐ ☐ ☐ ☐	4.10.5	7.1 8.1	4.13		211.165
11. Are reserve samples of finished products maintained?	☐ ☐ ☐ ☐ ☐			6.14		211.170
12. Is there an adequate, ongoing marketed-product stability program?	☐ ☐ ☐ ☐ ☐					211.166

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
F. Final Inspection (continued)						
13. Have the accuracy, sensitivity, specificity, and reproducibility of test methods been demonstrated via validation?	□ □ □ □ □	4.11	7.6	6.15	5.4	211.165
14. In cases of finished-product rejections that result in reprocessing, is another complete final inspection performed?	□ □ □ □ □	4.10.4 4.13.2	8.2.4 8.3	5.64		211.115
15. In cases where a product does not meet performance specifications, is there a formal investigation, including regulatory-requirement considerations, with corrective/preventive actions taken?	□ □ □ □ □	4.13.2 4.14	8.3 8.5.2 8.5.3	5.39 5.62	4.9 4.10 4.11	211.192
16. Does there appear to be a sufficient number of personnel to address all of the activities?	□ □ □ □ □	4.1	6.1	2.1	4.1.5	211.25

Total Number of Boxes Checked for Section F 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
G. Final Product Handling, Storage, Distribution, Installation, and Servicing						
1. Is a checklist used to verify shipping requirements?	☐ ☐ ☐ ☐ ☐					211.196
2. Is product configuration verified prior to shipments?	☐ ☐ ☐ ☐ ☐	4.15	7.5.5			211.150 211.196
3. Do packing and shipping records identify the individuals perform-ing and inspecting the shipping operations?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4 7.5.5			211.25
4. Are adequate storage facilities available and in use to safeguard the quality of the product between final acceptance and shipping?	☐ ☐ ☐ ☐ ☐	4.15.3	7.5.5	3.18 3.19 3.23 5.58 5.60		211.42 211.142
5. Is a rotated-stock system employed to assure that oldest approved products are shipped first?	☐ ☐ ☐ ☐ ☐	4.15.1	7.5.5	5.7		211.150
6. Are the packing and shipping containers acceptable to protect the product?	☐ ☐ ☐ ☐ ☐	4.15.4	7.5.5			211.130
7. Is there a system to assure that only products approved for release are distributed?	☐ ☐ ☐ ☐ ☐	4.12 4.13 4.15.5	7.5.3 7.5.5 8.3	1.2 5.58 5.59		211.150 211.165
8. Do distribution records indicate the location of the following:		4.16	4.2.4	4.25 8.12		211.196
a. Name and address of the consignee?	☐ ☐ ☐ ☐ ☐					
b. Date shipped?	☐ ☐ ☐ ☐ ☐					
c. Name and quantity of the item?	☐ ☐ ☐ ☐ ☐					
d. Control numbers of the item?	☐ ☐ ☐ ☐ ☐					
9. Is there an adequate recall procedure?	☐ ☐ ☐ ☐ ☐			4.25 8.8 8.9 8.10 8.11 8.12 8.13 8.14 8.15		211.150 211.196
10. Does there appear to be a sufficient number of people available to address all of the activities?	☐ ☐ ☐ ☐ ☐	4.1	6.1	2.1		211.25
Additional questions for controlled drugs						
11. For each controlled substance in finished form in the inventory, does the labeling include the following:						<1304.11>
a. Name of the substance?	☐ ☐ ☐ ☐ ☐					

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
	3 2 1 0 NA					
G. Final Product Handling, Storage, Distribution, Installation, and Servicing (continued)						
b. Dosage form (tablet, capsule, liquid, etc.)?	☐ ☐ ☐ ☐ ☐					
c. Number of units or volume in each commercial container?	☐ ☐ ☐ ☐ ☐					
d. Number of commercial containers of each form (4 100-tablet bottles, 3 2-milliliter vials)?	☐ ☐ ☐ ☐ ☐					
12. Before distributing a controlled substance, is a good faith inquiry made either with the Drug Enforcement Administration or an appropriate state-controlled agency to determine that the recipient is registered to possess the controlled substance?	☐ ☐ ☐ ☐ ☐					<1301.74>
13. Are registration certificates available and current for the authorization of handling controlled drug substances?	☐ ☐ ☐ ☐ ☐					<1301.74>
14. Is there a system that will assure the disclosure of suspicious orders that are received (e.g., unusual size, deviating order patterns, or unusual frequency)?	☐ ☐ ☐ ☐ ☐					<1301.74>
15. Are transit losses of controlled substances reported to the DEA?	☐ ☐ ☐ ☐ ☐					<1301.74>
16. Are controlled substances listed on Schedules II–V distributed as complimentary samples without prior written request to the customer?	☐ ☐ ☐ ☐ ☐					<1301.74>
17. In selecting common or contract carriers, is there an effort made to assure that adequate security is provided by those carriers?	☐ ☐ ☐ ☐ ☐					<1301.74>
18. When storing controlled substances in a public warehouse, is there an investigation made to assure that adequate, secure facilities are provided?	☐ ☐ ☐ ☐ ☐					<1301.74>
19. When distributing controlled drug substances through agents, is there an investigation to assure that appropriate provisions are on the premises to prevent against theft or diversion?	☐ ☐ ☐ ☐ ☐					<1301.74>
20. Prior to the initial distribution of etorphine hydrochloride or diprenorphine, is there an investigation to verify through the DEA that the recipient is authorized to handle the substance?	☐ ☐ ☐ ☐ ☐					<1301.74>
21. Does each commercial container have printed on it the symbol designating the schedule on which the controlled substance is listed?	☐ ☐ ☐ ☐ ☐					<1302.03>
22. Does the labeling of each controlled substance indicate the symbol for the schedule on which the controlled substance is listed?	☐ ☐ ☐ ☐ ☐					<1302.03>

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

Total Number of Boxes Checked for Section G 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

Audited by _____

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
H. Laboratories and Calibration						
Questions in this section are applicable to any testing/inspection function regardless of where it occurs (e.g., QC, Mfg., Eng., etc.)						
1. Are the laboratories adequate?	☐ ☐ ☐ ☐ ☐	4.11	7.6	3.26 3.27 3.28 3.29 6.6	5.3 5.5	211.22 211.42
2. Do the facilities have adequate equipment and associated controls for the performance of testing and inspection functions?	☐ ☐ ☐ ☐ ☐	4.11	7.6	1.4 6.5 6.6	5.3 5.5	211.22 211.63
3. Are test procedures and results properly documented?	☐ ☐ ☐ ☐ ☐	4.10.1 4.10.2	7.1 7.5.3 8.1 8.2.4	3.1 3.2 3.3 3.40 6.7 6.8 6.9 6.16 6.17 6.18	5.4 5.5 5.10	211.160
4. Is there an index of testing documents?	☐ ☐ ☐ ☐ ☐	4.10.1 4.10.2	7.1 8.1		5.4	211.160
5. Are there specific procedures that address the identification, collection, handling, storage, treatment, and disposal of samples?	☐ ☐ ☐ ☐ ☐	4.2 4.10		6.11 6.12 6.13 6.14	5.4 5.7	211.110 211.160 211.170
6. Are raw-material file samples maintained for future reference?	☐ ☐ ☐ ☐ ☐			1.4 6.12 6.13 6.14	5.6 5.7	211.170
7. Are the laboratory reagents and other chemical supplies identified, properly stored, and expiration dated?	☐ ☐ ☐ ☐ ☐			6.19 6.20 6.21	5.3 5.4 5.5 5.6	211.165
8. Are the laboratory instruments requiring calibration:		4.11	7.6 8.1	3.41	5.3 5.4 5.5 5.6	211.160
a. Maintained according to the calibration procedures?	☐ ☐ ☐ ☐ ☐					
b. Identified to reflect date due for net calibration?	☐ ☐ ☐ ☐ ☐					
c. Stored properly?	☐ ☐ ☐ ☐ ☐					
d. Calibrated to traceable standards?	☐ ☐ ☐ ☐ ☐					

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
	3 2 1 0 NA					
H. Laboratories and Calibration (continued)						
9. Are animals used in the testing of components, in-process materials, and final product maintained and controlled in a proper manner?	□ □ □ □ □			3.33 6.22		211.173
10. Where animals are used for testing, are adequate histories maintained?	□ □ □ □ □			6.22		211.173
11. Does there appear to be a sufficient number of personnel to address all of the activities?	□ □ □ □ □	4.1	6.1	2.1	4.1.5	211.25

Total Number of Boxes Checked for Section H 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
I. Computer Systems, Documentation Controls, and Quality Records						
1. Are adequate controls in effect to assure that current drawings, change notices, and specifications are available at the place of the operations?	☐ ☐ ☐ ☐ ☐	4.5.1 4.5.2	4.2.3	4.2 4.5	4.3.1	211.100
2. Are the documents up-to-date, and are unneeded/obsolete documents removed from use?	☐ ☐ ☐ ☐ ☐	4.5.1 4.5.2	4.2.3	4.5	4.3.2	211.100
3. Is at least 1 copy of each document, including obsolete documents, retained for at least the life of the product?	☐ ☐ ☐ ☐ ☐	4.5.2	4.2.3 7.2.1 7.3.2	4.8 6.8		211.100
4. Are the documents comprehensive in context?	☐ ☐ ☐ ☐ ☐	4.2 4.4.4	4.2.3 7.2.1 7.3.2	4.1 4.10 4.11 4.12 4.13 4.14 4.15 4.16	4.3.1	211.100
5. Do written procedures exist governing a document change-control system, and are they being followed?	☐ ☐ ☐ ☐ ☐	4.5	4.2.3	4.3 4.5 4.7 5.15	4.3.3	211.100
6. Are production records retained for appropriate time periods?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4	6.8		211.180
7. Is there documentation for each product that includes:		4.2		4.10 4.11 4.12 4.13 4.14 4.15 4.16		211.186
a. Production specifications?	☐ ☐ ☐ ☐ ☐					
b. Product drawings?	☐ ☐ ☐ ☐ ☐					
c. Product composition?	☐ ☐ ☐ ☐ ☐					
d. Product formulation?	☐ ☐ ☐ ☐ ☐					
e. Compendial references?	☐ ☐ ☐ ☐ ☐					
f. Component specifications?	☐ ☐ ☐ ☐ ☐					
g. Production-process specifications?	☐ ☐ ☐ ☐ ☐					
h. Production equipment?	☐ ☐ ☐ ☐ ☐					
i. Special precautions?	☐ ☐ ☐ ☐ ☐					
j. Production methods?	☐ ☐ ☐ ☐ ☐					
k. Cleaning methods?	☐ ☐ ☐ ☐ ☐					
l. Production procedures?	☐ ☐ ☐ ☐ ☐					
m. Production environmental specifications?	☐ ☐ ☐ ☐ ☐					
n. Quality-assurance procedures?	☐ ☐ ☐ ☐ ☐					
o. Quality-assurance specifications?	☐ ☐ ☐ ☐ ☐					
p. Quality-assurance checks performed?	☐ ☐ ☐ ☐ ☐					
q. Expected yields?	☐ ☐ ☐ ☐ ☐					

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
	3 2 1 0 NA					
I. Computer Systems, Documentation Controls, and Quality Records (continued)						
r. Quality-assurance apparatus used?	☐ ☐ ☐ ☐ ☐					
s. Packaging and labeling specifications?	☐ ☐ ☐ ☐ ☐					
t. Packaging and labeling methods?	☐ ☐ ☐ ☐ ☐					
u. Packaging and labeling procedures?	☐ ☐ ☐ ☐ ☐					
v. Copies of labels, labeling, and associated labeling procedures?	☐ ☐ ☐ ☐ ☐					
w. Storage conditions?	☐ ☐ ☐ ☐ ☐					
x. Shelf-life information?	☐ ☐ ☐ ☐ ☐					
8. Does a product "history record" exist for each batch of product, and does it include the following:		4.9 4.16	4.2.4 7.5.1 7.5.2	4.17 4.18 4.19 4.23 4.26		211.188
a. Date and times of manufacture?	☐ ☐ ☐ ☐ ☐					
b. Identity of equipment used?	☐ ☐ ☐ ☐ ☐					
c. Quantity released?	☐ ☐ ☐ ☐ ☐					
d. Control number used?	☐ ☐ ☐ ☐ ☐					
e. Specific label used?	☐ ☐ ☐ ☐ ☐					
f. Control number of each component used in the manufacture of the item?	☐ ☐ ☐ ☐ ☐					
g. Weights and measure units of each component used?	☐ ☐ ☐ ☐ ☐					
h. Acceptance record of the components?	☐ ☐ ☐ ☐ ☐					
i. Inspection/test results, dates, and signatures of individuals performing the inspection?	☐ ☐ ☐ ☐ ☐					
j. Line clearance sign-off?	☐ ☐ ☐ ☐ ☐					
k. Complete labeling records?	☐ ☐ ☐ ☐ ☐					
l. Sampling performed?	☐ ☐ ☐ ☐ ☐					
m. Identification of persons performing and supervising significant steps?	☐ ☐ ☐ ☐ ☐					
n. Product yield versus theoretical yield?	☐ ☐ ☐ ☐ ☐					
o. Any deviations/investigations?	☐ ☐ ☐ ☐ ☐					
9. Are records of activities properly generated and maintained to provide evidence of conformity to requirements?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4	4.4 4.8 4.9	4.12 5.10>	211.180
10. Are the records legible, readily identifiable, and easily retrievable?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4	4.6 4.9	4.12	211.180
11. Is there a procedure the describes how to make changes to entry errors?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4	4.7	4.12	
12. Is there an established retention schedule for quality records, and does it include the controls for identification, storage and protection?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4	4.8 4.9	4.12	211.180

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
I. Computer Systems, Documentation Controls, and Quality Records (continued)						
13. Does there appear to be a sufficient number of personnel to address all of the activities?	☐ ☐ ☐ ☐ ☐	4.1	6.1	2.1	4.1.5	211.25
Additional questions for controlled drugs						
14. Are records maintained for each controlled substance, and do they include the following:						<1304.22>
a. Name of the substance?	☐ ☐ ☐ ☐ ☐					
b. Quantity manufactured in bulk form?	☐ ☐ ☐ ☐ ☐					
c. Date, quantity, and lot number of each batch manufactured?	☐ ☐ ☐ ☐ ☐					
d. Quantity used in manufacturing the finished product?	☐ ☐ ☐ ☐ ☐					
e. Quantity used in manufacturing?	☐ ☐ ☐ ☐ ☐					
f. Finished-product dosage form, including strength?	☐ ☐ ☐ ☐ ☐					
g. Number of units manufactured?	☐ ☐ ☐ ☐ ☐					
h. Quantity used in quality-control activities?	☐ ☐ ☐ ☐ ☐					
i. Quantity lost during manufacturing and the cause?	☐ ☐ ☐ ☐ ☐					
j. Total quantity of the substance contained in the finished product?	☐ ☐ ☐ ☐ ☐					
k. Theoretical and actual yields?	☐ ☐ ☐ ☐ ☐					
l. Other information necessary to account for all controlled substances used?	☐ ☐ ☐ ☐ ☐					

Note: Complete the following checklist questions if the computer system creates, modifies, maintains, stores, archives, retrieves, transmits, records, or documents data, or computer system produces or stores data, records, or documents used in FDA submissions.

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR [Part 11]
15. Does the computer system have the ability to detect invalid or altered records?	☐ ☐ ☐ ☐ ☐			4.9		[11.10a]
16. Can accurate and complete records (including metadata) be generated in human-readable and electronic forms, such as screen display or printout, or copied to a media for review?	☐ ☐ ☐ ☐ ☐			4.9		[11.10b]
17. Does a retrieval mechanism exist to ensure the record (including the metadata) is available throughout the entire record retention period?	☐ ☐ ☐ ☐ ☐			4.9		[11.10c]
18. Are controls, such as password AND user identification, in place to limit access to the computer system?	☐ ☐ ☐ ☐ ☐			4.9		[11.10d]

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR [Part 11]
I. Computer Systems, Documentation Controls, and Quality Records (continued)						
19. Does the computer system generate secure computer-generated audit-trail information?	☐ ☐ ☐ ☐ ☐			4.9		[11.10e]
20. Does the audit trail capture operator entries or actions that create, modify or delete a record?	☐ ☐ ☐ ☐ ☐			4.9		[11.10e]
21. Does the audit trail have User ID, time, and date stamps?	☐ ☐ ☐ ☐ ☐			4.9		[11.10e]
22. Is the original data still accessible, and not obscured for records that have been changed?	☐ ☐ ☐ ☐ ☐			4.9		[11.10e]
23. Are electronic audit trails kept as long as the respective record?	☐ ☐ ☐ ☐ ☐			4.9		[11.10e]
24. Are electronic audit trails available for FDA review and copying?	☐ ☐ ☐ ☐ ☐			4.9		[11.10e]
25. Does the computer system (or systems) force the sequence of process steps or events during operations (as applicable)?	☐ ☐ ☐ ☐ ☐			4.9		[11.10f]
26. Does the computer system (or systems) control the sequences?	☐ ☐ ☐ ☐ ☐			4.9		[11.10f]
27. Are there system checks including authorization, level of access and privileges for access to the computer system (or systems)?	☐ ☐ ☐ ☐ ☐			4.9		[11.10g]
28. Are there system checks to verify input-device identification (as applicable)?	☐ ☐ ☐ ☐ ☐			4.9		[11.10h]
29. Is access to the system and records controlled by a designated security unit (i.e., closed system)?	☐ ☐ ☐ ☐ ☐			4.9		[11.30]
30. For an OPEN system, is document encryption (or alternative) used to protect confidentiality of the electronic records during transfer?	☐ ☐ ☐ ☐ ☐			4.9		[11.30]
31. For an OPEN system, are digital signatures (or alternative) used to protect the authenticity, confidentiality, and integrity of the electronic records of the systems?	☐ ☐ ☐ ☐ ☐			4.9		[11.30]
If the computer system uses electronic signatures, continue with the following questions.						
32. Is the electronic signature indicated on screen displays, printouts, and other human-readable formats?	☐ ☐ ☐ ☐ ☐			4.9		[11.50]
33. Does the electronic signature contain the printed name of the signer, date and time of the signing, and the meaning (review, approval, authorship) of the signature?	☐ ☐ ☐ ☐ ☐			4.9		[11.50]

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR [Part 11]
I. Computer Systems, Documentation Controls, and Quality Records (continued)						
34. Is the electronic or handwritten signature linked to the associated record such that it may not be removed copied transferred by ordinary means or repudiated?	☐ ☐ ☐ ☐ ☐			4.9		[11.70]
35. Are the e-signatures unique to the user only?	☐ ☐ ☐ ☐ ☐			4.9		[11.100a]
36. Are there procedures/mechanisms to prevent user IDs from being reused, reissued, or shared?	☐ ☐ ☐ ☐ ☐			4.9		[11.100b]
37. Do all nonbiometric signatures contain at a minimum, 2 components, such as a user ID and password?	☐ ☐ ☐ ☐ ☐			4.9		[11.200a]
38. Does the computer system enforce the 2 components for a single e-signature event?	☐ ☐ ☐ ☐ ☐			4.9		[11.200a]
39. Does the computer system have a mechanism to terminate an extended idle session during a continuous session when an individual could execute a series of e-signatures?	☐ ☐ ☐ ☐ ☐			4.9		[11.200a]
40. Does the computer-system design prevent another individual from altering a signed record, thus leaving the original individual's e-signature intact?	☐ ☐ ☐ ☐ ☐			4.9		[11.200a]
41. Is the password encrypted?	☐ ☐ ☐ ☐ ☐			4.9		[11.200a]
42. Does the system force the user to reset passwords after the initial administration setting?	☐ ☐ ☐ ☐ ☐			4.9		[11.200a]
43. Does the biometric signature capture an individual's unique physical feature or action (as applicable)?	☐ ☐ ☐ ☐ ☐			4.9		[11.200b]
44. Is there a control system/procedure/computer-system design to ensure that passwords and/or ID tokens are aged or not reissued?	☐ ☐ ☐ ☐ ☐			4.9		[11.300b]
45. Is there a control system/procedure that ensures the ID/password combinations are unique and revised periodically (e.g., every 90 days)?	☐ ☐ ☐ ☐ ☐			4.9		[11.300b]
46. Does the computer-system design include detection procedures/alarms to detect and report attempted security breaches?	☐ ☐ ☐ ☐ ☐			4.9		[11.300d]
47. Is there a procedure(s) to back up and restore, archive, and retrieve data/records from the computer system?	☐ ☐ ☐ ☐ ☐			4.9		[11.10c]
48. Is there a procedure(s) for computer system security? Does it include user access and responsibility?	☐ ☐ ☐ ☐ ☐			4.9		[11.10d]
49. Is there documented evidence of appropriate qualifications and training of system developers, users (supplier based), and maintenance personnel?	☐ ☐ ☐ ☐ ☐			4.9		[11.10I]

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR [Part 11]
I. Computer Systems, Documentation Controls, and Quality Records (continued)						
50. Is there a procedure(s) in place governing access to and use of documents containing sensitive information (e.g., password maintenance)?	□ □ □ □ □			4.9		[11.10k]
51. Is there a procedure(s) for change-control of computer-system documentation, including audit trail?	□ □ □ □ □			4.9		[11.10k]
52. Is there a procedure(s) to verify and document individual identity prior to issuing an electronic signature (supplier based)?	□ □ □ □ □			4.9		[11.100b]
53. Is there a procedure to limit use of electronic signatures to the genuine owner only (supplier based)?	□ □ □ □ □			4.9		[11.200b]
54. Is there a procedure(s) to periodically check the ID code and password issuance (supplier based)?	□ □ □ □ □			4.9		[11.300a]

Total Number of Boxes Checked for Section I 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
J. Internal Audits						
1. Is there a formal procedure for performing internal audits? ISO 10011–3, Part 4.6.3	□ □ □ □ □	4.1 4.17	5.5.1 5.6.1 8.5.1 8.2.2	1.2 9.2 9.3	4.13	
2. Are audits performed by individuals not having direct responsibility for that which is being audited? ISO 10011–1, Part 4.2.1.4 ISO 10011–3, Part 4.1	□ □ □ □ □	4.17	8.2.2	1.2 9.2	4.13	
3. If the audit team includes experts with specialized background, auditor trainees, or observers, are they indicated as such in the audit report and not listed as auditors? ISO 10011–1, Part 4.2.1.1	□ □ □ □ □	4.17	8.2.2	1.2 9.2	4.13	
4. Does the frequency of audits take into consideration significant changes in management, organization, techniques, or technologies that could affect the results of previous audits? ISO 10011–1, Part 5.1.2	□ □ □ □ □	4.17	5.6.2 8.2.2	1.2 9.1	4.13	
5. Is there an audit plan that includes the following: a. Objective and scope of audit? b. Identification of intended reference standards/regulations to be used? c. Identification of audit team members? d. Date and place of the audit? e. Agenda of items to be audited? f. Identification of the individuals having direct responsibility for the areas to be audited? g. Expected time and duration for each audit activity? h. An opening and closing meeting? ISO 10011–1, Part 5.2.1 ISO 10011–3, Part 4.2	□ □	4.17	8.2.2 8.2.3	1.2 9.1	4.13	
6. Is there a closing meeting where audit results are presented and discussed? ISO 10011–1, Part 5.2.1 ISO 10011–1, Part 5.3.3	□ □ □ □ □	4.1 4.17	5.6.2 8.2.2	1.2 9.3	4.13	
7. Is there a formal audit report, with a distribution list, that contains all audit observations and the specific requirements of the standard, regulation, or other document against which the observation was made? ISO 10011–1, Part 5.2.1 ISO 10011–1, Part 5.3.2.2 ISO 10011–3, Part 4.2 ISO 10011–3, Part 4.6.4	□ □ □ □ □	4.1 4.16 4.17	4.2.4 5.6.2 8.2.2	1.2 9.3	4.13	

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	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
J. Internal Audits (continued)						
8. Are documented corrective and preventive actions taken on noted audit deficiencies? ISO 10011–1, Part 7.0 ISO 10011–3, Part 4.6.5	□ □ □ □ □	4.1 4.14 4.16 4.17	4.2.4 5.5.1 5.6.2 8.2.2 8.5.2 8.5.3	1.2 9.3	4.9 4.10 4.11 4.13	
9. Do auditors have the required education, training, and experience? ISO 10011–2, Part 4.0 ISO 10011–2, Part 5.0 ISO 10011–2, Part 6.0 ISO 10011–3, Part 4.3.1 ISO 10011–3, Part 4.5.3	□ □ □ □ □	4.1 4.17 4.18	8.2.2	1.2 9.2	4.13 5.2	
10. Does there appear to be a sufficient number of personnel to accomplish audit-program objectives? ISO 10011–3, Part 4.6.2	□ □ □ □ □	4.1	6.1	2.1	4.1.5	211.25

Total Number of Boxes Checked for Section J 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
K. Training						
1. Is there a training procedure for new employees that includes good manufacturing practices (GMPs)?	□ □ □ □ □	4.18	6.2.2	2.8 2.9 2.10 2.11 2.12	5.2	211.25
2. Is there a refresher training program that includes GMPs?	□ □ □ □ □			2.8 2.9 2.10 2.11 2.12	5.2	211.25
3. Are all employees made aware of defects that may occur from improper performance of their respective jobs?	□ □ □ □ □	4.1 4.18	6.1 6.2.2	2.8 2.9 2.10 2.11 2.12	5.2	211.25
4. Is the training of employees properly documented?	□ □ □ □ □	4.16 4.18	4.2.4 6.2.2	2.8 2.9	5.2	211.25
5. Are written job descriptions available?	□ □ □ □ □	4.18	6.2.2	2.2 2.4 2.5 2.6 2.7	5.2	211.25
6. Is there sufficient assurance that consultants are qualified?	□ □ □ □ □	6.2.2			5.2.3	211.34
7. Are records kept of subjects on which the consultant advised?	□ □ □ □ □	4.16	4.2.4		5.2.3	211.34
8. Does there appear to be a sufficient number of personnel to address all of the functions?	□ □ □ □ □	4.1	6.1	2.1	4.1.5	211.25

Total Number of Boxes Checked for Section K 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
L. Validation						
1. Have the laboratory test methods been validated?	□ □ □ □ □	4.11	7.5.2 7.6	1.4 6.15 *91 **37	5.4	211.165 211.194
2. Is there a Validation Master Plan (VMP) that contains the following:				**4		
a. Validation policy?	□ □ □ □ □					
b. Organizational structure of validation activities?	□ □ □ □ □					
c. Summary of facilities, systems, equipment, and processes to be validated?	□ □ □ □ □					
d. Documentation format for protocols and reports?	□ □ □ □ □					
e. Planning and scheduling?	□ □ □ □ □					
f. Change control?	□ □ □ □ □					
g. Reference to existing documents?	□ □ □ □ □					
3. Have all the manufacturing/packaging/inspection processes been validated to address the following:		4.9 4.11	7.5.2 7.6	5.21 5.22 5.23 5.24	*19	211.63 211.67 211.68 211.100 211.110 211.113
a. Demonstrate that the product-specification acceptance requirements can be consistently satisfied?	□ □ □ □ □					
b. Have the operating limits/settings on the equipment been qualified as being capable of achieving the desired results?	□ □ □ □ □					
c. Are the operating limits from the validation reflected in an operating procedure for employees to follow?	□ □ □ □ □					
d. Was the validation achieved without equipment failures, interruptions, or significant down time?	□ □ □ □ □					
e. Was the validation long enough in duration to simulate a typical batch size? On continuous processes, was the validation long enough to encompass power fluctuations, employee shift changes, and other factors that occur during a 24-hour period?	□ □ □ □ □					
4. If reconciliation of labeling is not performed due to 100% inspection and the inspection is automated, has the inspection process been validated?	□ □ □ □ □			5.52		211.122 211.125
5. Have support systems (e.g., compressed air, vacuum, water) been validated (certified)?	□ □ □ □ □		7.5.2	5.18 5.19 5.20 *36 **1	5.3	211.110

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CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
L. Validation (continued)						
6. Have the environmental-control systems been validated (certified)?	□ □ □ □ □		7.5.2	5.18 5.19 5.20 **1	5.3	211.46
7. Have aseptic fill processes been validated with media fills for 3 consecutive runs, and repeated twice per year?	□ □ □ □ □		7.5.2	5.22 *8, *10, *36, *42,*55,*58 *69,*73,*81 *88 **1		211.113
8. Have all cleaning procedures been validated?	□ □ □ □ □		7.5.2	5.19 **36, **38, **39, **40 **41, **42	5.3	211.67
9. In cases of computer systems for control of processes, data collection, etc., have they systems been validated, and do they include the following:			7.5.2	4.9	5.3	211.68 [11.10a]
a. Hardware validation?	□ □ □ □ □					
b. Software validation?	□ □ □ □ □					
c. Qualification of the equipment environment?	□ □ □ □ □					
d. Distances between central processing units and peripheral devices validated?	□ □ □ □ □					
e. Validation of signal conversion, if applicable?	□ □ □ □ □					
f. Security from alteration or use of systems by unauthorized personnel?	□ □ □ □ □					
g. Error-detection features validated?	□ □ □ □ □					
h. Calibration program derived?	□ □ □ □ □					
i. Maintenance programs for computer derived?	□ □ □ □ □					
j. Check of alarm systems?	□ □ □ □ □					
k. Storage facilities from environmental/security perspectives?	□ □ □ □ □					
10. Do all the validation packages include the following:		4.9 4.16	4.2.4 7.5.2	5.21 5.22 5.23 5.24 **6, **7, **8, **11, **12, **13, **14, **15, **16, **17, **18		211.63 211.67 211.68 211.100 211.110 211.113 [11.10a]
a. Detailed description of the item/system (including flow diagrams)?	□ □ □ □ □					
b. Intended function of the system?	□ □ □ □ □					
c. Installation-qualification information?	□ □ □ □ □					
d. Operational-qualification information?	□ □ □ □ □					
e. Preapproved validation protocol?	□ □ □ □ □					
f. Performance qualification?	□ □ □ □ □					

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	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
L. Validation (continued)						
g. Explanation of any deviations made to the original signed-off protocol?	☐ ☐ ☐ ☐ ☐					
h. Validation results?	☐ ☐ ☐ ☐ ☐					
i. Conclusions/recommendations?	☐ ☐ ☐ ☐ ☐					
j. Quality assurance approval of validation before lot release?	☐ ☐ ☐ ☐ ☐					
11. Is there a formal change-control system that addresses change to validated systems/test methods and includes quality-assurance review/approval?	☐ ☐ ☐ ☐ ☐	4.5	4.2.3 7.5.2	5.23		211.22 211.100 [11.10a]
12. Does there appear to be a sufficient number of personnel available to address all activities?	☐ ☐ ☐ ☐ ☐	4.1	6.1	2.1	4.1.5	211.25
Additional questions for sterile products						
13. Is the system for closing the containers validated?	☐ ☐ ☐ ☐ ☐			*88		
14. Do sterilization processes address the following:				*55		
a. Validation of achieving desired sterilizing conditions in all parts of each type of load?	☐ ☐ ☐ ☐ ☐			*56 *57 *58		
b. Assurance that cooling cycles are adequate?	☐ ☐ ☐ ☐ ☐					
c. At least annual verification of validity of process?	☐ ☐ ☐ ☐ ☐					
d. Validation of loading configurations?	☐ ☐ ☐ ☐ ☐					
15. For ethylene oxide sterilization, are the conditions and times validated to permit proper degassing?	☐ ☐ ☐ ☐ ☐			*81		

Total Number of Boxes Checked for Section L 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
M. Facility Engineering and Maintenance						
1. Are the facilities acceptable for a drug product, and are clean areas classified by levels?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	3.1 3.4 3.9 3.32 3.33 *1 *2 *3	5.3	211.42
2. Are the sanitation and maintenance procedures for the manufacturing and ventilation equipment being followed?	☐ ☐ ☐ ☐ ☐		7.5.1	3.2 3.43	5.3	211.56 211.67
3. Is there a review to assure that the maintenance procedure will not present a product-quality risk?	☐ ☐ ☐ ☐ ☐			3.35		
4. For equipment utilized by engineering and maintenance personnel, are there adequate written calibration procedures? Is there a record of the calibrations that are being performed?	☐ ☐ ☐ ☐ ☐	4.11	7.6	3.32 3.40 3.41	5.3 5.5	211.160
5. Are the environmental systems adequate and monitored to control air pressure, humidity, temperature, microorganisms, air flow, and paticulate matter?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	3.3 3.12 *4 *5	5.3	211.42 211.46
6. Are there procedures and logs to assure sanitation and pest control?	☐ ☐ ☐ ☐ ☐				5.3	211.56
7. Are the adjacent exterior grounds manicured?	☐ ☐ ☐ ☐ ☐				5.3	211.56
8. Is there an adequate supply of potable water that meets the public health service drinking-water standards?	☐ ☐ ☐ ☐ ☐			3.30 3.31	5.1 5.3	211.48
9. Are adequate washing facilities with hot/cold water, soap, clean toilets, and air dryers or single-service towels provided?	☐ ☐ ☐ ☐ ☐			3.30 3.31	5.1 5.3	211.52
10. Is the lighting in all areas adequate?	☐ ☐ ☐ ☐ ☐			3.3 3.16	5.3	211.44
11. Are adequately constructed waste containers located in appropriate areas?	☐ ☐ ☐ ☐ ☐			5.61	5.3	211.50
12. Are drains to sewers designed with an air break to prevent back siphonage?	☐ ☐ ☐ ☐ ☐			3.11		211.48
13. Is there an adequate disposal-collection system?	☐ ☐ ☐ ☐ ☐				5.3	211.50
14. Is there an adequate sanitation program for the water system?	☐ ☐ ☐ ☐ ☐			3.43	5.3	211.56 211.67

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	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
M. Facility Engineering and Maintenance						
15. Are there designated areas for eating, drinking, and smoking?	□ □ □ □ □			3.30	5.1 5.3	211.42
16. Is there an acceptable separate gowning area?	□ □ □ □ □	4.9	7.5.1	3.31		211.42
17. Are the environmental-control systems periodically inspected, and are those inspections documented?	□ □ □ □ □	4.9	7.5.1	3.2 3.3 5.20	5.3	211.42 211.46
18. Is there a formal maintenance schedule of manufacturing equipment? Is it kept visibly near each piece of equipment?	□ □ □ □ □			3.34 3.35 5.20	5.5	211.42 211.56 211.67
19. Are periodic inspections made and documented to assure that the maintenance of manufacturing equipment is performed according to established schedules?	□ □ □ □ □			3.34 3.35 5.20	5.3 5.5	211.42 211.56 211.67 211.82
20. Are tools, gauges, and test equipment used by engineering and maintenance personnel:		4.11	7.6	3.41	5.3 5.5	211.160
a. Identified to reflect the date calibrated?	□ □ □ □ □					
b. Identified to reflect the date due for the next calibration?	□ □ □ □ □					
c. Marked with the identification of the person responsible for such calibration?	□ □ □ □ □					
21. Are adequate facilities used for storage of tools, gauges, and test equipment?	□ □ □ □ □	4.11	7.6	1.3 3.36	5.3 5.5	211.160
22. Are acceptable calibration standards employed?	□ □ □ □ □	4.11	7.6	3.41	5.3 5.5	211.160
24. Are the positive atmospheric controls calibrated and monitored?	□ □ □ □ □	4.9	7.5.1	5.20	5.3	211.42 211.58
25. Are there established air-controlled environments, and are they operating within limits?	□ □ □ □ □	4.9	7.5.1	3.6 3.7 5.20	5.3	211.42 211.58
26. Are facility and equipment drawings and blueprints adequately controlled?	□ □ □ □ □	4.5	4.2.3 7.5.1			211.100
27. Do pipes indicate contents and direction of flow?	□ □ □ □ □		7.5.1	3.42		211.42
28. Does there appear to be a sufficient number of personnel to address the activities?	□ □ □ □ □	4.1	6.1	2.1	4.1.5	211.25
Additional questions for sterile products						
29. Are isolators monitored for leaks?	□ □ □ □ □			*9		

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	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
	3 2 1 0 NA					
M. Facility Engineering and Maintenance						
30. Do the premises and equipment address the following:				*22 *23		
a. Smooth, impervious, and unbroken surfaces?	☐ ☐ ☐ ☐ ☐			*24		
b. No uncleanable recesses?	☐ ☐ ☐ ☐ ☐			*25 *27		
c. False ceilings sealed?	☐ ☐ ☐ ☐ ☐			*28		
d. No sinks or drains in grade A/B areas used for aseptic manufacture?	☐ ☐ ☐ ☐ ☐			*29 *30		
e. Other areas have air breaks between the machine or sink and the drains?	☐ ☐ ☐ ☐ ☐			*31 *32		
f. Air locks at appropriate grade levels?	☐ ☐ ☐ ☐ ☐			*33 *34		
g. Entrance and exit doors to air locks that do not open at the same time?	☐ ☐ ☐ ☐ ☐			*35 *37		
h. Warning systems to indicate air-control failures?	☐ ☐ ☐ ☐ ☐			*38 *39		
i. No conveyor belts traveling between Grade A and B areas unless continually sterilized?	☐ ☐ ☐ ☐ ☐					
j. Designs so that service to the area can be performed outside of it?	☐ ☐ ☐ ☐ ☐					
k. Planning and tracking of maintenance operations to assure against contamination before or after activities are performed?	☐ ☐ ☐ ☐ ☐					
l. Water treatment, distribution, and storage facilities that assure against microbial growth?	☐ ☐ ☐ ☐ ☐					
m. Sanitization of areas, equipment, etc. using approved agents and methods?	☐ ☐ ☐ ☐ ☐					
n. Monitoring of sanitization effectiveness?	☐ ☐ ☐ ☐ ☐					
Additional questions for controlled drugs						
31. For Schedule I and II materials:						<1301.72>
a. For small quantities, is there a safe or steel cabinet that provides:						
i. 30 man-minutes against surreptitious entry?	☐ ☐ ☐ ☐ ☐					
ii. 10 man-minutes against forced entry?	☐ ☐ ☐ ☐ ☐					
iii. 20 man-hours against lock manipulation?	☐ ☐ ☐ ☐ ☐					
iv. 20 man-hours against radiological techniques?	☐ ☐ ☐ ☐ ☐					
v. If safe weighs less than 750 lbs., is it bolted securely so that it cannot be removed?	☐ ☐ ☐ ☐ ☐					
vi. An alarm system that transmits to local or state police, or a 24-hour central station operated by the company?	☐ ☐ ☐ ☐ ☐					

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	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
	3 2 1 0 NA					
M. Facility Engineering and Maintenance						
b. For larger quantities, a vault that provides:						
i. Wall or perimeter line that transmits to a central station protection company, local or state police agency, or a 24-hour control station operated by the registrant?	☐ ☐ ☐ ☐ ☐					
ii. Contact switch connected to the alarm system on the door of the vault?	☐ ☐ ☐ ☐ ☐					
iii. One of the following to detect entry:						
– Complete electronic lacing of the walls?	☐ ☐ ☐ ☐ ☐					
– Ultrasonic equipment within the vault?	☐ ☐ ☐ ☐ ☐					
– A sound-accumulation system?	☐ ☐ ☐ ☐ ☐					
iv. Walls, floors, and ceilings constructed of at least 8 inches of reinforced concrete, reinforced vertically and horizontally with 0.5-inch steel rods tied 6 inches on the center?	☐ ☐ ☐ ☐ ☐					
v. A door and frame unit that provides:						
– 30 man-minutes against surreptitious entry?	☐ ☐ ☐ ☐ ☐					
– 10 man-minutes against forced entry?	☐ ☐ ☐ ☐ ☐					
– 20 man-hours against lock manipulation?	☐ ☐ ☐ ☐ ☐					
– 20 man-hours against radiological techniques?	☐ ☐ ☐ ☐ ☐					
vi. A "day gate" that is self-closing and self-locking during the hours of operation in which the vault doors open?	☐ ☐ ☐ ☐ ☐					
32. For Schedules III, IV, and V, are one of the following employed for storage:						<1301.72>
a. A safe or steel cabinet as described in question 31.a?	☐ ☐ ☐ ☐ ☐					
b. A vault as described in question 31.b?	☐ ☐ ☐ ☐ ☐					
c. A building with perimeter security that limits access during working hours?	☐ ☐ ☐ ☐ ☐					
i. A building that provides security after working hours with an alarm as described in question 31.a.vi?	☐ ☐ ☐ ☐ ☐					
ii. A building equipped with self-closing/locking doors with sealed or welded hinges to prevent removal?	☐ ☐ ☐ ☐ ☐					
iii. Are there locks on doors with limited access to a limited number of employees?	☐ ☐ ☐ ☐ ☐					

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
M. Facility Engineering and Maintenance						
d. A cage located within a building on the premises that:						
i. Has walls with not less than 10-gauge steel fabric mounted on steel posts?	☐ ☐ ☐ ☐ ☐					
ii. Has posts at least 1 inch in diameter?	☐ ☐ ☐ ☐ ☐					
iii. Has posts set in concrete or with lag bolts that are pinned or braised?	☐ ☐ ☐ ☐ ☐					
iv. Has posts that are not more than 10 feet apart with horizontal 1.5-inch reinforcements every 60 inches?	☐ ☐ ☐ ☐ ☐					
v. Has mesh construction of not more than 2.5 inches across the square?	☐ ☐ ☐ ☐ ☐					
vi. Has a ceiling of the same construction that is securely attached to the structural ceiling of the building?	☐ ☐ ☐ ☐ ☐					
vii. Has a door constructed of 10-gauge steel fabric on a metal frame in a metal flange?	☐ ☐ ☐ ☐ ☐					
viii. Is equipped with alarms as described in question 31.a.vi?	☐ ☐ ☐ ☐ ☐					

Total Number of Boxes Checked for Section M 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
N. Complaint Handling						
1. Is there a written procedure for handling written and oral complaints?	☐ ☐ ☐ ☐ ☐	4.14	8.5.2 8.5.3	8.2 8.3	4.8	211.198
2. Are complaints processed in a uniform and timely manner?	☐ ☐ ☐ ☐ ☐	4.14	8.5.2 8.5.3	8.2 8.3	4.8	211.198
3. Does the complaint record indicate the following:		4.14 4.16	4.2.4 8.5.2 8.5.3	8.2 8.3	4.8	211.198
a. Date of complaint?	☐ ☐ ☐ ☐ ☐					
b. Name and strength of the product?	☐ ☐ ☐ ☐ ☐					
c. Lot number?	☐ ☐ ☐ ☐ ☐					
d. Name of complainant?	☐ ☐ ☐ ☐ ☐					
e. Nature of complaint?	☐ ☐ ☐ ☐ ☐					
f. Reply to complainant?	☐ ☐ ☐ ☐ ☐					
4. Are complaints reviewed promptly to determine if the complaint represents a serious and unexpected adverse drug experience, that is required to be reported to the Food and Drug Administration (FDA)?	☐ ☐ ☐ ☐ ☐			8.6 8.7		211.198
5. Are complaints reviewed to determine if an investigation is necessary?	☐ ☐ ☐ ☐ ☐	4.14	8.5.2 8.5.3	8.6	4.8 4.10 4.11	211.198
6. If no investigation is deemed necessary, is the rationale for such decision documented and signed by the individual making that decision?	☐ ☐ ☐ ☐ ☐	4.14 4.16	4.2.4 8.5.2 8.5.3		4.8 4.10 4.11	211.198
7. If an investigation is performed, is it performed by the quality-control unit, and does the complaint record include the following (in addition to items in question #3):		4.14 4.16	4.2.4 8.5.2 8.5.3	8.2 8.3 8.4	4.10 4.11	211.198
a. Documented request for returned product/sample?	☐ ☐ ☐ ☐ ☐					
b. Determination of whether the product failed to meet specifications?	☐ ☐ ☐ ☐ ☐					
c. Dates and results of investigation?	☐ ☐ ☐ ☐ ☐					
d. Corrective/preventive actions taken?	☐ ☐ ☐ ☐ ☐					

Total Number of Boxes Checked for Section N 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
O. Quality System Management and Responsibilities						
1. Is there a formal quality policy by the management of the company, and does its communication to the organization include the importance of meeting statutory as well as regulatory requirements?	□ □ □ □ □	4.1	5.1 5.3 5.4.1		4.2	
2. Is there a "quality system" that addresses the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management?	□ □ □ □ □	4.1 4.2	4.1 5.5.1	1.2 1.3 1.4 2.3	4.2	211.22
3. Is there a "Quality Manual" that addresses the "quality system"?	□ □ □ □ □	4.1 4.2	4.2.1 4.2.2		4.2	
4. Are there periodic management reviews of the quality system, and are the following inputs included:		4.1 4.16	4.1 4.2.4 5.6.1 5.6.2 8.5.1		4.14	
a. Results of audits?	□ □ □ □ □					
b. Customer feedback?	□ □ □ □ □					
c. Process performance and product conformity?	□ □ □ □ □					
d. Status of corrective and preventive action?	□ □ □ □ □					
e. Follow-up actions from previous management reviews?	□ □ □ □ □					
f. Changes that could affect the quality-management system?	□ □ □ □ □					
g. Recommendations for improvement?	□ □ □ □ □					
5. Does the organization analyze appropriate data to demonstrate the suitability and effectiveness of the quality-management system in regards to the following:			8.4		4.14	
a. Customer satisfaction?	□ □ □ □ □					
b. Conformity to product requirements?	□ □ □ □ □					
c. Trends of processes and products, including opportunities for preventive action?	□ □ □ □ □					
d. Suppliers?	□ □ □ □ □					
6. Does top management provide communication within the organization regarding the effectiveness of the quality-management system?	□ □ □ □ □		5.5.3			
7. Is the individual responsible for the quality-assurance program (management representative) not directly responsible for the performance of a manufacturing operation?	□ □ □ □ □	4.1	4.1 5.5.2	2.3 2.4 2.6 2.7	4.1	
8. Does quality assurance have the authority to approve/reject plant, equipment, process, and procedural changes?	□ □ □ □ □	4.5	7.4.1 7.4.3 7.5.4	2.6 2.7 4.3 6.18		211.22

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
O. Quality System Management and Responsibilities						
9. Are personnel in contact with drugs given physical inspections or periodic health checks?	□ □ □ □ □			2.14		211.28
10. Is there a procedure for exclusion of ill personnel or personnel, who have open lesions, from product-contact jobs?	□ □ □ □ □			2.15		211.28

Total Number of Boxes Checked for Section O 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating 3 2 1 0 NA	Section
P. EC GMP ANNEX 1: Manufacture of Sterile Medicinal Products		
Facilities, Equipment and Processes	☐ ☐ ☐ ☐ ☐	
1. Are the clean areas for manufacturing divided into grades A, B, C, or D as defined in Annex 1?	☐ ☐ ☐ ☐ ☐	1, 2, 3
2. Are clean areas monitored for particulate and microbial contamination, humidity, temperature, and air flow?	☐ ☐ ☐ ☐ ☐	4, 5, 45
3. Are isolators monitored for leaks?	☐ ☐ ☐ ☐ ☐	9
4. For blow/fill/seal equipment, is an air shower part of the design, and does it meet grade A, B, C, or D as required?	☐ ☐ ☐ ☐ ☐	10
5. For aseptic/terminally sterilized items, are the components/products prepared in the right grade environment?	☐ ☐ ☐ ☐ ☐	11, 12
6. Do the premises and equipment address the following:		22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39
a. Exposed surfaces are smooth, impervious and unbroken?	☐ ☐ ☐ ☐ ☐	
b. No uncleanable recesses, ledges, shelves, pipes and equipment?	☐ ☐ ☐ ☐ ☐	
c. False ceilings sealed?	☐ ☐ ☐ ☐ ☐	
d. Sinks and drains prohibited in aseptic manufacturing areas?	☐ ☐ ☐ ☐ ☐	
e. Change rooms that act as air locks with doors that do not open simultaneously?	☐ ☐ ☐ ☐ ☐	
f. Positive pressure differentials?	☐ ☐ ☐ ☐ ☐	
g. Conveyor belts that do not pass through a processing area of lower air cleanliness unless continually sterilized?	☐ ☐ ☐ ☐ ☐	
h. An adequate continuous loop water system?	☐ ☐ ☐ ☐ ☐	
i. Validation of equipment?	☐ ☐ ☐ ☐ ☐	
7. Does processing of materials address the following:		42, 43, 44, 50, 51, 52, 53
a. Validation of aseptic processes via use of a media fill?	☐ ☐ ☐ ☐ ☐	
b. 3 consecutive validation runs on each shift?	☐ ☐ ☐ ☐ ☐	
c. Repeated at least twice per year?	☐ ☐ ☐ ☐ ☐	
d. Time limits between washing, drying, and sterilization?	☐ ☐ ☐ ☐ ☐	
e. Time limits between preparation, start of solution, and its sterilization or filtration?	☐ ☐ ☐ ☐ ☐	
f. Bioburden monitoring and absence of pyrogens assured?	☐ ☐ ☐ ☐ ☐	
g. Passing of solutions and noncombustible gases through a microorganism-retaining filter?	☐ ☐ ☐ ☐ ☐	
8. Do sterilization processes address the following?		55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81
a. Validation of achieving desired sterilizing conditions in all parts of each type of load?	☐ ☐ ☐ ☐ ☐	
b. Assurance that cooling cycles are adequate?	☐ ☐ ☐ ☐ ☐	
c. At least annual verification of validity of process?	☐ ☐ ☐ ☐ ☐	
d. Validation of loading configurations?	☐ ☐ ☐ ☐ ☐	
e. Use of biological/dosimeter indicators?	☐ ☐ ☐ ☐ ☐	
f. A clear means of differentiating between sterilized and nonsterilized lots?	☐ ☐ ☐ ☐ ☐	
g. Appropriate records/charts of each sterilizer run (e.g., time, temperature, pressure, etc.)?	☐ ☐ ☐ ☐ ☐	
h. Monitoring of drain temperatures in the sterilizer run?	☐ ☐ ☐ ☐ ☐	
i. Air used in the process is HEPA filtered?	☐ ☐ ☐ ☐ ☐	
j. Validated conditions and times to permit proper degassing from ethylene oxide use?	☐ ☐ ☐ ☐ ☐	

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating 3 2 1 0 NA	Section
P. EC GMP ANNEX 1: Manufacture of Sterile Medicinal Products		
9. Does filtration of products which cannot be sterilized in their final container address the following?		82, 83, 84,
a. Filtration through a filter pore size of 0.22 micron or less?	☐ ☐ ☐ ☐ ☐	85, 86, 87
b. Non fibre shedding filters?	☐ ☐ ☐ ☐ ☐	
c. Bubble point, diffusive flow or pressure hold testing for filter assembly integrity before and after use?	☐ ☐ ☐ ☐ ☐	
d. Length of filter use validated?	☐ ☐ ☐ ☐ ☐	
e. Compatibility of filter with product qualified?	☐ ☐ ☐ ☐ ☐	
Container/closure systems	☐ ☐ ☐ ☐ ☐	
10. Is the system for closing the container validated?	☐ ☐ ☐ ☐ ☐	88
11. Are containers closed by fusion (e.g., ampoles) 100% integrity tested?	☐ ☐ ☐ ☐ ☐	88
12. Are containers sealed under vacuum tested for maintenance of vacuum for an appropriate length of time?	☐ ☐ ☐ ☐ ☐	89
13. Are containers visually inspected for contamination and, if inspected electronically, is the process validated?	☐ ☐ ☐ ☐ ☐	90
Quality control	☐ ☐ ☐ ☐ ☐	
14. Are sterility tests performed on final product, and are the tests qualified for each product?	☐ ☐ ☐ ☐ ☐	91
15. Are sterility test samples taken in a manner representative of the entire batch?	☐ ☐ ☐ ☐ ☐	93
Personnel	☐ ☐ ☐ ☐ ☐	
16. Is there a maximum number of personnel allowed in clean areas performing activities?	☐ ☐ ☐ ☐ ☐	13
17. When outside staff (maintenance, service, visitors) are brought in, is there a procedure being followed that assures such personnel are properly instructed and supervised?	☐ ☐ ☐ ☐ ☐	14
18. Are personnel engaged in processing of animal-tissue materials or cultures of microorganisms restricted from sterile-product areas?	☐ ☐ ☐ ☐ ☐	15
19. Are personnel monitored for shedding of contaminants?	☐ ☐ ☐ ☐ ☐	16.
20. Are there specific procedures for changing clothes and washing before entering clean areas?	☐ ☐ ☐ ☐ ☐	17
21. Are wristwatches, makeup, and jewelry prohibited in clean areas?	☐ ☐ ☐ ☐ ☐	18
22. Is the type of gowning specified for the level of clean room?	☐ ☐ ☐ ☐ ☐	19

Total Number of Boxes Checked for Section P 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

CONTRACT DRUG MANUFACTURER/DEVELOPER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	EC GMP	ISO 17025	US 21 CFR Part 211 <Section 1301> [Part 11]
Q. Other Considerations						
1. Does there appear to be a desirable administrative attitude toward our requirements?	□ □ □ □ □	4.1 4.2 4.3	5.2		4.7	
2. Does there appear to be sufficient technically competent engineering, production, and quality-control support for the product intended?	□ □ □ □ □	4.2 4.3	5.2 6.2.2 6.3	2.1 2.2	4.1.5 5.2.1	
3. Does there appear to be an acceptable, functioning quality-control department that is capable of making decisions without fear of political repercussions?	□ □ □ □ □	4.1	6.4	2.3 2.4 2.6	4.1.5	
4. Does there appear to be a good, cooperative team approach among the departments in regard to solving quality problems?	□ □ □ □ □		6.4			
5. Does the facility appear to be operating in such manner that a shutdown or a sale of the operation is not imminent?	□ □ □ □ □	4.2 4.3	5.2		4.2 4.3 (4.2) (4.3)	

Total Number of Boxes Checked for Section Q 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

CONTRACT SOFTWARE
DEVELOPER AUDIT

CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

Scope: This checklist should be used to evaluate a source that develops or replicates software.

This checklist covers the following areas:

A. Contract Review and Customer Relations
B. Development and Design Control
C. Laboratories and Calibration
D. Final-Product Acceptance, Replication, Delivery, Installation, and Servicing
E. Computer Systems, Documentation Controls, and Quality Records
F. Internal Audits
G. Training
H. Complaint Handling
I. Medical Device Tracking, Reporting, and Recalls
J. Quality Assurance and Management Review
K. Other Considerations

The questions in this checklist include references to:

1. The United States Code of Federal Regulations 21 CFR, Part 820—Quality System Regulation (QSReg.), Current Good Manufacturing Practice (CGMP) Requirements for Medical Devices
2. The United States Code of Federal Regulations 21 CFR, Sections 803.17 and 803.18 for Medical Device Reporting
3. The United States Code of Federal Regulations 21 CFR, Section 806.10 for Corrections and Removals (Recalls)
4. The United States Code of Federal Regulations 21CFR, Section 821.25 for Medical Device Tracking
5. The United States Code of Federal Regulations 21 CFR Part 11—Electronic Records; Electronic Signatures. These questions are located in the Computer Systems, Documentation Controls, and Records section of the checklist
   Note: References in the checklist column is indicated with squared brackets [].
6. International Organization for Standardization (ISO) documents on Quality Systems, ISO 9001:1994, Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation and Servicing, and ISO 9001:2000. Both standards are still included because ISO 9000–3 has not been updated against ISO 9001:2000. It is still considered an extension of ISO 9001:1994.

CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

7. International Organization for Standardization (ISO) document ISO 9000–3:1997, Guidelines for the Application of ISO 9001:1994 to the Development, Supply, Installation and Maintenance of Computer Software
   Note: References to this standard are indicated in the checklist by an Asterisk.*
8. International Organization for Standardization (ISO) document ISO 13485:1996, Quality Systems—Medical Devices—Particular Requirements for the Application of ISO 9001. This ISO standard has been approved as equivalent to and a substitutition for European Standard EN 46001, Quality System Requirements for Medical Devices.
9. International Organization for Standardization (ISO) document ISO 17025:1999, General Requirements for the Competence of Testing and Calibration Laboratories
   Notes:
   a. The European Community (EC) has approved ISO 17025 as a replacement for EN 45001.
   b. References to ISO 17025 are indicated in the checklist by Arrow Brackets < >.
10. International Organization for Standardization (ISO) 10011–1:1990, 2:1991, and 3:1991, Guidelines for Auditing Quality Systems: Auditing; Qualification Criteria for Quality System Auditors and Management of Audit Programmes (American ISO equivalent, ANSI/ASQC Q10011–1, 2, and 3).
    Note: References to this standard are indicated under each appropriate question in the checklist.

Because audits may be performed by more than one person, signature spaces are provided at the end of each section to provide a record of each individual auditor's activities.

CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

Date(s) of Audit _____

Contractor's Name _____

Address _____

City _____ State _____ Zip _____

Telephone (plant) _____ (main office) _____ Fax _____

Is the company a division or subsidiary of another corporation?

If yes, describe relationship _____

_____

Audit Leader Name _____

Title _____

Audit Team Members Name _____

Function on Team _____

Name _____

Function on Team _____

Name _____

Function on Team _____

Name _____

Function on Team _____

Nature of Audit

1. Prospective Source _____ Current Source _____

2. Problem-Instigated Audit* _____ Routine Audit _____

*Nature of Problem _____

_____

_____

Items currently developed for our company:

1. _____

2. _____

3. _____

Items intended to be developed for our company:

1. _____

2. _____

3. _____

CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

Primary Individuals Contacted

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

How is a lot/batch defined?

_____

_____

What is the lot/batch-numbering system?

_____

_____

Approximate number of employees at facility?

Has a regulatory agency inspected the facility? If yes, provide dates and results.

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Is the plant an ISO-9000 registered oepration? _____

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CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

Opening Meeting Date _____

Attendees _____

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Closing Meeting Date _____

Attendees _____

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Audit Report Date Issued _____

Date Response Received _____

Date Response and Action Plan Approved _____

Date Actions Completed _____

Date Completed Actions Verified as Completed _____

Date Completed Actions Verified as Effective _____

Date Closed Out _____

Future Follow-up Items _____

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CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

QUALITY RATING SYSTEM

Rating	*Meaning*	*Interpretation*
3	Excellent	Item/area/system/knowledge is superior
2	Adequate	Item/area/system/knowledge meets basic minimum requirements.
1	Deficient	Item/area/system/knowledge is weak and not up to acceptable standards.
0	Unsatisfactory	Item/area/system/knowledge is missing or of a nature to warrant serious quality/compliance concerns.
NA	Not Applicable	Question is not applicable to type of operation, or item unable to be addressed during the audit.

Comment: Some users of the checklist may find the responses to some questions difficult to quantify on a 0–3 scale and may prefer to use a simple "yes" or "no" approach. In such cases, a "yes" should be assigned a "2" value, and a "no" should be assigned a "0" value.

CHECKLIST RESULTS AND RATING

	Number of Occurrences			
Section	**3s**	**2s**	**1s**	**0s**
A. Contract Review and Customer Relations				
B. Development and Design Control				
C. Laboratories and Calibration				
D. Final-Product Handling, Storage, Distribution, Installation, and Servicing				
E. Computer Systems, Documentation Controls, and Quality Records				
F. Internal Audits				
G. Training				
H. Complaint Handling				
I. Medical Device Tracking, Reporting, and Recalls				
J. Quality Assurance and Management Review				
K. Other Considerations				
Totals				

Audit Findings Summary

Number of questions rated excellent ( ) Times 3 = ( )
Number of questions rated adequate ( ) Times 2 = ( )
Number of questions rated deficient ( ) Times 1 = ( )
Number of questions rated unsatisfactory (_____) Times 0 = (_____)

Total Number of Questions Answered = (_____) Rating Total = (_____)

"Rating Total" divided by "Number of Questions Answered" = _____ Audit Rating

CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

I. Strengths

1. _____
2. _____
3. _____
4. _____
5. _____

II. Weaknesses

1. _____
2. _____
3. _____
4. _____
5. _____

III. Recommendations

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CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR Part 820
A. Contract Review and Customer Relations					
1. Are the requirements and expectations, including specifications and acceptance criteria, detailed in a contract?		4.3 4.3*	5.2 7.2.1	4.3 <4.4.1>	
Examples:					
a. Who will be responsible for procurement of packaging components?	☐ ☐ ☐ ☐ ☐				
b. Will the contractor have the authority and responsibility for supplier selection/qualification?	☐ ☐ ☐ ☐ ☐				
c. Who will retain product samples?	☐ ☐ ☐ ☐ ☐				
d. Who will perform final-release testing?	☐ ☐ ☐ ☐ ☐				
e. Who will release the product to market?	☐ ☐ ☐ ☐ ☐				
f. Who will store and distribute the product?	☐ ☐ ☐ ☐ ☐				
g. Who will accommodate regulatory inspections? May the contractor show specifications and records without our involvement?	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐				
h. Who will receive, process, and respond to product complaints?	☐ ☐ ☐ ☐ ☐				
i. Who will be responsible for recall capability?	☐ ☐ ☐ ☐ ☐				
j. Who will be responsible for installation and servicing?	☐ ☐ ☐ ☐ ☐				
k. Who will be responsible for the issuance and change control for the following:					
i. Labeling?	☐ ☐ ☐ ☐ ☐				
ii. Test methods?	☐ ☐ ☐ ☐ ☐				
iii. Procedures?	☐ ☐ ☐ ☐ ☐				
iv. Design input?	☐ ☐ ☐ ☐ ☐				
v. Verification and validation protocols?	☐ ☐ ☐ ☐ ☐				
2. Where appropriate, are customer documents translated into the company's internal documentation? If so, is the system of control adequate to assure that current editions will be utilized?	☐ ☐ ☐ ☐ ☐	4.3 4.3.2*	7.2.2	4.3 <4.4.5>	
3. Does the contract, or other document, specify how amendments are made to the same and communicated to the affected functions at the contractor?	☐ ☐ ☐ ☐ ☐	4.3 4.3.2*	7.2.2	4.3 <4.4.1> <4.4.4> <4.4.5>	
4. Are customer designs and specifications reviewed by quality control and other appropriate groups to assure the requirements can be satisfied?	☐ ☐ ☐ ☐ ☐	4.3 4.4.1 4.6.3 4.3* 4.4.1* 4.6.3*	7.2.2	4.3 <4.4.1>	820.30 830.40

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CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR Part 820
A. Contract Review and Customer Relations (continued)					
5. Are the contracts periodically reviewed to assure they are up-to-date and adequate in content?	□ □ □ □ □	4.3 4.3*	7.2.2	4.3 <4.4.2>	

Total Number of Boxes Checked for Section A 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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* ISO 9000-3 Software Development Supplement to ISO 9001 (ANSI/ASQC Q9000-3-1991)

CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR Part 820
B. Development and Design Control					
1. Are development projects organized according to a "life cycle" model?	☐ ☐ ☐ ☐ ☐	4.2.3* 4.4.1*	7.3		
2. Is there a Design History File (record) to demonstrate that the development was in accord with the requirements?	☐ ☐ ☐ ☐ ☐	4.4 4.16	4.2.4	4.4 4.16	820.30
3. Does the development plan address the following:		4.2 4.4.1 4.4.2 4.2* 4.4.1* 4.4.2*	7.3.1 7.3.2 7.3.3 7.3.4 7.3.5 7.3.6 7.3.7	4.2 4.4.1 4.4.2	820.30
a. Definition of the project, including the objectives?	☐ ☐ ☐ ☐ ☐				
b. Organization of resources and associated responsibilities?	☐ ☐ ☐ ☐ ☐				
c. Assessment of subcontractors?	☐ ☐ ☐ ☐ ☐				
d. List of development phases?	☐ ☐ ☐ ☐ ☐				
e. Project schedule?	☐ ☐ ☐ ☐ ☐				
f. Identification of associated plans for testing, integration, quality, etc.?	☐ ☐ ☐ ☐ ☐				
4. Does the development plan address the rules, practices, and conventions for development, including the tools and techniques to be utilized?	☐ ☐ ☐ ☐ ☐	4.4.2 4.4.2*	7.3.1 7.3.2 7.3.3 7.3.4 7.3.5 7.3.6 7.3.7	4.4.2	820.30
5. Do the development plans for each phase include the following:		4.4.2 4.10 4.4.2* 4.4.4* 4.4.5* 4.4.7* 4.10*	7.3.1 7.3.2 7.3.3 7.3.4 7.3.5 7.3.6 7.3.7	4.4.2 4.10	820.30
a. Description of what each phase consists of?	☐ ☐ ☐ ☐ ☐				
b. Required inputs for each phase?	☐ ☐ ☐ ☐ ☐				
c. Required outputs from each phase?	☐ ☐ ☐ ☐ ☐				
d. Verification procedures for each phase?	☐ ☐ ☐ ☐ ☐				
e. Acceptance criteria for each phase of development?	☐ ☐ ☐ ☐ ☐				
f. Types of testing, verification, and validation to be performed?	☐ ☐ ☐ ☐ ☐				
g. Responsibilities for these tasks?	☐ ☐ ☐ ☐ ☐				
6. Is there an adequate, formal "test" plan at each phase development?	☐ ☐ ☐ ☐ ☐	4.4 4.10 4.4* 4.10*	7.3.1 7.3.3	4.4 4.10	820.30
7. Is there a formal design output to verify fitness for use and, where appropriate, is "field testing," or independent verification, included in the "test" plan?	☐ ☐ ☐ ☐ ☐	4.4.5 4.4.5*	7.3.3	4.4.5	820.30

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CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR Part 820
B. Development and Design Control (continued)					
8. Are there design reviews after each phase to ensure no outstanding issues are arising that need to be addressed?	☐ ☐ ☐ ☐ ☐	4.1 4.4.6 4.1* 4.4.6*	7.3.4	4.1 4.4.6	820.30
9. Are similar progress reviews performed with subcontractors?	☐ ☐ ☐ ☐ ☐	4.1 4.4.6 5.4.3* 5.6.4*	7.3.4	4.1 4.4.6	820.30
10. Are these planned progress reviews shared with the purchaser?	☐ ☐ ☐ ☐ ☐	4.1 4.4.6 4.1* 4.4.6*	5.2 7.2.3 7.3.4	4.1 4.4.6	820.30
11. Does the design review address the following:		4.4 4.4.6 4.10.3	7.3.4 7.3.5 7.3.6 8.2.4	4.4 4.4.6 4.10.3	820.30
a. Comparison of customer needs with technical specifications for materials, products, and processes?	☐ ☐ ☐ ☐ ☐				
b. Validation of the design through prototype tests?	☐ ☐ ☐ ☐ ☐				
c. Ability to perform under expected conditions of use and environments?	☐ ☐ ☐ ☐ ☐				
d. Considerations of unintended uses and misuses?	☐ ☐ ☐ ☐ ☐				
e. Safety and environmental compatibility?	☐ ☐ ☐ ☐ ☐				
f. Compliance with regulatory requirements, national and international standards, and corporate practices?	☐ ☐ ☐ ☐ ☐				
g. Comparisons with competitive designs?	☐ ☐ ☐ ☐ ☐				
h. Comparisons with similar designs, especially analysis of internal and external problem histories to avoid repeating problems?	☐ ☐ ☐ ☐ ☐				
i. Reliability, serviceability, and maintainability requirements?	☐ ☐ ☐ ☐ ☐				
j. Permissible tolerances and comparison with process capabilities?	☐ ☐ ☐ ☐ ☐				
k. Product-acceptance/rejection criteria?	☐ ☐ ☐ ☐ ☐				
l. Installability, ease of assembly, storage needs, shelf life, and disposability?	☐ ☐ ☐ ☐ ☐				
m. Benign failure and fail-safe characteristics?	☐ ☐ ☐ ☐ ☐				
n. Failure modes and effects analysis, and fault tree analysis?	☐ ☐ ☐ ☐ ☐				
o. Ability to diagnose and correct problems?	☐ ☐ ☐ ☐ ☐				
p. Manufacturability of the design, including special process needs, mechanization, automation, assembly, and installation of components?	☐ ☐ ☐ ☐ ☐				

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CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR Part 820
B. Development and Design Control (continued)					
q. Capability to inspect and test the design, including special inspection and test requirements?	☐ ☐ ☐ ☐ ☐				
r. Specification of materials, components, and subassemblies, including approved supplies and suppliers, as well as availability?	☐ ☐ ☐ ☐ ☐				
s. Packaging, handling, and storage?	☐ ☐ ☐ ☐ ☐				
12. Upon completion of development, is the software validated?	☐ ☐ ☐ ☐ ☐	4.98 4.4.8*	7.3.6	4.4.8	820.30
13. Is subcontractor work validated?	☐ ☐ ☐ ☐ ☐	4.4.8 4.4.8*	7.3.6	4.4.8	820.5 820.30 820.50 820.75
14. Does the validation include assurance that the software will satisfy the purchaser's previously agreed-upon criteria?	☐ ☐ ☐ ☐ ☐	4.4.8 4.4.8*	7.3.6		820.30 820.75
15. Is there a configuration-management system that addresses the following for each software item:		4.2.3 4.4.9	7.3.7	4.2.3 4.4.9	820.30
a. A unique identification of each item?	☐ ☐ ☐ ☐ ☐	4.2.3* 4.4.9*			
b. A list of software items that comprise a complete product?	☐ ☐ ☐ ☐ ☐				
c. The build status of software products in development, delivered, or installed?	☐ ☐ ☐ ☐ ☐				
d. Control of simultaneous updating by more than one person?	☐ ☐ ☐ ☐ ☐				
e. Coordination for updating multiple products in or for more locations?	☐ ☐ ☐ ☐ ☐				
f. Identifing/tracking all actions/changes from initiation through release?	☐ ☐ ☐ ☐ ☐				
16. Is there a configuration-management plan that addresses:		4.2.3 4.4.1 4.4.2	7.3.1 7.3.7	4.2.3 4.4.1 4.4.2	
a. Organizations and responsibilities?	☐ ☐ ☐ ☐ ☐	4.2.3*			
b. Management activities to be carried out?	☐ ☐ ☐ ☐ ☐	4.4.1*			
c. Tools, techniques, and methodologies to be used?	☐ ☐ ☐ ☐ ☐	4.4.2*			
d. Metrics to be used for measurement of development and delivery process?	☐ ☐ ☐ ☐ ☐				
e. Stages at which items should be brought under control?	☐ ☐ ☐ ☐ ☐				

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CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR Part 820
B. Development and Design Control (continued)					
17. Can the following be identified for each version of software:		4.2 4.2*	7.3.1 7.5.1 7.5.3	4.2	
a. Functional and technical specifications?	☐ ☐ ☐ ☐ ☐				
b. Development tools that affect the functional and technical specifications?	☐ ☐ ☐ ☐ ☐				
c. Interfaces to other software and hardware?	☐ ☐ ☐ ☐ ☐				
d. All pertinent documents and computer files?	☐ ☐ ☐ ☐ ☐				
18. Is there an adequate system to assure changes are validated?	☐ ☐ ☐ ☐ ☐	4.4.8 4.4.9 4.4.8* 4.4.9*	7.3.6 7.3.7	4.4.8 4.4.9	820.30
19. Is there an adequate system to notify appropriate personnel of any changes made?	☐ ☐ ☐ ☐ ☐	4.5.1 4.5.1*	4.2.3 5.5.3 7.2.3 7.3.7 8.2.1	4.5.1	820.40 820.100
20. Is there an adequate document-approval, -issuance, and -control system?	☐ ☐ ☐ ☐ ☐	4.5 4.5*	4.2.3	4.5	820.40
21. Is there a procedure so the design of components are correctly translated into production documents?	☐ ☐ ☐ ☐ ☐	4.4 4.4*	7.3.2	4.4	820.30
22. Is there a change-control system?	☐ ☐ ☐ ☐ ☐	4.4.9 4.5.2 4.4.9* 4.5.2*	7.3.7	4.4.9 4.5.2	820.30
23. Is there a market readiness review that includes		4.4.2 4.4.2*	7.3.1	4.4	820.30
a. Availability and adequacy of operation, maintenance, and repair manuals?	☐ ☐ ☐ ☐ ☐				
b. Existence of an adequate distribution and customer-service organization?	☐ ☐ ☐ ☐ ☐				
c. Training of field personnel?	☐ ☐ ☐ ☐ ☐				
d. Availability of spare parts?	☐ ☐ ☐ ☐ ☐				

Total Number of Boxes Checked for Section B 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR Part 820
C. Laboratories and Calibration					
Note: Questions in this section are applicable to any testing or inspection function regardless of location (e.g., QC, Eng. etc.)					
1. Are the facilities (building) and laboratory environmental controls adequate?	□ □ □ □ □	4.11 4.11* 4.1.1*	7.6	4.11 <5.3> <5.5>	820.20 820.72 820.80
2. Do the facilities have adequate equipment and associated controls for the facilitation of testing and inspection functions?	□ □ □ □ □	4.11 4.11* 4.1.1*	7.6	4.11 <5.3> <5.5>	820.72
3. Are test procedures and results properly documented?	□ □ □ □ □	4.10.1 4.10.2 4.10.1* 4.10.2*	7.1 7.5.3 8.1 8.2.4	4.10.1 4.10.2 <5.4> <5.5> <5.10>	820.80 820.184
4. Is there an index of testing documents?	□ □ □ □ □	4.10.1 4.10.2 4.10.1* 4.10.2*	7.1 8.1	4.10.1 4.10.2 <5.4>	820.80
5. Are there specific procedures that address the identification, collection, handling, storage, and treatment of samples?	□ □ □ □ □	4.2 4.10 4.2* 4.10*		4.2 4.10 <5.4> <5.7>	
6. Are the laboratory instruments requiring calibration: a. Maintained according to the calibration procedures? b. Identified to reflect date due for next calibration? c. Stored properly? d. Calibrated to traceable standards?	□ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □	4.11 4.11*	7.6 8.1	4.11 <5.3> <5.4> <5.5> <5.6>	820.72

Total Number of Boxes Checked for Section C 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR Part 820
D. Final-Product Acceptance, Replication, Delivery, Installation, and Servicing					
1. Is there a final inspection performed by quality control on replicated product?	☐ ☐ ☐ ☐ ☐	4.10.3 4.10.4 4.10.3* 4.10.4*	8.2.4	4.10.3 4.10.4	820.80 820.86
2. Does quality control have written procedures to assure that replication records are reviewed?	☐ ☐ ☐ ☐ ☐	4.10.4 4.16 4.10.4* 4.16*	4.2.4 8.2.4	4.10.4 4.16	820.80 820.184
3. Is there a thorough investigation of all discrepancies found during the final review of the replication documents?	☐ ☐ ☐ ☐ ☐	4.13 4.13.1 4.13* 4.13.1*	8.3	4.13 4.13.1 <4.10>	820.90 820.100 820.184
4. Are records of inspection and test data maintained? Do they include the identity of the person performing the inspection or test?	☐ ☐ ☐ ☐ ☐	4.10.5 4.16 4.10.5* 4.16*	4.2.4 7.5.3 8.2.4	4.10.5 4.16 <4.12>	820.80
5. Is product configuration verified prior to shipment?	☐ ☐ ☐ ☐ ☐	4.15 4.15*	7.5.5		820.60 820.86 820.160
6. Is there a system to assure that only products approved for release are distributed?	☐ ☐ ☐ ☐ ☐	4.12 4.13 4.15.5 4.12* 4.13* 4.15.5*	7.5.3 7.5.5 8.3	4.12 4.13 4.15.5	820.86 820.160
7. Is there an acceptable procedure for, and are there records verifying correct installation of software?	☐ ☐ ☐ ☐ ☐	4.8 4.9 4.8* 4.9*	7.5.1 7.5.3	4.8 4.9	820.170
8. Are appropriate records of servicing maintained?	☐ ☐ ☐ ☐ ☐	4.16 4.16*	4.2.4 7.5.1 7.5.3	4.16	820.200
9. In cases where product does not meet performance specifications, is there a formal investigation, and are corrective and preventive actions taken?	☐ ☐ ☐ ☐ ☐	4.13.2 4.14 4.13.2* 4.14*	8.3 8.5.2 8.5.3	4.13.2 4.14	820.90 820.100

Total Number of Boxes Checked for Section D 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR Part 820
E. Computer Systems, Documentation Controls and Quality Records					
1. Are adequate controls in effect to assure that current drawings, change notices, and specifications are available at the place of the operations?	☐ ☐ ☐ ☐ ☐	4.5.1 4.5.2 4.5.1* 4.5.2*	4.2.3	4.5.1 4.5.2 <4.3.1>	820.40
2. Are the documents up-to-date, and are unneeded/obsolete documents removed from use?	☐ ☐ ☐ ☐ ☐	4.5.1 4.5.2 4.5.1* 4.5.2*	4.2.3	4.5.1 4.5.2 <4.3.2>	820.40
3. Are the documents comprehensive in context?	☐ ☐ ☐ ☐ ☐	4.2 4.4.4 4.2* 4.4.4*	4.2.3 7.2.1 7.3.2	4.2 4.4.4 <4.3.1>	820.40
4. Do written procedures exist governing a document change-control system, and are they being followed?	☐ ☐ ☐ ☐ ☐	4.5 4.5*	4.2.3	4.5 <4.3.3>	820.40
5. Are replication records retained for appropriate time periods?	☐ ☐ ☐ ☐ ☐	4.16 4.16*	4.2.4	4.16	820.180
6. Are records of activities properly generated and maintained to provide evidence of conformity to requirements?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4	4.16 <4.12> <5.10>	820.180
7. Are the records legible, readily identifiable, and easily retrievable?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4	4.16 <4.12>	
8. Is there a procedure that describes how to make changes to entry errors?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4	4.16 <4.12>	
9. Is there an established retention schedule for quality records, and does it include the controls for identification, storage, and protection?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4	4.16 <4.12>	

Note: Complete the following checklist questions if the computer system creates, modifies, maintains, stores, archives, retrieves, transmits, records, or documents data, or the computer system produces or stores data, records, or documents used in FDA submissions.

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR [Part 11]
10. Does the computer system have the ability to detect invalid or altered records?	☐ ☐ ☐ ☐ ☐				[11.10a]
11. Can accurate and complete records (including metadata) be generated in human-readable and electronic forms, such as screen display and printout, or copied to a media for review?	☐ ☐ ☐ ☐ ☐				[11.10b]
12. Does a retrieval mechanism exist to ensure the records (including the metadata) are available throughout the entire record-retention period?	☐ ☐ ☐ ☐ ☐				[11.10c]

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CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR [Part 11]
E. Computer Systems, Documentation Controls and Quality Records					
13. Are controls, such as password AND user identification, in place to limit access to the computer system?	□ □ □ □ □				[11.10d]
14. Does the computer system generate secure computer-generated audit-trail information?	□ □ □ □ □				[11.10e]
15. Does the audit trail capture operator entries or actions that create, modify, or deletes a record?	□ □ □ □ □				[11.10e]
16. Does the audit trail have User ID, time, and date stamps?	□ □ □ □ □				[11.10e]
17. Is the original data still accessible, and not obscured for records that have been changed?	□ □ □ □ □				[11.10e]
18. Are electronic audit trails kept as long as the respective records?	□ □ □ □ □				[11.10e]
19. Are electronic audit trails available for FDA review and copying?	□ □ □ □ □				[11.10e]
20. Does the computer system (or systems) force the sequence of process steps or events during operations (as applicable)?	□ □ □ □ □				[11.10f]
21. Does the computer system (or systems) control such sequences?	□ □ □ □ □				[11.10f]
22. Are there system checks for access to the computer system (or systems) including authorization, level of access, and privileges?	□ □ □ □ □				[11.10g]
23. Are there system checks to verify input-device identification (as applicable)?	□ □ □ □ □				[11.10h]
24. Is access to the system and records controlled by a designated security unit (i.e., closed system)?	□ □ □ □ □				[11.30]
25. For an OPEN system, is document encryption (or alternative) used to protect confidentiality of the electronic records during transfer?	□ □ □ □ □				[11.30]
26. For an OPEN system, are digital signatures (or alternative) used to protect the authenticity, confidentiality, and integrity of the electronic records of the systems?	□ □ □ □ □				[11.30]
If the computer system uses electronic signatures, continue with the following questions.					
27. Is the electronic signature indicated on screen displays, printouts, and other human-readable formats?	□ □ □ □ □				[11.50]
28. Does the electronic signature contain the printed name of the signer, date and time of the signing, and the meaning (review, approval, authorship) of the signature?	□ □ □ □ □				[11.50]

CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR [Part 11]
E. Computer Systems, Documentation Controls and Quality Records (continued)					
29. Is the electronic or handwritten signature linked to the associated record such that it may not be removed copied transferred by ordinary means or repudiated?	☐ ☐ ☐ ☐ ☐				[11.70]
30. Are the e-signatures unique to the user only?	☐ ☐ ☐ ☐ ☐				[11.100a]
31. Are there procedures/mechanisms to prevent user IDs from being reused, reissued, or shared?	☐ ☐ ☐ ☐ ☐				[11.100b]
32. Do all nonbiometric signatures contain at a minimum, 2 components, such as a user ID and password?	☐ ☐ ☐ ☐ ☐				[11.200a]
33. Does the computer system enforce the 2 components for a single e-signature event?	☐ ☐ ☐ ☐ ☐				[11.200a]
34. Does the computer system have a mechanism to terminate an extended idle session during a continuous session when an individual could execute a series of e-signatures?	☐ ☐ ☐ ☐ ☐				[11.200a]
35. Does the computer-system design prevent another individual from altering a signed record, thus leaving the original individual's e-signature intact?	☐ ☐ ☐ ☐ ☐				[11.200a]
36. Is the password encrypted?	☐ ☐ ☐ ☐ ☐				[11.200a]
37. Does the system force the user to reset passwords after the initial administration setting?	☐ ☐ ☐ ☐ ☐				[11.200a]
38. Does the biometric signature capture an individual's unique physical feature or action (as applicable)?	☐ ☐ ☐ ☐ ☐				[11.200b]
39. Is there a control system/procedure/computer-system design to ensure that passwords and/or ID tokens are aged or not reissued?	☐ ☐ ☐ ☐ ☐				[11.300b]
40. Is there a control system/procedure that ensures the ID/password combinations are unique, and revised periodically (e.g., every 90 days)?	☐ ☐ ☐ ☐ ☐				[11.300b]
41. Does the computer-system design include detection procedures/alarms to detect and report attempted security breaches?	☐ ☐ ☐ ☐ ☐				[11.300d]
42. Is there a procedure(s) to back up and restore, archive, and retrieve data/records from the computer system?	☐ ☐ ☐ ☐ ☐				[11.10c]
43. Is there a procedure(s), including user access and responsibility, for computer system security?	☐ ☐ ☐ ☐ ☐				[11.10d]
44. Is there documented evidence of appropriate qualifications and training of system developers, users (supplier based), and maintenance personnel?	☐ ☐ ☐ ☐ ☐				[11.10I]

CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR [Part 11]
E. Computer Systems, Documentation Controls and Quality Records (continued)					
45. Is there a procedure(s) in place governing access to and use of documents containing sensitive information (e.g., password maintenance)?	☐ ☐ ☐ ☐ ☐				[11.10k]
46. Is there a procedure(s) for change control of computer-system documentation, including audit trail?	☐ ☐ ☐ ☐ ☐				[11.10k]
47. Is there a procedure(s) to verify and document individual identity prior to issuing an electronic signature (supplier based)?	☐ ☐ ☐ ☐ ☐				[11.100b]
48. Is there a procedure to limit use of electronic signatures to the genuine owner only (supplier based)?	☐ ☐ ☐ ☐ ☐				[11.200b]
49. Is there a procedure(s) to periodically check the ID code and password issuance (supplier based)?	☐ ☐ ☐ ☐ ☐				[11.300a]

Total Number of Boxes Checked for Section E 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR Part 820
F. Internal Audits					
1. Is there a formal procedure for performing internal audits? ISO 10011–3, Part 4.6.3	□ □ □ □ □	4.1 4.17 4.1* 4.17*	5.5.1 5.6.1 8.2.2 8.5.1	4.1 4.17 <4.13>	820.20 820.22
2. Are audits performed by individuals not having direct responsibility for that which is being audited? ISO 10011–1, Part 4.1.2.4 ISO 10011–3, Part 4.1	□ □ □ □ □	4.17 4.17*	8.2.2	4.17 <4.13>	820.22
3. If the audit team includes experts with specialized background, auditor trainees, or observers, are they indicated as such in the audit report and not listed as auditors? ISO 10011–1, Part 4.2.1.1	□ □ □ □ □	4.17 4.17*	8.2.2	4.17 <4.13>	
4. Does the frequency of audits take into consideration significant changes in management, organization, techniques, or technologies that could affect the results of previous audits? ISO 10011–1, Part 5.1.2	□ □ □ □ □	4.17 4.17*	5.6.2 8.2.2	4.17 <4.13>	
5. Is there an audit plan that includes the following: a. Objective and scope of audit? b. Identification of intended reference standards/regulations to be used on the audit? c. Identification of audit team members? d. Date and place of the audit? e. Agenda of items to be audited? f. Identification of the individuals having direct responsibility for the areas to be audited? g. The expected time and duration for each audit activity? h. An opening and closing meeting? ISO 10011–1, Part 5.2.1 ISO 10011–3, Part 4.2	□ □	4.17 4.17*	8.2.2 8.2.3	4.17 <4.13>	
6. Is there a closing meeting where audit results are presented and discussed? ISO 10011–1, Part 5.2.1 ISO 10011–1, Part 5.3.3	□ □ □ □ □	4.1 4.17 4.1* 4.17*	5.6.2 8.2.2	4.1 4.17 <4.13>	820.20 820.22
7. Is there a formal audit report, with a distribution list, that contains all audit observations and the specific requirements of the standard, regulation, or other document against which the observation was made? ISO 10011–1, Part 5.2.1 ISO 10011–1, Part 5.3.2.2 ISO 10011–3, Part 4.2 ISO 10011–3, Part 4.6.4	□ □ □ □ □	4.1 4.16 4.17 4.1* 4.16* 4.17*	4.2.4 5.6.2 8.2.2	4.1 4.16 4.17 <4.13>	820.20 820.22

* ISO 9000-3 Software Development Supplement to ISO 9001 (ANSI/ASQC Q9000-3-1991)

CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR Part 820
F. Internal Audits					
8. Are documented corrective and preventive actions taken on noted audit deficiencies? ISO 10011–1, Part 7.0 ISO 10011–3, Part 4.6.5	□ □ □ □ □	4.1 4.14 4.16 4.17 4.1* 4.14* 4.16* 4.17*	4.2.4 5.5.1 5.6.2 8.2.2 8.5.2 8.5.3	4.1 4.14 4.16 4.17 <4.9> <4.10> <4.11> <4.13>	820.20 820.22 820.100
9. Do auditors have the required education, training and experience? ISO 10011–2, Part 4.0 ISO 10011–2, Part 5.0 ISO 10011–2, Part 6.0 ISO 10011–3, Part 4.3.1 ISO 10011–3, Part 4.5.3	□ □ □ □ □	4.1 4.17 4.18 4.1* 4.17* 4.18*	8.2.2	4.1 4.17 4.18 <4.13> <5.2>	820.20 820.22
10. Does there appear to be a sufficient number of personnel to accomplish audit program objectives? ISO 10011–3, Part 4.6.2	□ □ □ □ □	4.1 4.1*	6.1	4.1 <4.1.5>	820.20 820.25

Total Number of Boxes Checked for Section F 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

* ISO 9000-3 Software Development Supplement to ISO 9001 (ANSI/ASQC Q9000-3-1991)

CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR Part 820
G. Training					
1. Is there a training procedure for new employees?	□ □ □ □ □	4.18 4.18*	6.2.2	4.18 <5.2>	820.25
2. Are all employees made aware of defects that may occur from improper performance of their respective jobs?	□ □ □ □ □	4.1 4.18 4.1* 4.18*	6.1 6.2.2	4.1 4.18 <5.2>	820.25
3. Is the training of employees properly documented?	□ □ □ □ □	4.16 4.18 4.16* 4.18*	4.2.4 6.2.2	4.18 <5.2>	820.25
4. Are written job descriptions available?	□ □ □ □ □	4.18 4.18*	6.2.2	4.18 <5.2>	820.20 820.25
5. Is there sufficient assurance that consultants are qualified?	□ □ □ □ □		6.2.2	<5.2.3>	820.25 820.50
6. Are records kept of subjects on which the consultant advised?	□ □ □ □ □	4.16 4.16*	4.2.4	4.16 <5.2.3>	820.25 820.50

Total Number of Boxes Checked for Section G 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

* ISO 9000-3 Software Development Supplement to ISO 9001 (ANSI/ASQC Q9000-3-1991)

CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR Part 820
H. Complaint Handling					
1. Is there a procedure for receiving, reviewing, and evaluating complaints by a formally designated unit?	☐ ☐ ☐ ☐ ☐	4.14	8.5.2 8.5.3	4.14 <4.8>	820.198
2. Are the complaints processed per procedure in a uniform and timely manner?	☐ ☐ ☐ ☐ ☐	4.14	8.5.2 8.5.3	4.14 <4.8>	820.198
3. Are nonformal received complaints documented?	☐ ☐ ☐ ☐ ☐	4.14 4.16	4.2.4 8.5.2 8.5.3	4.14 <4.8>	820.198
4. Do all complaint records contain the following:		4.14 4.16	4.2.4 8.5.2 8.5.3	4.14 <4.8>	820.198
a. Name of device?	☐ ☐ ☐ ☐ ☐				
b. Date complaint was received?	☐ ☐ ☐ ☐ ☐				
c. Product identification and control numbers?	☐ ☐ ☐ ☐ ☐				
d. Name, address, and phone number of complainant?	☐ ☐ ☐ ☐ ☐				
e. Nature and details of complaint?	☐ ☐ ☐ ☐ ☐				
f. Reply to complainant?	☐ ☐ ☐ ☐ ☐				
5. Are complaints evaluated to determine whether an investigation is necessary?	☐ ☐ ☐ ☐ ☐	4.14	8.5.2 8.5.3	4.14 <4.8> <4.10> <4.11>	820.198
6. If no investigation is made, is the reason for that decision and the person making that decision documented?	☐ ☐ ☐ ☐ ☐	4.14 4.16	4.2.4 8.5.2 8.5.3	4.14 <4.8> <4.10> <4.11>	820.198
7. Do records of investigation include (in addition to items in question #4) the following:		4.14 4.16	4.2.4 8.5.2 8.5.3	4.14 <4.10> <4.11>	820.198
a. Documented request for return of product/sample?	☐ ☐ ☐ ☐ ☐				
b. Documented receipt of sample?	☐ ☐ ☐ ☐ ☐				
c. Determination of whether product failed to meet specifications?	☐ ☐ ☐ ☐ ☐				
d. Dates/results of investigation?	☐ ☐ ☐ ☐ ☐				
e. Corrective/preventive actions taken?	☐ ☐ ☐ ☐ ☐				
f. Technical references (where appropriate)?	☐ ☐ ☐ ☐ ☐				

Total Number of Boxes Checked for Section H 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR Part 803 Part 806 Part 821
	3 2 1 0 NA				
I. Medical Device Tracking, Reporting, and Recalls					
1. Is the company aware of its obligation to notify the FDA is it goes out of business, transfers the product to a purchaser, or discontinues manufacture so that tracking of the device can continue?	☐ ☐ ☐ ☐ ☐				821.25
2. Is there a tracking procedure that addresses the following:					821.25
a. Ability to retrieve from all internal and distributor locations devices that have not been distributed within a 3-working-day request time frame?	☐ ☐ ☐ ☐ ☐				
b. Ability to retrieve the following data within a 10-working-day request time frame:					
i. The lot number, batch number or serial number of the device, or other identifier necessary to track the device?	☐ ☐ ☐ ☐ ☐				
ii. The name, mailing address, telephone number, and social security number (if applicable) of the patient receiving the device?	☐ ☐ ☐ ☐ ☐				
iii. The date provided to the patient?	☐ ☐ ☐ ☐ ☐				
iv. The name, mailing address, and telephone number of the explanting physician?	☐ ☐ ☐ ☐ ☐				
3. Are tracking records retained for as long as the device is in use or in distribution for use?	☐ ☐ ☐ ☐ ☐				821.25
4. Does the company's procedures include a requirement to perform audits of each product tracked at not less than 6-month intervals for the first 3 years of distribution and at least once per year thereafter?	☐ ☐ ☐ ☐ ☐				821.25
5. Does the company have a written MDR (Medical Device Reporting) procedure that address the following:					803.17 803.18
a. Timely and effective identification, communication, and evaluation of events that may potentially be reportable?	☐ ☐ ☐ ☐ ☐				
b. A review process for determining whether the event is reportable?	☐ ☐ ☐ ☐ ☐				
c. Timely transmission of reportable events to the FDA?	☐ ☐ ☐ ☐ ☐				
d. Documentation and record keeping for the information that was evaluated to determine whether an event was reportable?	☐ ☐ ☐ ☐ ☐				
e. All associated information submitted to the FDA?	☐ ☐ ☐ ☐ ☐				

CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR Part 803 Part 806 Part 821
	3 2 1 0 NA				
I. Medical Device Tracking, Reporting, and Recalls					
6. Does the firm establish and maintain MDR event files for the following:					803.17 803.18
a. Information from any source that describes a device-related death, serious injury, or malfunction?	☐ ☐ ☐ ☐ ☐				
b. The company's evaluation of the information, including decisions to submit or not submit?	☐ ☐ ☐ ☐ ☐				
c. Supporting documentation, such as failure analysis, lab reports, etc.?	☐ ☐ ☐ ☐ ☐				
d. Decisions not to submit for a device-related death, serious injury or malfunction?	☐ ☐ ☐ ☐ ☐				
7. Does the firm retain the MDR files for 2 years or the life of the device, whichever is greater?	☐ ☐ ☐ ☐ ☐				803.18
8. Is there a procedure that requires all correction and removals be reported to the appropriate FDA District Office within 10 days of initiating the action?	☐ ☐ ☐ ☐ ☐				806.10
9. Based on review of files, has the 10-day requirement been complied with?	☐ ☐ ☐ ☐ ☐				806.10
10. Do the files contain evidence that the following have been provided to the FDA:					806.10
a. The 7-digit registration number of the entity responsible for submission of the report?	☐ ☐ ☐ ☐ ☐				
b. The month, day, and year that the report was made?	☐ ☐ ☐ ☐ ☐				
c. A sequential numbering system for MD's (e.g., 001, 002)?	☐ ☐ ☐ ☐ ☐				
d. Name, address, and telephone number of manufacture?	☐ ☐ ☐ ☐ ☐				
e. Brand name, classification name, or usual name of the device?	☐ ☐ ☐ ☐ ☐				
f. Intended use of the device?	☐ ☐ ☐ ☐ ☐				
g. Marketing status of the device?	☐ ☐ ☐ ☐ ☐				
h. Model, catalog, or code number of the device?	☐ ☐ ☐ ☐ ☐				
i. Manufacturing lot or serial number of the device(s)?	☐ ☐ ☐ ☐ ☐				
j. Description of events leading to correction and removal?	☐ ☐ ☐ ☐ ☐				
k. List of illnesses or injuries that have occurred?	☐ ☐ ☐ ☐ ☐				
l. Total number of devices manufactured or distributed?	☐ ☐ ☐ ☐ ☐				
m. Date of manufacture?	☐ ☐ ☐ ☐ ☐				

CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR Part 803 Part 806 Part 821
	3 2 1 0 NA				
I. Medical Device Tracking, Reporting, and Recalls					
n. Date of distribution?	☐ ☐ ☐ ☐ ☐				
o. Expiration date or expected device life?	☐ ☐ ☐ ☐ ☐				
p. Names, addresses, and telephone numbers of distributors?	☐ ☐ ☐ ☐ ☐				
q. Copies of all communications?	☐ ☐ ☐ ☐ ☐				

Total Number of Boxes Checked for Section I 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR Part 820
J. Quality Assurance and Management Review					
1. Is there a formal statement of the quality policy by the management of the company, and does its communication to the organization include the importance of meeting statutory as well as regulatory requirements?	□ □ □ □ □	4.1 4.1*	5.1 5.3 5.4.1	4.1 <4.2>	820.20
2. Is there a "quality system" that addresses the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management?	□ □ □ □ □	4.1 4.2 4.1* 4.2*	4.1 5.5.1	4.1 4.2 <4.2>	820.5 820.20
3. Is there a "Quality Manual" that addresses the "quality system"?	□ □ □ □ □	4.1 4.2 4.1* 4.2*	4.2.1 4.2.2	4.1 4.2 <4.2>	
4. Are there periodic management reviews of the quality system, and are the following inputs included:		4.1 4.16 4.1* 4.16*	4.1 4.2.4 5.6.1 5.6.2	4.1 4.16 <4.14>	820.20
a. Results of audits?	□ □ □ □ □				
b. Customer feedback?	□ □ □ □ □				
c. Process performance and product conformity?	□ □ □ □ □				
d. Status of corrective and preventive actions?	□ □ □ □ □				
e. Follow-up actions from previous management reviews?	□ □ □ □ □				
f. Changes that could affect the quality-management system?	□ □ □ □ □				
g. Recommendations for improvement?	□ □ □ □ □				
5. Does the organization analyze appropriate data to demonstrate the suitability and effectiveness of the quality-management system in regards to the following:			8.4	<4.14>	
a. Customer satisfaction?	□ □ □ □ □				
b. Conformity to product requirements?	□ □ □ □ □				
c. Trends of processes and products, including opportunities for preventive action?	□ □ □ □ □				
d. Suppliers?	□ □ □ □ □				
6. Does top management provide communication within the organization regarding the effectiveness of the quality management system?	□ □ □ □ □		5.5.3	<4.14>	
7. Is the individual responsible for the quality-assurance program (management representative) not directly responsible for the performance of a manufacturing operation?	□ □ □ □ □	4.1	4.1 5.5.2	4.1 <4.1>	820.20

* ISO 9000-3 Software Development Supplement to ISO 9001 (ANSI/ASQC Q9000-3-1991)

CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

Total Number of Boxes Checked for Section J 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

Audited by _____

CONTRACT SOFTWARE DEVELOPER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO <17025>	US 21 CFR Part 820
K. Other Considerations					
1. Does there appear to be a desirable administrative attitude toward our requirements?	□ □ □ □ □	4.1 4.2 4.3 4.1* 4.2* 4.3*	5.2	4.1 4.2 4.3 <4.7>	
2. Does there appear to be sufficient engineering, production, and quality-control support?	□ □ □ □ □	4.2 4.3 4.2* 4.3*	5.2 6.2.2 6.3	4.2 4.3 <4.1.5> <5.2.1>	820.20
3. Does there appear to be an acceptable, functioning quality-control department capable of making decisions without fear of political repercussions?	□ □ □ □ □	4.1.2	6.4	4.1 <4.1.5>	820.5 820.30
4. Does there appear to be a good, cooperative team approach among the departments in regard to solving quality problems?	□ □ □ □ □		6.4		
5. Does the facility appear to be operating in such a manner that a shutdown or a sale of the operation is not imminent?	□ □ □ □ □	4.2 4.3	5.2		

Total Number of Boxes Checked for Section K 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

* ISO 9000-3 Software Development Supplement to ISO 9001 (ANSI/ASQC Q9000-3-1991)

GENERAL SUPPLIER AUDIT

GENERAL SUPPLIER AUDIT CHECKLIST

Scope: This checklist should be used when performing an audit of a supplier that manufactures components that would not be classified as a chemical, electronic component, or printed material. There are specific checklists for those three types of items. If the supplier is developing a custom or unique item, the "Contract Device Manufacturer/Developer Audit Checklist" or the "Contract Drug Manufacturer/Developer Audit Checklist" should be utilized instead of this supplier checklist.

This checklist covers the following areas:

A. Contract Review and Customer Relations

B. Purchasing

C. Received/In-Process-Material Handling and Storage

D. Manufacturing Facilities, Equipment, and Controls

E. Final-Product Acceptance, Storage, and Distribution

F. Laboratories and Calibration

G. Document Control

H. Training and Internal Audit

I. Quality Assurance and Management Review

J. Other Considerations

The questions in this checklist include references to:

1. International Organization for Standardization (ISO) documents on Quality Systems, ISO 9001:1994, Quality Systems—A Model for Quality Assurance in Design, Development, Production, Installation and Servicing, and ISO 9001:2000, Quality Management Systems—Requirements

2. International Organization for Standardization (ISO) documents 13485:1996, Quality Systems—Medical Devices—Particular Requirements for the Application of ISO 9001, and 13488L1996, Quality Systems—Medical Devices—Particular Requirements for the Application of ISO 9002. These are now equivalent to and have replaced the European Standards EN 46001 and 46002, Quality System Requirements for Medical Devices.
   Note: References to 13488 are indicated in the checklist by Parentheses ().

3. International Organization for Standardization (ISO) document 17025:1999, General Requirements for the Competence of Testing and Calibration Laboratories
   Notes:
   a. References to ISO 17025 are indicated in the checklist by Arrow Brackets < >.
   b. The European Community (EC) has approved ISO 17025 as a replacement for EN 45001.

GENERAL SUPPLIER AUDIT CHECKLIST

4. International Organization for Standardization (ISO) 10011–1:1990, 2:1991, and 3:1991, Guidelines for Auditing Quality Systems: Auditing; Qualification Criteria for Quality System; and Management of Audit Programmes (American ISO equivalent, ANSI/ASQC Q10011–1, 2, and 3).
   Note: References to this standard are indicated under each appropriate question in the checklist.
5. The United States Military Specification Quality Program Requirements (MIL-Q-9858A).

Because supplier audits may be performed by more than one person, signature spaces are provided at the end of each section to provide a record of each individual auditor's activities.

GENERAL SUPPLIER AUDIT CHECKLIST

Date(s) of Audit _____

Supplier's Name _____

Address _____

City _____ State _____ Zip _____

Telephone (plant) _____ (main office) _____ Fax _____

Is the company a division or subsidiary of another corporation?

If yes, describe relationship _____

_____

Audit Leader Name _____

Title _____

Audit Team Members Name _____

Function on Team _____

Name _____

Function on Team _____

Name _____

Function on Team _____

Name _____

Function on Team _____

Nature of Audit

1. Prospective Source _____ Current Source _____

2. Problem-Instigated Audit* _____ Routine Audit _____

*Nature of Problem _____

_____

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Items currently procured from source:

1. _____

2. _____

3. _____

Items intended to be procured from company:

1. _____

2. _____

3. _____

GENERAL SUPPLIER AUDIT CHECKLIST

Are the components under consideration for purchase produced only at this location?

Yes _____ No _____

If no, where else could they originate:

1._____

2._____

3._____

How is a lot/batch defined?

_____

_____

What is the lot/batch-numbering system?

_____

_____

Is there a way to denote the site of manufacture if multiple sites are employed?

_____

_____

How many shifts are there? _____

Approximate number of employees at facility? _____

Approximate square footage of facility (including warehouse)? _____

Is the plant an ISO-9000 registered operation? _____

Has the facility been inspected by a government agency? If yes, provide dates and results.

_____

Primary Individuals Contacted

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

GENERAL SUPPLIER AUDIT CHECKLIST

Opening Meeting Date _____

Attendees _____

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Closing Meeting Date _____

Attendees _____

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Audit Report Date Issued _____

Date Response Received _____

Date Response and Action Plan Approved _____

Date Actions Completed _____

Date Completed Actions Verified as Completed _____

Date Completed Actions Verified as Effective _____

Date Closed Out _____

Future Follow-up Items _____

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GENERAL SUPPLIER AUDIT CHECKLIST

QUALITY RATING SYSTEM

Rating	*Meaning*	*Interpretation*
3	Excellent	Item/area/system/knowledge is superior
2	Adequate	Item/area/system/knowledge meets basic minimum requirements.
1	Deficient	Item/area/system/knowledge is weak and not up to acceptable standards.
0	Unsatisfactory	Item/area/system/knowledge is missing or of a nature to warrant serious quality/compliance concerns.
NA	Not Applicable	Question is not applicable to type of operation, or item unable to be addressed during the audit.

Comment: Some users of the checklist may find the responses to some questions difficult to quantify on a 0–3 scale and may prefer to use a simple "yes" or "no" approach. In such cases, a "yes" should be assigned a "2" value, and a "no" should be assigned a "0" value.

CHECKLIST RESULTS AND RATING

	Number of Occurrences			
Section	**3s**	**2s**	**1s**	**0s**
A. Contract Review and Customer Relations				
B. Purchasing				
C. Received/In-Process-Material Handling and Storage				
D. Manufacturing Facilities, Equipment, and Controls				
E. Final-Product Acceptance, Storage, and Distribution				
F. Laboratories and Calibration				
G. Document Control				
H. Training and Internal Audit				
I. Medical Device Tracking, Reporting, and Recalls				
I. Quality Assurance and Management Review				
J. Other Considerations				
Totals				

Audit Findings Summary

Number of questions rated excellent ( ) Times 3 = ( )
Number of questions rated adequate ( ) Times 2 = ( )
Number of questions rated deficient ( ) Times 1 = ( )
Number of questions rated unsatisfactory (_____) Times 0 = (_____)

Total Number of Questions Answered = (_____) Rating Total = (_____)

"Rating Total" divided by "Number of Questions Answered" = _____ Audit Rating

GENERAL SUPPLIER AUDIT CHECKLIST

I. Strengths

1. _____
2. _____
3. _____
4. _____
5. _____

II. Weaknesses

1. _____
2. _____
3. _____
4. _____
5. _____

III. Recommendations

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GENERAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
	3 2 1 0 NA				
A. Customer Relations					
This first set of questions is applicable to custom items to be provided.					
1. Are requirements, including specifications and acceptance criteria, adequately detailed in a contract?	☐ ☐ ☐ ☐ ☐	4.3	5.2 7.2.1	4.3 (4.3) <4.4.1>	1.3 1.4
2. Does the contract specify how amendments to the contract are to be made and communicated to affected functions?	☐ ☐ ☐ ☐ ☐	4.3	7.2.2	4.3 (4.3) <4.4.1> <4.4.4> <4.4.5>	1.3 1.4
3. Is the contract formally agreed to before execution?	☐ ☐ ☐ ☐ ☐	4.3	5.2 7.2	4.3 (4.3) <4.4.1>	1.3 1.4
4. Are the contracts periodically reviewed or inspected (US Military) for adequacy?	☐ ☐ ☐ ☐ ☐	4.3	7.2.2	4.3 (4.3) <4.4.2>	1.3 1.4
5. Are records of these periodic reviews maintained for a specified period of time?	☐ ☐ ☐ ☐ ☐	4.3 4.16	4.2.4 7.2.2	4.3 (4.3) <4.4.2>	1.3 1.4
This second set of questions is applicable to standard "off the shelf" items.					
6. Is there a product/service catalog/list that is revision controlled to assure that the contents are current and correct?	☐ ☐ ☐ ☐ ☐	4.3	5.2 7.2.2 7.2.3	4.3 (4.3)	1.3 1.4
7. Does the catalog/list provide enough information to assure that the purchaser will receive what is expected?	☐ ☐ ☐ ☐ ☐	4.3	5.2 7.2.1 7.2.3	4.3 (4.3)	1.3 1.4
This third set of questions is applicable to both types of items.					
8. Is there a procedure established and being followed that describes how oral and formal orders are to be processed?	☐ ☐ ☐ ☐ ☐	4.3	7.2.3	4.3 (4.3) <4.4.1>	1.3 1.4
9. Is there a procedure for resolving processed-order problems?	☐ ☐ ☐ ☐ ☐	4.3	7.2.3	4.3 (4.3) <4.4.2> <4.7> <4.8>	1.3 1.4

Total Number of Boxes Checked for Section A 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

GENERAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
B. Purchasing					
1. Is there a procedure for the qualification and control of raw-material sourcing?	□ □ □ □ □	4.6.4	7.4.1	4.6.4 (4.6.4) <4.6.1>	1.3 5.1
2. Does the vendor maintain a list of approved sources for materials employed in the manufacturing process?	□ □ □ □ □	4.2 4.6.4 4.6.3 4.10.1	7.4.1	4.2 4.6.3 4.6.4 4.10.1 (4.2) (4.6.3) (4.6.4) (4.10.1)	1.3 5.1 5.2
3. In appropriate situations, does the company audit sources of supply?	□ □ □ □ □	4.6.2	7.4.1	4.6.2 (4.6.2) <4.6.4>	5.1

Total Number of Boxes Checked for Section B 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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GENERAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
	3 2 1 0 NA				
C. Received/In-Process-Material Handling and Storage					
1. Are released items properly segregated from material awaiting testing and disposition?	☐ ☐ ☐ ☐ ☐	4.10.1	7.1 7.5.3 7.5.5 8.1	4.10.1 (4.10.1)	6.1
2. Is material adequately inspected, tested, and identified as accepted or rejected?	☐ ☐ ☐ ☐ ☐	4.10.1	7.1 7.5.3 7.5.5 8.1	4.10.1 (4.10.1)	6.1
3. Is rejected material adequately controlled?	☐ ☐ ☐ ☐ ☐	4.10.1 4.10.2 4.12 4.13	7.4.3 7.5.3 8.2.4 8.3	4.10.1 4.10.2 4.12 4.13 (4.10.1) (4.10.2) (4.12) (4.13)	6.1
4. Is there an acceptance area/procedure for sampling?	☐ ☐ ☐ ☐ ☐	4.11	7.5.3	4.11 (4.11)	6.1
5. Are materials properly handled and stored to prevent damage?	☐ ☐ ☐ ☐ ☐	4.10.1 4.15.2 4.15.3	7.5.5 8.2.4	4.10.1 4.15.2 4.15.3 (4.10.1) (4.15.2) (4.15.3)	6.1
6. Are stockrooms and storage areas restricted to authorized personnel?	☐ ☐ ☐ ☐ ☐	4.15.3	7.5.5	4.15.3 (4.15.3) <4.6.1> <5.8>	1.3
7. Are materials properly identified as to their contents to avoid errors in issuance?	☐ ☐ ☐ ☐ ☐	4.8 4.10.1	7.5.3	4.8 4.10.1 (4.8) (4.10.1)	6.1
8. Are materials adequately segregated to avoid mix-ups?	☐ ☐ ☐ ☐ ☐	4.8 4.10.1	7.5.3	4.8 4.10.1 (4.8) (4.10.1) <4.6.1> <5.8>	6.1
9. Are stocks reinspected and tested at intervals?	☐ ☐ ☐ ☐ ☐	4.15.3	7.5.5	4.15.3 (4.15.3) <4.6.1>	1.3 3.2

GENERAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
C. Received/In-Process-Material Handling and Storage (continued)					
10. Where required, how adequate is the controlled-environment storage (e.g., humidity, temperature, etc.)?	□ □ □ □ □	4.15.3	7.5.5	4.15.3 (4.15.3) <4.6.1>	1.3 3.2

Total Number of Boxes Checked for Section C 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

GENERAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
	3 2 1 0 NA				
D. Manufacturing Facilities, Equipment, and Control					
1. Are the items being manufactured identifiable throughout the operation?	☐ ☐ ☐ ☐ ☐	4.8	7.5.3	4.8 (4.8)	6.1
2. Are the manufacturing operations orderly in flow and organization?	☐ ☐ ☐ ☐ ☐	4.8 4.9	7.5.1 7.5.2	4.8 4.9 (4.8) (4.9)	6.2
3. Are the manufacturing processes and facilities adequate to produce quality components?	☐ ☐ ☐ ☐ ☐	4.9	4.2.3 7.5.1 7.5.2	4.9 (4.9)	6.2
4. Are lubricants and nonproduction materials properly controlled to prevent product contamination?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	1.3 6.2
5. Have equipment- and utensil-cleaning procedures been established and, if appropriate, validated?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1 7.5.2	4.9 (4.9)	6.2
6. Does the lot number reflect 1 homogeneous production run?	☐ ☐ ☐ ☐ ☐	4.8 4.9 4.12	7.5.1 7.5.2	4.8 4.9 4.12 (4.8) (4.9) (4.12)	1.3 6.2 6.5
7. Are formal line clearances performed between different labeling or packaging operations before they begin?	☐ ☐ ☐ ☐ ☐	4.8 4.9	7.5.1	4.8 4.9 (4.8) (4.9)	6.2
8. Is the difference between "line clearance" and "ready to run" (first-article approval) clearly understood?	☐ ☐ ☐ ☐ ☐		7.5.1		6.2
9. Does the quality-control group approve the start-up production?	☐ ☐ ☐ ☐ ☐	4.9 4.10.2 4.10.4 4.12	7.5.1 8.2.4	4.9 4.10.2 4.10.4 4.12 (4.9) (4.10.2) (4.10.4) (4.12)	3.1 3.3
10. Are the manufacturing procedures formalized and controlled?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	3.3 3.4 4.1 6.2
11. Is there a formal procedure for deviations to normal practice?	☐ ☐ ☐ ☐ ☐	4.9 4.13 4.13.1	7.5.1 8.3	4.9 4.13 4.13.1 (4.9) (4.13) (4.13.1)	1.3 2.2 3.3 4.1

GENERAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
	3 2 1 0 NA				
D. Manufacturing Facilities, Equipment, and Control (continued)					
12. Are there formal procedures for the handling of rework?	□ □ □ □ □	4.9 4.13 4.13.1	7.5.1 8.3	4.9 4.13.1 (4.9) (4.13.1)	1.3 2.2 3.3 3.4 4.1
13. Do the employees in the manufacturing areas appear to be knowledgeable and quality conscious?	□ □ □ □ □	4.18	6.2.2	4.18 (4.18)	1.3 3.1
14. Are current specifications/drawings readily accessible for the employees?	□ □ □ □ □	4.5.1 4.5.2	4.2.3 7.5.1	4.5.1 4.5.2 (4.5.1) (4.5.2)	3.3 4.1 6.2
15. Is the manufacturing environment acceptable for the type of item produced?	□ □ □ □ □	4.9	7.5.1 7.5.2	4.9 (4.9)	1.3 3.2 6.2
16. Are production areas that are very dusty or unique in regard to contamination properly controlled with exhaust systems or other methods of decontamination?	□ □ □ □ □	4.9	7.5.1 7.5.2	4.9 (4.9)	6.2
17. Are production employees neat in their appearance, with unnecessary jewelry and cosmetics kept out of the production areas?	□ □ □ □ □	4.9 4.18	6.2.2 7.5.1	4.9 4.18 (4.9) (4.18)	1.3 6.2
18. Are any special requirements for specific operator apparel (such as masks, gowns, etc.) being violated?	□ □ □ □ □	4.9 4.18	4.2.4 6.2.2 7.5.1	4.9 4.18 (4.9) (4.18)	6.2
19. Is there a formal record of production steps and quantities used?	□ □ □ □ □	4.8 4.9 4.10.2 4.10.4 4.16	4.2.4 7.5.1	4.8 4.9 4.10.2 4.10.4 4.16 (4.8) (4.9) (4.10.2) (4.10.4) (4.16)	3.4
20. Are waste materials clearly identified in proper containers?	□ □ □ □ □	4.9	7.5.1 8.3	4.9 (4.9)	
21. Are the ceiling fixtures and pipes free of accumulated dirt?	□ □ □ □ □	4.9	7.5.1	4.9 (4.9)	1.3 6.2
22. Are valves and associated pipes in the production areas free of leaks?	□ □ □ □ □	4.9	7.5.1	4.9 (4.9)	1.3 6.2

GENERAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
D. Manufacturing Facilities, Equipment, and Control (continued)					
23. Are the ceilings and walls in good condition to prevent contamination from paint chips?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	1.3 6.2
24. Are appropriate bathroom facilities available?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	1.3 6.2
25. Are smoking and eating prohibited where necessary?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	1.3 6.2
26. Is there an adequate pest-control program?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	1.3 6.2
27. Are the in-process inspection and test procedures adequate?	☐ ☐ ☐ ☐ ☐	4.10.3 4.10.4 4.11 4.16	8.2.4	4.10.3 4.10.4 4.11 4.16 (4.10.3) (4.10.4) (4.11) (4.16)	6.2 6.3
28. Are there adequate specifications (including a classification of defects) to control in-process materials?	☐ ☐ ☐ ☐ ☐	4.10.2	8.2.3	4.10.3 (4.10.3)	6.6
29. Is statistical process control (SPC) utilized, where appropriate, to assure production quality?	☐ ☐ ☐ ☐ ☐	4.20	8.1	4.20 (4.20)	6.6
30. If in-process material is rejected, is there an indication of the reason?	☐ ☐ ☐ ☐ ☐	4.13 4.13.1 4.14	8.3 8.5.2 8.5.3	4.13 4.13.1 4.14 (4.13) (4.13.1) (4.14)	3.5 6.5 6.7
31. If in-process material is rejected, is there a corrective action indicated to prevent the same problem from recurring?	☐ ☐ ☐ ☐ ☐	4.14	8.5.2 8.5.3	4.14 (4.14)	3.5 6.5 6.7

Total Number of Boxes Checked for Section D 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

GENERAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
E. Final-Product Acceptance, Storage, and Distribution					
1. How adequate are the procedures for final-product inspection, sampling, and testing?	□ □ □ □ □	4.10.4	8.2.4	4.10.4 (4.10.4)	6.3
2. Are final inspection/test results recorded?	□ □ □ □ □	4.10.4 4.10.5	4.2.4 8.2.4	4.10.4 4.10.5 (4.10.4) (4.10.5) <5.4.3> <5.4.4>	3.4 6.3
3. How adequate is the final review of the production-documentation package?	□ □ □ □ □	4.12 4.16	8.2.4	4.12 4.16 (4.12) (4.16)	3.4 6.3
4. Are production-documentation packages stored properly and retained for an adequate length of time?	□ □ □ □ □	4.16	4.2.4	4.16 (4.16)	3.4
5. Are discrepancies found during the final review properly investigated?	□ □ □ □ □	4.13	8.3	4.13 (4.13)	3.5 6.5
6. How adequate is the procedure for release of product?	□ □ □ □ □	4.2 4.10.4 4.12	7.5.3 8.2.4	4.2 4.10.4 4.12 (4.2) (4.10.4) (4.12)	1.3 3.1 6.2 6.5
7. How well is final-product material identified and segregated?	□ □ □ □ □	4.8 4.15.2 4.15.5	7.5.3 7.5.5	4.8 4.15.2 4.15.5 (4.8) (4.15.2) (4.15.5)	6.7
8. How well is nonconforming material controlled?	□ □ □ □ □	4.13	8.3	4.13 (4.13)	6.5
9. How adequate is the retained-sample program?	□ □ □ □ □	4.3		4.3 (4.3)	3.4
10. Do adequate facilities exist to store materials awaiting shipment?	□ □ □ □ □	4.15.3	7.5.5	4.15.3 (4.15.3)	6.4
11. Where appropriate, how adequate is controlled access to final-product stockrooms and material-storage areas?	□ □ □ □ □	4.15.1 4.15.3	7.5.5	4.15.1 4.15.3 (4.15.1) (4.15.3)	6.4

GENERAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
E. Final-Product Acceptance, Storage, and Distribution (continued)					
12. Are the shipping containers sufficiently marked to identify the contents?	☐ ☐ ☐ ☐ ☐	4.8 4.15.4 4.15.5	7.5.5	4.8 4.15.4 4.15.5 (4.8) (4.15.4) (4.15.5)	6.4 6.7
13. How well are items with shelf-life requirements identified and controlled?	☐ ☐ ☐ ☐ ☐	4.15.3	7.5.5	4.15.3 (4.15.3)	6.4
14. How adequate is the lot-recall/withdrawal system?	☐ ☐ ☐ ☐ ☐	4.2 4.8 4.16	7.5.1 7.5.3 7.5.5	4.2 4.8 4.16 (4.2) (4.8) (4.16)	3.4
15. If "clean room" operations are performed, is the final sampling and inspection of the parts performed in the same area or some other area with clean-room controls?	☐ ☐ ☐ ☐ ☐	4.9 4.10.3 4.11	7.5.1 7.5.5	4.9 4.10.3 4.11 (4.9) (4.10.3) (4.11)	6.2 6.3 6.7

Audited by _____

Total Number of Boxes Checked for Section E 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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GENERAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
F. Laboratories and Calibration					
1. Does the quality-control department appear to have sufficient equipment and facilities?	□ □ □ □ □	4.1.2	5.5.1 6.1 6.2	4.1 (4.1) <5.3> <5.5>	1.3 3.1 4.2 4.5
2. Are samples that are brought into the quality-control laboratory from incomings, in-process- and final-product materials properly controlled?	□ □ □ □ □	4.10.1 4.10.2 4.10.3	7.4.3 8.2.4	4.10.1 4.10.2 4.10.3 (4.10.1) (4.10.2) (4.10.3) <5.4> <5.7>	5.1 6.1 6.2 6.3 6.6
3. Are all tests/inspections properly documented?	□ □ □ □ □	4.10.4 4.10.5	4.2.4 7.4.3 8.2.4	4.10.4 4.10.5 (4.10.4) (4.10.5) <5.4> <5.5> <5.10>	3.4
4. Are certificates of inspection/test results available to the customers?	□ □ □ □ □	4.3 4.6.1	5.2 8.2.1	4.3 4.6.1 (4.3) (4.6.1)	
5. Are there acceptable procedures to assure that gauges, tools, and test equipment are maintained in proper order?	□ □ □ □ □	4.11	7.6	4.11 (4.11) <5.3> <5.4> <5.5> <5.6>	4.2 4.3 4.5
6. Is there a system to assure that gauges (including go-no-go gauges) and testing equipment are calibrated on a periodic basis?	□ □ □ □ □	4.11	7.6	4.11 (4.11) <5.3> <5.4> <5.5> <5.6>	4.2 4.3 4.5
7. If calibration is performed by the facility, are these calibration procedures formalized and traceable to appropriate standards?	□ □ □ □ □	4.11	7.6	4.11 (4.11) <5.3> <5.4> <5.5> <5.6>	3.3 4.2 4.3 4.5

GENERAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
	3 2 1 0 NA				
F. Laboratories and Calibration (continued)					
8. If external sources are utilized for calibration, have the sources been audited to assure competence?	□ □ □ □ □	4.6.2 4.11	7.4.1 7.6	4.6.2 4.11 (4.6.2) (4.10) <4.5>	1.3 4.2 4.3 4.5 5.1

Total Number of Boxes Checked for Section F 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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GENERAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
G. Document Control					
1. Are the specifications and other documents comprehensive in content?	□ □ □ □ □	4.2 4.4.4	4.2.1 4.2.3 7.2.1 7.3.2	4.2 4.4.4 (4.2) <4.3.1>	3.3 4.1
2. Are the documents current, and are unneeded/obsolete documents removed from usage?	□ □ □ □ □	4.5.1	4.2.3	4.5.1 (4.5.1) <4.3.2>	3.3 4.1
3. Do written procedures exist that address a change-control system for documents, and are the procedures being followed?	□ □ □ □ □	4.5	4.2.3	4.5 (4.5) <4.3.3>	3.3 4.1

Total Number of Boxes Checked for Section G 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

GENERAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
	3 2 1 0 NA				
H. Training and Internal Audit					
1. Is there a training program for all employees in appropriate areas?	☐ ☐ ☐ ☐ ☐	4.16 4.18	6.2.2	4.16 4.18 (4.16) (4.18) <5.2>	1.3 3.1 3.3
2. Is there a program for periodic retraining?	☐ ☐ ☐ ☐ ☐	4.18	6.2.2	4.18 (4.18)	
3. Is there a formal procedure for performing internal quality audits? ISO 10011–3, Part 4.6.3	☐ ☐ ☐ ☐ ☐	4.1 4.17	5.5.1 5.6.1 8.2.2 8.5.1	4.1 4.17 (4.1) (4.17) <4.13>	
4. Are audits performed by properly educated, trained, and experienced individuals not having direct responsibility for that which is being audited? ISO 10011–1, Part 4.2.1.4 ISO 10011–2, Part 4.0 ISO 10011–2, Part 6.0 ISO 10011–3, Part 4.1 ISO 10011–3, Part 4.3.1 ISO 10011–3, Part 4.5.3	☐ ☐ ☐ ☐ ☐	4.17 4.18	8.2.2 8.2.3	4.1 4.17 (4.1) (4.17) <4.13>	
5. Is there an audit plan that includes the following: a. Objective/scope of audit? b. Date and items to be audited? c. Applicable standards/regulations? d. Provision for an opening and closing meeting? ISO 10011–1, Part 5.2.1 ISO 10011–3, Part 4.2	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	4.17	8.2.2 8.2.3	4.17 (4.17)	
6. Is there a formal audit report that details the observations requiring corrective and preventive action? ISO 10011–1, Part 5.2.1 ISO 10011–1, Part 5.3.2.2 ISO 10011–3, Part 4.2 ISO 10011–3, Part 4.5.3	☐ ☐ ☐ ☐ ☐	4.1 4.17	5.5.1 8.2.2 8.2.3	4.1 4.17 (4.1) (4.17) <4.9> <4.10> <4.11> <4.13>	

GENERAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
H. Training and Internal Audit (continued)					
7. Are documented corrective and preventive actions taken on audit observations? ISO 10011–1, Part 7.0 ISO 10011–3, Part 4.6.5	□ □ □ □ □	4.1 4.14 4.16 4.17	4.2.4 5.6.2 5.5.1 8.5.2 8.5.3 8.2.2	4.1 4.14 4.16 4.17 (4.1) (4.14) (4.16) (4.17) <4.9> <4.10> <4.11> <4.13>	

Total Number of Boxes Checked for Section H 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

GENERAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
	3 2 1 0 NA				
I. Quality Assurance and Management Review					
1. Is there a formal statement of the corporate quality policy by the management of the company?	☐ ☐ ☐ ☐ ☐	4.1	5.1 5.3 5.4.1	4.1 (4.1) <4.2>	1.3 3.1
2. Is there a "quality system" that addresses the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management?	☐ ☐ ☐ ☐ ☐	4.1 4.2	4.1 5.5.1	4.1 4.2 (4.1) (4.2) <4.2>	1.3 3.1
3. Is there a "Quality Manual" that addresses the "quality system"?	☐ ☐ ☐ ☐ ☐	4.1 4.2	4.2.1 4.2.2	4.1 4.2 (4.1) (4.2) <4.2>	1.3 3.1
4. Are there periodic management reviews of the quality system and are the following inputs included:		4.1 4.16	4.1 4.2.4 5.6.1 5.6.2 8.5.1	4.1 4.16 (4.1) (4.16) <4.14>	3.1
a. Results of audits?	☐ ☐ ☐ ☐ ☐				
b. Customer feedback?	☐ ☐ ☐ ☐ ☐				
c. Process performance and product conformity?	☐ ☐ ☐ ☐ ☐				
d. Status of corrective and preventive actions?	☐ ☐ ☐ ☐ ☐				
e. Follow-up actions from previous management reviews?	☐ ☐ ☐ ☐ ☐				
f. Changes that could affect the quality-management system?	☐ ☐ ☐ ☐ ☐				
g. Recommendations for improvement?	☐ ☐ ☐ ☐ ☐				
5. Does the organization analyze appropriate data to demonstrate the suitability and effectiveness of the quality-management system in regards to the following:			8.4	<4.14>	
a. Customer satisfaction?	☐ ☐ ☐ ☐ ☐				
b. Conformity to product requirements?	☐ ☐ ☐ ☐ ☐				
c. Trends of processes and products, including opportunities for preventive action?	☐ ☐ ☐ ☐ ☐				
d. Suppliers?	☐ ☐ ☐ ☐ ☐				
6. Does top management provide communication within the organization regarding the effectiveness of the quality-management system?	☐ ☐ ☐ ☐ ☐		5.5.3	<4.14>	
7. Does the quality-control function appear to have the independence necessary to make decisions without fear of political repercussions?	☐ ☐ ☐ ☐ ☐	4.1	4.1 5.5.2	4.1 (4.1) <4.1>	1.3 3.1 4.1

GENERAL SUPPLIER AUDIT CHECKLIST

Total Number of Boxes Checked for Section I 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

Audited by _____

GENERAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
	3 2 1 0 NA				
J. Other Considerations					
1. Does there appear to be a desirable administrative attitude toward our requirements?	□ □ □ □ □	4.1 4.2 4.3	5.2	4.1 4.2 4.3 (4.1) (4.2) (4.3) <4.7>	1.3 3.2
2. Is there a clear understanding of our requirements and needs?	□ □ □ □ □	4.2 4.3	5.2	4.2 4.3 (4.2) (4.3) <4.7>	3.2
3. Does there appear to be sufficient engineering, production, and quality-control support to meet our needs?	□ □ □ □ □	4.2 4.3	5.2 6.2.2 6.3	4.2 4.3 (4.2) (4.3) <4.1.5> <5.2.1>	1.3 3.1
4. How well does the company maintain the entire facility in general?	□ □ □ □ □	4.9	6.3 7.5.1	4.9 (4.9) <5.3>	1.3 6.2
5. Does there appear to be sufficient administrative commitment to adequately staff departments?	□ □ □ □ □	4.1 4.18	6.1 6.2.1	4.1 4.18 (4.1) (4.18) <4.1.5>	
6. Does the facility appear to be operating in such a manner that a shutdown or sale of the operation is not imminent?	□ □ □ □ □		4.2 4.3	5.2	

Total Number of Boxes Checked for Section J 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

BULK CHEMICAL SUPPLIER AUDIT CHECKLIST

Scope: This checklist should be used in the evaluation of a bulk chemical source.

This checklist covers the following areas:

A. Contract Review and Customer Relations
B. Purchasing and Consultants
C. Received/In-Process-Material Handling and Storage
D. Manufacturing Facilities, Equipment, and Controls
E. Final-Product Acceptance, Storage, and Distribution
F. Validation
G. Laboratories and Calibration
H. Computer Systems, Document Control, and Quality Records
I. Training and Internal Audit
J. Complaint Handling and Recalls
K. Management Responsibility
L. Other Considerations

The questions in this checklist include references to:

1. The United States Code of Federal Regulations, 21 CFR, Part 11—Electronic Records; Electronic Signatures. Questions pertinent to this regulation can be found in the Validation and Computer Systems, Document Control; and Quality Records sections of the checklist.
   Note: The referenced sections of the regulation are in brackets [].
2. United States Food and Drug Administration (FDA) and ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients
3. International Pharmaceutical Excipients Council (IPEC) Good Manufacturing Practice Guideline for Bulk Pharmaceutical Excipients
   Note: The referenced sections of this guideline are in parenthesis ().
4. The United States Code of Federal Regulations 21 CFR, Parts 1301 and 1304, Requirements for Controlled Drug Substances
5. The United States Military Specification Quality Program Requirements (MIL-Q-9858A)
6. International Organization for Standardization (ISO) documents on Quality Systems, ISO 9001:1994, Quality Systems—Model and Quality Assurance in Design, Development, Production, Installation and Servicing, and ISO 9001:2000, Quality Management Systems—Requirements

BULK CHEMICAL SUPPLIER AUDIT CHECKLIST

7. International Organization for Standardization (ISO) document 17025:1999, General Requirements for the Competence of Testing and Calibration Laboratories. The European Community has approved ISO 17025 as a replacement for European Standard EN 45001, General Criteria for the Operation of Testing Laboratories.
   Note: References to ISO 17025 are indicated in the checklist by Arrow Brackets < >.
8. International Organization for Standardization (ISO) 10011–1:1999, 2:1991, and 3:1991, Guidelines for Auditing Quality Systems: Auditing; Qualification Criteria for Quality System; and Management of Audit Programmes (American ISO equivalent, ANSI/ASQC Q10011–1, 2 and 3).
   Note: References to this standard are indicated under each appropriate question in the checklist.

Because supplier audits may be performed by more than one person, signature spaces are provided at the end of each section to provide a record of each individual auditor's activities.

BULK CHEMICAL SUPPLIER AUDIT CHECKLIST

Date(s) of Audit _____

Supplier's Name _____

Address _____

City _____ State _____ Zip _____

Telephone (plant) _____ (main office) _____ Fax _____

Is the company a division or subsidiary of another corporation?

If yes, describe relationship _____

_____

Audit Leader Name _____

Title _____

Audit Team Members Name _____

Function on Team _____

Name _____

Function on Team _____

Name _____

Function on Team _____

Name _____

Function on Team _____

Nature of Audit

1. Prospective Source _____ Current Source _____

2. Problem-Instigated Audit* _____ Routine Audit _____

*Nature of Problem _____

_____

_____

Items currently procured from source:

1. _____

2. _____

3. _____

Items intended to be procured from company:

1. _____

2. _____

3. _____

BULK CHEMICAL SUPPLIER AUDIT CHECKLIST

Are the components under consideration for purchase produced only at this location?

Yes _____ No _____

If no, where else could they originate:

1._____

2._____

3._____

How is a lot/batch defined?

_____

_____

What is the lot/batch-numbering system?

_____

_____

Is there a way to denote the site of manufacture if multiple sites are employed?

_____

_____

Is the list of ingredients for the chemical item available to the purchaser?

_____

How many shifts are there? _____

Approximate number of employees at facility? _____

Approximate square footage of facility (including warehouse)? _____

Is the plant a registered bulk pharmaceutical manufacturer? If so, registration number is _____

_____

Has the facility been inspected by a government agency? If yes, provide dates and results.

_____

_____

Is the plant an ISO-9000 registered operation? _____

_____

_____

BULK CHEMICAL SUPPLIER AUDIT CHECKLIST

Primary Individuals Contacted

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

BULK CHEMICAL SUPPLIER AUDIT CHECKLIST

Opening Meeting Date _____

Attendees _____

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Closing Meeting Date _____

Attendees _____

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Audit Report Date Issued _____

Date Response Received _____

Date Response and Action Plan Approved _____

Date Actions Completed _____

Date Completed Actions Verified as Completed _____

Date Completed Actions Verified as Effective _____

Date Closed Out _____

Future Follow-up Items _____

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BULK CHEMICAL SUPPLIER AUDIT CHECKLIST

QUALITY RATING SYSTEM

Rating	*Meaning*	*Interpretation*
3	Excellent	Item/area/system/knowledge is superior
2	Adequate	Item/area/system/knowledge meets basic minimum requirements.
1	Deficient	Item/area/system/knowledge is weak and not up to acceptable standards.
0	Unsatisfactory	Item/area/system/knowledge is missing or of a nature to warrant serious quality/compliance concerns.
NA	Not Applicable	Question is not applicable to type of operation, or item unable to be addressed during the audit.

Comment: Some users of the checklist may find the responses to some questions difficult to quantify on a 0–3 scale and may prefer to use a simple "yes" or "no" approach. In such cases, a "yes" should be assigned a "2" value, and a "no" should be assigned a "0" value.

CHECKLIST RESULTS AND RATING

	Number of Occurrences			
Section	**3s**	**2s**	**1s**	**0s**
A. Contract Review and Customer Relations				
B. Purchasing and Consultants				
C. Received/In-Process-Material Handling and Storage				
D. Manufacturing Facilities, Equipment, and Controls				
E. Final-Product Acceptance, Storage, and Distribution				
F. Validation				
G. Laboratories and Calibration				
H. Computer Systems, Document Control, and Quality Records				
I. Training and Internal Audit				
J. Complaint Handling and Recalls				
K. Management Responsibility				
L. Other Considerations				
Totals				

Audit Findings Summary

Number of questions rated excellent ( ) Times 3 = ( )
Number of questions rated adequate ( ) Times 2 = ( )
Number of questions rated deficient ( ) Times 1 = ( )
Number of questions rated unsatisfactory (_____) Times 0 = (_____)

Total Number of Questions Answered = (_____) Rating Total = (_____)

"Rating Total" divided by "Number of Questions Answered" = _____ Audit Rating

BULK CHEMICAL SUPPLIER AUDIT CHECKLIST

I. Strengths

1. _____
2. _____
3. _____
4. _____
5. _____

II. Weaknesses

1. _____
2. _____
3. _____
4. _____
5. _____

III. Recommendations

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BULK CHEMICAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	US 21 CFR 1301–1304 US 21 CFR [Part 11]	Q7A GMP Guide for Actives (GMP Guide for Excipients)	US-MIL-Q-9858A <ISO 17025>
	3 2 1 0 NA					
A. Contract Review and Customer Relations						
The following set of questions apply when the supplier will be designing/producing a "custom" item.						
1. Are requirements, including specifications and acceptance criteria, adequately detailed in a contract?	☐ ☐ ☐ ☐ ☐	4.3	5.2 7.2.1		11.1 (7.2.1) (7.2.2)	1.3 1.4 <4.4.1>
2. Where appropriate, are customer documents translated into the company's internal documentation? If so, is the system of control adequate to assure that current editions will be utilized in manufacturing the items?	☐ ☐ ☐ ☐ ☐	4.3	7.2.1		11.1 (7.2.1) (7.2.2)	1.3 1.4
3. Does the contract specify how amendments are to be made and communicated to affected functions?	☐ ☐ ☐ ☐ ☐	4.3	7.2.2		11.1	1.3 1.4 <4.4.1> <4.4.4> <4.4.5>
4. Is the contract formally agreed to before execution?	☐ ☐ ☐ ☐ ☐	4.3	5.2 7.2		11.1 (7.2.1) (7.2.2)	1.3 1.4 <4.4.1>
5. Are the contracts periodically reviewed or inspected (US Military) for adequacy?	☐ ☐ ☐ ☐ ☐	4.3	7.2.2			1.3 1.4 <4.4.2>
6. Are records of these periodic reviews maintained for a specified period of time?	☐ ☐ ☐ ☐ ☐	4.3 4.16	4.2.4 7.2.2			1.3 1.4
The following questions apply when the source will be providing a "standard" off-the-shelf item.						
7. Is there a product/service catalog/list that is revision controlled to assure that the contents are current and correct?	☐ ☐ ☐ ☐ ☐	4.3	5.2 7.2.2 7.2.3		11.1	1.3 1.4
8. Does the catalog/list provide enough information to assure the purchaser will receive what is expected?	☐ ☐ ☐ ☐ ☐	4.3	7.2.1 7.2.3			1.3 1.4
The following questions pertain to a standard or custom item.						
9. Is there a procedure established and being followed that describes how verbal and formal orders are to be processed?	☐ ☐ ☐ ☐ ☐	4.3	7.2.3			1.3 1.4
9. Is there a procedure established and being followed that describes how verbal and formal orders are to be processed?	☐ ☐ ☐ ☐ ☐	4.3	7.2.3			1.3 1.4

BULK CHEMICAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	US 21 CFR 1301–1304 US 21 CFR [Part 11]	Q7A GMP Guide for Actives (GMP Guide for Excipients)	US-MIL-Q-9858A <ISO 17025>
	3 2 1 0 NA					
A. Contract Review and Customer Relations (continued)						
10. Is there a procedure for resolving processed-order problems?	□ □ □ □ □	4.3	7.2.3			1.3 1.4 <4.4.2> <4.7> <4.8>
11. Is there a procedure to notify the customer when subcontractors are proposed to be used?	□ □ □ □ □				(7.2.3)	

Total Number of Boxes Checked for Section A 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

BULK CHEMICAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	US 21 CFR 1301–1304 US 21 CFR [Part 11]	Q7A GMP Guide for Actives (GMP Guide for Excipients)	US-MIL-Q-9858A <ISO 17025>
	3 2 1 0 NA					
B. Purchasing and Consultants						
1. Does the vendor maintain a list of approved/qualified sources for materials employed in the manufacturing process?	□ □ □ □ □	4.2 4.6.3 4.6.4 4.10.1	7.4.1		7.1 (7.4)	1.3 5.1 5.2
2. In appropriate situations, does the company audit sources of supply?	□ □ □ □ □	4.6.2	7.4.1		7.1 (7.4)	5.1 <4.6.4>
3. Are records of consultants maintained that demonstrate they have the necessary qualifications to advise on the subject for which they have been retained?	□ □ □ □ □				3.3 (6.2.4)	

Total Number of Boxes Checked for Section B 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

BULK CHEMICAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	US 21 CFR 1301–1304 US 21 CFR [Part 11]	Q7A GMP Guide for Actives (GMP Guide for Excipients)	US-MIL-Q-9858A <ISO 17025>
C. Received/In-Process-Material Handling and Storage						
1. Where a supplier's count or weight is utilized, is it verified upon receipt?	□ □ □ □ □	4.10.1	7.1 8.1		6.3 7.1 9.1	6.1 <4.6.2>
2. Is there an acceptable area/procedure for sampling?	□ □ □ □ □	4.11	7.5.3		7.1 7.3 9.1	6.1
3. Is at least one identity test performed on each received batch of raw material?	□ □ □ □ □				7.3 (7.4.3)	
4. Are released items properly segregated from material awaiting testing and disposition?	□ □ □ □ □	4.10.1	7.1 7.5.3 7.5.5 8.1		6.3 7.1 7.2 9.1 (7.5.3.2)	6.1
5. Is material adequately inspected, tested, and identified as accepted or rejected?	□ □ □ □ □	4.10.1	7.1 7.5.3 7.5.5 8.1		6.3 7.2 9.1 (7.4.3) (7.5.3.2)	6.1
6. Is rejected material adequately controlled?	□ □ □ □ □	4.10.1 4.10.2 4.12 4.13	7.4.3 7.5.3 8.2.4 8.3		6.3 7.1 7.2 9.1 (7.5.3.2)	6.1 <4.6.2> <5.8>
7. Are materials properly handled and stored to prevent damage?	□ □ □ □ □	4.10.1 4.15.2 4.15.3	7.5.5 8.2.4		6.3 7.1 7.4 9.2 (7.5.5.1) (7.5.3.2)	6.1
8. Are storage areas restricted to authorized personnel?	□ □ □ □ □	4.15.3	7.5.5		7.1 7.4 9.2	1.3 <4.6.1> <5.8>
9. Are materials properly identified as to their contents to avoid errors in issuance?	□ □ □ □ □	4.8 4.10.1	7.5.3		6.3 7.1 7.2 7.4 9.1 (7.5.3.1) (7.5.3.2) (7.5.3.3)	6.1

BULK CHEMICAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	US 21 CFR 1301–1304 US 21 CFR [Part 11]	Q7A GMP Guide for Actives (GMP Guide for Excipients)	US-MIL-Q-9858A <ISO 17025>
C. Received/In-Process-Material Handling and Storage (continued)						
10. Are materials adequately segregated to avoid mix-ups?	□ □ □ □ □	4.8 4.10.1	7.5.3		7.1 7.2 7.4 9.1	6.1 <4.6.1> <5.8>
11. Are stocks reinspected and tested at intervals?	□ □ □ □ □	4.15.3	7.5.5		6.3 7.5	1.3 3.2 <4.6.1>
12. Where required, how adequate is the controlled-environment storage (e.g., humidity, temperature, etc.)?	□ □ □ □ □	4.15.3	7.5.5		7.4 (7.5.5.1)	1.3 3.2 <4.6.1>
13. Are there sufficient facilities and systems to assure control of labels?	□ □ □ □ □	4.15	7.5.5		9.3	

Total Number of Boxes Checked for Section C 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

BULK CHEMICAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	US 21 CFR 1301–1304 US 21 CFR [Part 11]	Q7A GMP Guide for Actives (GMP Guide for Excipients)	US-MIL-Q-9858A <ISO 17025>
	3 2 1 0 NA					
D. Manufacturing Facilities, Equipment, and Control						
1. Are the items being manufactured identifiable throughout the operation?	□ □ □ □ □	4.8	7.5.3		4.1 4.2 5.1 5.2 8.1 9.4 (7.5.3)	6.1
2. Are pipes labeled to show contents and direction of flow?	□ □ □ □ □		7.5		4.1 4.2 4.3 5.1	6.1
3. Are different grades of the same chemical distinguishable in manufacturing to prevent mix-ups?	□ □ □ □ □	4.8 4.9	7.5.3		4.1 4.2 4.4 8.5	6.1
4. Are the manufacturing operations orderly in flow and organization?	□ □ □ □ □	4.9	7.5.1 7.5.2		4.1 4.2 4.3 4.4 5.1 9.4 (6.3.1) (7.1) (7.5.1.4)	6.2
5. Is there a process flow diagram available for each item produced?	□ □ □ □ □	4.9	7.5.1 7.5.2		4.2 5.1 14.2 (7.1)	6.2
6. Are the manufacturing processes and facilities (including lighting) adequate to produce quality components?	□ □ □ □ □	4.9	4.2.3 7.5.1 7.5.2		4.1 4.2 4.4 4.5 4.6 5.1 8.5 (6.3.1) (6.3.2) (7.5.1.1) (7.5.1.4)	6.2
7. Do current drawings exist for equipment and utilities?	□ □ □ □ □				5.1	

BULK CHEMICAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	US 21 CFR 1301–1304 US 21 CFR [Part 11]	Q7A GMP Guide for Actives (GMP Guide for Excipients)	US-MIL-Q-9858A <ISO 17025>
D. Manufacturing Facilities, Equipment, and Control (continued)						
8. Are lubricants and nonproduction materials properly controlled to prevent product contamination?	□ □ □ □ □	4.9	7.5.1		4.4 4.6 5.1 8.5 (6.4.1) (7.5.1.1) (7.5.1.4)	1.3 6.2
9. Have equipment, feed stock pipes, tank farm cleaning schedules and procedures been established and validated?	□ □ □ □ □	4.9	7.5.2		4.7 5.2 8.5 (6.4.1) (7.5.1.2) (7.5.1.3)	6.2
10. If drums are recycled from clients, are they cleaned via validated cleaning procedures and inspected before use?	□ □ □ □ □	4.9	7.5.2		5.2 8.5 (7.5.5.2)	6.1
11. If product is filled into trucks or railroad cars, are they cleaned via validated procedures and inspected for use?	□ □ □ □ □	4.9	7.5.2		5.2 8.5 (7.5.5.2)	
12. Are utensils properly cleaned and stored between usages?	□ □ □ □ □	4.9	7.5.1 7.5.2		5.2 8.5 (7.5.1.2) (7.5.1.3)	6.2
13. Does the lot number reflect 1 homogeneous production run?	□ □ □ □ □	4.8 4.9 4.12	7.5.1 7.5.2		6.4 8.1 8.2 8.4 (4.2.4) (9.2.3)	1.3 6.2 6.5
14. Are formal line clearances performed between different labeling or packaging operations before they begin?	□ □ □ □ □	4.8 4.9	7.5.1		5.2 9.3 9.4 (4.2.4)	
15. Are the manufacturing procedures formalized and controlled?	□ □ □ □ □	4.9	7.5.1		6.4 8.2 9.4 14.2 14.3 (7.1) (7.5.1)	3.3 3.4 4.1 6.2

BULK CHEMICAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	US 21 CFR 1301–1304 US 21 CFR [Part 11]	Q7A GMP Guide for Actives (GMP Guide for Excipients)	US-MIL-Q-9858A <ISO 17025>
	3 2 1 0 NA					
D. Manufacturing Facilities, Equipment, and Control (continued)						
16. Is there a formal procedure for deviations to normal practice?	□ □ □ □ □	4.9 4.13 4.13.1	7.5.1 8.3		2.1 6.5 14 (9.2.2)	1.3 2.2 3.3 4.1
17. Are there formal procedures for the handling of mother liquors and rework (including the blending of unsatisfactory material in order to salvage lots)?	□ □ □ □ □	4.9 4.13.1	7.5.1 8.3		4.4 6.4 8.1 8.4 14.2 14.3 (7.5.1.9) (7.5.1.10)	3.4
18. Do the employees in the manufacturing areas appear to be knowledgeable and quality conscious?	□ □ □ □ □	4.18	6.2.2		3.1 (6.2.1) (6.2.2) (6.2.3)	1.3 3.1
19. Are current specifications readily accessible for the employees?	□ □ □ □ □	4.5.1 4.5.2	4.2.3		2.3 6.2 9.4 (4.2.3)	3.3 4.1
20. Is the manufacturing environment acceptable for the type of item produced, especially in the case of aseptic/sterile processing?	□ □ □ □ □	4.9	7.5.1 7.5.2		2.3 4.1 4.2 8.5 (6.3.1) (7.5.1.5) (7.5.1.6)	1.3 3.2 6.2
21. Are production areas that are very dusty or unique in regard to contamination properly controlled with exhaust systems or other methods of decontamination?	□ □ □ □ □	4.9	7.5.1 7.5.2		2.3 4.4 8.5 (6.3.1) (7.5.1.4) (7.5.1.5) (7.5.1.6)	6.2
22. Are production employees neat in their appearance, with unnecessary jewelry and cosmetics kept out of the production areas?	□ □ □ □ □	4.9 4.18	6.2.2 7.5.1		3.2 8.5 (6.2.3)	1.3 6.2
23. Are any special requirements for specific operator apparel (such as masks, gowns, etc.) being violated?	□ □ □ □ □	4.9 4.18	6.2.2 7.5.1		3.2 8.5 (6.2.3)	6.2

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	3 2 1 0 NA					
D. Manufacturing Facilities, Equipment, and Control (continued)						
24. Is there a provision to assure that personnel suffering from an infectious disease or open lesion are not engaged in activities that could compromise product quality?	□ □ □ □ □	4.9	6.2.2 7.5.1		3.2 4.4 8.5 (6.2.3)	
25. Is there a formal record of production steps/quantities used from the point in the process that the chemical or essential moiety can be identified/quantified? Are the following included in the record:		4.8 4.9 4.10.2 4.10.4 4.16	4.2.4 7.5.1		1.3 2.3 6.3 6.5 8.1 8.2 9.1 9.3 9.4 (4.2.4) (7.5.1.11) (9.2.2) (9.2.3) (9.2.4)	3.4
a. Dates and times of actions (versus time limits)?	□ □ □ □ □					
b. Identity of major equipment?	□ □ □ □ □					
c. Weights, measures, and batch numbers of:						
i. Raw materials?	□ □ □ □ □					
ii. Intermediates?	□ □ □ □ □					
iii. Reprocessed items?	□ □ □ □ □					
d. Records of critical process-parameter readings?	□ □ □ □ □					
e. Any sampling performed?	□ □ □ □ □					
f. Signatures for each critical step in the operations?	□ □ □ □ □					
g. In-process and lab results?	□ □ □ □ □					
h. Actual yield at phases/times?	□ □ □ □ □					
i. Description of packaging and labeling?	□ □ □ □ □					
j. Sample label?	□ □ □ □ □					
k. Deviations noted and investigations performed?	□ □ □ □ □					
l. Results of release testing?	□ □ □ □ □					
m. Reconciliation of label quantities issued, returned, destroyed, etc.?	□ □ □ □ □					
26. Are waste materials clearly identified in proper containers and disposed of in a timely manner?	□ □ □ □ □	4.9	7.5.1 8.3		4.6 8.1 8.5 (6.3.1) (6.4.1)	
27. Are the ceiling fixtures and pipes free of accumulated dirt?	□ □ □ □ □	4.9	7.5.1		4.7 (6.3.1)	1.3 6.2
28. Are valves and associated pipes in the production areas free of leaks?	□ □ □ □ □	4.9	7.5.1		4.7 (6.3.1)	1.3 6.2
29. Are the ceilings and walls in good condition to prevent contamination from paint chips?	□ □ □ □ □	4.9	7.5.1		4.1 4.7 (6.3.1) (6.3.2)	1.3 6.2

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	Rating	Reference				
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	3 2 1 0 NA					
D. Manufacturing Facilities, Equipment, and Control (continued)						
30. Are appropriate bathroom facilities available?	□ □ □ □ □	4.9	7.5.1		4.1 (6.4.5)	1.3 6.2
31. Are smoking and eating prohibited where necessary?	□ □ □ □ □	4.9	7.5.1		4.1 (7.5.1.6)	1.3 6.2
32. Is there an adequate pest-control program?	□ □ □ □ □	4.9	7.5.1		4.7 (6.4.2)	1.3 6.2
33. Are the in-process test procedures adequate?	□ □ □ □ □	4.10.3 4.10.4 4.11 4.16	8.2.4		6.3 9.4 (7.5.1.12) (7.5.1.13)	6.2 6.3
34. Are there adequate specifications and sampling plans to control in-process materials?	□ □ □ □ □	4.10.3	8.2.4		6.4 (7.5.1.12) (7.5.1.13)	6.6
35. If in-process material is rejected, is there an indication of the reason?	□ □ □ □ □	4.13 4.13.1 4.14	8.3		6.3 (7.5.1.17) (8.3) (8.5)	3.5 6.5 6.7
36. If in-process material is rejected, is there a corrective action indicated to prevent the same problem from recurring?	□ □ □ □ □	4.14	8.5.2 8.5.3		6.6 14.1 (8.3) (8.5)	3.5 6.5 6.7
37. Is there an acceptable grade of water or steam being utilized, and are associated systems maintained properly?	□ □ □ □ □	4.8	7.5.1 7.5.2		4.2 4.3 4.7 (7.5.1.7)	1.3 6.1 6.2
38. Do drains have an air break or device to prevent back siphonage?	□ □ □ □ □				4.2 (4.2) 6.4.4	
39. Are all in-process items returned to the controlled storage areas at the termination of the process or work day? If not, are the materials securely locked to prevent access?	□ □ □ □ □			1301.73	7.1 7.4 8.5 9.1 9.4 (7.5.5.1)	
40. Are manufacturing areas for controlled substances clearly defined and limited in access?	□ □ □ □ □			1301.73	4.1 8.5 9.4 (6.3.1)	

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	3 2 1 0 NA					
D. Manufacturing Facilities, Equipment, and Control (continued)						
41. Are the limited-access areas under the surveillance of a designated individual, and is such designation provided in writing?	□ □ □ □ □			1301.73	4.1 8.5 9.1 9.4 (5.5.2)	
42. When nonemployees such as visitors enter the area, are they observed by the designated responsible persons?	□ □ □ □ □			1301.73	4.4 8.5 (6.2.1)	

Total Number of Boxes Checked for Section D 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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BULK CHEMICAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	US 21 CFR 1301–1304 US 21 CFR [Part 11]	Q7A GMP Guide for Actives (GMP Guide for Excipients)	US-MIL-Q-9858A <ISO 17025>
	3 2 1 0 NA					
E. Final Product Acceptance Storage and Distribution						
1. How adequate are the procedures for final-product inspection, sampling, and testing?	□ □ □ □ □	4.10.4	8.2.4		6.6 (4.2.4) (7.5.1.12) (7.5.1.14) (7.5.1.16)	6.3
2. Are final inspection/test results recorded?	□ □ □ □ □	4.10.4 4.10.5	4.2.4 8.2.4		6.6 (4.2.4) (7.5.1.14) (9.2.3)	3.4 6.3
3. Does quality control review the production records as part of the release criteria?	□ □ □ □ □	4.1 4.12	8.2.4		2.1 6.5 6.7 (4.2.4) (7.5.1.14)	
4. Are production-documentation packages stored properly and retained for an adequate length of time?	□ □ □ □ □	4.16	4.2.4		6.5 6.7 (4.2.4)	3.4
5. Are discrepancies found during the final review properly investigated?	□ □ □ □ □	4.13	8.3		6.7 14.1 (4.2.4) (9.2)	3.5 6.5
6. How adequate is the procedure for release of product?	□ □ □ □ □	4.2 4.10.4 4.12	7.5.3 8.2.4		2.1 6.7 10.2 (4.2.4) (5.5.1)	1.3 3.1 6.2 6.5
7. How well is final-product material identified and segregated?	□ □ □ □ □	4.8 4.15.2 4.15.5	7.5.3 7.5.5		8.1 8.3 9.1 10.1 (7.5.3)	6.7
8. How well is nonconforming material controlled?	□ □ □ □ □	4.13	8.3		8.3 (8.3)	6.5
9. How adequate is the retained-sample/stability program?	□ □ □ □ □	4.3			11.5 11.7 (7.5.1.19) (9.2.3)	3.4
10. Do adequate facilities exist to store materials awaiting shipment?	□ □ □ □ □	4.15.3	7.5.5		10.1 10.2 (7.5.5.3)	6.4

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	3 2 1 0 NA					
E. Final Product Acceptance Storage and Distribution (continued)						
11. Where appropriate, how adequate is controlled access to final-product stockrooms and material-storage areas?	☐ ☐ ☐ ☐ ☐	4.15.1 4.15.3	7.5.5		9.4 10.1 10.2 (7.5.5)	6.4
12. Are the shipping containers sufficiently marked to identify the contents?	☐ ☐ ☐ ☐ ☐	4.8 4.15.4 4.15.5	7.5.5		9.2 10.1 10.2 (7.5.3.3) (7.5.5.3)	6.4 6.7
13. How well are items with shelf life requirements identified and controlled?	☐ ☐ ☐ ☐ ☐	4.15.3	7.5.3		10.1 (7.5.5)	
14. Is there a procedure for processing returned goods?	☐ ☐ ☐ ☐ ☐				14.5 (7.5.5.4)	
15. How adequate is the lot-recall/withdrawal system?	☐ ☐ ☐ ☐ ☐	4.2 4.8 4.16	7.5.1 7.5.3 7.5.5		10.2 (7.5.3.1)	
16. Is an inventory taken every 2 years?	☐ ☐ ☐ ☐ ☐			1304.11		
17. Does the inventory-records system contain the following for each controlled substance:				1304.11		
a. Name of the substance?	☐ ☐ ☐ ☐ ☐					
b. Total quantity in metric unit weights?	☐ ☐ ☐ ☐ ☐					
18. For in-process items, does the following documentation exist:				1304.11		
a. Name of the substance?	☐ ☐ ☐ ☐ ☐					
b. Quantity of substance at each stage of manufacturing?	☐ ☐ ☐ ☐ ☐					
c. Physical form that the substance is to take upon completion of the processing (e.g., solution, granules)?	☐ ☐ ☐ ☐ ☐					
d. Batch number in process?	☐ ☐ ☐ ☐ ☐					
19. Do the inventory records include the following:				1304.11		
a. Name/quantities of materials held for quality purposes, disposal, or compounding?	☐ ☐ ☐ ☐ ☐					
b. Reasons for being held?	☐ ☐ ☐ ☐ ☐					

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	Rating	Reference				
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	3 2 1 0 NA					
E. Final Product Acceptance Storage and Distribution (continued)						
20. For Schedules I, II, III, IV, and V materials:				1301.72		
a. Are certificates available that authorize the manufacture of controlled drug substances?	□ □ □ □ □					
b. Are noncontrolled drugs stored with controlled drugs? If so, has formal permission been obtained from the Drug Enforcement Administration (DEA) to store them together?	□ □ □ □ □					
21. For Schedule I and II materials:				1301.72		
a. For small quantities, is there a safe or steel cabinet that provides:						
i. 10 man-minutes against surreptitious/forced entry?	□ □ □ □ □					
ii. 20 man-hours against lock manipulation?	□ □ □ □ □					
iii. 20 man-hours against radiological techniques?	□ □ □ □ □					
iv. If the safe weighs less than 750 pounds, is it bolted securely?	□ □ □ □ □					
v. An alarm system that transmits to police or a 24-hour central station?	□ □ □ □ □					
b. For larger quantities, a vault that provides:						
i. Wall or perimeter line that transmits to a protection company, police, or a 24-hour control station?	□ □ □ □ □					
ii. A contact switch, connected to the alarm system, on the door of the vault?	□ □ □ □ □					
iii. One of the following to detect entry:						
– Complete electric lacing of the walls?	□ □ □ □ □					
– Ultrasonic equipment within the vault?	□ □ □ □ □					
– A sound-accumulation system?	□ □ □ □ □					
iv. Walls, floors, and ceilings constructed of at least 8 inches of reinforced concrete, reinforced vertically and horizontally with 0.5-inch steel rods tied 6 inches on the center?	□ □ □ □ □					
v. A door and frame unit that provides:						
– 30 man-minutes against surreptitious entry?	□ □ □ □ □					
– 10 man-minutes against forced entry?	□ □ □ □ □					
– 20 man-hours against lock manipulation?	□ □ □ □ □					
– 20 man-hours against radiological techniques?	□ □ □ □ □					
vi. A “day gate” that is self-closing and self-locking during the hours of operation in which the vault doors are open?	□ □ □ □ □					

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	3 2 1 0 NA					
E. Final Product Acceptance Storage and Distribution (continued)						
22. For Schedule III, IV, and V materials, one of the following:				1301.72		
a. A safe or steel cabinet as described in 21.a?	☐ ☐ ☐ ☐ ☐					
b. A vault as described in 21.b?	☐ ☐ ☐ ☐ ☐					
c. A building with perimeter security that limits access during working hours including:						
i. A building that provides security after working hours with an alarm as described in 21.a.v?	☐ ☐ ☐ ☐ ☐					
ii. A building equipped with self-closing/locking doors with sealed or welded hinges to prevent removal?	☐ ☐ ☐ ☐ ☐					
iii. Are there locks on said doors with limited access to a limited number of employees?	☐ ☐ ☐ ☐ ☐					
d. A cage located within a building on the premises that:						
i. Has walls with not less than 10-gauge steel fabric mounted on steel posts?	☐ ☐ ☐ ☐ ☐					
ii. Has posts at least 1 inch in diameter?	☐ ☐ ☐ ☐ ☐					
iii. Has posts set in concrete or with lag bolts that are pinned or braised?	☐ ☐ ☐ ☐ ☐					
iv. Has posts that are not more than 10 feet apart with horizontal 1.5-inch reinforcements every 60 inches?	☐ ☐ ☐ ☐ ☐					
v. Has mesh construction of not more than 2.5 inches across the square?	☐ ☐ ☐ ☐ ☐					
vi. Has a ceiling of the same construction that is securely attached to the structural ceiling of the building?	☐ ☐ ☐ ☐ ☐					
vii. Has a door constructed of 10-gauge steel fabric on a metal frame in a metal flange?	☐ ☐ ☐ ☐ ☐					
viii. Is equipped with alarms as described in 21.a.v?	☐ ☐ ☐ ☐ ☐					

Total Number of Boxes Checked for Section E 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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	3 2 1 0 NA					
F. Validation						
1. Have the laboratory test methods been validated?	□ □ □ □ □	4.11	7.5.2 7.6		12.8 (7.5.1.12)	4.2
2. Have all the manufacturing and purification processes been validated to address the following:		4.9 4.11	7.5.2 7.6		12.2 12.3 12.4 (7.5.2)	
a. Demonstrate that the product-specification acceptance requirements can be consistently satisfied?	□ □ □ □ □					
b. Have the operating limits/settings on the equipment been qualified as being capable of achieving the desired results?	□ □ □ □ □					
c. Are the operating limits from the validation reflected in an operating procedure for employees to follow?	□ □ □ □ □					
d. Was the validation achieved without equipment failures, interruptions, or significant downtime?	□ □ □ □ □					
e. Was the validation long enough in duration to simulate a typical batch size? On continuous processes, was the validation long enough to encompass power fluctuations, employee shift changes, and other factors that occur during a 24-hour period?	□ □ □ □ □					
3. Have support systems (e.g., compressed air, vacuum, water) been validated (certified)?	□ □ □ □ □		7.5.2		12.1 12.3 (7.5.2)	<5.3>
4. Have the environmental-control systems been validated (certified)?	□ □ □ □ □		7.5.2		12.1 12.3 (7.5.2)	<5.3>
5. Have aseptic processes been validated?	□ □ □ □ □		7.5.2		(7.5.2)	
6. Have all cleaning procedures been validated?	□ □ □ □ □		7.5.2		12.7 (7.5.2)	<5.3>
7. In cases of computer systems for control of processes, data collection, etc., have they been validated, and do they include the following:			7.5.2	[11.10a]	5.4 (7.1)	<5.3>
a. Hardware validation?	□ □ □ □ □					
b. Software validation?	□ □ □ □ □					
c. Qualification of the equipment environment?	□ □ □ □ □					
d. Distances between central processing units and peripheral devices validated?	□ □ □ □ □					
e. Validation of signal conversion, if applicable?	□ □ □ □ □					

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	Rating	Reference				
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	3 2 1 0 NA					
F. Validation (continued)						
f. Security from alteration or use of systems by unauthorized personnel?	☐ ☐ ☐ ☐ ☐					
g. Error-detection features validated?	☐ ☐ ☐ ☐ ☐					
h. Calibration program derived?	☐ ☐ ☐ ☐ ☐					
i. Maintenance programs for computer derived?	☐ ☐ ☐ ☐ ☐					
j. Check of alarm systems?	☐ ☐ ☐ ☐ ☐					
k. Storage facilities from environmental/security perspectives?	☐ ☐ ☐ ☐ ☐					
8. Do all the validation packages include the following:		4.9 4.16	4.2.4 7.5.2	[11.10a]	5.4 12.1 12.2	
a. Detailed description of the item/system (including flow diagrams)?	☐ ☐ ☐ ☐ ☐					
b. Intended function of the system?	☐ ☐ ☐ ☐ ☐					
c. Preapproved validation protocol?	☐ ☐ ☐ ☐ ☐					
d. Explanation of any deviations made to the original signed-off protocol?	☐ ☐ ☐ ☐ ☐					
e. Validation results?	☐ ☐ ☐ ☐ ☐					
f. Conclusions/recommendations?	☐ ☐ ☐ ☐ ☐					
g. Quality-assurance approval of validation?	☐ ☐ ☐ ☐ ☐					
9. Is there a formal change-control system that addresses changes to validated systems and includes quality-assurance review/approval?	☐ ☐ ☐ ☐ ☐	4.5	4.2.3 7.5.2	[11.10a]	5.4 12.6 (7.5.1.21)	
10. Are validated systems periodically reviewed to verify that they are still operating in a valid manner?	☐ ☐ ☐ ☐ ☐				12.6	

Total Number of Boxes Checked for Section F 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	US 21 CFR 1301–1304 US 21 CFR [Part 11]	Q7A GMP Guide for Actives (GMP Guide for Excipients)	US-MIL-Q-9858A <ISO 17025>
	3 2 1 0 NA					
G. Laboratories and Calibration						
1. Does the quality-control department appear to have sufficient equipment and facilities?	□ □ □ □ □	4.1.2	5.5.1 6.1 6.2		4.1 4.2 4.4 4.5 4.6 (6.3.1)	1.3 3.1 4.2 4.5 <5.3> <5.5>
2. Are samples that are brought into the quality-control laboratory from incoming, in-process, and final-product materials properly controlled?	□ □ □ □ □	4.10.1 4.10.2 4.10.3	7.4.3 8.2.4		6.6 (7.5.1.12) (7.5.1.13) (7.5.1.14) (7.5.1.16)	5.1 6.1 6.2 6.3 6.6 <5.4> <5.7>
3. Are raw-material file samples retained for future reference?	□ □ □ □ □				11.7 (7.5.1.16) (7.5.1.17)	
4. Is there an index of testing documents?	□ □ □ □ □	4.10.1 4.10.2	7.1 8.1		11.1 11.3	<5.4>
5. Are all tests/inspections properly documented?	□ □ □ □ □	4.10.4 4.10.5	4.2.4 7.4.3 8.2.4		6.6 11.1 11.2 11.4	3.4 <5.4> <5.5> <5.10>
6. Are animals that are used for testing of components, in-process materials, and final product maintained and controlled in a proper manner?	□ □ □ □ □					
7. In regard to animals used for testing, are adequate history records maintained?	□ □ □ □ □					
8. Is there a written microbial testing program for sterile and nonsterile products?	□ □ □ □ □	4.10.3	7.1 8.1 8.2.4		(7.5.1.8)	1.3 6.2
9. Are certificates of inspection/test results available to the customers?	□ □ □ □ □	4.3 4.6.1	5.2		11.4	4.2 4.3 4.5
10. Are there acceptable procedures to assure that test equipment is maintained in proper order?	□ □ □ □ □	4.11	7.6		4.7 5.3 (7.6)	4.2 4.3 4.5 <5.3> <5.4> <5.5> <5.6>

BULK CHEMICAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	US 21 CFR 1301–1304 US 21 CFR [Part 11]	Q7A GMP Guide for Actives (GMP Guide for Excipients)	US-MIL-Q-9858A <ISO 17025>
G. Laboratories and Calibration (continued)						
11. Is there a system to assure that testing equipment is calibrated at appropriate intervals?	□ □ □ □ □	4.11	7.6		5.3 (7.6)	4.2 4.3 4.5 <5.3> <5.4> <5.5> <5.6>
12. If calibration is performed by the facility, are these calibration procedures formalized and traceable to appropriate standards?	□ □ □ □ □	4.11	7.6		5.3 (7.6)	3.3 4.2 4.3 4.5 <5.3> <5.4> <5.5> <5.6>
13. If external sources are utilized for calibration, have the sources been audited to assure competence?	□ □ □ □ □	4.6.2 4.11	7.4.1 7.6		5.3 (7.6)	1.3 4.2 4.3 4.5 5.1 <4.5>
14. On test equipment requiring daily or "at time of use" calibration, is there assurance that the items used to calibrate the instrument are fresh?	□ □ □ □ □	4.11	7.6		5.3 (7.6)	4.2 6.2 <5.6.3.3>
15. Is there a reagent-control program in the laboratory to assure continued potency (i.e., date received, date opened, date prepared, and date expires)?	□ □ □ □ □	4.11	7.6		5.3 11.5 (7.6)	<5.6.3.3>

Total Number of Boxes Checked for Section G 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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BULK CHEMICAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
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	3 2 1 0 NA					
H. Computer Systems, Document Control, and Quality Records						
1. Are the specifications and other documents comprehensive in content?	□ □ □ □ □	4.2 4.4.4	4.2.1 4.2.3 7.2.1 7.3.2		6.1 (4.2.3)	3.3 4.1 <4.3.1>
2. Are the documents current, and are unneeded/obsolete documents removed from usage?	□ □ □ □ □	4.5.1	4.2.3		6.1 (4.2.3)	3.3 4.1 <4.3.2>
3. Do written procedures exist that address a change-control system for documents, and are the procedures being followed?	□ □ □ □ □	4.5	4.2.3		13 (4.2.3)	3.3 4.1 <4.3.3>
4. Are quality-related activities recorded at the time they are performed?	□ □ □ □ □				2.1 (4.2.4)	
5. Are deviations documented, explained, investigated, and, when appropriate, is corrective/preventive action pursued?	□ □ □ □ □				2.1 (4.2.4)	
6. Is there a retention schedule for quality records?	□ □ □ □ □				6.1 (4.2.4)	
7. Does the computer system have the ability to detect invalid or altered records?	□ □ □ □ □			[11.10a]	5.4 (7.1)	
8. Can accurate and complete records (including metadata) be generated in human-readable and electronic forms, such as screen display or printout, or copied to a media for review?	□ □ □ □ □			[11.10b]	5.4 (7.1)	
9. Does a retrieval mechanism exist to ensure the records (including the metadata) are available throughout the entire record-retention period?	□ □ □ □ □			[11.10c]	5.4 (7.1)	
10. Are controls, such as password AND user identification, in place to limit access to the computer system?	□ □ □ □ □			[11.10d]	5.4 (7.1)	
11. Does the computer system generate secure computer-generated audit-trail information?	□ □ □ □ □			[11.10e]	5.4 (7.1)	
12. Does the audit trail capture operator entries or actions that create, modify, or delete a record?	□ □ □ □ □			[11.10e]	5.4 (7.1)	
13. Does the audit trail have User ID, time, and date stamps?	□ □ □ □ □			[11.10e]	5.4 (7.1)	
14. Is the original data still accessible and not obscured for records that have been changed?	□ □ □ □ □			[11.10e]	5.4 (7.1)	

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	3 2 1 0 NA					
H. Computer Systems, Document Control, and Quality Records (continued)						
15. Are electronic audit trails kept as long as the respective record?	□ □ □ □ □			[11.10e]	5.4 (7.1)	
16. Are electronic audit trails available for FDA review and copying?	□ □ □ □ □			[11.10e]	5.4 (7.1)	
17. Does the computer system (or systems) force the sequence of process steps or events during operations (as applicable)?	□ □ □ □ □			[11.10f]	5.4 (7.1)	
18. Does the computer system (or systems) control these sequences?	□ □ □ □ □			[11.10f]	5.4 (7.1)	
19. Are there system checks, including authorization, level of access and privileges, for access to the computer system (or systems)?	□ □ □ □ □			[11.10g]	5.4 (7.1)	
20. Are there system checks to verify input-device identification (as applicable)?	□ □ □ □ □			[11.10h]	5.4 (7.1)	
21. Is access to the system and records controlled by a designated security unit (i.e., closed system)?	□ □ □ □ □			[11.30]	5.4 (7.1)	
22. For an OPEN system, is document encryption (or alternative) used to protect confidentiality of the electronic records during transfer?	□ □ □ □ □			[11.30]	5.4 (7.1)	
23. For an OPEN system, are digital signatures (or alternative) used to protect the authenticity, confidentiality, and integrity of the electronic records of the systems?	□ □ □ □ □			[11.30]	5.4 (7.1)	
24. Is the electronic signature indicated on screen displays, printouts, and other human-readable formats?	□ □ □ □ □			[11.50]	5.4 (7.1)	
25. Does the electronic signature contain the printed name of the signer, date and time of the signing, and the meaning (review, approval, authorship) of the signature?	□ □ □ □ □			[11.50]	5.4 (7.1)	
26. Is the electronic or handwritten signature linked to the associated record such that it may not be removed, copied or transferred by ordinary means, or repudiated?	□ □ □ □ □			[11.70]	5.4 (7.1)	
27. Are the e-signatures unique to the user only?	□ □ □ □ □			[11.100a]	5.4 (7.1)	
28. Are there procedures/mechanisms to prevent user IDs from being reused, reissued, or shared?	□ □ □ □ □			[11.100b]	5.4 (7.1)	

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	3 2 1 0 NA					
H. Computer Systems, Document Control, and Quality Records (continued)						
29. Do all nonbiometric signatures contain at a minimum, 2 components, such as a user ID and password?	□ □ □ □ □			[11.200a]	5.4 (7.1)	
30. Does the computer system enforce the 2 components for a single e-signature event?	□ □ □ □ □			[11.200a]	5.4 (7.1)	
31. Does the computer system have a mechanism to terminate an extended idle session during a continuous session when an individual could execute a series of e-signatures?	□ □ □ □ □			[11.200a]	5.4 (7.1)	
32. Does the computer-system design prevent another individual from altering a signed record, thus leaving the original individual's e-signature intact?	□ □ □ □ □			[11.200a]	5.4 (7.1)	
33. Is the password encrypted?	□ □ □ □ □			[11.200a]	5.4 (7.1)	
34. Does the system force the user to reset passwords after the initial administration setting?	□ □ □ □ □			[11.200a]	5.4 (7.1)	
35. Does the biometric signature capture an individual's unique physical feature or action?	□ □ □ □ □			[11.200b]	5.4 (7.1)	
36. Is there a control system/procedure/computer-system design to ensure that passwords and/or ID tokens are aged or not reissued?	□ □ □ □ □			[11.300b]	5.4 (7.1)	
37. Is there a control system/procedure that ensures the ID/password combinations are unique and revised periodically (e.g., every 90 days)?	□ □ □ □ □			[11.300b]	5.4 (7.1)	
38. Does the computer system design include detection procedures/alarms to detect and report attempted security breaches?	□ □ □ □ □			[11.300d]	5.4 (7.1)	
39. Is there a procedure(s) to back up and restore, archive, and retrieve data/records from the computer system?	□ □ □ □ □			[11.10c]	5.4 (7.1)	
40. Is there a procedure(s) for computer-system security? Does it include user access and responsibility?	□ □ □ □ □			[11.10d]	5.4 (7.1)	
41. Is there documented evidence of appropriate qualifications and training of system developers, users (supplier based), and maintenance personnel?	□ □ □ □ □			[11.10I]	3.1 3.3 5.4 (7.1)	
42. Is there a procedure(s) in place governing access to and use of documents containing sensitive information (e.g., password maintenance)?	□ □ □ □ □			[11.10k]	5.4 (7.1)	

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	3 2 1 0 NA					
H. Computer Systems, Document Control, and Quality Records (continued)						
43 Is there a procedure(s) for change control of computer-system documentation? Does it include an audit trail?	□ □ □ □ □			[11.10k]	5.4 (7.1)	
44. Is there a procedure(s) to verify and document individual identity prior to issuing an electronic signature (supplier based)?	□ □ □ □ □			[11.100b]	5.4 (7.1)	
45. Is there a procedure to limit use of electronic signatures to the genuine owner only (supplier based)?	□ □ □ □ □			[11.200b]	5.4 (7.1)	
46. Is there a procedure(s) to periodically check the ID code and password issuance (supplier based)?	□ □ □ □ □			[11.300a]	5.4 (7.1)	

Total Number of Boxes Checked for Section H 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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	3 2 1 0 NA					
I. Training and Internal Audit						
1. Is there a sufficient training program for all employees in all appropriate areas?	□ □ □ □ □	4.18	6.2.2		3.1 (6.2)	1.3 3.1 3.3 <5.2>
2. Is there a program for periodic retraining?	□ □ □ □ □	4.18	6.2.2		3.1 (6.2)	
3. Is there a formal procedure and schedule for performing internal quality audits? ISO 10011–3, Part 4.6.3	□ □ □ □ □	4.1 4.17	5.5.1 5.6.1 8.2.2 8.5.1		2.1 2.4 (5.4.2)	<4.1.3>
4. Are audits performed by properly educated, trained, and experienced individuals not having direct responsibility for that which is being audited? ISO 10011–1, Part 4.2.1 ISO 10011–2, Part 4.0 ISO 10011–2, Part 6.0 ISO 10011–3, Part 4.1 ISO 10011–3, Part 4.3.1 ISO 10011–3, Part 4.5.3	□ □ □ □ □	4.17 4.18	8.2.2 8.2.3		3.1 (9)	<4.13>
5. Is there an audit plan that includes the following:		4.17	8.2.2 8.2.3		(9.1)* (9.2)*	
a. Objective/scope of the audit?	□ □ □ □ □					
b. Date and items to be audited?	□ □ □ □ □					
c. Applicable standards/regulations?	□ □ □ □ □					
d. Provision for opening and closing meetings? ISO 10011–1, Part 5.2.1 ISO 10011–3, Part 4.2	□ □ □ □ □					
6. Is there a formal audit report that details the observations requiring corrective and preventive action? ISO 10011–1, Part 5.2.1 ISO 10011–1, Part 5.3.2 ISO 10011–3, Part 4.2 ISO 10011–3, Part 4.5.3	□ □ □ □ □	4.1 4.17	5.5.1 8.2.2 8.2.3		2.4 (9.1)* (9.2)*	<4.9> <4.10> <4.11> <4.13>

* These sections in the document instruct one to refer to the IPEC GMP Audit Guideline for audit guidance. However, the guidance document consists of checklists only and they are very similar to those contained in this manual. The document is void of actual guidance on how to plan, make observations, generate reports, follow up on actions, etc. The author therefore recommends use of the ISO 10011 documents for such guidance.

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	3 2 1 0 NA					
I. Training and Internal Audit (continued)						
7. Are documented corrective and preventive actions taken on audit observations? ISO 10011–1, Part 7.0 ISO 10011–3, Part 4.6.5	□ □ □ □ □	4.1 4.14 4.16 4.17	4.24 5.5.1 5.6.2 8.2.2 8.5.2 8.5.3		2.4 (8.5.2) (8.5.3)	<4.9> <4.10> <4.11> <4.13>

Total Number of Boxes Checked for Section I 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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	3 2 1 0 NA					
J. Complaint Handling and Recalls						
1. Is there a formal complaint-handling procedure that requires the following:		4.14.2	5.2 7.2.3		2.1 15	<4.8>
a. Name and address of complainant?	☐ ☐ ☐ ☐ ☐				(8.2.1) (8.5.1)	
b. Name and phone number of person submitting the complaint?	☐ ☐ ☐ ☐ ☐					
c. Nature of complaint?	☐ ☐ ☐ ☐ ☐					
d. Date complaint is received?	☐ ☐ ☐ ☐ ☐					
e. Action initially taken?	☐ ☐ ☐ ☐ ☐					
f. Follow-up action taken?	☐ ☐ ☐ ☐ ☐					
g. Response provided to complainant?	☐ ☐ ☐ ☐ ☐					
h. Final decision on intermediates, batches, or lots?	☐ ☐ ☐ ☐ ☐					
2. Are records of complaints trended to determine whether additional corrective actions are needed?	☐ ☐ ☐ ☐ ☐				15 (8.5.1)	
3. Is there a formal recall procedure?	☐ ☐ ☐ ☐ ☐				15 (7.5.5.3)	

Total Number of Boxes Checked for Section J 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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	3 2 1 0 NA					
K. Management Responsibility						
1. Is there a formal statement of the corporate quality policy by the management of the company?	□ □ □ □ □	4.1	5.1 5.3 5.4.1		(5.3)	1.3 3.1 <4.2>
2. Is there a "quality system" that addresses the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management?	□ □ □ □ □	4.1 4.2	4.1 5.5.1		2.1 (5.1) (5.4)	1.3 3.1 <4.2>
3. Is there a "Quality Manual" that addresses the "quality system"?	□ □ □ □ □	4.1 4.2	4.2.1 4.2.2		(4.2.2)	1.3 3.1 <4.2>
4. Is there a management representative assigned with sufficient authority to periodically report to top management on conformance to the quality system?	□ □ □ □ □				(5.5.2)	
5. Are there periodic management reviews of the "quality system" and are the following inputs included:		4.1 4.16	4.1 4.2.4 5.6.1 5.6.2 8.5.1		2.1 2.5 15 (5.1) (5.6.1) (5.6.2) (5.6.3)	3.1 <4.1.4>
a. Results of audits?	□ □ □ □ □					
b. Customer feedback?	□ □ □ □ □					
c. Process performance and product conformity?	□ □ □ □ □					
d. Test results and nonconformances?	□ □ □ □ □					
e. Stability results?	□ □ □ □ □					
f. Status of corrective and preventive actions?	□ □ □ □ □					
g. Follow-up actions from previous management reviews?	□ □ □ □ □					
h. Changes that could affect the quality-management system?	□ □ □ □ □					
i. Recommendations for improvement?	□ □ □ □ □					
6. Does the organization analyze appropriate data to demonstrate the suitability and effectiveness of the quality-management system in regards to the following:			8.4		2.1 15 (5.1) (5.2) (5.6)	<4.1.4>
a. Customer satisfaction?	□ □ □ □ □					
b. Conformity to product requirements?	□ □ □ □ □					
c. Trends of processes and products, including opportunities for preventive action?	□ □ □ □ □					
d. Suppliers?	□ □ □ □ □					
7. Does top management provide communication within the organization regarding the effectiveness of the quality-management system?	□ □ □ □ □		5.5.3		(5.5.3)	<4.1.4>

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	3 2 1 0 NA					
K. Management Responsibility						
8. Is there a quality function independent of production that has the following responsibilities/authorities:					2.1 2.2	
a. Approving of quality-related documents?	☐ ☐ ☐ ☐ ☐				(5.5.1) (5.5.2)	
b. Releasing/rejecting of actives?	☐ ☐ ☐ ☐ ☐					
c. Establishing a system to release or reject raw materials, intermediates, or packaging and labeling materials?	☐ ☐ ☐ ☐ ☐					
d. Investigating critical deviations?	☐ ☐ ☐ ☐ ☐					
e. Approving specifications?	☐ ☐ ☐ ☐ ☐					
f. Approving production instructions?	☐ ☐ ☐ ☐ ☐					
g. Approving contract manufacturers?	☐ ☐ ☐ ☐ ☐					
h. Approving validation protocols and reports?	☐ ☐ ☐ ☐ ☐					
i. Investigating/resolving complaints?	☐ ☐ ☐ ☐ ☐					
j. Assuring stability data exists for expiration dating on intermediates and actives?	☐ ☐ ☐ ☐ ☐					
k. Performing quality reviews?	☐ ☐ ☐ ☐ ☐					
9. Does the quality-control function appear to have the independence necessary to make decisions without fear of political repercussions?	☐ ☐ ☐ ☐ ☐	4.1	6.4		(5.5.1) (5.5.2)	1.3 3.1 4.1 <4.1.5>
10. Is there a production unit with responsibility and/or authority to:					2.3	
a. Prepare, revise, approve, and distribute manufacturing instructions?	☐ ☐ ☐ ☐ ☐					
b. Follow approved instructions?	☐ ☐ ☐ ☐ ☐					
c. Review batch records for acceptability?	☐ ☐ ☐ ☐ ☐					
d. Assure deviations are reported, evaluated, investigated, and resolved?	☐ ☐ ☐ ☐ ☐					
e. Assure facilities are clean and disinfected?	☐ ☐ ☐ ☐ ☐					
f. Assure calibrations are performed and recorded?	☐ ☐ ☐ ☐ ☐					
g. Assure validation records are reviewed and approved?	☐ ☐ ☐ ☐ ☐					
h. Evaluate changes to product, process or equipment?	☐ ☐ ☐ ☐ ☐					
i. Ensure new/modified equipment is qualified?	☐ ☐ ☐ ☐ ☐					

BULK CHEMICAL SUPPLIER AUDIT CHECKLIST

Total Number of Boxes Checked for Section K 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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	3 2 1 0 NA					
L. Other Considerations						
1. Does there appear to be a desirable administrative attitude toward our requirements?	□ □ □ □ □	4.1 4.2 4.3	5.2		(5.1) (5.2)	1.3 3.2 <4.7>
2. Is there a clear understanding of our requirements and needs?	□ □ □ □ □	4.2 4.3	5.2		(5.1) (5.2)	3.2 <4.7>
3. Does there appear to be sufficient engineering, production, and quality-control support to meet our needs?	□ □ □ □ □	4.2 4.3	5.2 6.2.2 6.3		(5.1) (5.2)	1.3 3.1 <4.1.5> <5.2.1>
4. How well does the company maintain the entire facility in general?	□ □ □ □ □	4.9	6.3 7.5.1		(6.3)	1.3 6.2 <5.3>
5. Does there appear to be sufficient administrative commitment to adequately staff departments?	□ □ □ □ □	4.1 4.18	6.1 6.2.1		3.1 (5.4.2)	<4.1.5>
6. Does the facility appear to be operating in such a manner that a shutdown or sale of the operation is not imminent?	□ □ □ □ □	4.2 4.3	5.2			

Total Number of Boxes Checked for Section L 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

Scope: This checklist should be used to evaluate any sourced component that could be considered a label or some type of labeling.

This checklist covers the following areas:

A. Contract Review and Customer Relations

B. Purchasing

C. Received/In-Process-Material Handling and Storage

D. Manufacturing Facilities, Equipment, and Controls

E. Final-Product Acceptance, Storage, and Distribution

F. Laboratories and Calibration

G. Document Control

H. Training and Internal Audit

I. Quality Assurance and Management Review

J. Other Considerations

The questions in this checklist include references to:

1. International Organization for Standardization (ISO) documents on Quality Systems, ISO 9001:1994, Quality Systems—Model and Quality Assurance in Design, Development, Production, Installation and Servicing, and ISO 9001:2000, Quality Management Systems—Requirements
2. International Organization for Standardization (ISO) documents 13485:1996, Quality Systems—Medical Devices—Particular Requirements for the Application of ISO 9001, and 13488:1996, Quality Systems—Medical Devices—Particular Requirements for the Application of ISO 9002. These are now equivalent to and have replaced European Standards EN 46001 and 46002, Quality System Requirements for Medical Devices
   Note: References to 13488 are indicated in the checklist by Parentheses ( ).
3. International Organization for Standardization (ISO) document 17025:1999, General Requirements for the Competence of Testing and Calibration Laboratories. The European Community (EC) has approved ISO as a replacement for European Standard EN 45001, General Criteria for the Operation of Testing Laboratories.
   Note: References to ISO 17025 are indicated in the checklist by Arrow Brackets < >.
4. The United States Military Specification Quality Program Requirements (MIL-Q-9858A).

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

5. International Organization for Standardization (ISO) 10011–1:1999, 2:1991, and 3:1991, Guidelines for Auditing Quality Systems: Auditing; Qualification Criteria for Quality System Auditors and Management of Audit Programmes (American ISO equivalent, ANSI/ASQC Q10011–1, 2, and 3)
   Note: References to this standard are indicated under each appropriate question in the checklist.

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

Date(s) of Audit _____

Supplier's Name _____

Address _____

City _____ State _____ Zip _____

Telephone (plant) _____ (main office) _____ Fax _____

Is the company a division or subsidiary of another corporation?

If yes, describe relationship _____

_____

Audit Leader Name _____

Title _____

Audit Team Members Name _____

Function on Team _____

Name _____

Function on Team _____

Name _____

Function on Team _____

Name _____

Function on Team _____

Nature of Audit

1. Prospective Source _____ Current Source _____

2. Problem-Instigated Audit* _____ Routine Audit _____

*Nature of Problem _____

_____

_____

Items currently procured from source:

1. _____

2. _____

3. _____

Items intended to be procured from company:

1. _____

2. _____

3. _____

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

Are the components under consideration for purchase produced only at this location?

Yes _____ No _____

If no, where else could they originate:

1._____

2._____

3._____

How is a lot/batch defined?

_____

_____

What is the lot/batch-numbering system?

_____

_____

Is there a way to denote the site of manufacture if multiple sites are employed?

_____

_____

Is there a way to denote the site of manufacture if multiple sites are employed?

_____

_____

How many shifts are there? _____

Approximate number of employees at facility? _____

Approximate square footage of facility (including warehouse)? _____

Is the plant an ISO-9000 registered operation? _____

_____

_____

Has the facility been inspected by a government agency? If yes, provide dates and results.

_____

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PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

Primary Individuals Contacted

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

Opening Meeting Date _____

Attendees _____

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Closing Meeting Date _____

Attendees _____

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Audit Report Date Issued _____

Date Response Received _____

Date Response and Action Plan Approved _____

Date Actions Completed _____

Date Completed Actions Verified as Completed _____

Date Completed Actions Verified as Effective _____

Date Closed Out _____

Future Follow-up Items _____

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PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

QUALITY RATING SYSTEM

Rating	*Meaning*	*Interpretation*
3	Excellent	Item/area/system/knowledge is superior
2	Adequate	Item/area/system/knowledge meets basic minimum requirements.
1	Deficient	Item/area/system/knowledge is weak and not up to acceptable standards.
0	Unsatisfactory	Item/area/system/knowledge is missing or of a nature to warrant serious quality/compliance concerns.
NA	Not Applicable	Question is not applicable to type of operation, or item unable to be addressed during the audit.

Comment: Some users of the checklist may find the responses to some questions difficult to quantify on a 0–3 scale and may prefer to use a simple "yes" or "no" approach. In such cases, a "yes" should be assigned a "2" value, and a "no" should be assigned a "0" value.

CHECKLIST RESULTS AND RATING

	Number of Occurrences			
Section	**3s**	**2s**	**1s**	**0s**
A. Contract Review and Customer Relations				
B. Purchasing				
C. Received/In-Process-Material Handling and Storage				
D. Manufacturing Facilities, Equipment, and Controls				
E. Final-Product Acceptance, Storage, and Distribution				
F. Laboratories and Calibration				
G. Document Control				
H. Training and Internal Audit				
I. Quality Assurance and Management Review				
J. Other Considerations				
Totals				

Audit Findings Summary

Number of questions rated excellent ( ) Times 3 = ( )
Number of questions rated adequate ( ) Times 2 = ( )
Number of questions rated deficient ( ) Times 1 = ( )
Number of questions rated unsatisfactory (_____) Times 0 = (_____)

Total Number of Questions Answered = (_____) Rating Total = (_____)

"Rating Total" divided by "Number of Questions Answered" = _____ Audit Rating

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

I. Strengths

1. _____
2. _____
3. _____
4. _____
5. _____

II. Weaknesses

1. _____
2. _____
3. _____
4. _____
5. _____

III. Recommendations

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PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
A. Customer Relations and Customer Relations					
1. Are requirements, including specifications and acceptance criteria, adequately detailed in a contract?	☐ ☐ ☐ ☐ ☐	4.3	5.2 7.2.1	4.3 (4.3) <4.4.1>	1.3 1.4
2. Does the contract specify how amendments are to be made and communicated to affected functions?	☐ ☐ ☐ ☐ ☐	4.3	7.2.2 <4.4.1> <4.4.4> <4.4.5>	4.3 (4.3)	1.3 1.4
3. Are the contracts formally agreed to before execution?	☐ ☐ ☐ ☐ ☐	4.3	5.2 7.2	4.3 (4.3)	1.3 1.4
4. Are the contracts periodically reviewed/inspected (US Military) for adequacy?	☐ ☐ ☐ ☐ ☐	4.3	7.2.2	4.3 (4.3) <4.4.2>	1.3 1.4
5. Are records of these periodic reviews maintained for a specified period of time?	☐ ☐ ☐ ☐ ☐	4.3 4.16	4.2.4 7.2.2	4.3 (4.3)	1.3 1.4
6. Is there a system to assure that previous revisions of negatives and plates are destroyed upon receipt of the new revision?	☐ ☐ ☐ ☐ ☐	4.3	4.2.4	4.3 (4.3)	1.3 1.4
7. If requested, is a system available whereby the customer can be notified when negatives and plates are destroyed?	☐ ☐ ☐ ☐ ☐	4.4	4.3.2	4.3 (4.3)	1.3 1.4
8. If more than 1 revision of negatives and plates is necessary to be on hand at the same time, is there proper authorization from the customer?	☐ ☐ ☐ ☐ ☐	4.3	4.1	4.3 (4.3)	1.3 1.4
9. Is there a procedure established and being followed that describes how verbal and formal orders are to be processed?	☐ ☐ ☐ ☐ ☐	4.3	7.2.3	4.3 (4.3)	1.3 1.4
10. Is there a procedure for resolving processed-order problems?	☐ ☐ ☐ ☐ ☐	4.3	7.2.3 <4.4.2> <4.7> <4.8>	4.3 (4.3)	1.3 1.4

Total Number of Boxes Checked for Section A 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
B. Purchasing					
1. Is there a procedure for the qualification and control of raw-material sourcing?	□ □ □ □ □	4.6.4	7.4.1	4.6.4 (4.6.4) <4.6.1>	1.3 5.1
2. Does the vendor maintain a list of approved sources for materials employed in the manufacturing process?	□ □ □ □ □	4.2 4.6.3 4.6.4 4.10.1	7.4.1	4.2 4.6.3 4.6.4 4.10.1 (4.2) (4.6.3) (4.6.4) (4.10.1)	1.3 5.1 5.2
3. In appropriate situations, does the company audit sources of supply?	□ □ □ □ □	4.6.2	7.4.1	4.6.2 (4.6.2) <4.6.4>	5.1

Total Number of Boxes Checked for Section B 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
C. Received/In-Process Material Handling and Storage					
1. Are released items properly segregated from material awaiting testing and disposition?	□ □ □ □ □	4.10.1	7.1 7.5.3 7.5.5 8.1	4.10.1 (4.10.1)	6.1
2. Is material adequately inspected, tested, and identified as accepted or rejected?	□ □ □ □ □	4.10.1	7.1 7.5.3 7.5.5 8.1	4.10.1 (4.10.1)	6.1
3. Is rejected material adequately controlled?	□ □ □ □ □	4.10.1 4.10.2 4.12 4.13	7.4.3 7.5.3 8.2.4 8.3	4.10.1 4.10.2 4.12 4.13 (4.10.1) (4.10.2) (4.12) (4.13) <4.6.2> <5.8>	6.1
4. Is there an acceptance area/procedure for sampling?	□ □ □ □ □	4.11	7.5.3	4.11 (4.11)	6.1
5. Are materials properly handled and stored to prevent damage?	□ □ □ □ □	4.10.1 4.15.2 4.15.3	7.5.5 8.2.4	4.10.1 4.15.2 4.15.3 (4.10.1) (4.15.2) (4.15.3)	6.1
6. Are stockrooms and storage areas restricted to authorized personnel?	□ □ □ □ □	4.15.3	7.5.5	4.15.3 (4.15.3) <4.6.1> <5.8>	1.3
7. Are materials properly identified as to their contents to avoid errors in issuance?	□ □ □ □ □	4.8 4.10.1	7.5.3	4.8 4.10.1 (4.8) (4.10.1)	6.1
8. Are materials adequately segregated to avoid mix-ups?	□ □ □ □ □	4.8 4.10.1	7.5.3	4.8 4.10.1 (4.8) (4.10.1) <4.6.1> <5.8>	6.1
9. Are label stocks reinspected and tested at intervals to detect aging?	□ □ □ □ □	4.15.3	7.5.5	4.15.3 (4.15.3) <4.6.1>	1.3 3.2

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
	3 2 1 0 NA				
C. Received/In-Process Material Handling and Storage (continued)					
10. Where required, how adequate is the controlled-environment storage (e.g., humidity, temperature, etc.)?	□ □ □ □ □	4.15.3	7.5.5	4.15.3 (4.15.3) <4.6.1>	1.3 3.2

Total Number of Boxes Checked for Section C 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
D. Manufacturing Facilities, Equipment and Control					
1. Are the items being manufactured identifiable throughout the operation?	□ □ □ □ □	4.8	7.5.3	4.8 (4.8)	6.1
2. Are the manufacturing operations orderly in flow and organization?	□ □ □ □ □	4.8 4.9	7.5.1 7.5.2	4.8 4.9 (4.8) (4.9)	6.2
3. Are the manufacturing processes and facilities adequate to produce high-quality items?	□ □ □ □ □	4.9	4.2.3 7.5.1 7.5.2	4.9 (4.9)	6.2
4. If gang printing is allowed by the customer, how adequate are the controls to prevent mix-ups?	□ □ □ □ □	4.9	7.5.1	4.9 (4.9)	1.3
5. Would the customer be advised if gang-printing or trailing-run procedures were to be employed?	□ □ □ □ □	4.3 4.6.1	7.5.1 7.5.2 7.5.3	4.3 4.6.1 (4.3) (4.6.1)	6.2
6. Is there an adequate system for the control of labels with preprinted lot numbers and/or expiration dates?	□ □ □ □ □	4.9	7.5.1 7.5.2	4.9 (4.9)	1.3 6.2
7. Are multiple-impression printing plates designed so that there is traceability from a sample back to individual impressions within the plate?	□ □ □ □ □	4.9	7.5.1 7.5.2	4.9 (4.9)	1.3 6.2
8. Does the lot number reflect 1 homogeneous production run?	□ □ □ □ □	4.8 4.9 4.12	7.5.1 7.5.2	4.8 4.9 4.12 (4.8) (4.9) (4.12)	1.3 6.2 6.5
9. Are formal line clearances performed between different labeling or packaging operations before they begin?	□ □ □ □ □	4.8 4.9	7.5.1	4.8 4.9 (4.8) (4.9)	6.2
10. Is the difference between “line clearance” and “ready to run” (first-article approval) clearly understood?	□ □ □ □ □		7.5.1		6.2
11. Does the quality-control group approve the start-up of production?	□ □ □ □ □	4.9 4.10.2 4.10.4 4.12	7.5.1 8.2.4	4.9 4.10.2 4.10.4 4.12 (4.9) (4.10.2) (4.10.4) (4.12)	3.1 3.3

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
	3 2 1 0 NA				
D. Manufacturing Facilities, Equipment and Control (continued)					
12. Are the manufacturing procedures formalized and controlled?	□ □ □ □ □	4.9	7.5.1	4.9 (4.9)	3.3 3.4 4.1 6.2
13. Is there a formal procedure for deviations to normal practice?	□ □ □ □ □	4.9 4.13 4.13.1	7.5.1 8.3	4.9 4.13 4.13.1 (4.9) (4.13) (4.13.1)	1.3 2.2 3.3 3.4 4.1
14. Are there formal procedures for the handling of rework?	□ □ □ □ □	4.9 4.13.1	7.5.1 8.3	4.9 4.13.1 (4.9) (4.13.1)	3.4
15. Do the employees in the manufacturing areas appear to be knowledgeable and quality conscious?	□ □ □ □ □	4.18	6.2.2	4.18 (4.18)	1.3 3.1
16. Are current specifications/drawings readily accessible for the employees?	□ □ □ □ □	4.5.1 4.5.2	4.2.3	4.5.1 4.5.2 (4.5.1) (4.5.2)	3.3
17. Is the manufacturing environment acceptable for the type of item produced?	□ □ □ □ □	4.9	7.5.1 7.5.2	4.9 (4.9)	1.3 3.2 6.2
18. Are production areas that are likely to be very dusty or unique in regard to contamination properly controlled with exhaust systems or other methods of decontamination?	□ □ □ □ □	4.9	7.5.1 7.5.2	4.9 (4.9)	6.2
19. Are production employees neat in their appearance, with unnecessary jewelry and cosmetics kept out of the production areas?	□ □ □ □ □	4.9 4.18	6.2.2 7.5.1	4.9 4.10 (4.9) (4.18)	1.3 6.2
20. Is there an adequate automated system for accountability?	□ □ □ □ □	4.9	7.5.1 7.5.2	4.9 (4.9)	1.3 3.2 6.2
21. Is the automated counting system calibrated periodically and checked after maintenance/repair to assure accurate counting reliability?	□ □ □ □ □	4.11	7.6	4.11 (4.11)	1.3 4.2
22. Are waste materials clearly identified in proper containers?	□ □ □ □ □	4.9	7.5.1 8.3	4.9 (4.9)	
23. Are the ceiling fixtures and pipes free of accumulated dirt?	□ □ □ □ □	4.9	7.5.1	4.9 (4.9)	1.3 6.2

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
	3 2 1 0 NA				
D. Manufacturing Facilities, Equipment and Control (continued)					
24. Are valves and associated pipes in the production areas free of leaks?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	1.3 6.2
25. Are the ceilings and walls in good condition to prevent contamination from paint chips?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	1.3 6.2
26. Are appropriate bathroom facilities available?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	1.3 6.2
27. Are smoking and eating prohibited where necessary?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	1.3 6.2
28. Is there an adequate pest-control program?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	1.3 6.2
29. Are the in-process inspection and test procedures adequate?	☐ ☐ ☐ ☐ ☐	4.10.3 4.10.4 4.11 4.16	8.2.4	4.10.2 4.10.4 4.11 4.16 (4.10.3) (4.10.4) (4.11) (4.16)	6.2 6.3
30. Are color standards available, and are they checked on a periodic basis for fading?	☐ ☐ ☐ ☐ ☐	4.10.3 4.10.4	8.2.4	4.10.3 4.10.4 (4.10.3) (4.10.4)	4.3 6.2 6.3
31. Is there a system for 100% inspection of labels?	☐ ☐ ☐ ☐ ☐	4.9 4.10.3	8.2.4	4.9 4.10.3 (4.10.2) (4.10.3)	1.3 3.2 6.3
32. Are there adequate specifications, sampling plans, and classifications of defects to control in-process materials?	☐ ☐ ☐ ☐ ☐	4.10.2	8.2.3	4.10.3 (4.10.3)	6.6
33. If in-process material is rejected, is there an indication of the reason?	☐ ☐ ☐ ☐ ☐	4.13 4.13.1 4.14	8.3 8.5.2 8.5.3	4.13 4.13.1 4.14 (4.13) (4.13.1) (4.14)	3.5 6.5 6.7
34. If in-process material is rejected, is there a corrective action indicated to prevent the same problem from recurring?	☐ ☐ ☐ ☐ ☐	4.14	8.5.2 8.5.3	4.14 (4.14)	3.5 6.5 6.7

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

Total Number of Boxes Checked for Section D 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

Audited by _____

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
E. Final Product Acceptance, Storage, and Distribution					
1. How adequate are the procedures for final-product inspection, sampling, and testing?	□ □ □ □ □	4.10.3	8.2.4	4.10.4 (4.10.4) <5.4.1>	6.3
2. Are final inspection/test results recorded?	□ □ □ □ □	4.10.4 4.10.5	4.2.4 8.2.4	4.10.4 4.10.5 (4.10.4) (4.10.5) <5.4.3> <5.4.4>	3.4 6.3
3. How adequate is the final review of the production-documentation package?	□ □ □ □ □	4.12 4.16	8.2.4	4.12 4.16 (4.12) (4.16)	3.4 6.3
4. Are production-documentation packages stored properly and retained for an adequate length of time?	□ □ □ □ □	4.16	4.2.4	4.16 (4.16)	3.4
5. Are discrepancies found during the final review properly investigated?	□ □ □ □ □	4.13	8.3	4.13 (4.13)	3.5 6.5
6. How adequate is the procedure for release of product?	□ □ □ □ □	4.2 4.10.4 4.12	7.5.3 8.2.4	4.2 4.10.4 4.12 (4.2) (4.10.4) (4.12)	1.3 3.1 6.2 6.5
7. How well is final-product material identified and segregated?	□ □ □ □ □	4.8 4.15.2 4.15.5	7.5.3 7.5.5	4.8 4.15.2 4.15.5 (4.8) (4.15.2) (4.15.5)	6.7
8. How well is nonconforming material controlled?	□ □ □ □ □	4.13	8.3	4.13 (4.13)	6.5
9. How adequate is the system for disposal of rejected printed materials?	□ □ □ □ □	4.2 4.9 4.13	7.5.1 8.3	4.2 4.9 4.13 (4.2) (4.9) (4.13)	6.5
10. Do adequate facilities exist to store materials awaiting shipment?	□ □ □ □ □	4.15.3	7.5.5	4.15.3 (4.15.3)	6.4
11. How adequate is the security system for controlled drug labels?	□ □ □ □ □	4.15.3	7.5.5	4.15.3 (4.15.3)	6.4

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
	3 2 1 0 NA				
E. Final Product Acceptance, Storage, and Distribution (continued)					
12. How well are items with shelf-life requirements (print fading, adhesive deterioration, etc.) identified and controlled?	□ □ □ □ □	4.15.3	7.5.5	4.15.3 (4.15.3)	6.4
13. How adequate is the lot-recall/withdrawal system? (e.g., if a lot was found to have an adhesive problem, could the original lot of print stock be traced back to? Then forward again to see what other printed lots are implicated?)	□ □ □ □ □	4.2 4.8 4.16	7.5.1 7.5.3 7.5.5	4.2 4.8 4.16 (4.2) (4.8) (4.16)	3.4

Total Number of Boxes Checked for Section E 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
F. Laboratories and Calibration					
1. Does the quality-control department appear to have sufficient equipment and facilities?	□ □ □ □ □	4.1.2	5.5.1 6.1 6.2	4.1 (4.1) <5.3> <5.5>	1.3 3.1 4.2 4.5
2. Are samples from incoming, in-process, and final-product materials properly controlled?	□ □ □ □ □	4.10.1 4.10.2 4.10.3	7.4.3 8.2.4	4.10.1 4.10.2 4.10.3 (4.10.1) (4.10.2) (4.10.3) <5.4> <5.7>	5.1 6.1 6.2 6.3 6.6
3. Does quality control possess bar-code verifiers to check for sufficient bar code quality and correct character imprint?	□ □ □ □ □	4.10.3 4.10.4 4.11 4.12	8.1 8.2.3 8.2.4	4.10.3 4.10.4 4.11 4.12 (4.10.3) (4.10.4) (4.11) (4.12)	6.2 6.3
4. Does quality control check print color for conformance to color standards?	□ □ □ □ □	4.10.3 4.10.4 4.12	8.1 8.2.3 8.2.4	4.10.3 4.10.4 4.12 (4.10.3) (4.10.4) (4.12)	6.2 6.3
5. Is each lot checked against customer-approved copy for correct printing?	□ □ □ □ □	4.10.3 4.10.4 4.12	8.1 8.2.1 8.2.3 8.2.4	4.10.3 4.10.4 4.12 (4.10.3) (4.10.4) (4.11)	6.2 6.3
6. Is each lot checked against a drawing for correct die cut?	□ □ □ □ □	4.10.3 4.10.4 4.12	8.1 8.2.3 8.2.4	4.10.3 4.10.4 4.12 (4.10.3) (4.10.4) (4.11)	6.2 6.3
7. Are all tests/inspections properly documented?	□ □ □ □ □	4.10.4 4.10.5	4.2.4 7.4.3 8.2.4	4.10.4 4.10.5 (4.10.4) (4.10.5) <5.4> <5.5> <5.10>	3.4

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
F. Laboratories and Calibration (continued)					
8. Are certificates of inspection/test results available to the customers?	☐ ☐ ☐ ☐ ☐	4.3 4.6.1	5.2 8.2.1	4.3 4.6.1 (4.3) (4.6.1)	
9. Are there acceptable procedures to assure that gauges, tools, and test equipment are maintained in proper order?	☐ ☐ ☐ ☐ ☐	4.11	7.6	4.11 (4.11) <5.3> <5.4> <5.5> <5.6>	4.2 4.3 4.5
10. Is there a system to assure that gauges (including "go-no-go" gauges) and testing equipment are calibrated on a periodic basis?	☐ ☐ ☐ ☐ ☐	4.11	7.6	4.11 (4.11) <5.3> <5.4> <5.5> <5.6>	4.2 4.3 4.5
11. If calibration is performed by the facility, are these calibration procedures formalized and traceable to appropriate standards?	☐ ☐ ☐ ☐ ☐	4.11	7.6	4.11 (4.11) <5.3> <5.4> <5.5> <5.6>	3.3 4.2 4.3 4.5
12. If external sources are utilized for calibration, have the sources been audited to assure competence?	☐ ☐ ☐ ☐ ☐	4.6.2 4.11	7.4.1 7.6	4.6.2 4.11 (4.6.2) (4.11) <4.5>	1.3 4.2 4.3 4.5 5.1

Total Number of Boxes Checked for Section F 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
G. Document Control					
1. Are the specifications and other documents comprehensive in content?	□ □ □ □ □	4.2 4.4.4	4.2.1 4.2.3 7.2.1 7.3.2	4.2 4.4.4 (4.2) <4.3.1>	3.3 4.1
2. Are the documents current, and are unneeded/obsolete documents removed from usage?	□ □ □ □ □	4.5.1	4.2.3	4.5.1 (4.5.1) <4.3.2>	3.3 4.1
3. Do written procedures exist that address a change-control system for documents, and are the procedures being followed?	□ □ □ □ □	4.5	4.2.3	4.5 (4.5) <4.3.3>	3.3 4.1

Total Number of Boxes Checked for Section G 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
	3 2 1 0 NA				
H. Training and Internal Audit					
1. Is there a training program for all employees in appropriate areas?	□ □ □ □ □	4.18	6.2.2	4.18 (4.18) <5.2>	1.3 3.1 3.3
2. Is there a program for periodic retraining?	□ □ □ □ □	4.18	6.2.2	4.18 (4.18)	
3. Is there a formal procedure for performing internal quality audits? ISO 10011–3, Part 4.6.3	□ □ □ □ □	4.1 4.17	5.5.1 5.6.1 8.2.2 8.5.1	4.1 4.17 (4.1) (4.17) <4.13>	
4. Are audits performed by properly educated, trained, and experienced individuals not having direct responsibility for that which is being audited? ISO 10011–1, Part 4.2.1.4 ISO 10011–2, Part 4.0 ISO 10011–2, Part 6.0 ISO 10011–3, Part 4.1 ISO 10011–3, Part 4.3.1 ISO 10011–3, Part 4.5.3	□ □ □ □ □	4.17 4.18	8.2.2 8.2.3	4.1 4.17 (4.1) (4.17) <4.13>	
5. Is there an audit plan that includes the following: a. Objective/scope of audit? b. Date and items to be audited? c. Applicable standards/regulations? d. Provision for an opening and closing meeting? ISO 10011–1, Part 5.2.1 ISO 10011–3, Part 4.2	□ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □	4.17	8.2.2 8.2.3	4.17 (4.17)	
6. Is there a formal audit report that details the observations requiring corrective and preventive action? ISO 10011–1, Part 5.2.1 ISO 10011–1, Part 5.3.2.2 ISO 10011–3, Part 4.2 ISO 10011–3, Part 4.5.3	□ □ □ □ □	4.1 4.17	5.5.1 8.2.2 8.2.3	4.1 4.17 (4.1) (4.17) <4.9> <4.10> <4.11> <4.13>	
7. Are documented corrective and preventive actions taken on audit observations? ISO 10011–1, Part 7.0 ISO 10011–3, Part 4.6.5	□ □ □ □ □	4.1 4.14 4.16 4.17	4.2.4 5.5.1 5.6.2 8.2.2 8.5.2 8.5.3	4.1 4.14 4.16 4.17 (4.1) (4.14) (4.16) (4.17) <4.9> <4.10> <4.11> <4.13>	

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

Total Number of Boxes Checked for Section H 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

Audited by _____

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
	3 2 1 0 NA				
I. Quality Assurance and Management Review					
1. Is there a formal statement of the corporate quality policy by the management of the company?	☐ ☐ ☐ ☐ ☐	4.1	5.1 5.3 5.4.1	4.1 (4.1) <4.2>	1.3 3.1
2. Is there a "quality system" that addresses the organizational structure, responsibilities, procedures, processes and resources for implementing quality management?	☐ ☐ ☐ ☐ ☐	4.1 4.2	4.1 5.5.1	4.1 4.2 (4.1) (4.2) <4.2>	1.3 3.1
3. Is there a "quality manual" that addresses the "quality system"?	☐ ☐ ☐ ☐ ☐	4.1 4.2	4.2.1 4.2.2	4.1 4.2 (4.1) (4.2) <4.2>	1.3 3.1
4. Are there periodic management reviews of the quality system, and are the following inputs included:		4.1 4.16	4.1 4.2.4 5.6.1 5.6.2 8.5.1	4.1 4.16 (4.1) (4.16) <4.14>	3.1
a. Results of audits?	☐ ☐ ☐ ☐ ☐				
b. Customer feedback?	☐ ☐ ☐ ☐ ☐				
c. Process performance and product conformity?	☐ ☐ ☐ ☐ ☐				
d. Status of corrective and preventive actions?	☐ ☐ ☐ ☐ ☐				
e. Follow-up actions from previous management reviews?	☐ ☐ ☐ ☐ ☐				
f. Changes that could affect the quality management system?	☐ ☐ ☐ ☐ ☐				
g. Recommendations for improvement?	☐ ☐ ☐ ☐ ☐				
5. Does the organization analyze appropriate data to demonstrate the suitability and effectiveness of the quality-management system in regards to the following:			8.4	<4.14>	
a. Customer satisfaction?	☐ ☐ ☐ ☐ ☐				
b. Conformity to product requirements?	☐ ☐ ☐ ☐ ☐				
c. Trends of processes and products, including opportunities for preventive action?	☐ ☐ ☐ ☐ ☐				
d. Suppliers?	☐ ☐ ☐ ☐ ☐				
6. Does top management provide communication within the organization regarding the effectiveness of the quality-management system?	☐ ☐ ☐ ☐ ☐		5.5.3	<4.14>	
7. Does the quality-control function appear to have the independence necessary to make decisions without fear of political repercussions?	☐ ☐ ☐ ☐ ☐	4.1	4.1 5.5.2	4.1 (4.1) <4.1>	1.3 3.1 4.1

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

Total Number of Boxes Checked for Section I 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

Audited by _____

PRINTED MATERIAL SUPPLIER AUDIT CHECKLIST

	Rating	Reference			
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US MIL-Q-9858A
	3 2 1 0 NA				
J. Other Considerations					
1. Does there appear to be a desirable administrative attitude toward our requirements?	□ □ □ □ □	4.1 4.2 4.3	5.2	4.1 4.2 4.3 (4.1) (4.2) (4.3) <4.7>	1.3 3.2
2. Is there a clear understanding of our requirements and needs?	□ □ □ □ □	4.2 4.3	5.2 6.2.2 6.3	4.2 4.3 (4.2) (4.3) <4.7>	3.2
3. Does there appear to be sufficient engineering, production, and quality-control support to meet our needs?	□ □ □ □ □	4.2 4.3	5.2 6.2.2 6.3	4.2 4.3 (4.2) (4.3) <4.1.5> <5.2.1>	1.3 3.1
4. How well does the company maintain the entire facility in general?	□ □ □ □ □	4.9	6.3 7.5.1	4.9 (4.9) <5.3>	1.3 6.2
5. Does there appear to be sufficient administrative commitment to adequately staff departments?	□ □ □ □ □	4.1 4.18	6.1 6.2.1	4.1 4.18 (4.1) (4.18) <4.1.5>	
6. Does the facility appear to be operating in such a manner that a shutdown or sale of the operation is not imminent?	□ □ □ □ □	4.2 4.3	5.2		

Total Number of Boxes Checked for Section J 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

ELECTRONIC COMPONENT
SUPPLIER AUDIT

ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

Scope: This checklist should be used when performing an audit of a supplier who manufactures electronic components. If the supplier is developing a custom or unique item, the Development and Design Control section of the "Contract Device Manufacturer/Developer Audit Checklist" should be used as an adjunct to this checklist.

This checklist covers the following areas:

Contract Review

Purchasing

C. Received/In-Process-Material Handling and Storage

D. Manufacturing Facilities, Equipment, and Controls

E. Final-Product Acceptance, Storage, and Distribution

F. Laboratories and Calibration

G. Document Control

H. Training and Internal Audit

I. Quality Assurance and Management Review

J. Other Considerations

The questions in this checklist include references to:

1. International Organization for Standardization (ISO) documents on Quality Systems, ISO 9001:1994, Quality Systems—Model and Quality Assurance in Design, Development, Production, Installation and Servicing, and ISO 9001:2000, Quality Management Systems—Requirements
2. International Organization for Standardization (ISO) documents 13485:1996, Quality Systems—Medical Devices—Particular Requirements for the Application of ISO 9002 and 13488:1996, Quality Systems—Medical Devices—Particular Requirements for the Application of ISO 9002. They are now equivalent to and have replaced EN 46001 and 46002.
   Note: References to 13488 are indicated in the checklist by Parentheses ( ).
3. International Organization for Standardization (ISO) document 17025:1999, General Requirements for the Competence of Testing and Calibration Laboratories. The European Community (EC) has approved ISO 17025 as a replacement for EN 45001
   Note: References to ISO 17025 are indicated in the checklist by Arrow Brackets < >.
4. The United States Military Specification Quality Program Requirements (MIL-Q-9858A).
5. The United States Military Standard—790 (MIL-STD-790) Established Reliability and High Reliability Qualified Products List (QPL) Systems for Electrical, and Fiber Optic Parts Specifications.

ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

6. International Organization for Standardization (ISO) 10011–1:1990, 2:1991, and 3:1991, Guidelines for Auditing Quality Systems: Auditing; Qualification Criteria for Quality System; and Management of Audit Programmes
   Note: References to this standard are indicated under each appropriate question in the checklist.

ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

Date(s) of Audit _____

Supplier's Company Name _____

Address _____

City _____ State _____ Zip _____

Telephone (plant) _____ (main office) _____ Fax _____

Is the company a division or subsidiary of another corporation?

If yes, describe relationship _____

_____

Audit Leader Name _____

Title _____

Audit Team Members Name _____

Function on Team _____

Name _____

Function on Team _____

Name _____

Function on Team _____

Name _____

Function on Team _____

Nature of Audit

1. Prospective Source _____ Current Source _____

2. Problem-Instigated Audit* _____ Routine Audit _____

*Nature of Problem _____

_____

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Items currently procured from source:

1. _____

2. _____

3. _____

Items intended to be procured from company:

1. _____

2. _____

3. _____

ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

Are the components under consideration for purchase produced only at this location?

Yes _____ No _____

If no, where else could they originate:

1._____

2._____

3._____

How is a lot/batch defined?

_____

_____

What is the lot/batch-numbering system?

_____

_____

Is there a way to denote the site of manufacture if multiple sites are employed?

_____

_____

How many shifts are there? _____

Approximate number of employees at facility? _____

Approximate square footage of facility (including warehouse)? _____

Is the plant an ISO-9000 registered operation? _____

_____

_____

Has the facility been inspected by a government agency? If yes, provide dates and results.

_____

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ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

Primary Individuals Contacted

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

Opening Meeting Date _____

Attendees _____

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Closing Meeting Date _____

Attendees _____

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Audit Report Date Issued _____

Date Response Received _____

Date Response and Action Plan Approved _____

Date Actions Completed _____

Date Completed Actions Verified as Completed _____

Date Completed Actions Verified as Effective _____

Date Closed Out _____

Future Follow-up Items _____

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ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

QUALITY RATING SYSTEM

Rating	*Meaning*	*Interpretation*
3	Excellent	Item/area/system/knowledge is superior
2	Adequate	Item/area/system/knowledge meets basic minimum requirements.
1	Deficient	Item/area/system/knowledge is weak and not up to acceptable standards.
0	Unsatisfactory	Item/area/system/knowledge is missing or of a nature to warrant serious quality/compliance concerns.
NA	Not Applicable	Question is not applicable to type of operation, or item unable to be addressed during the audit.

Comment: Some users of the checklist may find the responses to some questions difficult to quantify on a 0–3 scale and may prefer to use a simple "yes" or "no" approach. In such cases, a "yes" should be assigned a "2" value, and a "no" should be assigned a "0" value.

CHECKLIST RESULTS AND RATING

	Number of Occurrences			
Section	**3s**	**2s**	**1s**	**0s**
A. Contract Review				
B. Purchasing				
C. Received/In-Process-Material Handling and Storage				
D. Manufacturing Facilities, Equipment, and Controls				
E. Final-Product Acceptance, Storage, and Distribution				
F. Laboratories and Calibration				
G. Document Control				
H. Training and Internal Audit				
I. Quality Assurance and Management Review				
J. Other Considerations				
Totals				

Audit Findings Summary

Number of questions rated excellent ( ) Times 3 = ( )
Number of questions rated adequate ( ) Times 2 = ( )
Number of questions rated deficient ( ) Times 1 = ( )
Number of questions rated unsatisfactory (_____) Times 0 = (_____)

Total Number of Questions Answered = (_____) Rating Total = (_____)

"Rating Total" divided by "Number of Questions Answered" = _____ Audit Rating

ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

I. Strengths

1. _____
2. _____
3. _____
4. _____
5. _____

II. Weaknesses

1. _____
2. _____
3. _____
4. _____
5. _____

III. Recommendations

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ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US-MIL-Q-9858A	US-MIL-STD-790
A. Contract Review						
This first set of questions is applicable to custom items to be provided.						
1. Are requirements, including specifications and acceptance criteria, adequately detailed in a contract?	□ □ □ □ □	4.3	5.2 7.2.1	4.3 (4.3) <4.4.1>	1.3 1.4	
2. Does the contract specify how amendments are to be made and communicated to affected functions?	□ □ □ □ □	4.3	7.2.2	4.3 (4.3) <4.4.1> <4.4.4>	1.3 1.4	
3. Is the contract formally agreed to before execution?	□ □ □ □ □	4.3	5.2 7.2	4.3 (4.3) <4.4.1>	1.3 1.4	
4. Are the contracts periodically reviewed or inspected (US Military) for adequacy?	□ □ □ □ □	4.3	7.2.2	4.3 (4.3) <4.4.2>	1.3 1.4	
5. Are records of such periodic reviews maintained for a specified period of time?	□ □ □ □ □	4.16 4.3	4.2.4 7.2.2	4.3 (4.3)	1.3 1.4	
This second set of questions is applicable to standard "off-the-shelf" items to be provided.						
6. Is there a product/service catalog/list that is revision controlled to assure that the contents are current and correct?	□ □ □ □ □	4.3	5.2 7.2.2 7.2.3	4.3 (4.3)	1.3 1.4	
7. Does the catalog/list provide enough information to assure the purchaser will receive what is expected?	□ □ □ □ □	4.3	5.2 7.2.1 7.2.3	4.3 (4.3)	1.3 1.4	
This third set of questions is applicable to both types of items.						
8. Is there a procedure established and being followed that describes how verbal and formal orders are to be processed?	□ □ □ □ □	4.3	7.2.3	4.3 (4.3) <4.4.1>	1.3 1.4	
9. Is there a procedure for resolving processed-order problems?	□ □ □ □ □	4.3	7.2.3	4.3 (4.3) <4.4.2> <4.7> <4.8>	1.3 1.4	

Total Number of Boxes Checked for Section A 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US-MIL-Q-9858A	US-MIL-STD-790
B. Purchasing						
1. Is there a procedure for the qualification and control of raw-material sourcing?	☐ ☐ ☐ ☐ ☐	4.6.4	7.4.1	4.6.4 (4.6.4) <4.6.1>	1.3 5.1	5.2.8
2. Does the vendor maintain a list of approved sources for materials employed in the manufacturing process?	☐ ☐ ☐ ☐ ☐	4.2 4.6.3 4.6.4 4.10.1	7.4.1	4.2 4.6.3 4.6.4 4.10.1 (4.2) (4.6.3) (4.6.4) (4.10.1)	1.3 5.1 5.2	5.2.8
3. In appropriate situations, does the company audit sources of supply?	☐ ☐ ☐ ☐ ☐	4.6.2	7.4.1	4.6.2 (4.6.2) <4.6.4>	5.1	5.2.8

Total Number of Boxes Checked for Section B 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US-MIL-Q-9858A	US-MIL-STD-790
C. Received/In-Process Material Handling and Storage						
1. Are released items properly segregated from material awaiting testing and disposition?	□ □ □ □ □	4.10.1	7.1 7.5.3 7.5.5 8.1	4.10.1 (4.10.1)	6.1	5.2.11 5.2.12.1
2. Is material adequately inspected, tested, and identified as accepted or rejected?	□ □ □ □ □	4.10.1	7.1 7.5.3 7.5.5 8.1	4.10.1 (4.10.1)	6.1	5.2.12.1 5.2.12.2 5.2.12.3 5.2.12.4
3. Is rejected material adequately controlled?	□ □ □ □ □	4.10.1 4.10.2 4.12 4.13	7.4.3 7.5.3 8.2.4 8.3	4.10.1 4.10.2 4.12 4.13 (4.10.1) (4.10.2) (4.12) (4.13) <4.62> <5.8>	6.1	5.2.10 5.2.12.3
4. Is there an acceptance area/procedure for sampling?	□ □ □ □ □	4.11	7.5.3	4.11 (4.11)	6.1	5.2.9 5.2.10
5. Are materials properly handled and stored to prevent damage?	□ □ □ □ □	4.10.1 4.15.2 4.15.3	7.5.5 8.2.4	4.10.1 4.15.2 4.15.3 (4.10.1) (4.15.2) (4.15.3)	6.1	5.2.11 5.2.14
6. Are stockrooms and storage areas restricted to authorized personnel?	□ □ □ □ □	4.15.3	7.5.5	4.15.3 (4.15.3) <4.6.1> <5.8>	1.3	5.2.11 5.2.14
7. Are materials properly identified as to their contents to avoid errors in issuance?	□ □ □ □ □	4.8 4.10.1	7.5.3	4.8 4.10.1 (4.8) (4.10.1)	6.1	5.2.11 5.2.12 5.2.14
8. Are materials adequately segregated to avoid mix-ups?	□ □ □ □ □	4.8 4.10.1	7.5.3	4.8 4.10.1 (4.8) (4.10.1) <4.6.1> <5.8>	6.1	5.2.11 5.2.12.1 5.2.12.2 5.2.12.3 5.2.14
9. Are stocks reinspected and tested at intervals?	□ □ □ □ □	4.15.3	7.5.5	4.15.3 (4.15.3) <4.6.1>	1.3 3.2	5.2.12.1

ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US-MIL-Q-9858A	US-MIL-STD-790
C. Received/In-Process Material Handling and Storage						
10. Where required, how adequate is the controlled-environment storage (e.g., humidity, temperature, etc.)?	□ □ □ □ □	4.15.3	7.5.5	4.15.3 (4.15.3) <4.6.1>	1.3 3.2	5.2.12.1 5.2.14

Total Number of Boxes Checked for Section C 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US-MIL-Q-9858A	US-MIL-STD-790
D. Manufacturing Facilities, Equipment and Control						
1. Are the items being manufactured identifiable throughout the operation?	□ □ □ □ □	4.8	7.5.3	4.8 (4.8)	6.1	5.2.12.1 5.2.12.4 5.2.13
2. Are the manufacturing operations orderly in flow and organization?	□ □ □ □ □	4.8 4.9	7.5.1 7.5.2	4.8 4.9 (4.8) (4.9)	6.2	5.2.7
3. Are the manufacturing processes and facilities adequate to produce quality components?	□ □ □ □ □	4.9	4.2.3 7.5.1 7.5.2	4.9 (4.9)	6.2	5.2.6 5.2.7
4. Are the prototype parts for change evaluation properly evaluated on line?	□ □ □ □ □	4.4	7.5.1 7.5.2	4.4	4.1	5.2.5.1
5. Are lubricants and nonproduction materials properly controlled to prevent product contamination?	□ □ □ □ □	4.9	7.5.1	4.9 (4.9)	1.3 6.2	5.2.6 5.2.7
6. Does the lot number reflect 1 homogeneous production run?	□ □ □ □ □	4.8 4.9 4.12	7.5.1 7.5.2	4.8 4.9 4.12 (4.8) (4.9) (4.12)	1.3 6.2 6.5	5.2.7
7. Are formal line clearances performed between different labeling or packaging operations before they begin?	□ □ □ □ □	4.8 4.9	7.5.1	4.8 4.9 (4.8) (4.9)	6.2	5.2.11 5.2.12.2
8. Is the difference between "line clearance" and "ready to run" (first-article approval) clearly understood?	□ □ □ □ □		7.5.1		6.2	5.2.11 5.2.12.1
9. Does the quality-control group approve the start-up production?	□ □ □ □ □	4.9 4.10.2 4.10.4 4.12	7.5.1 8.2.4	4.9 4.10.2 4.10.4 4.12 (4.9) (4.10.2) (4.10.4) (4.12)	3.1 3.3	5.2.10 5.2.13 5.2.15
10. Are the manufacturing procedures formalized and controlled?	□ □ □ □ □	4.9	7.5.1	4.9 (4.9)	3.3 3.4 4.1 6.2	5.2.7 5.2.8
11. Is there a formal procedure for deviations to normal practice?	□ □ □ □ □	4.9 4.13 4.13.1	7.5.1 8.3	4.9 4.13 4.13.1 (4.9) (4.13) (4.13.1)	1.3 2.2 3.3 4.1	5.1.6 5.2.8 5.2.17

ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US-MIL-Q-9858A	US-MIL-STD-790
D. Manufacturing Facilities, Equipment and Control						
12. Are there formal procedures for the handling of rework?	☐ ☐ ☐ ☐ ☐	4.9 4.13.1	7.5.1 8.3	4.9 4.13.1 (4.9) (4.13.1)	3.4	5.2.5
13. Do the employees in the manufacturing areas appear to be knowledgeable and quality conscious?	☐ ☐ ☐ ☐ ☐	4.18	6.2.2	4.18 (4.18)	1.3 3.1	5.1.1 5.2.1
14. Are current specifications/drawings readily accessible for the employees?	☐ ☐ ☐ ☐ ☐	4.5.1 4.5.2	4.2.3 7.5.1	4.5.1 4.5.2 (4.5.1) (4.5.2)	3.3 4.1 6.2	5.2.7 5.2.10
15. Is the manufacturing environment acceptable for the type of item produced?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1 7.5.2	4.9 (4.9)	1.3 3.2 6.2	5.2.6 5.2.7
16. Are production areas that are very dusty or unique in regard to contamination properly controlled with exhaust systems or other methods of decontamination?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1 7.5.2	4.9 (4.9)	6.2	5.2.6
17. Are production employees neat in their appearance, with unnecessary jewelry and cosmetics kept out of the production areas?	☐ ☐ ☐ ☐ ☐	4.9 4.18	6.2.2 7.5.1	4.9 4.18 (4.9) (4.18)	1.3 6.2	5.2.6
18. Are any special requirements for specific operator apparel (e.g., masks, gown, etc.) being violated?	☐ ☐ ☐ ☐ ☐	4.9 4.18	4.2.4 6.2.2 7.5.1	4.9 4.18 (4.9) (4.18)		6.2
19. Is there a formal record of production steps and quantities used?	☐ ☐ ☐ ☐ ☐	4.8 4.9 4.10.2 4.10.4 4.16	4.2.4 7.5.1	4.8 4.9 4.10.2 4.10.4 4.16 (4.8) (4.9) (4.10.2) (4.10.4) (4.16)		3.4
20. Are waste materials clearly identified in proper containers?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1 8.3	4.9 (4.9)		5.2.11 5.2.12
21. Are the ceiling fixtures and pipes free of accumulated dirt?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	1.3 6.2	5.2.6
22. Are valves and associated pipes in the production areas free of leaks?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	1.3 6.2	5.2.6
23. Are the ceilings and walls in good condition to prevent contamination from paint chips?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	1.3 6.2	5.2.6

ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US-MIL-Q-9858A	US-MIL-STD-790
D. Manufacturing Facilities, Equipment and Control						
24. Are appropriate bathroom facilities available?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9)	1.3 6.2	
25. Are smoking and eating prohibited where necessary?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9	1.3 6.2	
26. Is there an adequate pest-control program?	☐ ☐ ☐ ☐ ☐	4.9	7.5.1	4.9 (4.9	1.3 6.2	
27. Are the in-process inspection and test procedures adequate?	☐ ☐ ☐ ☐ ☐	4.10.3 4.10.4 4.11 4.16	8.2.4	4.10.3 4.10.4 4.11 4.16 (4.10.3) (4.10.4) (4.11) (4.16)	6.2 6.3	5.1.2 5.2.4 5.2.7 5.2.15
28. Are there adequate specifications (including a classification of defects) to control in-process materials?	☐ ☐ ☐ ☐ ☐	4.10.3	8.2.4	4.10.3 (4.10.3)	6.6	5.2.7
29. Is statistical process control (SPC) utilized, where appropriate, to assure production quality?	☐ ☐ ☐ ☐ ☐	4.20	8.1	4.20 (4.20)	6.6	
30. If in-process material is rejected, is there an indication of the reason?	☐ ☐ ☐ ☐ ☐	4.13 4.13.1 4.14	8.3 8.5.2 8.5.3	4.13 4.13.1 4.14 (4.13) (4.13.1) (4.14)	3.5 6.5 6.7	5.2.4 5.2.15
31. If in-process material is rejected, is there a corrective action indicated to prevent the same problem from recurring?	☐ ☐ ☐ ☐ ☐	4.14	8.5.2 8.5.3	4.14 (4.14)	3.5 6.5 6.7	5.2.4 5.2.5

Total Number of Boxes Checked for Section D 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US-MIL-Q-9858A	US-MIL-STD-790
E. Final Acceptance and Distribution						
1. How adequate are the procedures for final-product inspection, sampling, and testing?	☐ ☐ ☐ ☐ ☐	4.10.4	8.2.4	4.10.4 (4.10.4)	6.3	5.1.2 5.2.7 5.2.10 5.2.12.1
2. Are final inspection/test results recorded?	☐ ☐ ☐ ☐ ☐	4.10.4 4.10.5	4.2.4 8.2.4	4.10.4 4.10.5 (4.10.4) (4.10.5)	3.4 6.3	5.2 5.2.10 5.2.12.1
3. How adequate is the final review of the production-documentation package?	☐ ☐ ☐ ☐ ☐	4.12 4.16	8.2.4	4.12 4.16 (4.12) (4.16)	3.4 6.3	5.2.15
4. Are production-documentation packages stored properly and retained for an adequate length of time?	☐ ☐ ☐ ☐ ☐	4.16	4.2.4	4.16 (4.16)	3.4	5.2 5.2.15
5. Are discrepancies found during the final review properly investigated?	☐ ☐ ☐ ☐ ☐	4.13	8.3	4.13 (4.13)	3.5 6.5	5.2.4 5.2.4.1
6. How adequate is the procedure for release of product?	☐ ☐ ☐ ☐ ☐	4.2 4.10.4 4.12	7.5.3 8.2.4	4.2 4.10.4 4.12 (4.2) (4.10.4) (4.12)	1.3 3.1 6.2 6.5	5.2.15
7. How well is final-product material identified and segregated?	☐ ☐ ☐ ☐ ☐	4.8 4.15.2 4.15.5	7.5.3 7.5.5	4.8 4.15.2 4.15.5 (4.8) (4.15.2) (4.15.5)	6.7	5.2.12 5.2.13
8. How well is nonconforming material controlled?	☐ ☐ ☐ ☐ ☐	4.13	8.3	4.13 (4.13)	6.5	5.2.12.3
9. Do adequate facilities exist to store materials awaiting shipment?	☐ ☐ ☐ ☐ ☐	4.15.3	7.5.5	4.15.3 (4.15.3)	6.4	5.2.11 5.2.12 5.2.14
10. Where appropriate, how adequate is controlled access to final-product stockrooms and material-storage areas?	☐ ☐ ☐ ☐ ☐	4.15.1 4.15.3	7.5.5	4.15.1 4.15.3 (4.15.1) (4.15.3)	6.4	5.2.11 5.2.14
11. Are the shipping containers sufficiently marked to identify the contents?	☐ ☐ ☐ ☐ ☐	4.8 4.15.4 4.15.5	7.5.5	4.8 4.15.4 4.15.5 (4.8) (4.15.4) (4.15.5)	6.4 6.7	5.2.11 5.2.14

ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US-MIL-Q-9858A	US-MIL-STD-790
E. Final Acceptance and Distribution (continued)						
12. How well are items with shelf-life requirements identified and controlled?	□ □ □ □ □	4.15.3	7.5.5	4.15.3 (4.15.3)	6.4	5.2.12.1
13. If "clean room" operations are performed, is the final sampling and inspection of the parts performed in the same area or some other area with clean-room controls?	□ □ □ □ □	4.9 4.10.3 4.11	7.5.1 7.5.5		6.2 6.3 6.7	5.2.6

Total Number of Boxes Checked for Section E 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US-MIL-Q-9858A	US-MIL-STD-790
F. Laboratories and Calibration						
Questions in this section are applicable to any testing or inspection function regardless of where it occurs (e.g., QC, Mfg., Eng., etc.)						
1. Does the quality-control department appear to have sufficient equipment and facilities?	□ □ □ □ □	4.1.2	5.5.1 6.1 6.2	4.1 (4.1) <5.3> <5.5>	1.3 3.1 4.2 4.5	5.1.1 5.1.2
2. Are samples that are brought into the quality control laboratory from incoming, in-process, and final-product materials properly controlled?	□ □ □ □ □	4.10.1 4.10.2 4.10.3	7.4.3 8.2.4	4.10.1 4.10.2 4.10.3 (4.10.1) (4.10.2) (4.10.3) <5.4> <5.7>	5.1 6.1 6.2 6.3 6.6	5.2.10
3. Are all tests/inspections properly documented?	□ □ □ □ □	4.10.4 4.10.5	4.2.4 7.4.3 8.2.4	4.10.4 4.10.5 (4.10.4) (4.10.5) <5.4> <5.5> <5.10>	3.4	5.2.10
4. Are certificates of inspection/test results available to the customers?	□ □ □ □ □	4.3 4.6.1	5.2 8.2.1	4.3 4.6.1 (4.3) (4.6.1)		5.2.10
5. Are there acceptable procedures to assure that gauges, tools, and test equipment are maintained in proper order?	□ □ □ □ □	4.11	7.6	4.11 (4.11) <5.3> <5.4> <5.5> <5.6>	4.2 4.3 4.5	5.1.2 5.2.2
6. Is there a system to assure that gauges (including "go-no-go" gauges) and testing equipment are calibrated on a periodic basis?	□ □ □ □ □	4.11	7.6	4.11 (4.11) <5.3> <5.4> <5.5><5.6>	4.2 4.3 4.5	5.1.2 5.2.2
7. If calibration is performed by the facility, are these calibration procedures formalized and traceable to appropriate standards?	□ □ □ □ □	4.11	7.6	4.11 (4.11) <5.3> <5.4.> <5.5> <5.6>	3.3 4.2 4.3 4.5	5.1.2 5.2.2

ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US-MIL-Q-9858A	US-MIL-STD-790
F. Laboratories and Calibration (continued)						
8. If external sources are utilized for calibration, have the sources been audited to assure competence?	□ □ □ □ □	4.6.2 4.11	7.4.1 7.6	4.6.2 4.11 (4.6.2) (4.10) <4.5>	1.3 4.2 4.3 4.5 5.1	

Total Number of Boxes Checked for Section F 3 _____ 2 _____ 1 _____ 0 _____ NA _____

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ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US-MIL-Q-9858A	US-MIL-STD-790
G. Document Control						
1. Are the specifications and other documents comprehensive in content?	☐ ☐ ☐ ☐ ☐	4.2 4.4.4	4.2.1 4.2.3 7.2.1 7.3.2	4.2 4.4.4 (4.2) <4.3.1>	3.3 4.1	5.2
2. Are the documents current, and are unneeded/obsolete documents removed from usage?	☐ ☐ ☐ ☐ ☐	4.5.1	4.2.3	4.5.1 (4.5.1)	3.3 4.1	
3. Do written procedures exist that address a change-control system for documents, and are the procedures being followed?	☐ ☐ ☐ ☐ ☐	4.5	4.2.3	4.5 (4.5)	3.3 4.1	5.2.17
4. Are there documentation and "flow charts" that address:						5.2.7
a. A listing of process-control equipment?	☐ ☐ ☐ ☐ ☐					
b. Records of periodic calibration?	☐ ☐ ☐ ☐ ☐					
c. Control of chemical purity and ionization of water?	☐ ☐ ☐ ☐ ☐					
d. Composition of all gases and chemicals used in the processes, and control of fabrication?	☐ ☐ ☐ ☐ ☐					
e. Definition of controlled-environment requirements?	☐ ☐ ☐ ☐ ☐					
f. Process specifications and tolerances?	☐ ☐ ☐ ☐ ☐					
g. Part specifications?	☐ ☐ ☐ ☐ ☐					
h. Inspection operations?	☐ ☐ ☐ ☐ ☐					
i. Identification of production lots through all phases with a date or lot code?	☐ ☐ ☐ ☐ ☐					
j. All manufacturing, inspections, and testing results?	☐ ☐ ☐ ☐ ☐					
k. Points where all materials and subassemblies enter the process flow?	☐ ☐ ☐ ☐ ☐					
l. Identification of all pertinent documents, by name and number, pertaining to the production and quality control points and processes?	☐ ☐ ☐ ☐ ☐					

Total Number of Boxes Checked for Section G 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US-MIL-Q-9858A	US-MIL-STD-790
H. Training and InternalAudit						
1. Is there a training program for all employees in appropriate areas?	□ □ □ □ □	4.16 4.18	6.2.2	4.16 4.18 (4.16) (4.18) <5.2>	1.3 3.1 3.3	5.2.1
2. Is there a program for periodic retraining?	□ □ □ □ □	4.18	6.2.2	4.18 (4.18)		5.2.1
3. Is there a formal procedure for performing internal quality audits? ISO 10011–3, Part 4.6.3	□ □ □ □ □	4.1 4.17	5.5.1 5.6.1 8.2.2 8.5.1	4.1 4.17 (4.1) (4.17) <4.13>		A.3.1 A.3.7
4. Are audits performed by properly educated, trained, and experienced individuals not having direct responsibility for that which is being audited? ISO 10011–1, Part 4.2.1.4 ISO 10011–2, Part 4.0 ISO 10011–2, Part 6.0 RISO 10011–3, Part 4.1 RISO 10011–3, Part 4.3.1 RISO 10011–3, Part 4.5.3	□ □ □ □ □	4.17 4.18	8.2.2 8.2.3	4.1 4.17 (4.1) (4.17) <4.13>		A.3.2
5. Is there an audit plan that includes: a. Objective/scope of audit? b. Date and items to be audited? c. Applicable standards/regulations? d. Provision for an opening and closing meeting? ISO 10011–1, Part 5.2.1 ISO 10011–3, Part 4.2	□ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □	4.17	8.2.2 8.2.3	4.17 (4.17)		A.3.5 A.3.7
6. Is there a formal audit report that details the observations requiring corrective and preventive action? ISO 10011–1, Part 5.2.1 ISO 10011–1, Part 5.3.2.2 ISO 10011–3, Part 4.2 RISO 10011–3, Part 4.5.3	□ □ □ □ □	4.1 4.17	5.5.1 8.2.2 8.2.3	4.1 4.17 (4.1) (4.17) <4.9> <4.10> <4.11> <4.13>		A.3.6

ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US-MIL-Q-9858A	US-MIL-STD-790
H. Training and InternalAudit						
7. Are documented corrective and preventive actions taken on audit observations? ISO 10011–1, Part 7.0 ISO 10011–3, Part 4.6.5	□ □ □ □ □	4.1 4.14 4.16 4.17	4.2.4 5.5.1 5.6.2 8.2.7 8.5.2 8.5.3	<4.9> <4.10> <4.11> <4.13> 4.1 4.14 4.16 4.17 (4.1) (4.14) (4.16) (4.17)		A.3.3 A.3.4

Total Number of Boxes Checked for Section H 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US-MIL-Q-9858A	US-MIL-STD-790
I. Quality Assurance and Management Review						
1. Is there a formal statement by the management of the company of the corporate quality policy?	□ □ □ □ □	4.1	5.1 5.3 5.4.1	4.1 (4.1) <4.2>	1.3 3.1	
2. Is there a "quality system" that addresses the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management?	□ □ □ □ □	4.1 4.2	4.1 5.5.1	4.1 4.2 (4.1) (4.2) <4.2>	1.3 3.1	4.1 5.2
3. Is there a "Quality Manual" that addresses the "quality system"?	□ □ □ □ □	4.1 4.2	4.2.1 4.2.2	4.1 4.2 (4.1) (4.2) <4.2>	1.3 3.1	
4. Are there periodic management reviews of the quality system and are the following inputs included:		4.1 4.16	4.1 4.2.4 5.6.1 5.6.2 8.5.1	4.1 4.16 (4.1) (4.16) <4.14>	3.1	5.2.4
a. Results of audits?	□ □ □ □ □					
b. Customer feedback?	□ □ □ □ □					
c. Process performance and product conformity?	□ □ □ □ □					
d. Status of corrective and preventive actions?	□ □ □ □ □					
e. Follow-up actions from previous management reviews?	□ □ □ □ □					
f. Changes that could affect the quality-management system?	□ □ □ □ □					
g. Recommendations for improvements?	□ □ □ □ □					
5. Does the organization analyze appropriate data to demonstrate the suitability and effectiveness of the quality-management system in regards to the following:			8.4	<4.14>		5.2.4
a. Customer satisfactions?	□ □ □ □ □					
b. Conformity to product requirements?	□ □ □ □ □					
c. Trends of processes and products, including opportunities for preventive action?	□ □ □ □ □					
d. Suppliers?	□ □ □ □ □					
6. Does top management provide communication within the organization regarding the effectiveness of the quality-management system?	□ □ □ □ □		5.5.3	<4.14>		
7. Does the quality-control function appear to have the independence necessary to make decisions without fear of political repercussions?	□ □ □ □ □	4.1	4.1 5.5.2	4.1 (4.1) <4.1>	1.3 3.1 4.1	

ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

Total Number of Boxes Checked for Section I 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

Audited by _____

ELECTRONIC COMPONENT SUPPLIER AUDIT CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488) ISO <17025>	US-MIL-Q-9858A	US-MIL-STD-790
J. Other Considerations						
1. Does there appear to be a desirable administrative attitude toward our requirements?	□ □ □ □ □	4.1 4.2 4.3	5.2	4.1 4.2 4.3 (4.1) (4.2) (4.3) <4.7>	1.3 3.2	
2. Is there a clear understanding of our requirements and needs?	□ □ □ □ □	4.2 4.3	5.2 6.2.2 6.3	4.2 4.3 (4.2) (4.3) <4.7>	3.2	
3. Does there appear to be sufficient engineering, production, and quality control support to meet our needs?	□ □ □ □ □	4.2 4.3	5.2 6.2.2 6.3	4.2 4.3 (4.2) (4.3) <4.1.5> <5.2.1>	1.3 3.1	
4. How well does the company maintain the entire facility in general?	□ □ □ □ □	4.9	6.3 7.5.1	4.9 (4.9) <5.3>	1.3 6.2	
5. Does there appear to be sufficient administrative commitment to adequately staff departments?	□ □ □ □ □	4.1 4.18	6.1 6.2.1	4.1 4.18 (4.1) (4.18) <4.1.5>		
6. Does the facility appear to be operating in such a manner that a shutdown or sale of the operation is not imminent?	□ □ □ □ □	4.2 4.3	5.2			

Total Number of Boxes Checked for Section J 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

QSIT AUDIT FOR MEDICAL DEVICES

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR MEDICAL DEVICES CHECKLIST

Scope: This audit checklist is intended for use in simulating the new process being used by the United States Food and Drug Administration (FDA) for inspection of medical device companies. The inspection technique consists of inspecting per a specific sequence of activities. The checklist is therefore organized as follows to simulate that sequence.

This checklist covers the following areas:

A. Management Controls

B. Design Control

C. Corrective and Preventive Action

D. Corrective and Preventive Action—Medical Device Reporting

E. Corrective and Preventive Action—Corrections and Removals (Recalls)

F. Medical Device Tracking

G. Production- and Process-Control Systems

Note: FDA identifies seven key subsystems as part of the Quality system, but does not include three of them in QSIT because of time constraints. These three subsystems are:

- *Equipment Facility Controls*
- *Records, Documents, and Change Controls*
- *Material Controls*

QSIT inspections may easily lead into these three areas even though they are not the prime focus initially.

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR MEDICAL DEVICES CHECKLIST

Date(s) of Simulated Inspection _____

Facility Location Name _____

Address _____

Inspection Leader Name _____

Title _____

Inspection Team Members

Name _____

Function on Team _____

Name _____

Function on Team _____

Name _____

Function on Team _____

Product for Inspection

List No.

(or other identifying number) _____

Size _____

Strength _____

Package Type _____

Lot Numbers _____

Size _____

Primary Individuals Contacted

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

Name _____ Title _____

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR MEDICAL DEVICES CHECKLIST

Opening Meeting Date _____

Attendees _____

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Closing Meeting Date _____

Attendees _____

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Audit Report Date Issued _____

Date Response Received _____

Date Response and Action Plan Approved _____

Date Actions Completed _____

Date Completed Actions Verified as Completed _____

Date Completed Actions Verified as Effective _____

Date Closed Out _____

Future Follow-up Items _____

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QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR MEDICAL DEVICES CHECKLIST

QUALITY RATING SYSTEM

Rating	*Meaning*	*Interpretation*
3	Excellent	Item/area/system/knowledge is superior
2	Adequate	Item/area/system/knowledge meets basic minimum requirements.
1	Deficient	Item/area/system/knowledge is weak and not up to acceptable standards.
0	Unsatisfactory	Item/area/system/knowledge is missing or of a nature to warrant serious quality/compliance concerns.
NA	Not Applicable	Question is not applicable to type of operation, or item unable to be addressed during the audit.

Comment: Some users of the checklist may find the responses to some questions difficult to quantify on a 0–3 scale and may prefer to use a simple "yes" or "no" approach. In such cases, a "yes" should be assigned a "2" value, and a "no" should be assigned a "0" value.

CHECKLIST RESULTS AND RATING

	Number of Occurrences			
Section	**3s**	**2s**	**1s**	**0s**
A. Management Controls				
B. Design Control				
C. Corrective and Preventive Action				
D. Corrective and Preventive Action—Medical Device Reporting				
E. Corrective and Preventive Action—Corrections and Removals (Recalls)				
F. Medical Device Tracking				
G. Production- and Process-Control Systems				
Totals				

Audit Findings Summary

Number of questions rated excellent ( ) Times 3 = ( )
Number of questions rated adequate ( ) Times 2 = ( )
Number of questions rated deficient ( ) Times 1 = ( )
Number of questions rated unsatisfactory (_____) Times 0 = (_____)

Total Number of Questions Answered = (_____) Rating Total = (_____)

"Rating Total" divided by "Number of Questions Answered" = _____ Audit Rating

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR MEDICAL DEVICES CHECKLIST

I. Strengths

1. _____
2. _____
3. _____
4. _____
5. _____

II. Weaknesses

1. _____
2. _____
3. _____
4. _____
5. _____

III. Recommendations

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QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR MEDICAL DEVICES CHECKLIST

	Rating 3 2 1 0 NA
A. Management Controls (US Quality System Regulation 820.20)	
Note: Normal auditing technique consists of reviewing policies, procedures, and associated quality records to determine compliance. It also includes asking the person providing the information a series of questions. The QSIT approach goes beyond this technique by posing the questions to executive management or, where appropriate, the Management Representative. Where a question should be posed to the Management Representative or other executives, the question is following by an asterisk.*	
1. Is there a written quality policy?	☐ ☐ ☐ ☐ ☐
2. Are people familiar with the quality policy? They need not be able to recite it, but need to be familiar with it.	☐ ☐ ☐ ☐ ☐
3. Does the quality policy reflect the overall intentions and directions of the organization in regards to quality?*	☐ ☐ ☐ ☐ ☐
4. Does the quality policy have clear, achievable objectives?*	☐ ☐ ☐ ☐ ☐
5. How are the objectives translated into actual methods and procedures?	☐ ☐ ☐ ☐ ☐
6. How does management with executive responsibility assure that the policy and objectives are understood and implemented at all levels of the organization?*	☐ ☐ ☐ ☐ ☐
7. Is the quality policy readily available, and is there a record showing that employees have been trained in the quality policy and objectives?	☐ ☐ ☐ ☐ ☐
8. Are there procedures for conducting management reviews?	☐ ☐ ☐ ☐ ☐
9. Are there procedures for conducting internal audits?	☐ ☐ ☐ ☐ ☐
10. Is there a written quality plan that defines the quality practices, resources, and activities? *Note: Quality plans may be specific to one device or generic to all devices. They can also be specific to processes or overall systems.*	☐ ☐ ☐ ☐ ☐
11. Are there organizational charts that reveal the authority and responsibility of individual positions? *Note: Begin this process with the highest-level organization chart and work down.*	☐ ☐ ☐ ☐ ☐
12. Is there a designated individual who acts as the Management Representative?	☐ ☐ ☐ ☐ ☐
13. Is the Management Representative indicated on all of the organizational charts?	☐ ☐ ☐ ☐ ☐
14. Do the organizational charts provide insight into the independence and authority needed to manage, perform, or assess work affecting quality?	☐ ☐ ☐ ☐ ☐
15. Is the Management Representative able to describe the process for obtaining financial and human resources?*	☐ ☐ ☐ ☐ ☐
16. Does the appointed Management Representative have the responsibility and authority to:	
a. Sign off on changes to documents?	☐ ☐ ☐ ☐ ☐
b. Sign off on changes to processes?	☐ ☐ ☐ ☐ ☐
c. Sign off on product designs?	☐ ☐ ☐ ☐ ☐
d. Review internal audit findings?	☐ ☐ ☐ ☐ ☐
e. Interact with corrective and preventive actions?	☐ ☐ ☐ ☐ ☐
f. Interact with design-control issues?	☐ ☐ ☐ ☐ ☐
g. Interact with complaints?	☐ ☐ ☐ ☐ ☐
h. Interact with Medical Device Reports (MDRs)?	☐ ☐ ☐ ☐ ☐
i. Interact with in-process or final-product failures?	☐ ☐ ☐ ☐ ☐

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR MEDICAL DEVICES CHECKLIST

	Rating 3 2 1 0 NA
A. Management Controls (US Quality System Regulation 820.20) (continued)	
17. Is the Management Representative reporting on the performance of the quality system to management with executive responsibility?*	☐ ☐ ☐ ☐ ☐
18. Are formal Management Reviews being performed frequently enough to keep them informed of ongoing quality issues and problems? *Note: The basic sense of acceptability with the FDA appears to be "at least quarterly."*	☐ ☐ ☐ ☐ ☐
19. Is there a method to provide the dates of the management reviews without providing the actual reviews themselves?	☐ ☐ ☐ ☐ ☐
20. Is there an adequate internal audit schedule? *Note: The FDA expectation has been that all sections of the Quality System Regulation be covered within a 12-month period each year.*	☐ ☐ ☐ ☐ ☐
21. Are audits performed per an adequately detailed procedure? *Note: Author's experience has been that a comprehensive checklist is well received by the FDA. It helps demonstrate the comprehensiveness and objectivity of the auditing, of which the FDA must ascertain the status without looking at audit reports.*	☐ ☐ ☐ ☐ ☐
22. Are audits performed by qualified individuals who are independent of the areas being audited? *Note: If significant system deficiencies are noted in other areas, the audit system can also be determined to be deficient for not finding such problems.*	☐ ☐ ☐ ☐ ☐
23. Is there provision for review of audit findings in the Management Review?	☐ ☐ ☐ ☐ ☐
24. Is there provision for reaudit of deficient areas?	☐ ☐ ☐ ☐ ☐
25. Is there an adequate system for follow-up from audit observations on corrective and preventive actions?	☐ ☐ ☐ ☐ ☐

Total Number of Boxes Checked for Section A 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR MEDICAL DEVICES CHECKLIST

	Rating 3 2 1 0 NA
B. Design Control (US Quality System Regulation 820.30)	
Select two or three products and audit against the following criteria: *Note: Inspectors will select products pending FDA approval or those that they think have been problematic in terms of quality, safety, and efficacy. Auditors should do the same.*	
1. Is there a design plan that includes:	
a. Major design tasks?	☐ ☐ ☐ ☐ ☐
b. Project milestones?	☐ ☐ ☐ ☐ ☐
c. Key decision points?	☐ ☐ ☐ ☐ ☐
d. Provision for the conduct of risk analysis throughout the design process?	☐ ☐ ☐ ☐ ☐
2. Does the design plan define responsibility for implementation of the design and development activities?	☐ ☐ ☐ ☐ ☐
3. Does the design plan define the interfaces with different groups or activities?	☐ ☐ ☐ ☐ ☐
4. Are copies of the design plan maintained in a Design History File?	☐ ☐ ☐ ☐ ☐
5. When conducting risk analysis, does it include possible hazards associated with the design in both normal and fault conditions? *Note: The FDA expectation is Fault Tree Analysis (FTA) or Failure Modes and Effects Analysis (FMEA).*	☐ ☐ ☐ ☐ ☐
6. Are there formal inputs for the device design, and do they include the following relevant aspects:	
a. Intended use?	☐ ☐ ☐ ☐ ☐
b. Performance characteristics?	☐ ☐ ☐ ☐ ☐
c. Risk?	☐ ☐ ☐ ☐ ☐
d. Biocompatibility?	☐ ☐ ☐ ☐ ☐
e. Compatibility with the environment of intended use, including:	
i. Human factors?	☐ ☐ ☐ ☐ ☐
ii. Voluntary standards?	☐ ☐ ☐ ☐ ☐
iii. Sterility?	☐ ☐ ☐ ☐ ☐
iv. Electromagnetic compatibility?	☐ ☐ ☐ ☐ ☐
7. Are the design inputs retained in a Design History File?	☐ ☐ ☐ ☐ ☐
8. Are there formal design outputs or deliverables, such as:	
a. Diagrams?	☐ ☐ ☐ ☐ ☐
b. Drawings?	☐ ☐ ☐ ☐ ☐
c. Specifications?	☐ ☐ ☐ ☐ ☐
d. Procedures?	☐ ☐ ☐ ☐ ☐
e. The device?	☐ ☐ ☐ ☐ ☐
f. Packaging?	☐ ☐ ☐ ☐ ☐
g. Labeling?	☐ ☐ ☐ ☐ ☐
h. Device master record?	☐ ☐ ☐ ☐ ☐
9. Were the design outputs comprehensive enough to characterize the device design to allow for verification and validation?	☐ ☐ ☐ ☐ ☐
10. Are the design outputs maintained in a Design History File?	☐ ☐ ☐ ☐ ☐
11. Was an acceptance criteria established before verification and validation activities began?	☐ ☐ ☐ ☐ ☐
12. Did the design-verification activities provide objective evidence that design outputs met the design-input requirements?	☐ ☐ ☐ ☐ ☐

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR MEDICAL DEVICES CHECKLIST

	Rating 3 2 1 0 NA
B. Design Control (US Quality System Regulation 820.30) (continued)	
13. Did the verification include tests, inspections, analyses, measurements, or demonstrations?	☐ ☐ ☐ ☐ ☐
14. Was design validation completed before commercialization of the product?	☐ ☐ ☐ ☐ ☐
15. Did the design validation include clinical evaluations and testing under actual- or simulated-use conditions?	☐ ☐ ☐ ☐ ☐
16. Did the validation address all of the relevant intended uses?	☐ ☐ ☐ ☐ ☐
17. Did the validation address the human-factor implications of the labeling and packaging?	☐ ☐ ☐ ☐ ☐
18. Did all detected discrepancies between the device specifications (outputs) and the needs of the intended user or use of the device get addresses and resolved?	☐ ☐ ☐ ☐ ☐
19. If the device contained software, was it validated?	☐ ☐ ☐ ☐ ☐
20. Did the validation include a risk analysis?	☐ ☐ ☐ ☐ ☐
21. Were design validations accomplished using initial-production devices or their equivalents? *Note: It is acceptable to perform process validation on design-validation batches.*	☐ ☐ ☐ ☐ ☐
22. Are design-validation protocols and results retained in the Design History File?	☐ ☐ ☐ ☐ ☐
23. Is there a design change-control system that begins with the initial design inputs and continues through the life of the product?	☐ ☐ ☐ ☐ ☐
24. Were any design changes verified and validated?	☐ ☐ ☐ ☐ ☐
25. Were all design changes retained in the Design History File?	☐ ☐ ☐ ☐ ☐
26. Were formal design reviews performed at the end of each design phase and retained in the Design History File?	☐ ☐ ☐ ☐ ☐
27. Did design reviews include risk analysis and action items that were completed?	☐ ☐ ☐ ☐ ☐
28. Was the design correctly transferred through the generation of:	
a. Drawings?	☐ ☐ ☐ ☐ ☐
b. Inspection and test specifications?	☐ ☐ ☐ ☐ ☐
c. Manufacturing instructions?	☐ ☐ ☐ ☐ ☐
d. Electronic records?	☐ ☐ ☐ ☐ ☐
e. Training materials?	☐ ☐ ☐ ☐ ☐
f. Device master record?	☐ ☐ ☐ ☐ ☐
g. Process validation?	☐ ☐ ☐ ☐ ☐
29. Was documentation from the design-transfer process retained in the Design History File?	☐ ☐ ☐ ☐ ☐

Total Number of Boxes Checked for Section B 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR MEDICAL DEVICES CHECKLIST

	Rating 3 2 1 0 NA
C. Corrective and Preventive Action (US Quality System Regulation 820.100)	
1. Is there a procedure for correcting a quality problem and preventing recurrence? This is commonly referred to as a "CAPA" system.	☐ ☐ ☐ ☐ ☐
2. Are the terms "nonconforming product," "correction," "corrective action" and "preventive action," defined?	☐ ☐ ☐ ☐ ☐
3. If the word "timely" is used in place of specific time frames, is there a definition of "timely"?	☐ ☐ ☐ ☐ ☐
4. Is there an adequate system to input the following types of nonconformance, noncompliance or other quality-concern information into the CAPA system:	
a. All acceptance activities?	☐ ☐ ☐ ☐ ☐
b. Complaints?	☐ ☐ ☐ ☐ ☐
c. Servicing?	☐ ☐ ☐ ☐ ☐
d. Installations?	☐ ☐ ☐ ☐ ☐
e. Returned goods?	☐ ☐ ☐ ☐ ☐
f. Component testing?	☐ ☐ ☐ ☐ ☐
g. In process testing?	☐ ☐ ☐ ☐ ☐
h. Final-device testing?	☐ ☐ ☐ ☐ ☐
i. Quality-record deficiencies?	☐ ☐ ☐ ☐ ☐
j. Quality audits?	☐ ☐ ☐ ☐ ☐
k. On market stability-testing failures?	☐ ☐ ☐ ☐ ☐
l. Lawsuits?	☐ ☐ ☐ ☐ ☐
5. Is the previously mentioned CAPA information being reviewed routinely as part of Management Reviews?	☐ ☐ ☐ ☐ ☐
6. Based on historical records such as trending data, corrective actions, acceptance-activity records and other quality-system records, are unfavorable trends existing? *Note: The FDA will use the company's trending data to determine what direction to proceed with further investigation. FDA will also ask for objective evidence that negative trends have been an item on the Management Review agenda. Auditors should do the same.*	☐ ☐ ☐ ☐ ☐
7. If unfavorable trends exist, have preventive actions previously taken not been effective?	☐ ☐ ☐ ☐ ☐
8. If CAPA data is entered into a system, is it traceable and has the transfer of information been complete/accurate?	☐ ☐ ☐ ☐ ☐
9. In the analysis of problems, is there consideration given to whether the problem could also be occurring on other products, or in other areas or manufacturing sites?	☐ ☐ ☐ ☐ ☐
10. Does the analysis include comparison of acceptance-activity nonconformances with field-quality data (complaints) to see if there is a correlation?	☐ ☐ ☐ ☐ ☐
11. Are statistical techniques used in analyzing problems? Examples:	
a. Pareto analysis	☐ ☐ ☐ ☐ ☐
b. Spreadsheets	☐ ☐ ☐ ☐ ☐
c. Pie charts	☐ ☐ ☐ ☐ ☐
12. Are nonstatistical techniques used in analyzing problems? Examples:	
a. Quality-review boards	☐ ☐ ☐ ☐ ☐
b. Quality-review committees	☐ ☐ ☐ ☐ ☐

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR MEDICAL DEVICES CHECKLIST

	Rating 3 2 1 0 NA
C. Corrective and Preventive Action (US Quality System Regulation 820.100) (continued)	
13. Does the analysis of problems include a failure investigation and determination of the probability of reoccurrence and the significance of risk before CAPA is initiated?	☐ ☐ ☐ ☐ ☐
14. Is there a procedure that details how and to what degree to perform an investigation, depending on the type of problem?	☐ ☐ ☐ ☐ ☐
15. In situations where no CAPA was indicated, was there a sound justification for not taking action?	☐ ☐ ☐ ☐ ☐
16. Based on the available system, select individual CAPAs. Were the actions taken verified for completion and evaluated later for effectiveness?	☐ ☐ ☐ ☐ ☐
17. Where appropriate, were the actions taken validated? Example: process change.	☐ ☐ ☐ ☐ ☐
18. Viewing complaint-trend data, have quality-problem CAPAs resulted in a decrease of the complaint occurring?	☐ ☐ ☐ ☐ ☐

Total Number of Boxes Checked for Section C 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR MEDICAL DEVICES CHECKLIST

	Rating 3 2 1 0 NA
D. Corrective and Preventive Action – Medical Device Reporting US Quality System Regulation (820.198), US 21 CFR Sections 803.17 and 803.18	
1. Does the company have a written MDR (Medical Device Report) procedure that addresses the following:	
a. Timely and effective identification, communication, and evaluation of events that may potentially be reportable?	☐ ☐ ☐ ☐ ☐
b. A review process for determining whether the event is reportable?	☐ ☐ ☐ ☐ ☐
c. Timely transmission of reportable events to the FDA?	☐ ☐ ☐ ☐ ☐
d. Documentation and record keeping for the information that was evaluated to determine whether an event was reportable?	☐ ☐ ☐ ☐ ☐
e. All associated information submitted to the FDA?	☐ ☐ ☐ ☐ ☐
2. Does the company establish and maintain MDR event files for the following:	
a. Information from any source that describes a device-related death, serious injury, or malfunction?	☐ ☐ ☐ ☐ ☐
b. The company's evaluation of the information, including decisions to submit or not submit?	☐ ☐ ☐ ☐ ☐
c. Supporting documentation, such as failure analysis, lab reports, etc.?	☐ ☐ ☐ ☐ ☐
d. Decisions not to submit for a device-related death, serious injury, or malfunction?	☐ ☐ ☐ ☐ ☐
Note: The company should assume that the FDA will be aware of and have copies of MDRs that they will use to provide direction on the inspection. Auditors should obtain the MDRs before auditing and also use them as a guide.	
3. Does the company retain the MDR files for 2 years or the life of the device, whichever is greater?	☐ ☐ ☐ ☐ ☐

Total Number of Boxes Checked for Section D 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR MEDICAL DEVICES CHECKLIST

	Rating 3 2 1 0 NA
E. Corrective and Preventive Action—Corrections Removals (Recalls) 21 CFR Section 806.10	
1. Is there a procedure that requires all corrections and removals to be reported to the appropriate FDA District Office within 10 days of initiating the action?	☐ ☐ ☐ ☐ ☐
2. Based on review of files, has the 10-day requirement been complied with?	☐ ☐ ☐ ☐ ☐
3. Do the files contain evidence that the following have been provided to the FDA:	
a. The 7-digit registration number of the entity responsible for submission of the report?	☐ ☐ ☐ ☐ ☐
b. The month, day, and year that the report was made?	☐ ☐ ☐ ☐ ☐
c. A sequential numbering system for MDRs (e.g., 001, 002)?	☐ ☐ ☐ ☐ ☐
d. Name, address, and telephone number of manufacture?	☐ ☐ ☐ ☐ ☐
e. Brand name, classification name, or usual name of the device?	☐ ☐ ☐ ☐ ☐
f. Intended use of the device?	☐ ☐ ☐ ☐ ☐
g. Marketing status of the device?	☐ ☐ ☐ ☐ ☐
h. Model, catalog, or code number of the device?	☐ ☐ ☐ ☐ ☐
i. Manufacturing lot or serial number of the device(s)?	☐ ☐ ☐ ☐ ☐
j. Description of events leading to correction and removal?	☐ ☐ ☐ ☐ ☐
k. List of illnesses or injuries that have occurred?	☐ ☐ ☐ ☐ ☐
l. Total number of devices manufactured or distributed?	☐ ☐ ☐ ☐ ☐
m. Date of manufacture?	☐ ☐ ☐ ☐ ☐
n. Date of distribution?	☐ ☐ ☐ ☐ ☐
o. Expiration date or expected device life?	☐ ☐ ☐ ☐ ☐
p. Names, addresses, and telephone numbers of distributors?	☐ ☐ ☐ ☐ ☐
q. Copies of all communications?	☐ ☐ ☐ ☐ ☐

Note: The FDA will use actual recalls to guide them through retrieval of actual case information. Auditors should do the same.

Total Number of Boxes Checked for Section E 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR MEDICAL DEVICES CHECKLIST

	Rating 3 2 1 0 NA
F. Medical Device Tracking *Note: The following checklist is applicable if the company manufactures or imports a medical device subject to the Medical Device Tracking Regulation (21 CFR 821.25).*	
1. Is the company aware of its obligation to notify the FDA if it goes out of business, transfers the product to a purchaser, or discontinues manufacture?	☐ ☐ ☐ ☐ ☐
2. Is there a procedure that addresses the following:	
a. Ability to retrieve from all internal and distributor locations within a 3-working-day request time frame devices that have not been distributed?	☐ ☐ ☐ ☐ ☐
b. Ability to retrieve the following data within a 10-working-day request time frame:	
i. The lot number, batch number, or serial number of the device or other identifier necessary to track the device?	☐ ☐ ☐ ☐ ☐
ii. The name, mailing address, telephone number, and social security number (if applicable) of the patient receiving the device?	☐ ☐ ☐ ☐ ☐
iii. The date provided to the patient?	☐ ☐ ☐ ☐ ☐
iv. The name, mailing address, and telephone number of the implanting physician?	☐ ☐ ☐ ☐ ☐
3. Are records retained for as long as the device is in use or in distribution for use?	☐ ☐ ☐ ☐ ☐
4. Does the company's procedures include a requirement to perform audits of each product tracked at not less than 6-month intervals for the first 3 years of distribution and at least once per year thereafter?	☐ ☐ ☐ ☐ ☐

Total Number of Boxes Checked for Section F 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR MEDICAL DEVICES CHECKLIST

	Rating 3 2 1 0 NA
G. Production- and Process-Control Systems	
Select in-process and final-product processes to audit based on the following criteria: Processes that have a higher risk to cause device failures *Note: Sterilization and freeze-drying operations are almost always subject to inspection.* Newer processes or processes that are less familiar to the company Indicators of process problems in the corrective and preventive action data Processes used to manufacture higher-risk devices Processes associated with product that is barely meeting on-market stability-test limits toward the end of the expiration period	
1. Are the procedures detailed sufficiently to provide direction?	☐ ☐ ☐ ☐ ☐
2. Do the procedures adequately detail the controls, items to be monitored, and operating limits (including environmental- and contamination-control measures)?	☐ ☐ ☐ ☐ ☐
3. Based on the operating limits, review device history records and determine:	
a. Are the process-monitoring activities being documented?	☐ ☐ ☐ ☐ ☐
b. Are the processes operating within the required tolerances and setting ranges?	☐ ☐ ☐ ☐ ☐
c. Are appropriate calibrations and maintenance being performed?	☐ ☐ ☐ ☐ ☐
d. Do the key operating variables and tolerances match what was validated in the validation package?	☐ ☐ ☐ ☐ ☐
e. Is the process consistent from run to run?	☐ ☐ ☐ ☐ ☐
f. Is there a valid sampling plan for process and environmental monitoring?	☐ ☐ ☐ ☐ ☐
g. If there were any deviations or nonconformances, were they properly investigated and pursued via the corrective and preventive action system?	☐ ☐ ☐ ☐ ☐
4. Based on the current Device Master Record and Quality System Record, are the versions of procedures and other documents the edition that is supposed to be in use?	☐ ☐ ☐ ☐ ☐
5. If the process is software controlled, has the software been properly validated?	☐ ☐ ☐ ☐ ☐
6. Have the personnel associated with the production and testing of the lots being audited been properly trained to implement the validated processes?	☐ ☐ ☐ ☐ ☐
7. Does the training include awareness of device defects that may occur as a result of improper performance of their assigned responsibilities?	☐ ☐ ☐ ☐ ☐
8. How is the effectiveness of the training of personnel determined?	☐ ☐ ☐ ☐ ☐
9. Is the building of suitable design, and is there sufficient space to perform necessary operations? If not, observation should be cited against management responsibility if there is no indication or action plan cited in a Management Review.	☐ ☐ ☐ ☐ ☐
10. Based on a selection of device history records, determine whether all the component lots used in the manufacture of the product have been previously released by a receiving/release procedure?	☐ ☐ ☐ ☐ ☐

Total Number of Boxes Checked for Section G 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

QSIT AUDIT FOR DRUGS

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR DRUG COMPANY CHECKLIST

Scope: This audit checklist is intended for use in simulating the new process being used by the United States Food and Drug Administration (FDA) for inspection of drug firms. The inspection technique consists of inspecting per a specific sequence of activities. The checklist is therefore organized as follows to simulate that sequence.

This checklist covers the following areas:

A. Quality System
B. Facilities and Equipment System
C. Materials System
D. Production System
E. Packaging and Labeling System
F. Laboratory Control System

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR DRUG COMPANY CHECKLIST

Date(s) of Simulated Inspection _____

Facility Location Name _____

Address _____

Inspection Leader Name _____

Title _____

Inspection Team Members

Name _____

Function on Team _____

Name _____

Function on Team _____

Name _____

Function on Team _____

Product for Inspection

List No.

(or other identifying number) _____

Dosage Form _____

Strength _____

Package Type _____

Lot Numbers _____

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR DRUG COMPANY CHECKLIST

Opening Meeting Date _____

Attendees _____

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Closing Meeting Date _____

Attendees _____

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Audit Report Date Issued _____

Date Response Received _____

Date Response and Action Plan Approved _____

Date Actions Completed _____

Date Completed Actions Verified as Completed _____

Date Completed Actions Verified as Effective _____

Date Closed Out _____

Future Follow-up Items _____

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QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR DRUG COMPANY CHECKLIST

QUALITY RATING SYSTEM

Rating	*Meaning*	*Interpretation*
3	Excellent	Item/area/system/knowledge is superior
2	Adequate	Item/area/system/knowledge meets basic minimum requirements.
1	Deficient	Item/area/system/knowledge is weak and not up to acceptable standards.
0	Unsatisfactory	Item/area/system/knowledge is missing or of a nature to warrant serious quality/compliance concerns.
NA	Not Applicable	Question is not applicable to type of operation, or item unable to be addressed during the audit.

Comment: Some users of the checklist may find the responses to some questions difficult to quantify on a 0–3 scale and may prefer to use a simple "yes" or "no" approach. In such cases, a "yes" should be assigned a "2" value, and a "no" should be assigned a "0" value.

CHECKLIST RESULTS AND RATING

	Number of Occurrences			
Section	**3s**	**2s**	**1s**	**0s**
A. Quality System				
B. Facilities and Equipment System				
C. Materials System				
D. Production System				
E. Packaging and Labeling System				
F. Laboratory Control System				
Totals				

Audit Findings Summary

Number of questions rated excellent ( ) Times 3 = ( )
Number of questions rated adequate ( ) Times 2 = ( )
Number of questions rated deficient ( ) Times 1 = ( )
Number of questions rated unsatisfactory (_____) Times 0 = (_____)

Total Number of Questions Answered = (_____) Rating Total = (_____)

"Rating Total" divided by "Number of Questions Answered" = _____ Audit Rating

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR DRUG COMPANY CHECKLIST

I. Strengths

1. _____
2. _____
3. _____
4. _____
5. _____

II. Weaknesses

1. _____
2. _____
3. _____
4. _____
5. _____

III. Recommendations

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QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR DRUG COMPANY CHECKLIST

	Rating 3 2 1 0 NA
A. Quality System (21 CFR 211 Subparts B, E, F, G, and K)	
1. Does the quality-control unit have the responsibility to review and approve all procedures related to production, quality control, and quality assurance to assure that they are adequate for their intended use?	☐ ☐ ☐ ☐ ☐
2. Does the quality-control unit have the responsibility to review and approve record-keeping systems?.	☐ ☐ ☐ ☐ ☐
3. Is there a procedure for performing product reviews?	☐ ☐ ☐ ☐ ☐
4. Are product reviews performed at least annually?	☐ ☐ ☐ ☐ ☐
5. Do product reviews include quality trends and other information that are based on batches of each product manufactured?	☐ ☐ ☐ ☐ ☐
6. Is there a procedure for performing quality and medical complaint reviews?	☐ ☐ ☐ ☐ ☐
7. Do the complaint reviews provide insight into how well complaints are documented, evaluated, and investigated in a timely manner?	☐ ☐ ☐ ☐ ☐
8. Do the complaint reviews indicate how effective the corrective actions have been?	☐ ☐ ☐ ☐ ☐
9. Is there an adequate procedure that addresses discrepancies and failure investigations related to manufacturing to assure that they are documented, evaluated, and investigated in a timely manner, including corrective-action completion/effectiveness checks?	☐ ☐ ☐ ☐ ☐
10. Is there an adequate change-control system that assures changes are documented, evaluated properly (including revalidation consideration), and approved?	☐ ☐ ☐ ☐ ☐
11. Is there a procedure on how product-improvement projects are handled for marketed products?	☐ ☐ ☐ ☐ ☐
12. Is there a procedure for handling reprocessing/rework?	☐ ☐ ☐ ☐ ☐
13. Does the procedure for reprocessing/rework address the following:	
a. Evaluation of the reprocessed/reworked product?	☐ ☐ ☐ ☐ ☐
b. Impact assessment on validation and stability?	☐ ☐ ☐ ☐ ☐
c. Review and approval of the reprocessing/rework plan and results?	☐ ☐ ☐ ☐ ☐
14. Is there an adequate procedure that addresses the return and salvaging of products?	☐ ☐ ☐ ☐ ☐
15. Does the process for return and salvage of product include assessment of the product and investigation of the causes of the situation?	☐ ☐ ☐ ☐ ☐
16. Are reject situations properly investigated and, where appropriate, are corrective and preventive actions taken?	☐ ☐ ☐ ☐ ☐
17. Is there a procedure to require investigation are corrective and preventive action as a result of a stability failure?	☐ ☐ ☐ ☐ ☐
18. Is there a procedure that defines when product is to be quarantined and how it is to be controlled, and a procedure for ultimate disposition as release or reject?	☐ ☐ ☐ ☐ ☐
19. Is there a dedicated area for quarantine components, and in-process and final product?	☐ ☐ ☐ ☐ ☐
20. Is there a formal program for validation of equipment, facilities, utilities, processes, laboratory methods, and computer systems?	☐ ☐ ☐ ☐ ☐
21. Is there a tracking system to manage the status of validated items (i.e., validated, revalidated, due for revalidation, etc.)?	☐ ☐ ☐ ☐ ☐
22. Is there a program to assure that quality-department personnel are qualified and properly trained against predetermined criteria?	☐ ☐ ☐ ☐ ☐

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR DRUG COMPANY CHECKLIST

Total Number of Boxes Checked for Section A 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

Audited by _____

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR DRUG COMPANY CHECKLIST

	Rating 3 2 1 0 NA
B. Facilities and Equipment System (Ref. 21CFR 211 Subparts B,C,D and J)	
1. Is there a program, including schedules, for cleaning and maintenance of facilities?	☐ ☐ ☐ ☐ ☐
2. Are drawings available that detail the facility layout?	☐ ☐ ☐ ☐ ☐
3. Does the layout or some other document reveal the air-handling systems necessary to prevent cross-contamination or mix-ups?	☐ ☐ ☐ ☐ ☐
4. Is there a system for controlling changes made to the facilities?	☐ ☐ ☐ ☐ ☐
5. Are the facilities acceptable in the following aspects:	
a. Lighting?	☐ ☐ ☐ ☐ ☐
b. Potable water?	☐ ☐ ☐ ☐ ☐
c. Washing and toilet facilities?	☐ ☐ ☐ ☐ ☐
d. Sewage disposal?	☐ ☐ ☐ ☐ ☐
e. Refuse disposal?	☐ ☐ ☐ ☐ ☐
6. Is there a system for approval and control of rodenticides, fungicides, insecticides, and cleaning and sanitizing agents?	☐ ☐ ☐ ☐ ☐
7. Are there formal requirements for installation and operational qualification of equipment?	☐ ☐ ☐ ☐ ☐
8. Is equipment of adequate design, size, and location?	☐ ☐ ☐ ☐ ☐
9. Are equipment surfaces nonreactive, additive, or absorptive?	☐ ☐ ☐ ☐ ☐
10. Is there a system for approval and control of lubricants, coolants, refrigerants, etc.?	☐ ☐ ☐ ☐ ☐
11. Are cleaning methods for equipment formalized?	☐ ☐ ☐ ☐ ☐
12. Are cleaning methods validated for removal of material and nonretention of residuals from any cleaning solutions used?	☐ ☐ ☐ ☐ ☐
13. Are refrigerators and freezers qualified, calibrated, and maintained properly?	☐ ☐ ☐ ☐ ☐
14. Are computer systems associated with refrigerators and freezers controls, including security systems, validated?	☐ ☐ ☐ ☐ ☐
15. Is there a system for controlling changes made to equipment, including revalidation consideration?	☐ ☐ ☐ ☐ ☐
16. Are personnel properly qualified and trained (including contract employees) for performing cleaning, sanitizing, maintenance, and validation activities?	☐ ☐ ☐ ☐ ☐

Total Number of Boxes Checked for Section B 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR DRUG COMPANY CHECKLIST

	Rating 3 2 1 0 NA
C. Materials System (21 CFR 211 Subparts B, E, H, and J)	
1. Are components, containers, closures, and in-process and final product items properly identified by an identification number/text, lot number, expiration date, and quality status?	☐ ☐ ☐ ☐ ☐
2. Is there an acceptable inventory control system for all items, including "first in, first out" (FIFO) for components, containers, and closures?	☐ ☐ ☐ ☐ ☐
3. Are storage conditions adequate?	☐ ☐ ☐ ☐ ☐
4. Are materials stored under quarantine until tested or examined before release?	☐ ☐ ☐ ☐ ☐
5. When testing or inspection is performed, are representive samples collected, tested, or examined by appropriate methods?	☐ ☐ ☐ ☐ ☐
6. Is at lease one specific identity test performed on each lot of components?	☐ ☐ ☐ ☐ ☐
7. Are rejected lots of any component, container, or closure fully investigated and, when appropriate, are corrective and preventive actions taken?	☐ ☐ ☐ ☐ ☐
8. Is there a supplier-qualification and -control system?	☐ ☐ ☐ ☐ ☐
9. Are associated product makeup materials, such as water, nitrogen, and compressed air, provided via a properly designed, maintained, and validated system?	☐ ☐ ☐ ☐ ☐
10. Are container and closure systems properly qualified to assure that they are not additive or reactive to, or absorptive of, the drug product?	☐ ☐ ☐ ☐ ☐
11. Is there a system for control of changes in material sources, grades, and handling operations?	☐ ☐ ☐ ☐ ☐
12. Are finished-product distribution records maintained by lot number?	☐ ☐ ☐ ☐ ☐
13. Are personnel associated with materials handling qualified and properly trained?	☐ ☐ ☐ ☐ ☐

Total Number of Boxes Checked for Section C 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR DRUG COMPANY CHECKLIST

	Rating 3 2 1 0 NA
D. Production System (21 CFR 211 Subparts B, F, and J)	
1. Is there a system for the control, implementation, and validation of process changes?	☐ ☐ ☐ ☐ ☐
2. Are procedures adequate for the charge-in of components to assure that only the correct material is available on line for use in a process?	☐ ☐ ☐ ☐ ☐
3. Are formulations and manufacturing of lots targeted at not less than 100%?	☐ ☐ ☐ ☐ ☐
4. Is the equipment properly identified as to contents, lot number, and quality status?	☐ ☐ ☐ ☐ ☐
5. Are cleaning, sterilization, and depyrogenation of containers and closures verified and validated?	☐ ☐ ☐ ☐ ☐
6. Do master production and control records exist for all products?	☐ ☐ ☐ ☐ ☐
7. Are actual and theoretical yield percentages calculated and documented?	☐ ☐ ☐ ☐ ☐
8. Are nonconformances to yield expectations investigated and resolved?	☐ ☐ ☐ ☐ ☐
9. Are complete production and control records generated for each lot?	☐ ☐ ☐ ☐ ☐
10. Are time limits established for completion of phases of production?	☐ ☐ ☐ ☐ ☐
11. Have in-process controls, tests, and examinations been implemented, and are the results recorded?	☐ ☐ ☐ ☐ ☐
12. Does justification exist for the in-process and final-product specifications?	☐ ☐ ☐ ☐ ☐
13. Is there a program to assure prevention of objectionable microorganisms in nonsterile products?	☐ ☐ ☐ ☐ ☐
14. Are preprocessing procedures required and adhered to (e.g., set-up, line clearance, etc.)?	☐ ☐ ☐ ☐ ☐
15. Are equipment-cleaning/use logs maintained?	☐ ☐ ☐ ☐ ☐
16. Have processes, including computer and automated processes, been validated?	☐ ☐ ☐ ☐ ☐
17. Is their a change-control process that includes revalidation considerations?	☐ ☐ ☐ ☐ ☐
18. Are production discrepancies and deviations investigated and resolved?	☐ ☐ ☐ ☐ ☐
19. Are production employees neat in appearance, and do they appear knowledgeable in performing their assigned tasks?	☐ ☐ ☐ ☐ ☐
20. Are production employees formally trained and qualified for their jobs?	☐ ☐ ☐ ☐ ☐

Total Number of Boxes Checked for Section D 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR DRUG COMPANY CHECKLIST

	Rating 3 2 1 0 NA
E. Packaging and Labeling System (Ref. 21 CFR211 Subparts B, G and J)	
1. Are operations checked for acceptability before packaging and labeling activities commence?	☐ ☐ ☐ ☐ ☐
2. Are there verification systems to assure that the packaging and labeling operations are using the correct revision of the correct material?	☐ ☐ ☐ ☐ ☐
3. Is there a system to assure control of changes to packaging and labeling materials?	☐ ☐ ☐ ☐ ☐
4. Is there a change-control system for the packaging and labeling operations, and does it include revalidation consideration?	☐ ☐ ☐ ☐ ☐
5. Are there adequate and secure storage areas for both approved and unapproved labels and labeling?	☐ ☐ ☐ ☐ ☐
6. Are there adequate procedures for the return and control of unused issued material to the packaging and labeling operations?	☐ ☐ ☐ ☐ ☐
7. Are there adequate controls to prevent mix-up of labels that may be similar in size, shape, or color?	☐ ☐ ☐ ☐ ☐
8. For finished-product cut labels that are similar in appearance, is there a 100%, electronic, validated verification system, or are dedicated lines used?	☐ ☐ ☐ ☐ ☐
9. Is gang printing prohibited unless differentiation by size, shape, or color would be obvious?	☐ ☐ ☐ ☐ ☐
10. Is there an adequate control and identification system for unlabeled containers that are labeled later or under multiple private labels?	☐ ☐ ☐ ☐ ☐
11. Are adequate packaging records generated that include specimens of all labels used?	☐ ☐ ☐ ☐ ☐
12. Is there a comprehensive system of issuance of labeling, examination of issued labels, and reconciliation of usage?	☐ ☐ ☐ ☐ ☐
13. Is labeled finished product examined?	☐ ☐ ☐ ☐ ☐
14. Is there an adequate inspection (proofing) of incoming labels?	☐ ☐ ☐ ☐ ☐
15. Is the control of lot/control numbering adequate, including destruction of excess labeling bearing lot/control numbers?	☐ ☐ ☐ ☐ ☐
16. Is the physical/spatial separation between different labeling and packaging lines adequate to assure against mix-ups (including separation of documentation packets)?	☐ ☐ ☐ ☐ ☐
17. Are printing devices monitored to assure uniform consistency throughout manufacturing?	☐ ☐ ☐ ☐ ☐
18. Are comprehensive, documented line clearances and inspections performed?	☐ ☐ ☐ ☐ ☐
19. Is there assurance that expiration dates are calculated correctly and appear properly on the labels?	☐ ☐ ☐ ☐ ☐
20. Have tamper-evident packaging requirements (per CFR 211.132 and Compliance Policy Guide 7132a.17) been implemented?	☐ ☐ ☐ ☐ ☐
21. Have packaging and labeling operations, including security of computerized processes, been validated?	☐ ☐ ☐ ☐ ☐
22. Are production discrepancies and deviations investigated and resolved, and, where appropriate, are correct and preventive action pursued?	☐ ☐ ☐ ☐ ☐
23. Are the employees qualified and properly trained per established requirements?	☐ ☐ ☐ ☐ ☐

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR DRUG COMPANY CHECKLIST

Total Number of Boxes Checked for Section E 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

Audited by _____

QSIT AUDIT (NEW FDA INSPECTION APPROACH) FOR DRUG COMPANY CHECKLIST

	Rating 3 2 1 0 NA
F. Laboratory Control System (Ref. 21CFR211 Subparts B,I, J and K)	
1. Based on the functions being addressed (i.e., incoming, in-process, final, stability), volume of lots tested, documentation generated/reviewed, the amount of testing per lot, the organizational chart, etc., does the laboratory appear to be properly staffed?	☐ ☐ ☐ ☐ ☐
2. Are the facilities and equipment adequate for the intended use?	☐ ☐ ☐ ☐ ☐
3. Are the maintenance and calibration programs for analytical instruments and equipment adequate?	☐ ☐ ☐ ☐ ☐
4. Have the validation and security of computerized or automated processes been assured?	☐ ☐ ☐ ☐ ☐
5. Have source, purity, and assay reference standards; and tests been verified as being equivalent to current official reference standards?	☐ ☐ ☐ ☐ ☐
6. Are suitability checks performed on chromatographic systems before use?	☐ ☐ ☐ ☐ ☐
7. Are clear specifications and standards used to determine the acceptability of results?	☐ ☐ ☐ ☐ ☐
8. Are the sampling plans acceptable?	☐ ☐ ☐ ☐ ☐
9. Are methods of analysis formally approved documents, and are they being followed?	☐ ☐ ☐ ☐ ☐
10. Is there a protocol for the validation and verification of analytical methods?	☐ ☐ ☐ ☐ ☐
11. Is there a change-control system for proposing and approving changes to the laboratory operation?	☐ ☐ ☐ ☐ ☐
12. Are all required tests being performed on the correct samples?	☐ ☐ ☐ ☐ ☐
13. Are deviations/discrepancies properly investigated and resolved, and are corrective/preventive actions taken when appropriate?	☐ ☐ ☐ ☐ ☐
14. Are analytical records of tests and summaries complete?	☐ ☐ ☐ ☐ ☐
15. Is raw data being retained in a neat, orderly, and easily retrievable manner?	☐ ☐ ☐ ☐ ☐
16. Do the summaries of results correlate properly to the raw data?	☐ ☐ ☐ ☐ ☐
17. Is there an adequate Out of Specification (OOS) procedure, and are investigations being performed in a timely manner?	☐ ☐ ☐ ☐ ☐
18. Are adequate reserve samples being retained?	☐ ☐ ☐ ☐ ☐
19. Are the examinations of reserve samples properly documented?	☐ ☐ ☐ ☐ ☐
20. Is there an acceptable stability-testing program?	☐ ☐ ☐ ☐ ☐
21. Can the laboratory demonstrate that the test methods for the stability-testing program are stability indicating?	☐ ☐ ☐ ☐ ☐

Total Number of Boxes Checked for Section F 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

NEW PRODUCT AUDIT CHECKLIST

NEW PRODUCT MARKET LAUNCH CHECKLIST

Scope: This checklist is intended for use in assisting product development and QA project personnel to assess if key elements of the quality system are at an acceptable level to support a new product launch.

This checklist covers the following areas:

A. Chemical Components

B. Packaging and/or Device Components

C. In-Process Items/Subassemblies/Bulk Product/Final Product

D. Manufacturing, Engineering, and Maintenance

E. Compliance

F. Customer Support

The questions in this checklist include references to:

1. International Organization for Standardization (ISO) documents on Quality Systems, ISO 9001:1994, Quality Systems—Model and Quality Assurance in Design, Development, Production, Installation and Servicing, and ISO 9001:2000, Quality Management Systems—Requirements
2. International Organization for Standardization (ISO) documents for Medical Devices, ISO 13485:1996, Quality Systems—Medical Devices—Particular Requirements for the Application of ISO 9901, and 13488:1996, Quality Systems—Medical Devices—Particular Requirements for the Application of ISO 9002. These international standards have recently been approved as equivalent to and substitutes for the European standards EN 46001 and EN46002.
3. The European Community (EC) Guide to Good Manufacturing Practices (GMP) for Medicinal Products
   *Note: References in the checklist designated with "AN" and an Asterisk * refer to the Annex of guidelines included in the EC GMP document.*
4. The United States Code of Federal Regulations 21 CFR, Part 211, Current Good Manufacturing Practice (CGMP) for Finished Pharmaceuticals. (In the United States, producers of bulk pharmaceutical ingredient [active or inactive] are subject to the Good Manufacturing Practices For Drug Products.)
5. The United States Code of Federal Regulations 21 CFR, Part 820—Quality System Regulation (QSReg.), Current Good Manufacturing Practice (CGMP) Requirements for Medical Devices
   Note: References to these regulations are indicated in the checklist by arrow brackets < >.

Because new product market launch audits may be performed by more than one person, signature spaces are provided at the end of each section to provide a record of each individual auditor's activities.

NEW PRODUCT MARKET LAUNCH CHECKLIST

QUALITY RATING SYSTEM

Rating	*Meaning*	*Interpretation*
3	Excellent	Item/area/system/knowledge is superior
2	Adequate	Item/area/system/knowledge meets basic minimum requirements.
1	Deficient	Item/area/system/knowledge is weak and not up to acceptable standards.
0	Unsatisfactory	Item/area/system/knowledge is missing or of a nature to warrant serious quality/compliance concerns.
NA	Not Applicable	Question is not applicable to type of operation, or item unable to be addressed during the audit.

Comment: Some users of the checklist may find the responses to some questions difficult to quantify on a 0–3 scale and may prefer to use a simple "yes" or "no" approach. In such cases, a "yes" should be assigned a "2" value, and a "no" should be assigned a "0" value.

CHECKLIST RESULTS AND RATING

	Number of Occurrences			
Section	**3s**	**2s**	**1s**	**0s**
A. Chemical Components				
B. Packaging and/or Device Components				
C. In-Process Items/Subassemblies/Bulk Product/Final Product				
D. Manufacturing, Engineering, and Maintenance				
E. Compliance				
F. Customer Support				

Audit Findings Summary

Number of questions rated excellent ( ) Times 3 = ( )
Number of questions rated adequate ( ) Times 2 = ( )
Number of questions rated deficient ( ) Times 1 = ( )
Number of questions rated unsatisfactory (_____) Times 0 = (_____)

Total Number of Questions Answered = (_____) Rating Total = (_____)

"Rating Total" divided by "Number of Questions Answered" = _____ Audit Rating

NEW PRODUCT MARKET LAUNCH CHECKLIST

Summary Compliance Status

Product Name _____

List (Product) Number _____

Item	Status
A. Chemical Components	_____
B. Packaging and/or Device Components	_____
C. In-Process Items/Subassemblies/Bulk Product/Final Product	_____
D. Manufacturing, Engineering, and Maintenance	_____
E. Compliance	_____
F. Customer Support	_____

Recommendations:

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NEW PRODUCT MARKET LAUNCH CHECKLIST

Market Launch Approvals

Research and Development _____ Date _____

Technical Support _____ Date _____

Purchasing _____ Date _____

Materials Control _____ Date _____
(including warehousing)

Engineering _____ Date _____

Maintenance _____ Date _____

Manufacturing _____ Date _____

Marketing _____ Date _____

Regulatory Affairs _____ Date _____

Quality Control _____ Date _____

Quality Assurance _____ Date _____

A. Chemical Components Checklist

ITEM	STATUS						
	Specifications	Test Methods	Sampling Plans	Sampling Methods	Suppliers	Storage Conditions	Stability
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							
11.							
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13.							
14.							
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16.							
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18.							
19.							
20.							
21.							

NEW PRODUCT MARKET LAUNCH CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488)	EC GMP	USA DRUG GMP <QSReg.>
	3 2 1 0 NA					
A. Chemical Components						
1. Specifications						
a. Have comprehensive documents been written and approved by quality control?	□ □ □ □ □	4.2	4.2.2	4.2 (4.2)	4.12	211.84 <820.181>
b. Have they been reviewed and agreed to by the suppliers?	□ □ □ □ □	4.6	7.4.2	4.6		<820.50>
2. Test Methods			4.1			
a. Do formalized, acceptable test methods exist for each material?	□ □ □ □ □	4.2	4.2.2	4.2 (4.2)	6.15 6.16	211.160 <820.80>
b. Are the methods the same as those employed by the source of the item? If not, has the source agreed to accept the different methodology as a basis for release/rejection of material?	□ □ □ □ □	4.2 4.6	4.1 4.2.2	4.2 4.6 (4.2)		<820.50>
c. Have the test methods been validated?	□ □ □ □ □			4.2 4.11 (4.2) (4.11)	1.4 6.15	211.165 211.194 <820.72> <820.80>
d. Does the quality-control laboratory have the necessary equipment to perform all testing properly?	□ □ □ □ □	4.11	7.6	4.11 (4.11)	6.5	211.22 <820.72>
e. Have the laboratory personnel been properly trained to perform the test methods?	□ □ □ □ □	4.18	6.2.1 6.2.2	4.18 (4.18)	2.8 2.9	211.25 <820.25>
f. From a safety perspective, is the present laboratory facility acceptable for performing all the testing?	□ □ □ □ □				6.5	211.22
g. Have all the necessary standards and reagents for tests been procured and the shelf-life/retest periods for each been determined?	□ □ □ □ □	4.11	7.6	4.11 (4.11)	6.19 6.20 6.21	211.165
3. Sampling Plans Have formalized, acceptable statistical sampling plans been derived for each item?	□ □ □ □ □	4.20	8.1 8.2.3 8.2.4 8.4	4.20 (4.20)	4.22	211.84 <820.80> <820.250>
4. Sampling Methods Have formal methods been derived for obtaining the sample? Have safety precautions been taken into consideration?	□ □ □ □ □	4.20	8.1 8.2.3 8.2.4 8.4	4.20 (4.20)	3.14 3.22	211.80 211.84 <820.250>
5. Suppliers			7.4.2		2.74.1	211.84 <820.50>
a. Has at least 1 supplier been qualified and approved for each item?	□ □ □ □ □					
b. Have the shipping requirements, such as drum, bags, and quantity per pallet been specified?	□ □ □ □ □	4.15	7.5.5	4.15 (4.15)	4.10 4.11	211.84 <820.50>

NEW PRODUCT MARKET LAUNCH CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488)	EC GMP	USA DRUG GMP <QSReg.>
	3 2 1 0 NA					
A. Chemical Components (continued)						
6. Storage Conditions/Materials Handling Have the storage and handling of each item been considered, planned for, and agreed upon with materials-control functions?	□ □ □ □ □	4.15	7.5.5	4.15 (4.15)	3.1 3.2 3.3 3.4	211.82 211.87 <820.80> <820.140> <820.150>
7. Stability Are the materials and sources the same as those qualified by research and development? If not, have studies been performed to qualify the material to ensure that it will not have a negative impact on product stability?	□ □ □ □ □	4.6	7.4.2	4.4 4.6	2.7	211.68 <820.30>

Total Number of Boxes Checked for Section A 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

NEW PRODUCT MARKET LAUNCH CHECKLIST

B. Packaging and Device Component Checklist

ITEM	STATUS							
	Specifications	Test/Insp. Methods	Sampling Plans	Sampling Methods	Suppliers	Storage Conditions	Stability
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							
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14.							
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17.							
18.							
19.							
20.							
21.							

NEW PRODUCT MARKET LAUNCH CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488)	EC GMP	USA DRUG GMP <QSReg.>
	3 2 1 0 NA					
B. Packaging and/or Device Components						
1. Specifications		4.2	4.2.1	4.2 (4.2)	4.12	211.84 <820.181>
a. Have comprehensive documents been written and approved by quality control?	☐ ☐ ☐ ☐ ☐					
b. Have they been reviewed and agreed to by the intended vendors?	☐ ☐ ☐ ☐ ☐	4.6	7.4.2	4.6		<820.50>
c. Have tolerances been established for each critical parameter?	☐ ☐ ☐ ☐ ☐	4.2	7.4.2	4.2 (4.2)	4.12	211.84 <820.50> <820.80>
d. Have defect classifications been derived?	☐ ☐ ☐ ☐ ☐	4.2	7.4.2	4.2 (4.2)	4.12	211.84 <820.50> <820.80>
e. Have acceptance quality levels (AQLs) been established for each defect?	☐ ☐ ☐ ☐ ☐	4.2	7.4.2	4.2 (4.2)	4.12	211.84 <820.50> <820.80>
f. Do drawings of parts and, where applicable, tools exist?	☐ ☐ ☐ ☐ ☐	4.2	7.4.2	4.2 (4.2)	4.12	211.84 <820.50> <820.80>
2. Test and Inspection Methods		4.2	7.4.2	4.2 (4.2)	6.15 6.16	211.160 <820.80>
a. Do formalized, acceptable methods exist for each component and material?	☐ ☐ ☐ ☐ ☐					
b. Are the methods the same as those employed by the source of the item? If not, has the source agreed to accept the different methodology as a basis for release/rejection of component lots?	☐ ☐ ☐ ☐ ☐	4.2 4.6	7.4.2	4.2 4.6 (4.2)		<820.50>
c. Does the quality-control laboratory have the necessary equipment to do the testing and inspections properly?	☐ ☐ ☐ ☐ ☐	4.11	7.6	4.11 (4.11)	6.5	211.22 <820.72>
d. Have the inspection and test methods been performed in a laboratory to assure that there are no problems?	☐ ☐ ☐ ☐ ☐	4.2 4.11	7.4.2	4.2 4.11 (4.2) (4.11)	1.4 6.15	211.165 211.194 <820.80>
e. Have the personnel who will be performing the testing and inspections been properly trained?	☐ ☐ ☐ ☐ ☐	4.18	6.2.1 6.2.2	4.18 (4.18)	2.8 2.9	211.25 <820.25>
f. Have safety precautions been taken into consideration for each test and inspection method to assure that the present laboratory facilities are acceptable?	☐ ☐ ☐ ☐ ☐			4.11 (4.11)	6.5	211.22

NEW PRODUCT MARKET LAUNCH CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488)	EC GMP	USA DRUG GMP <QSReg.>
	3 2 1 0 NA					
B. Packaging and/or Device Components (continued)						
3. Sampling Plans Have formalized, acceptable statistical sampling plans been derived for each item?	□ □ □ □ □	4.20	8.1 8.2.3 8.2.4 8.4	4.20 (4.20)	4.22	211.84 <820.250>
4. Suppliers			7.4.2			
a. Has at least 1 supplier been qualified and approved for each item?	□ □ □ □ □				2.74.1	211.84 <820.50>
b. Have the shipping requirements, such as drum, bags, quantity per pallet, been specified?	□ □ □ □ □	4.15	7.5.5	4.15 (4.15)	4.10 4.11	211.84 <820.50> <820.80>
c. In the case of molded components, has each cavity been tooled with a number that is viewable on the actual component for problem-solving purposes and traceability?	□ □ □ □ □	4.8 4.9	7.5.1 7.5.2 7.5.3	4.8 4.9 (4.8) (4.9)	1.3	211.80 <820.50> <820.80>
5. Storage Conditions/Materials Handling Has the storage and handling of each item been considered, planned for, and agreed upon with the materials-control functions?	□ □ □ □ □	4.15	7.5.5	4.15 (4.15)	3.1 3.2 3.3 3.4	211.80 211.82 211.87 <820.80> <820.140> <820.150>
6. Stability Are the material or component sources the same as those qualified by research and development? If not, have studies been performed to qualify the material or component to ensure that it will not have a negative impact on product quality?	□ □ □ □ □	4.4 4.6	7.3.7	4.4 4.6 (4.6)	2.7	211.668 <820.30>

Total Number of Boxes Checked for Section B 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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Audited by _____

C. In-Process Product, Subassemblies, Bulk Product, Final Product Checklist

PROCESS STAGE	STATUS					
	Specifications	Test/Insp. Methods	Sampling Plans	Sampling Methods	Storage Conditions	Stability
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
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16.						
17.						
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19.						
20.						
21.						

NEW PRODUCT MARKET LAUNCH CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488)	EC GMP	USA DRUG GMP <QSReg.>
	3 2 1 0 NA					
C. In-Process Items/Subassemblies/Bulk Product/Final Product						
1. Specifications Have comprehensive documents been written and approved by quality control for each phase of production?	□ □ □ □ □	4.2 4.9	4.2.3 7.5.1	4.2 4.9 (4.2) (4.9)	1.2 6.1 6.2 6.3 6.4	211.22 211.84 211.100 211.160 <820.70> <820.80>
2. Is there a Design History File for each design that demonstrates it was developed in accord with all requirements?	□ □ □ □ □	4.2 4.9	4.2.4	4.4 (4.4)		<820.30>
3. Test and Inspection Methods a. Do validated test methods exist for each material stage?	□ □ □ □ □	4.10 4.11	7.4.3 8.2.4	4.10 4.11 (4.10) (4.11)	6.15	211.160 211.165 <820.80>
b. Have the personnel who will be performing the testing or inspections been properly trained?	□ □ □ □ □	4.18	6.2.1 6.2.2		2.8 2.9 2.10 2.11 2.12	211.25 <820.25>
c. Have all the necessary standards and reagents for tests been procured? Have the shelf-life/retest periods for each been determined?	□ □ □ □ □	4.11	7.6	4.11 (4.11)	6.19 6.20 6.21	211.165
d. Does the quality-control laboratory have the necessary equipment to do the testing/inspection properly and safely?	□ □ □ □ □	4.11	7.6	4.11 (4.11)	6.5	211.22 211.160 <820.72>
4. Sampling Plans Have formalized, acceptable statistical sampling plans been derived for each stage of processing?	□ □ □ □ □	4.20	8.1 8.2.3 8.2.4 8.4	4.20 (4.20)	6.11	211.65 <820.250>
5. Have formal methods been derived for obtaining the sample from the manufacturing process? Have necessary safety precautions been taken into consideration?	□ □ □ □ □				6.13	211.165 <820.70> <820.250>
6. Storage Conditions/Materials Handling a. Have the storage and handling of each item been taken into consideration, planned for, and agreed upon?	□ □ □ □ □	4.15	7.5.5	4.15 (4.15)	3.1 3.2 3.3 3.4 5.29 AN-54*	211.80 <820.140> <820.150>
b. Have the expiration periods for storage of in-process and final-product items been established? Has a retest program been derived for in-process items that have exceeded the expiration period?	□ □ □ □ □	4.15	7.5.5	4.15.3 (4.15)	4.11 4.15 5.31	211.87 211.111 <820.80> <820.150>

* Annex to EC GMP

NEW PRODUCT MARKET LAUNCH CHECKLIST

Total Number of Boxes Checked for Section C 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

Audited by _____

D. Manufacturing, Engineering and Maintenance Checklist

EQUIPMENT NUMBER PROCESS OR SYSTEM	STATUS				
	Specifications	Validation	Manufacturing Procedures	Maintenance Procedures	Maintenance Schedules
1.					
2.					
3.					
4.					
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6.					
7.					
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11.					
12.					
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21.					

NEW PRODUCT MARKET LAUNCH CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488)	EC GMP	USA DRUG GMP <QSReg.>
	3 2 1 0 NA					
D. Manufacturing, Engineering and Maintenance						
1. Specifications Has a file of equipment specifications been derived and maintained for future reference?	□ □ □ □ □	4.2 4.5		4.2 4.5 (4.2) (4.5)	4.2	211.100 <820.70>
2. Validation Have all necessary and appropriate validations pertinent to the product been performed?	□ □ □ □ □	4.9		4.9 (4.9)	5.21 5.22 5.23 5.24 AN-30* AN-38* AN-49* AN-50* AN-64*	211.63 211.67 211.68 211.113 <820.75>
3. Procedures a. Have specific manufacturing operating procedures been written for each piece of equipment and each manufacturing process?	□ □ □ □ □	4.2 4.9		4.2 4.9 (4.2) (4.9)	4.4 4.5 4.6	211.100 <820.70>
b. Have personnel been properly trained in performing manufacturing and maintenance functions?	□ □ □ □ □	4.18		4.18 (4.18)	2.8 2.9 2.10 2.11 2.12 AN-8*	211.25 <820.25>
4. Schedules Has the maintenance department, in conjunction with the quality-control and engineering departments, derived specific, formalized maintenance procedures and schedules for each piece of equipment, process, and support system, such as water, compressed air, and vacuum?	□ □ □ □ □	4.2 4.9		4.2 4.9 (4.2) (4.9)	3.34 3.35 3.44	

Total Number of Boxes Checked for Section D 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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* Annex to EC GMP

NEW PRODUCT MARKET LAUNCH CHECKLIST

E. Compliance Checklist

ITEM	STATUS
1.	
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NEW PRODUCT MARKET LAUNCH CHECKLIST

	Rating	Reference				
		ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488)	EC GMP	USA DRUG GMP <QSReg.>
	3 2 1 0 NA					
E. Compliance						
1. Registration Have all the appropriate registrations for the facility, manufacturing processes, and product been submitted and approved by the appropriate regulatory agencies?	□ □ □ □ □					
2. Verification						
a. Have verifications been made at the manufacturing location to assure that the operation is still in compliance with the documents that were originally submitted to regulatory agencies?	□ □ □ □ □			4.4	1.2 1.3	211.100
b. Has all appropriate labeling for the product been properly reviewed and approved, and have samples been retained for future reference?	□ □ □ □ □				4.2 4.3	<820.120>
c. Is there a system in place, with appropriate individuals trained, to assure that the regulatory department will be advised of changes that may impact compliance with registrations and labeling?	□ □ □ □ □			4.2 4.18 (4.2) (4.18)	4.2 4.3	211.22 211.100 <820.40>
d. Have the manufacturing facility and associated operations been reviewed to assure that they are in compliance with all applicable regulations and guidelines?	□ □ □ □ □			4.17 (4.17)	1.2 9.1 9.2 9.3	211.1 211.100 <820.22>

Total Number of Boxes Checked for Section E 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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NEW PRODUCT MARKET LAUNCH CHECKLIST

F. Customer Service Checklist

ITEM	STATUS
1.	
2.	
3.	

NEW PRODUCT MARKET LAUNCH CHECKLIST

	Rating	Reference				
	3 2 1 0 NA	ISO 9001:1994	ISO 9001:2000	ISO 13485 ISO (13488)	EC GMP	USA DRUG GMP <QSReg.>
F. Customer Support						
1. Is there an adequate customer-service operation staffed by properly trained personnel?	□ □ □ □ □	4.19	7.5.1	4.19		<820.200>
2. Are field-service personnel adequately trained?	□ □ □ □ □	4.19	7.5.1	4.19		<820.200> <820.25>
3. Where applicable, are spare parts for the product readily available?	□ □ □ □ □	4.19	7.5.1	4.19		<820.200>

Total Number of Boxes Checked for Section F 3 _____ 2 _____ 1 _____ 0 _____ NA _____

Observations/Comments

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