Good Practice Guide

Good Engineering Practice

ENGINEERING PHARMACEUTICAL INNOVATION

ISPE

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ISBN 1-931879-54-0

Preface

This ISPE Good Practice Guide: Good Engineering Practice (GEP) aims to provide both a definition and explanation of the term "Good Engineering Practice." The Guide covers the complete life cycle of engineering, from concept to retirement, and describes the fundamental elements of GEP as they should exist in pharmaceutical and related industries.

It brings together a wealth of information on GEP and provides tools to allow benchmarking of current company practices against what is considered industry good practice.

The Guide includes attachments which provide industry examples, currently in use, of GEP and auditing methods, together with checklists that may be of use to the reader.

Acknowledgements

The ISPE Good Practice Guide (GPG): Good Engineering Practice (GEP) was produced by a Task Team led by Chris Derrett (Schering-Plough Corp., USA) and Mark Foss (Boehringer Ingelheim Ltd., United Kingdom). The members of the task team contributed and reviewed new material.

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The ISPE GPG: GEP Task Team would like to thank ISPE for technical writing and editing support by Gail Evans (ISPE Technical Documents Writer/Editor) and Sion Wyn (ISPE Technical Consultant).

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1 Introduction

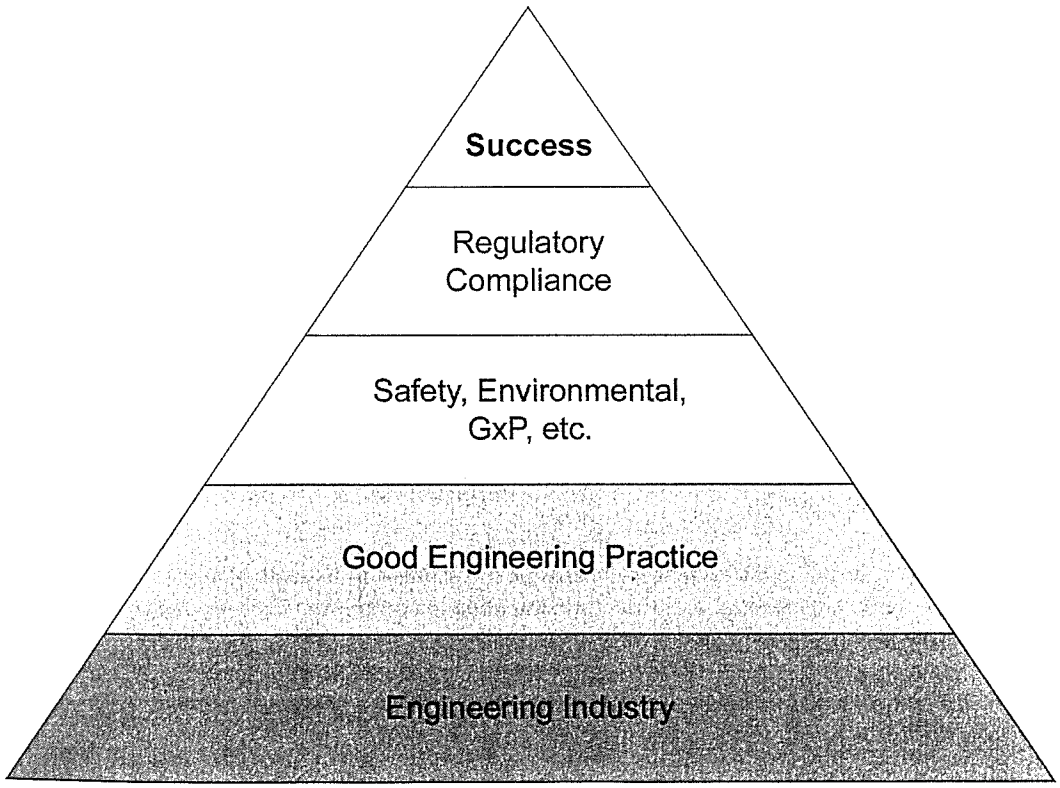
47 This ISPE Good Practice Guide aims to provide a definition and explanation of the term "Good Engineering Practice"
51 (GEP). It describes the fundamental elements of GEP as they should exist in pharmaceutical and related industries. It
59 should be noted that the concepts are fundamental and applicable in many industries.

1.1 Overview

71 In the context of pharmaceutical engineering and GxP guidance, GEP is frequently referred to in documents as
77 a prerequisite to compliance activity and may be loosely defined. GEP is often used to describe an engineering
83 management system that is expected in a regulated company, but which is not mandated by GxP regulations. For
89 example, effective project progress monitoring and control is not a regulatory issue, but is necessary for the efficient
operation of a company, and is part of GEP.

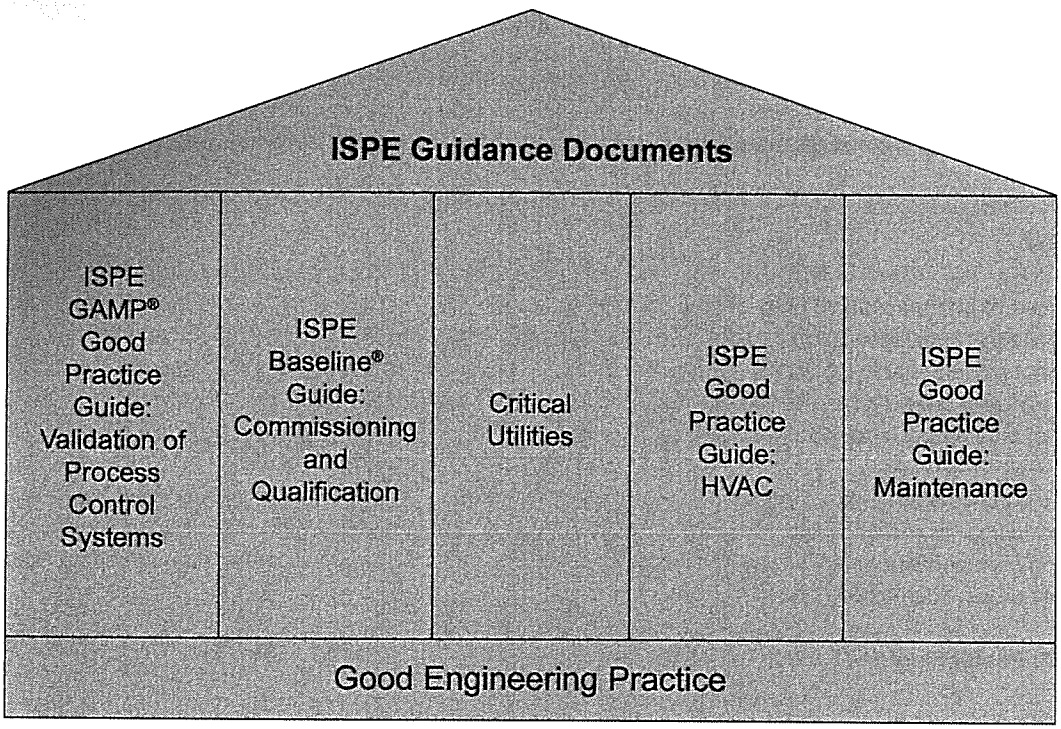
03 This Guide considers the entire range of pharmaceutical engineering activity and identifies key attributes of GEP
05 within it, including how GEP relates to, and interfaces with GxP. The scope of GEP covers the complete life cycle of
engineering from concept to retirement. GEP provides a foundation required across the pharmaceutical industry upon
which other areas, such as GxP, build.

13 **Figure 1.1: Positioning of GEP in relation to GxP**



The aspects of GEP discussed in this Guide are intended to describe the minimum requirements for GEP in engineering activities.

Figure 1.2: How this GPG relates to other ISPE Technical Documents



The efficient running of a business, demands working practices which will deliver optimum value for a given scope of work. This guide is by its nature generic and specific requirements will need to be selected and adapted.

1.2 Purpose

This document was developed through the collaboration of representative professionals from various sectors and geographic regions of the pharmaceutical industry with the intention of determining a common understanding of the concept and principles of GEP.

This document identifies practices which exemplify how GEP concepts may be applied in the pharmaceutical industry.

1.3 Scope and Benefit Objectives

The scope of this Guide is limited to the healthcare industry but considers all aspects of engineering. The motives for aspiring to practice "good engineering" are wider than the need to comply with GxP regulatory expectations and encompass productivity and business related drivers.

The adoption of GEP should lead to a balance of expenditure and activity in relation to benefits. Benefit is most likely gained when finite resources are focused on identified higher risk aspects.

1.4 Key Concepts

The typical aspects of a GEP program may be categorized into three subsections:

- project engineering

- common practices
- operation and maintenance

Project Engineering: The activities associated with implementing new or significantly changed equipment or facilities; typically associated with allocation of capital funding and additional resources.

Common Practices: Those practices with relevance to both project engineering and normal operation and maintenance

Operation and Maintenance: The activities required to sustain equipment and facilities in a satisfactory condition and use them for production purposes.

Common to these three key concepts are the further key concepts of "risk management," "cost management," and "organization and control:"

- Risk management: the systematic application of quality management policies, procedures, and practices to the tasks of assessing, controlling, communicating, and reviewing risk (see ICH Q9, Reference 1, Appendix 3). Risk management is at the core of most GEP activity.
- Cost management should ensure that the cost impact of any activity is understood, assessed, and managed, in order to return best value for the regulated company. Value is measured as a balance between cost, quality, and progress.
- Organization and control: organizational structure should ensure maximum efficiency and that the overhead to output ratio is acceptable. Control mechanisms within an organization should monitor the performance and progress of assigned activities. A clear structure of organization and control is required to respond effectively to the changing demands of the business.

Key terms:

Supplier

An organization or individual internal or external to the user associated with the supply and/or support of products or services at any phase throughout a systems life cycle.

User

The pharmaceutical customer or user organization contracting a supplier to provide a product. In the context of this document it is, therefore, not intended to apply only to individuals who use the system, and is synonymous with customer.

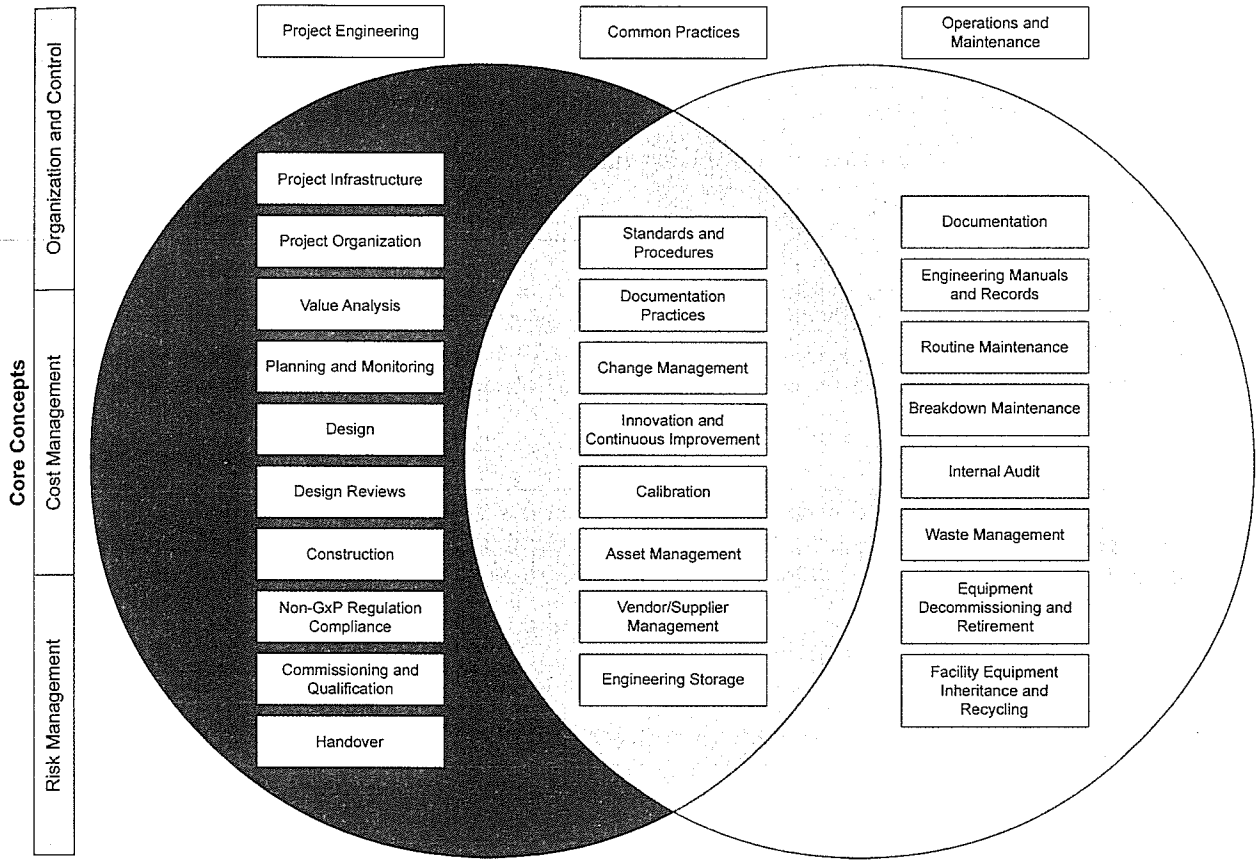
1.5 Structure of the Guide

The structure of the Guide divides GEP activity into project engineering, common practices and operation and maintenance. Each section of this Guide is prefaced with the definition of the key concept. Within each of these sections, practices and sub-practices are identified and described to provide illustrative examples of GEP.

2 Breadth and Coverage of GEP

Figure 2.1 illustrates the breadth and coverage of Good Engineering Practices in the disciplines of Project Engineering (blue), Operations and Maintenance (green), and practices that are common between the two (teal). Core Concepts which permeate all aspects of Good Engineering Practices also are indicated.

Figure 2.1: Breadth and Coverage of Good Engineering Practices



3 Good Engineering Practice

3.1 Core Concepts

3.1.1 *Risk Management*

Risk management is at the core of most GEP activity such that there is a balanced evaluation of risks against benefits. Where practicable efforts should be made to design out or minimize identified risks to an acceptable level.

Sub-Practice 1: Identify

A regulated company should identify significant risks which may threaten its activities.

Sub-Practice 2: Evaluate

Risks should be assessed using appropriate methods to determine if they are long or short term. The threat level should be evaluated, considering likelihood, severity of consequences, and probability of detection. It should be understood that risk is an integral component of all activity and it is necessary to accept a certain level of risk in order to function. Risk assessments should be performed by appropriately skilled personnel.

Sub-Practice 3: Document

Some level of documentation is always appropriate to capture the thought processes and the logic involved for communications and future reference. The significance of the risk to the business and purpose should define the level of documentation involved. Wherever possible established assessment and documentation processes be should be used.

Sub-Practice 4: Mitigation Strategy

Risk management should include back up strategies, contingency planning, and risk mitigation. Examples of risk and mitigation include:

- back up of key computer systems and data
- stand-by power generation
- redundant capacity for steam, air, and gases
- run and stand-by pumps
- insurance for unmitigated risks
- safety/shutdown systems

3.1.2 *Cost Management*

Cost management is a key aspect of good engineering practice ensuring the cost impact of any activity is understood, assessed, and managed in order to return good value. Value is measured as a balance between cost, quality, and progress.

Sub-Practice 1: Initial Estimate

A regulated company should have an established system for obtaining an initial cost estimate for a given scope of work in order to evaluate its viability. Throughout the course of the activity the estimate should be updated and expenditure tracked to predict final cost and ensure continuing viability.

Sub-Practice 2: Planning

The appropriate technical and engineering departments should work with the financial and contract departments to develop models determining contract strategy, factoring in net present value, monetary cost, Return on Investment (ROI), and cost of acceleration. The relationship between schedule and cost should be understood and optimized for best ROI.

Sub-Practice 3: Return on Investment

The relationship between the costs of an activity and the ROI should be understood and used to provide a rationale for proceeding during each stage of development.

Sub-Practice 4: Front End Loading

Committing more resources in the planning and design stage of a project may improve design coordination and definition, and, therefore, help minimize the risk of cost and schedule overrun. It may, however, seem to slow down progress during the early stages of a project.

Sub-Practice 5: Payback Policy

ROI should be subject to rules determining acceptable payback periods compatible with a regulated company's investment and long term business strategies.

Sub-Practice 6: Cost of Ownership

The full cost of ownership, including operating costs, decommissioning and disposal costs should be considered in investment decisions.

Sub-Practice 7: Cost Control

Cost estimates should be finalized at design approval. Controls should be established to ensure that all proposed changes to an approved design are assessed for cost and schedule impact in a timely manner before they are approved.

3.1.3 Organization and Control

A clear structure of organization and control is required to respond effectively to the changing demands of the business.

Sub-Practice 1: Clear Structure

Reporting relationships and responsibilities within a regulated company should be clearly understood and documented. The use of matrix management for a particular activity may redefine or amend the relationships, so should be used only when clear reporting lines are defined.

Sub-Practice 2: Review

Regulated companies should periodically review their organizational structure to ensure maximum efficiency and to ensure that the overhead to output ratio is acceptable when compared to similar regulated companies.

Sub-Practice 3: Monitor

Control mechanisms within a regulated company should monitor the performance and progress of assigned activities.

3.2 Project Engineering

3.2.1 *Project Infrastructure*

The regulated company should organize its project engineering activities according to defined procedures and processes.

Sub-Practice 1: Defined Organization

For each project, regulated companies should have defined project groups with clear decision making responsibilities and financial authority. Key stakeholders should be identified, and should have ownership, accountability, and responsibility for a project and its outcome.

Sub-Practice 2: Defined Procedures

Regulated companies should have defined procedures to cover the anticipated range of projects, including appropriate governance procedures, either on a general basis or for an individual project. These procedures should include the project group structure, reporting structure, and include a documentation strategy, describing:

- retention and storage criteria
- planning, progress, and cost reporting
- change control (appropriate to each stage and activity)
- design reviews
- quality control

For an example of GEP guidance and project quality planning guidance refer to Attachments A and B.

Sub-Practice 3: Assessment

Regulated companies should ensure that project objectives, (e.g., process, product, and equipment) are defined during the early stages of a project, and that subsequent methods and procedures are established for the application of risk and impact assessments to identify and mitigate identified risks to a project's objectives.

Sub-Practice 4: Scalability

Regulated companies should ensure that project groups, procedures, and responsibilities for a project are appropriate for the size and type of project activities and the impact of the project on GxP regulated systems.

Sub-Practice 5: Appropriate Staff

Regulated companies should ensure that project personnel are suitably trained, resourced, and supported in accordance with the number, size, and type of project activities and technical requirements.

3.2.2 *Project Organization*

The management of projects within a regulated company should be an organized, defined activity, driven by the need to achieve cost and quality effective improvement.

Sub-Practice 1: Project Identification

Regulated companies should have systems for recurring review of current and future requirements against current capabilities and available technologies. This information should be used to identify the need and justification for change.

Sub-Practice 2: Project Definition

Regulated companies should have mechanisms for the review of proposed changes and a method of defining the scope of work (e.g., User Requirements Specification (URS)).

For an example of a high level project URS refer to Attachment C.

Sub-Practice 3: Project Approach

Regulated companies should ensure that appropriate methods, such as risk assessments and impact assessments, are used to establish the optimum approach to a project. The approach adopted should consider the full life cycle and associated risks, e.g., the lowest initial cost option may not be optimal due to higher operational costs or other significant risk factors.

In an extended project, such decisions should be re-evaluated based upon a pre-determined schedule.

Sub-Practice 4: Project Implementation

Regulated companies should have methods to determine the most appropriate approach for implementation of the project with both a budget and a schedule.

Sub-Practice 5: Project Management Resources

Regulated companies should ensure that projects have access to adequate resources including for example, appropriate personnel, communications, funding, offices and systems.

3.2.3 *Value Analysis*

A regulated company should have defined methods of rational decision making regarding the implementation of projects based upon their ability to yield value.

Sub-Practice 1: ROI and Risk Analysis

Regulated companies should assess the ROI and consider any potential risks and benefits in determining the viability and manner of execution of the project. The need for timely execution and the risks associated with failure should be clearly understood by stakeholders.

For an example of project risk analysis guidance refer to Attachment D.

Sub-Practice 2: Supplier Selection

Regulated companies should ensure that appropriate methods are established to assess and select suppliers based on defined project acceptance criteria, including:

- quality
- costs
- experience
- technical support
- scope of work
- schedule

Sub-Practice 3: Cost Control

Regulated companies should be capable of estimating the anticipated costs of projects, reviewing and controlling them during project implementation on an ongoing basis.

For an example of project management guidance refer to Attachment E.

Sub-Practice 4: Value Engineering

Regulated companies should have systems for reviewing proposed solutions against the defined project requirements to ensure that adequate quality is delivered at optimum cost. The total life cycle cost of any proposed solution should be considered in this review.

3.2.4 Planning and Monitoring

A regulated company should have a long term business strategy, which may include formal site/organization plans. There should be a formal method of developing a project plan to achieve the defined objectives, reviewing them against the organization strategies/plans with a means of monitoring project progress against the project plan.

Sub-Practice 1: Long Term Strategy

Regulated companies should have long term business strategies, which may include formal site master plans. These should be reviewed and revised as required to ensure that they reflect the commercial and political environment.

For an example of a strategic plan refer to Attachment F.

Sub-Practice 2: Project Planning

Regulated companies should have systems for developing project plans, which define:

- time lines
- activities
- methodologies
- dependencies
- resource requirements

For an example of a project execution plan refer to Attachment G.

Sub-Practice 3: Project Quality Planning

Regulated companies should ensure project quality plans are available and appropriate for the proposed project, and managed in accordance with an agreed project schedule. The project quality plan should define acceptable quality standards and how they will be achieved and assessed, e.g., include review stages, approval, and quality management of suppliers.

For an example of project quality guidance refer to Attachment B.

The project quality plan should cover:

- change control process and implementation
- the application of the risk management strategy (how to manage risks and when to perform assessments)
- document checking, review, and approval before issuing at pre-defined stages (e.g., concept, approved for design, and approved for construction)
- document numbering and version control
- equipment and instrument identification
- design and progress reviews
- document distribution and control

Sub-Practice 4: Monitoring

Regulated companies should have systems for identifying the most appropriate means of monitoring progress against the project plan (ongoing costs, work progress, activities completed) and for predicting final cost and completion date. This information should be regularly communicated to the key stakeholders (e.g., users, senior management, and finance departments).

Sub-Practice 5: Change Management

Regulated companies should have systems for recognizing the need for change within project activities.

A change management system should have a method for timely reviewing of change options and determining the most appropriate course of action. The change management system should revise and amend the scope, schedule, and budget to reflect the selected outcome. The change and its potential impact should be communicated to the key stakeholders (e.g., users, quality department, project cost control, and senior management). The change management system, and associated review and approval method, should be adapted to the project stage and regulatory impact, allowing effective and rapid change control.

For an example of project change control guidance refer to Attachment H.

3.2.5 Design

The regulated company should have a structured design process to achieve the optimum value in relation to the project size and scope.

Sub-Practice 1: User Requirements

Regulated companies should have established methods for developing and reviewing a formal User Requirements Specification (URS), capturing both the fundamental aspects and scope of the users' requirements. Users should be involved as much as possible in this process. As a minimum, users should be required to review and approve these requirements. Requirements should be objectively stated such that they can be verified *during testing and commissioning*. Alignment with objectives of any company strategy or master plan should be confirmed.

Requirements should be focused on product and process requirements and as far as possible leave engineering aspects open for subsequent definition.

URSs vary immensely in their scope and complexity; examples and approaches for equipment may be seen at the JETT Web site hosted by ISPE (see Reference 6, Appendix 3).

For examples of a high level project URS and a more detailed system URS refer to Attachments C and I.

Sub-Practice 2: Design Development

User requirements should be written in measurable terms and should be used as the basis for developing project specifications and drawings. Users and designers should determine appropriate iterative design stages, with increasing project definition, at which a project can be reviewed. This process should enable increasingly accurate cost and schedule estimates and maintain quality,

The stages at which the project design should be reviewed will vary according to type, scale, and risk. Each stage, typically, will require a further contractual commitment by the owner or his agent.

Stages typically will include:

- Initiation (definition of project goals and initial project URSs)
- Justification (confirmation of the business case with definition of acceptable project cost)
- GxP impact/risk assessment (understanding how much additional effort is necessary to verify formally the system)
- Design Acceptance
- Execution (design development through to the stage of Issued for Construction (IFC) drawings and specifications)

For an example of a design review template refer to Attachment J.

Sub-Practice 3: Design Deliverables

The structure and level of detail in the design deliverables will be determined by the chosen contract strategy, acceptable degree of risk, and the size and make-up of the project support team.

For each stage of a project, specific design deliverables will vary according to the project, and may include:

- concept drawings: sections; layouts material flow, personnel flow and process flow
- intermediate stage: development of Process and Instrumentation Diagrams (P&IDs), preliminary equipment specs, outline architectural drawings

- final stage: detail drawings specifications and purchase orders
- specific local documentation deliverables for compliance with regulations (e.g., health and safety (EHS) regulations, pressure regulations) and obtaining approvals

3.2.6 *Design Reviews*

The regulated company should have a formal system for reviewing the design against objectives to ensure that adequate quality is delivered at optimum cost.

Sub-Practice 1: Design Quality Control

Users should agree with designers a system for quality control of drawings, specifications, and calculations, typically defined in a project quality plan.

Sub-Practice 2: Design Review Stages

The design should be reviewed at pre-defined stages and appropriately documented during development targeted to address specific issues such as:

- does the design meet the defined user requirements
- concept review to consider basis of design and its suitability for:
  - delivery of expectations
  - site location
  - available materials
  - local technology levels
  - local skills
- code compliance considering applicable local, international regulatory and corporate codes
- risk management and safety review, including:
  - materials of construction
  - Highly Protected Risk (HPR) design strategies
  - fire and explosion risks
  - natural hazards
  - security
- ergonomic review
- environmental review
- energy efficiency and costs of ownership

- value engineering to ensure capability against cost targets
- progress monitoring review against schedule
- constructability review (e.g., services coordination, shipping routes, contract strategy)
- ability to be maintained (e.g., access and space, material handling)
- review for ability to be commissioned (e.g., flushing points, adjustment and measuring accessibility)

Sub-Practice 3: Design Review Mechanism

Regulated companies should define methods of reviewing the project design according to type, scale, and risk, using suitably skilled people, including users, to challenge the design and ensure that specified requirements are delivered.

The methods should identify all relevant codes, regulations, technical norms, and standards that may require compliance, and formally confirm applicability and conformance.

Regulated companies should ensure that the review includes all factors likely to be significant at a given review stage.

For an example of a design review template refer to Attachment J.

Sub-Practice 4: Design Review Outcome

Regulated companies should have appropriate methods for recording and disseminating the results of design reviews, and managing any consequent changes.

The results should confirm the continuing suitability of the design.

3.2.7 Construction

The regulated company should have an appropriate means of selecting and managing the method of construction.

Sub-Practice 1: Management Systems

Regulated companies should have established methods of reviewing the options for the construction contract strategy suitable to its type, scale, and risk.

Management systems should consider local custom and practice and address:

- conformance to the design drawings and specifications (quality control)
- reporting of progress and issues
- management of items constructed offsite
- the interface between the supplier's quality management system and the organization's internal Quality Management System (QMS), e.g., the application of project change control versus site change control
- site physical access to plant and management of personnel, while working on the organization's facility, (including site visits to clarify design needs)

- housekeeping and safety
- generation and approval of method statements
- generation of appropriate documentation and records, e.g., system build records
- punch listing and definition of completion
- handover for commissioning
- management of subcontractors
- contractor training

Sub-Practice 2: Quality Standards

Regulated companies should ensure adequate means of defining and achieving quality standards.

Quality management systems should include:

- risk assessments
- review and approval of samples
- means of defining quality standards, e.g., construction of example rooms
- management of materials, and equipment delivered to site
- construction quality control – maintaining cleanliness of ductwork, pipework, inter stage inspections/project hold points
- construction quality tests
- documentation standards and delivery of construction records

Sub-Practice 3: Construction Execution

Off-site and site practices should be developed based upon a pragmatic assessment of relevant local practices to deliver project objectives.

3.2.8 Non-GxP Regulation Compliance

The regulated company should have a mechanism for identifying and ensuring compliance with all relevant statutory and regulatory requirements to achieve compliant construction.

Sub-Practice 1: Non-GxP Statutory and Regulatory Requirements Compliance

Project procedures should ensure responsibility is assigned for formal identification and enforcement of relevant non-GxP statutory and regulatory codes and regulations (or obtaining variances and waivers). This may apply to site based construction practices, construction tests and records, as well as the specification of equipment (e.g., pressure regulations, electrical codes, and CE marking).

Sub-Practice 2: Construction Permitting

Requirements for various permits required to construct, occupy, and approve designs should be determined and responsibilities clearly assigned to obtain the appropriate permits.

Sub-Practice 3: Construction Records

The specific local regulatory requirements for formal records should be defined, and responsibility for creating, updating, and filing the records required be clearly assigned.

For an example of a document certifying electrical completion refer to Attachment K.

3.2.9 *Commissioning and Qualification*

The regulated company should have a system to ensure satisfactory commissioning and qualification/verification for projects. For an example of facility commissioning guidance refer to Attachment L.

Sub-Practice 1: System Definition

Regulated companies should have established methods for defining systems and sub systems to be used in commissioning and qualification. These should be logical sub-divisions and wherever possible divide systems into GxP and non-GxP to reduce the GxP qualification effort.

For an example of strategies for defining system boundaries effectively refer to Attachment N.

Sub-Practice 2: System Risk Assessment

Regulated companies should have established methods for risk assessment of systems and determining the level of risk to product quality and patient safety.

Sub-Practice 3: Commissioning

Regulated companies should have systems to ensure that effective commissioning is performed and appropriately documented, particularly where it relates to high risk systems. Commissioning should be referenced to user requirements and testing should verify that the requirements have been met. The commissioning team should have a means of procuring consumables, managing maintenance and calibration requirements, and maintaining operational logs during the startup to handover period.

For examples of commissioning plans refer to Attachments O and P.

Sub-Practice 4: Qualification/Verification

Regulated companies should have a method of risk assessment to ensure that an appropriate degree of qualification is carried out based on identified Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs).

3.2.10 *Handover*

The regulated company should have a defined system for handover of the completed project to the user.

Sub-Practice 1: Documentation Requirements

Handover to the user should include documentation which confirms function, capability that will adequately facilitate future support, e.g.:

- construction drawings and 'as built' records
- commissioning reports, initial operating and maintenance records
- spare parts and operating and maintenance manuals/procedures
- data for entry into relevant maintenance/calibration systems
- appropriate training and associated documentation
- qualification/verification packages

The project should be finalized and adequate records issued (to provide a record of the 'as built' status) of the system.

Sub-Practice 2: Standard Operating and Other Procedures

Regulated companies should prepare policy, strategy, Standard Operating Procedures (SOPs), planned maintenance procedures, and other plans, as necessary, required to operate and maintain the system. Operators and maintenance personnel should be trained on the system prior to handover.

Sub-Practice 3: Staged Handover

Large or time critical projects may justify a staged turnover of systems. Where this is the case the methodology and division of responsibilities should be clearly defined. Deviations (exceptions and punch list items) which require further follow-up action in subsequent stages should be clearly documented in reports to ensure continuity.

3.3 Common Practices

3.3.1 Standards and Procedures

The regulated company should have written standards and procedures for all key aspects of operation. This should include a process for checking and approving issuing and retrieving standards and procedures.

Sub-Practice 1: Review and Approval

Standards and procedures should maintained current and effective, they should be reviewed and approved by appropriate personnel.

There should be a system for issue of new standards and procedures and for the retrieval of superseded standards and procedures.

Sub-Practice 2: Structure

A structure should be in place to define the difference between guidance and work instructions. Work instructions should be adequate to define practices and methods ensuring consistent understanding and execution.

3.3.2 *Documentation Practices*

The regulated company should have systems for the generation, review, approval, retrieval, and archiving of written standards, procedures, and records, whether paper-based or electronic. The system should have methods to ensure the security and integrity of documents, depending on the assessed importance of these from a legal, operational, or professional perspective. Engineering documents should be generated and maintained in a manner to ensure that information contained therein is accurate, clear, unambiguous, and current.

Sub-Practice 1: Storage

Regulated companies should have secure defined systems and locations for retention of key documentation.

The systems should allow rapid access to copies and data to appropriate staff. The systems also should manage according to the risks involved, the recall, destruction, or obsolescence of outdated information. Access to key documentation should be controlled.

Sub-Practice 2: Engineering Drawings and Specifications

The system should define the level of accuracy required for engineering drawings, specifications, supplier, and third party documents.

The system should define which documents will be maintained as 'as built' records, how they will be maintained as accurate and checked on completion of the work.

Documents may need to be maintained as 'living documents' and frequently updated to reflect latest concepts and requirements.

The use of hand 'marked up' (red lined) as opposed to redrafted documents can be appropriate, but should be used in a manner consistent with the inherent risks and limitations, i.e., there should be a clear understanding of where the 'master' documents are and a consideration of the risks of using obsolete documents.

Consideration should be given to the archiving and retention of superseded documents where required.

Sub-Practice 3: Test and Inspection Records

Test and inspection records may be of value as baseline performance data or as contractual evidence of performance.

Regulated companies should define documentation standards to ensure records are clear and unambiguous. Typical company documentation standards may stipulate, e.g., the following:

- Written entries should be clear and legible using an indelible medium (e.g., ink) that can be photocopied.
- Information or data should be accurately recorded in a prescribed and controlled book, form, sheet, or electronic template at the time each action is taken or observation is made.
- Compliance of observed condition or status to pre-approved specifications may be indicated by a 'O,' 'X,' or other recognizable symbol (i.e., a checklist). Where symbols are used it should be clear from the document what the symbol means. Consideration of using 'pass' or 'fail' for test results should be given for key information. Space on forms should be adequate for the clear entry of data, etc. Expected results need not be pre-printed on the form as long as they are clearly referenced.
- Quantifiable data should be recorded as observed, rather than indicating only that specifications are met.

- Temporary records such as Post-it® notes or scrap paper must not to be used.
- For unstable media a copy should be made in addition to the original record (e.g., thermal paper print-outs).
- Records containing photocopied information should reference the original source. (Note: Source of the photocopy may be annotated manually.)
- All pages and printouts from instruments or data acquisition systems should be identified appropriately.
- Pages should be numbered; the "pg. x of y" notation is recommended.
- Blank spaces may be filled in with "N/A," slash, dash, or other recognizable symbol. It is considered not necessary to initial or date blanks.
- Record sheets should be signed and dated by the person performing the function. It may not be necessary to sign, initial, and date each entry if it is well identified and complete once in the document.
- Data superseded by a subsequent test or inspection (e.g., after a repair or correction) may be deleted. The final record should be annotated to indicate if a repair or correction has been made.
- Corrections may be made by a single-line cross out. No initials, dates, or explanations are required as long as an entry is clear and unambiguous.
- Entries should not be altered, obliterated, or over written. The use of correction fluid, correct tape, etc., should not be permitted.
- It should be permissible to transcribe data from one form to another (e.g., printed tabular summary of manual entries). Transcribed data should be signed and dated. The date of the actual data should be included. Original data sheets and checklists should be available for review until such time that the transmitted document has been accepted and approved.
- Changes to approved documents should require re-approval.

Sub-Practice 4: Review and Approval of Documents – General

Approvers should be able to understand the record and be appropriately educated, trained, and experienced. They should not be required to approve beyond their competence.

Good Practice requires that the responsibility and significance of a given approval signature should also be stated (e.g., accepted on behalf of maintenance).

Delegation of authority to a designee should be sanctioned in project procedures or documented in a memo.

Review and approval of a major document (e.g., specification, report, or drawing) normally requires full signature and date. Initials may be used for review and approval of calculations, data sheets, and checklists.

Signature and initials of reviewers should be clearly identifiable and documented according to project procedures (e.g., a signature/initials log).

Sub-Practice 5: Retention of Documents

Regulated companies should define the periods of retention required for different documents.

The storage conditions should be defined, and appropriate for the retention period.

Regulated companies should have policies for duplicate records, and protection of stored original documents.

Project turnover procedures should indicate which records and documents will be turned over to the operating unit at the completion of the project.

Sub-Practice 6: Destruction of Documents

Procedures for destruction of documents should be established to ensure destruction, where required, at the expiry of the retention period of documents.

Sub-Practice 7: Electronic Records

Electronic records of GEP documents are permissible and not subject to any specific regulation. Records should be controlled in a manner to ensure that they are secure; a means of reading them and of ensuring that their integrity is maintained. Electronic records should have the same level of control and acceptability as the equivalent paper records.

3.3.3 Change Management

Change management is critical to GEP. Processes should be defined for change management which are scaled to the risk, complexity, and stage in the system lifecycle. For example, minutes of meetings for conceptual discussion (low risk – early stage). Use of a formal procedure with a template form and routing through impacted groups to authorize a proposed change (for high risk – late stage).

Proposed changes to project requirements or design specifications should be assessed for potential impact on scope, cost, and schedule.

Proposed changes to operational assets should be assessed for potential impact on operation and maintenance.

Change management processes should specify controls appropriate to assessed risk (e.g., 'like for like' component substitutions should be subject to simple review, whereas more complex changes may require formal multi-disciplinary review and approval).

Sub-Practice 1: Change Request

Regulated companies should have a change management system to request changes. Users, maintenance engineers, vendors, and business owners are the most likely sources of change requests. Change requests should be recorded and uniquely identified. A change request should briefly state the reasons why the change is required, referring to additional documentation as appropriate to the scale of the change.

Sub-Practice 2: Regulatory Assessment

In an environment where both regulated and non-regulated assets are in use the assessment process should define whether a change has potential GxP impact.

Changes with potential GxP impact should go through a formal (documented) process to consider the potential impact, the intended purpose, and the work required to implement the change. Appropriate review and approval with notification to the Quality unit should be included.

For non-GxP changes the process may be less formalized.

Sub-Practice 3: Project Impact

The system for project change control should consider the benefits of the change as well as the potential impact on scope, cost, and schedule, with stakeholder agreement obtained where necessary.

There should be a formal process to communicate the change to the stakeholders e.g., users, the quality department, project cost control, and senior management.

Sub-Practice 4: Operational Impact

The change management system for existing assets should be consider potential impact upon operation and on maintenance.

Where the scope or scale of a change is significant, managing the work performed through the project engineering process should be considered.

Sub-Practice 5: Change Plan

The proposed method of implementing a change request should be defined. The level of detail contained in this plan should be appropriate to the assessed impact of the change.

Sub-Practice 6: Testing

The level of testing and documentation applied to changes should be commensurate with the associated risk.

Sub-Practice 7: Records and Change Completion

Any changes implemented should be recorded via updates to appropriate records (e.g., design specification, drawings, or maintenance procedures), either as supplemental data or revisions to existing records. A concise change history that includes the unique change identifier should be incorporated in revised records.

The system should provide confirmation that work has been completed in a timely manner. So called 'Living Documents,' which need to document current status should be maintained in a similar manner.

Sub-Practice 8: Analysis

Regulated companies should establish systems to monitor changes, e.g., by type or location, to identify trends and identify potential underlying issues (e.g., a poorly defined design) which may require an alternative approach in order to eliminate the root cause.

Sub-Practice 9: Audits

Regulated companies should have audit processes, using prearranged external or internal auditors, to ensure that change control procedures are being followed. The review period should be commensurate with the associated risk.

For further information see Section 3.4.5 of this Guide.

3.3.4 Innovation and Continuous Improvement

A regulated company should create an atmosphere which encourages staff to have a desire to innovate and continuously improve themselves, processes, and products.

Sub-Practice 1: Benchmarking

Regulated companies should be aware of their performance compared with similar enterprises and 'best in class.' Benchmarking should consider areas such as:

- costs of commissioning

- calibration and maintenance
- building costs and times
- equipment utilization
- manpower and staffing levels

This data should be used to determine areas for improvement and define best practices. Best practices should be used to improve performance.

Sub-Practice 2: Continuous Improvement

Regulated companies should have a system for evaluating returns and complaints. Evaluation of down time and time taken for maintenance and operational tasks should be included

Regulated companies should have processes to improve products and processes continuously.

For an example of a project management completion document that seeks to drive continuous improvement refer to Attachment Q.

Sub-Practice 3: Training and Development

Regulated companies should recognize the need for, encourage, and facilitate staff training and development using cost effective methods. Value rather than cost should be the main consideration. This may include financial support or incentives, together with release from day to day activity subject to review and approval. The membership of professional institutions and active participation in their activities should be encouraged.

Sub-Practice 4: Professional Pathways

Regulated companies should define career growth paths allowing professional development and encourage succession planning and personal development to the benefit of the company.

Sub-Practice 5: Staff Retention

Regulated companies should appreciate the value of retaining staff and the expertise appropriate to their business, and review staff capabilities against requirements to ensure best fit, adjusting the structure where necessary. Benchmarking to ensure renumeration and terms are aligned with local and industry norms should be performed.

Sub-Practice 6: Position Requirements

Regulated companies should be aware of professional qualifications required for individual positions. These should be available as part of job descriptions/role profiles.

3.3.5 Calibration

The regulated company should have a system to ensure that all instruments are managed, to guarantee that they are maintained in a state of calibration appropriate to the risk to product quality and business success, see the ISPE GAMP® Good Practice Guide: Calibration Management (see Reference 5, Appendix 3).

Sub-Practice 1: Instrument Selection and Assessment

All instruments should have a clearly defined function in particular whether the data output is used to support product quality. Each instrument should be assessed by the appropriate staff before being put into service, to determine their potential to affect product quality and productivity (risk), and the risk of instrument uncertainty increasing with time (need for calibration). This data should be used to determine:

- the selection of the type of instrument used for the application
- the initial frequency of calibration and periodic review against performance
- the instrument category, e.g., product, process, EHS, or non-critical
- the calibration range and accuracy required

Sub-Practice 2: Instrument Schedule and Records

An accurate record should be maintained of instruments entered into the calibration program. The process requirements, calibration activity, and any adjustment required for an instrument should be recorded.

Sub-Practice 3: Calibration Record Review

Records should be securely stored, retained for a defined period and evaluated periodically to ensure that the appropriate instrumentation is in use and is routinely calibrated at the appropriate frequency.

Sub-Practice 4: Cost Control

Data from the calibration management system should be periodically reviewed to determine the cost of calibration according to instrument category.

Sub-Practice 5: Performance review

Data from calibration activities should be reviewed to assess trends and drift. These should be used to determine the frequency of calibration instrument type required to maintain the desired accuracy at an acceptable level of risk.

3.3.6 Asset Management

Asset management includes the requirement for documenting, managing, and tracking the life cycle of assets.

Sub-Practice 1: Asset Register

Asset registers may exist for a number of purposes:

- regulatory requirements
- financial accounting (e.g., auditing depreciation or general ledger entries)
- file and record keeping organization and identification tagging
- security and ownership verification
- maintenance
- calibration

- soft assets versus hard assets

Financial asset registers are required for accounting purposes, depreciation, and security. Asset register and asset register tags are useful identification tools to facilitate this.

Equipment and tag numbering systems may exist for other purposes, e.g., identifying process elements for calibration or maintenance. The numbering system should indicate function as well as location.

Prior to equipment and facilities being used, they should be assessed and inventoried on an asset register recording usage and value. This data can be used to make informed forward planning assessments and ROI decisions. This register could link with other components (e.g., maintenance and breakdown cost, calibration, productivity data, preventative maintenance, or spares) so that ROI reporting can be performed for major equipment and systems.

Sub-Practice 2: Strategy and Planning

Major systems should have maintenance and support strategies as well as plans and procedures for future enhancements and upgrades. Evaluation tools such as Reliability Centered Maintenance (RCM), Failure Mode and Effect Analysis (FMEA), and Root Cause Analysis (RCA) should be considered.

Sub-Practice 3: Support

Systems and equipment should have defined, documented support procedures whether support is performed in-house or via system supplier or third party support.

Sub-Practice 4: Computer Systems

Prior to a computer system or software package being used, it should be assessed and recorded on an asset register or systems register to record its usage and status. Where a system is used for GxP as well as GEP purposes then this fact should be recorded on the register.

3.3.7 *Vendor/Supplier Management*

A documented process of supplier management should be in place to ensure that supplier facilities practices and standards, present an acceptable risk to the regulated company.

Sub-Practice 1: Supplier Management

Regulated companies should have systems for continuing research and accreditation of suppliers of services and materials, ensuring adequate quality standards are maintained, with core suppliers and a back-up strategy.

Sub-Practice 2: Supplier Audit Plan

An audit plan should be established to cover the routine audit of key external suppliers.

Use should be made of supplier audit check lists to ensure consistency. These may be used for trend data.

For an example of an audit template and a postal quality audit refer to Attachments R and S.

3.3.8 *Engineering Storage*

The regulated company has a system ensuring that appropriate storage systems exist to ensure adequate engineering spares, tools, equipment, and materials are available to be supplied to the business in a timely manner.

Sub-Practice 1: Facilities

Regulated companies should have established central or local storage with suitable security, environmental conditions, storage, and retrieval systems to maintain and deliver items in an undamaged state.

Sub-Practice 2: Inspection

Regulated companies should have systems to inspect goods received against agreed specifications.

Sub-Practice 3: Inventory Control

Regulated companies should manage stores inventories to ensure adequate stocks for envisaged requirements, and manage the following activities to yield best value:

- purchasing (e.g., order quantities, delivery times, storage costs)
- storage (First In First Out (FIFO)/ First Expired First Out (FEFO) if appropriate)
- sub contract supply and storage

Sub-Practice 4: Identification

Regulated companies should have systems to correctly identify and label spares, materials, tools, test equipment, and change parts. This may be part of an overall asset management system.

Sub-Practice 5: Cleaning

Regulated companies should have established appropriate procedures for decontamination and cleaning of change parts, materials, tools, and calibration equipment to prevent cross contamination by engineering activities.

Sub-Practice 6: Project Storage

Where necessary, regulated companies should create separate set down areas or storage with the associated procedures required for project equipment not part of routine operations.

3.4 Operations and Maintenance

3.4.1 Documentation

Operations and Maintenance activities should have supporting documentation to allow routine activities to be performed consistently and trace the history of work done. Supporting documentation should allow trained staff to perform activities efficiently.

Sub-Practice 1: Procedures

Operation and maintenance activities should have written procedures to ensure that activities are repeatedly performed against an approved method. Procedures should follow the practice defined in equipment manuals. The level of detail should allow appropriately qualified and trained staff to understand the actions required.

Sub-Practice 2: Records

Operation and engineering records should be maintained. Records should be kept current to maintain a state of compliance and approval. Procedures should allow the use of redline mark ups with periodic updates for maintenance reference purposes.

Records should be stored and retained for a predefined period, and trends should be monitored.

Sub-Practice 3: Record Availability

Engineering records should be readily available to support staff and routinely inspected for accuracy, completeness.

3.4.2 Engineering Manuals and Records

A regulated company should have a defined method of creating and maintaining engineering manuals and records relating to facilities, equipment, and products.

Sub-Practice 1: Assessment and Review

Regulated companies should have methods for determining which records are required, and the most effective format for storing and maintaining those records. Records should be reviewed by staff according to the level of risk involved.

Sub-Practice 2: Maintenance of Records

Systems should be established to ensure that stored records are current, and issued on request, with obsolete versions of earlier releases retained and issued only when specifically requested. There should be a system for version control with history.

Sub-Practice 3: Revision Control

There should be an established system to notify personnel who need to know of any changes to a specific record which may be in their possession. Retrieval or destruction of superseded documents should be a part of this system.

Sub-Practice 4: Access

Engineering manuals should be readily available to maintenance personnel. Consideration should be given to storage of manuals adjacent to relevant equipment. This should be balanced against the need to control the documents and keep them complete, accurate and current.

3.4.3 Routine Maintenance

Preventative Maintenance (PM) provides schedules and procedures for routine activities such as adjusting, cleaning, modifying, maintaining, and overhauling equipment to assure continued performance, in accordance with specifications. Operations and maintenance methods and resources are arranged to maximize business benefits, minimize the consequences of functional failure to product and business activities, and deliver the quality assurance aspects of the process to an organization.

Sub-Practice 1: Assessment

Equipment should be assessed for potential failure modes before being put into productive use to determine the potential to affect product quality and productivity. Risk assessments should be used to determine the initial frequency of maintenance for failure mitigation, and should be periodically reviewed against the results obtained.

Sub-Practice 2: Maintenance Interval

The maintenance interval should take into account manufacturers recommendations, the user's experience with the type of equipment, and its inherent design. Typically, equipment will have some maintenance risk based criticality level assigned based on EHS, GxP, product impact, or operational criticality. Maintenance should be performed against manufacturer's procedures modified on the basis of experience and user requirements. Data review and change management rationale should be used to adjust maintenance intervals.

Sub-Practice 3: Prioritization

Routine maintenance activities should be prioritized and scheduled according to product/patient impact, regulatory non-compliance, or productivity consequences Resources should be matched to the manpower and equipment maintenance requirements.

Sub-Practice 4: Maintenance Schedule and Records

A record should be maintained of all equipment entered into the maintenance program detailing the activity and any work performed.

Preventative maintenance should include scheduling tasks based on both running hours and time.

Sub-Practice 5: Procedures

Preventative maintenance should be performed against approved procedures and recorded adequately by noting activities performed. Feedback should be obtained from the personnel performing the tasks to determine the continuing benefit and relevance and any potential adjustments needed.

For an example of a PM completion document that seeks to drive continuous improvement refer to Attachment Q.

Records should be stored and retained for a predefined period and trends monitored. Data review and Change Management should be used to revise maintenance procedures and intervals. This information should also be used to determine the continuing suitability and service life of the equipment.

Sub-Practice 6: Reliability Based Maintenance

Reliability based maintenance is an example of using risk based measures to focus and adapt GEP effort where most needed, according to measured reliability performance.

Sub-Practice 7: Utilization Monitoring

A GEP tool facilitating optimization of asset usage is the use of on-line performance monitoring of equipment activity and downtime.

Sub-Practice 8: Design Considerations for Maintenance

The need to maintain equipment and minimize disruption to operations should be considered as a factor in system and facility design, e.g., duty and standby pumps; allowing one pump to be maintained while the process runs using the alternative pump.

Allowing adequate space for withdrawal and disassembly of fixed equipment.

System utilities should be designed to allow isolation and segregation, thereby mitigating or minimizing the adverse consequences of functional failure and shutdowns. Equipment design should be reviewed to ensure that it will allow easy routine maintenance. Where the risk and benefit justify, provision in the design should be made for lifting and removal of heavy equipment that may require replacement.

Sub-Practice 9: Cost Control

Data from the maintenance record system is periodically reviewed to determine the cost of maintenance activities according to criticality level. This is reviewed for trends and benchmarked against external references. Results are used to assist decision making in relation to equipment and system upgrades, continuous improvement strategy, selection, replacement, and to optimize maintenance practices.

Sub-Practice 10: Spares

GEP preventative maintenance should consider spares holding requirements, determined against a risk assessment considering the:

- criticality of activity
- Mean Time Between Failures (MTBF)
- Predicted Mean Time To Replacement (MTTR)
- associated cost of production down time and lost revenue

For support activities beyond the regulated company or site capability, vendor support contracts, spares storage, and supply of spares should be considered in regard to turn-around time for replacement.

Sub-Practice 11: Software

Maintenance to a software system includes correcting software errors, adapting software to a new environment, or making enhancements to software. Supplier records and specifications should be updated for system maintenance.

Specifications may be updated periodically to roll up a number of changes into one updated software version. Records of on-going changes should be maintained. Updates to specifications should be performed under change management.

Sub-Practice 12: Continuous Improvement

Maintenance activities should be included in a continuous improvement program, e.g., implementation of RCM, to review and improve the effectiveness of maintenance activities. This should include the analysis of life cycle costs and efficiencies, opportunities for quality improvement, failure consequence reduction, and cost improvement by revising equipment, processes, and practices.

Sub-Practice 13: Analysis

Data from maintenance and calibration should be analyzed to determine:

- validity of the maintenance interval
- ongoing equipment suitability
- service life of the equipment
- calibration accuracy
- cost of ownership
- underlying trends
- failure impact and mitigation

3.4.4 Breakdown Maintenance

Breakdown of equipment and systems should be rectified in a timely and cost effective manner.

Sub-Practice 1: Organization

Regulated companies should have trained staff available to attend to breakdowns promptly and return equipment back to operational use. Operations staff should be trained in call procedures, fault finding, and fault rectification methods for routine issues and where simple equipment maintenance is required. Engineering maintenance staff will be trained for other issues involving engineering skills or for specialized equipment needs. Contingency plans should be established for mitigation of probable risk events.

Sub-Practice 2: Analysis

Analysis of maintenance history, breakdowns, and trends should be performed to determine root causes with preventive and corrective measures instigated to address recurrent problems.

Sub-Practice 3: Breakdown Recovery Plans

Regulated companies should have established breakdown recovery plans based upon a risk assessment, which would identify critical equipment and risk to its operation. Mitigation measures could establish run/standby pairs, critical spares holding and supply, or service agreements and plans for alternative production.

Sub-Practice 4: Business Continuity Plan

In the event of major failure, organizations should have established Business Continuity Plans.

Sub-Practice 5: Computer Systems

Regulated companies should have trained staff available to attend failures of computer hardware and software. These individuals should also perform preventative maintenance, monitoring, routine testing, and housekeeping (e.g., maintaining back-ups, archiving data) activities. Planning should be established to mitigate the effects of a major system failure. This could involve off-site storage of back-up data; redundant and high integrity systems where considered appropriate. Computer system performance monitoring is commensurate with GEP.

Sub-Practice 6: Spares Holding

Regulated companies should have systems to identify and maintain a reasonable level of the spare parts required to repair equipment considered essential to the business. Spares holding and supply should be assessed using equipment suppliers' recommendations.

For further information see Section 3.3.8 of this Guide.

Sub-Practice 7: Emergency Systems

Regulated companies should have a readily available list of suppliers that hold and can quickly supply spare parts, or can provide specialist manufacturing or repair of the equipment in use.

Sub-Practice 8: Utility Failure

Regulated companies should have procedures and design to compensate and manage utility failures.

Sub-Practice 9: Review

The maintenance history of equipment should be reviewed to ensure that the procedures for maintenance are effective and that there are no reoccurring breakdowns indicative of design or operational maintenance problems.

3.4.5 *Internal Audit*

A documented process should be established to ensure that GEP is adequate and effective in all areas.

Sub-Practice 1: Audit Plan

Regulated companies should have established plans to cover the routine audit of internal engineering functions (including projects) and key external suppliers.

Sub-Practice 2: Audit Check Lists

Use should be made of audit check lists to ensure consistency of activity. These may be used for trend data.

3.4.6 *Waste Management*

The regulated company should have effective systems for disposal of waste products and materials in a manner that does not compromise business operations and meets applicable standards for environmental protection.

Sub-Practice 1: Waste Collection

Regulated companies should have appropriate systems for the collection, sorting, and intermediate storage and handling of waste.

Sub-Practice 2: Design

Waste streams: solid, liquid, and gas and their appropriate disposal should be considered during facility design.

It may be more cost effective to sub categorize and segregate waste at the point of generation.

In cases of hazardous or potentially hazardous waste, environmental safety should be addressed, e.g., containment of fire sprinkler discharge, or cytotoxic waste systems.

Sub-Practice 3: Treatment and Disposal

Regulated companies should have appropriate established methods of treatment and disposal based upon risk and statutory requirements, and cost benefit. The potential affect on public relations for a particular solution should be considered.

Sub-Practice 4: Design

The need for and cost associated with waste streams should be considered during facility design.

3.4.7 *Equipment Decommissioning and Retirement*

The regulated company should have a method for decommissioning and disposal of facilities and equipment.

Sub-Practice 1: Facility and Equipment Evaluation

Regulated companies should have appropriate systems for evaluating performance and ROI of existing assets against current best technologies. This should be used to determine the need to replace, supplement, modify, or refurbish existing assets on a cost/quality/efficiency basis.

Sub-Practice 2: Disposal

Regulated companies should have established methods of determining environmental/commercial/social risks associated with the various means of disposal in order to select the optimum.

Sub-Practice 3: Associated Activities

Regulated companies should have established methods to ensure that:

- associated records are archived and retained, as required
- qualification/verification records are closed
- maintenance and calibration routines/contracts are adapted in a timely and cost effective manner
- spares inventory requirements are modified and existing stock disposed of, as required
- required permits and licenses are obtained

Sub-Practice 4: Environmental Risks

Regulated companies should have established methods to ensure that potential environmental contamination is identified and addressed appropriately and in accordance with all relevant regulatory requirements.

3.4.8 Facility and Equipment Inheritance and Recycling

The regulated company should have a system for due diligence assessment and management of potential acquisitions to ensure that they are cost effective.

Sub-Practice 1: Inheritance

Regulated companies should review any potential asset relocation or acquisition to determine associated risks and evaluate the benefit against alternative options.

Where regulated companies do not have adequate skills internally, suitably qualified consultants should be identified to ensure that all areas of risk are considered.

Sub-Practice 2: Recycling

Regulated companies should evaluate the continuing requirement for any piece of equipment. Where utilization is low, alternatives for its use, or disposal should be considered.

Equipment efficiency should be reviewed against current technologies, and a determination made of the potential benefit of replacing, modifying, refurbishing, or recycling the equipment.

4 Appendix 1 – Explanation of Example Engineering Management Process

Figure 4.1 is an **example** of a management process for the specification, purchase, project management, commissioning, acceptance, maintenance and use of functional equipment.

Each box in the diagram represents a documented activity. It loosely groups these activities in columns. From left-to-right these columns are:

- specification and testing
- financial and contractual control
- project management and project review
- engineering asset registration and recommended spares holdings
- calibration and maintenance schedule and tasks
- training and production use

Supporting the last two items are:

- maintenance history
- production measures

Data from these two activities continuously feeds into Key Performance Indicator (KPI) analysis. The results of KPI analysis may generate improvement requests.

Improvement requests, like any other requests for change, feed into an underlying Change Management process. Each change is assessed for its impact on:

- requirements specifications in the project delivery phase
- design specifications in the project delivery phase
- cost/time in the project delivery phase
- maintenance and use of the asset

A change may have one or more of the above impacts. The diagram shows the points in the process where these impacts have a consequential effect. Once the affects of the change have been assessed it is submitted for approval or rejection.

Implemented changes affect configuration records held for the assets. Configuration records are held to provide an audit trail of change versus impact.

The diagram does not specifically show a risk assessment activity. Instead it indicates, through the use of shaded boxes, documented activities in the process that may require enhancement as a result of criticality and risk assessment.

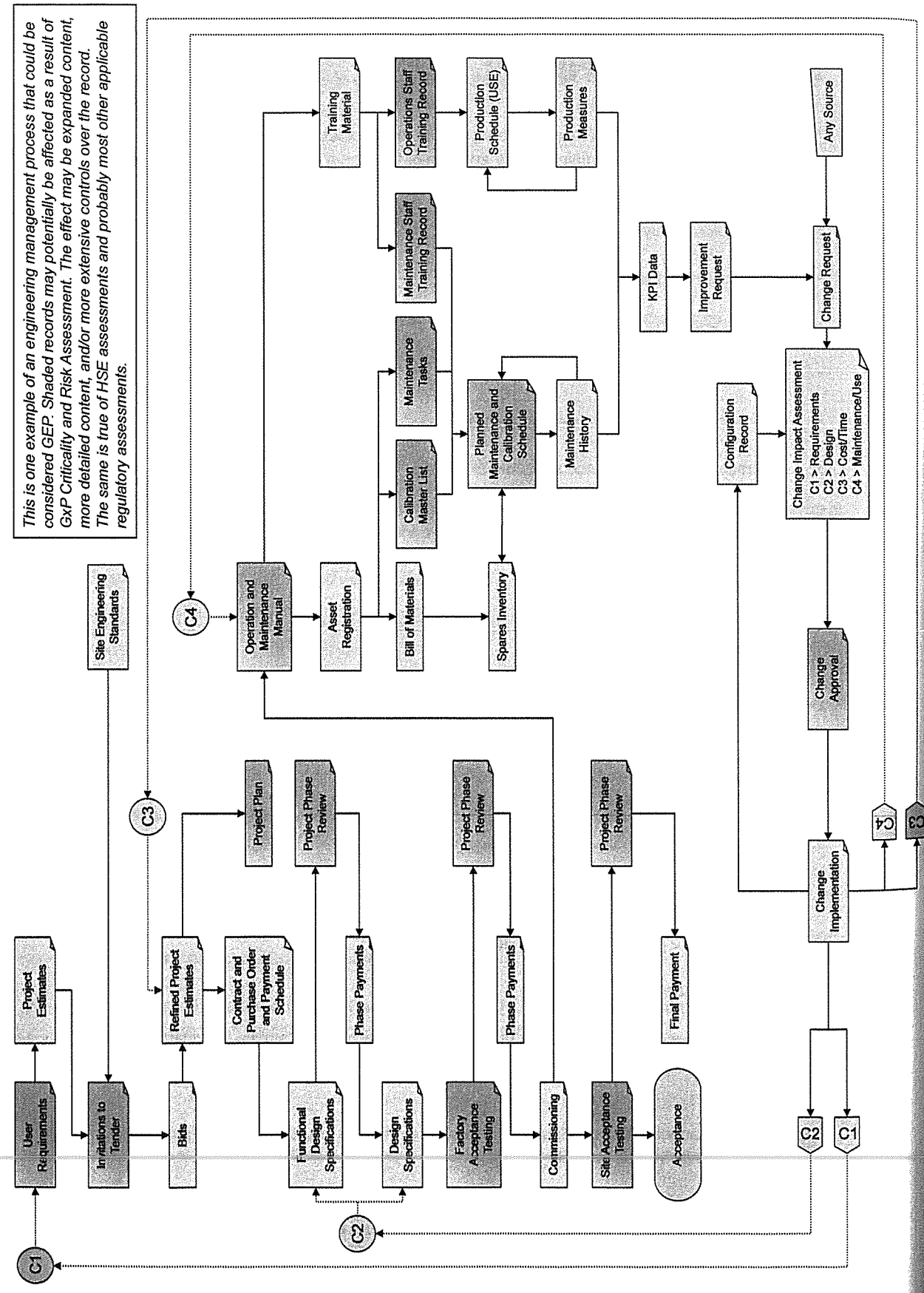


Figure 4.1: Example Engineering Management Process

5 Appendix 2 – Glossary and Acronyms

For further information on these definitions, please see the ISPE Online Glossary at www.ISPE.org/glossary.

5.1 Glossary

Change Control (FDA Glossary) (1) (API Baseline® Guide) (2)

(1) The processes, authorities for, and procedures to be used for all changes that are made to the computerized system and/or the system's data. Change control is a vital subset of the Quality Assurance (QA) program within an establishment and should be clearly described in the establishment's SOPs. (2) A formal system by which qualified representatives of appropriate disciplines review proposed or actual changes which might affect validated status. The intent is to determine the need for action which would ensure that the system is maintained in a validated state.

Critical Quality Attribute (CQA) (PQLI)

A physical, chemical, biological or microbiological property or characteristic that needs to be controlled (directly or indirectly) to ensure product quality.

Design Review (IEEE)

A process or meeting during which a system, hardware, or software design is presented to project personnel, managers, users, customers, or other interested parties for comment or approval. Types include critical design review, preliminary design review, system design review.

Design Reviews Traceability Matrix (IEEE)

A matrix that records the relationship between two or more products; e.g., a matrix that records the relationship between the requirements and the design of a given software component.

GxP Regulation

The underlying international pharmaceutical requirements, such as those set forth in the US FD&C Act, US PHS Act, FDA regulations, EU Directives, Japanese regulations, or other applicable national legislation or regulations under which a company operates. These include but are not limited to:

- Good Manufacturing Practice (GMP) (pharmaceutical, including Active Pharmaceutical Ingredient (API), veterinary, and blood)
- Good Clinical Practice (GCP)
- Good Laboratory Practice (GLP)
- Good Distribution Practice (GDP)
- Good Quality Practice (GQP)
- Good Pharmacovigilance Practice
- Medical Device Regulations
- Prescription Drug Marketing Act (PDMA)

Maintenance *(QA)*

Activities such as adjusting, cleaning, modifying, overhauling equipment to assure performance in accordance with requirements. Maintenance to a software system includes correcting software errors, adapting software to a new environment, or making enhancements to software.

Project Plan (NIST)

A management document describing the approach taken for a project. The plan typically describes work to be done, resources required, methods to be used, the configuration management and quality assurance procedures to be followed, the schedules to be met, the project organization, etc. Project in this context is a generic term. Some projects may also need integration plans, security plans, test plans, quality assurance plans, etc.

Requirement (ISO)

Need or expectation that is stated, generally implied or obligatory.

Requirements Traceability Matrix (IEEE)

A matrix that records the relationship between two or more products; e.g., a matrix that records the relationship between the requirements and the design of a given software component.

Risk Analysis (ICH Q9)

Estimation of the risk associated with the identified hazards. It is the qualitative or quantitative process of linking the likelihood of occurrence and severity of harms. In some risk management tools, the ability to detect the harm (detectability) also factors in the estimation of the risk.

Risk Assessment (ICH Q9)

A systematic process of organizing information to support a risk decision to be made within a risk management process. It consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards.

Risk Management (ICH Q9)

Systematic application of quality management policies, procedures, and practices to the tasks of assessing, controlling, communicating and reviewing risk.

Risk Review (ICH Q9)

Review or monitoring of output/results of the risk management process considering (if appropriate) new knowledge and experience about the risk.

Quality Plan (ISO)

Document specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract.

Supplier (GAMP® 5)

An organization or individual internal or external to the user associated with the supply and/or support of products or services at any phase throughout a systems life cycle.

User (GAMP® 5)

The pharmaceutical customer or user organization contracting a supplier to provide a product. In the context of this document it is, therefore, not intended to apply only to individuals who use the system, and is synonymous with customer.

User Requirement Specification (URS) (GAMP® 4) (1) (Biopharm Baseline® Guide) (2) (C&Q of W&S Systems GPG) (3)

(1) A requirement specification that describes what the equipment or system is supposed to do, thus containing at least a set of criteria or conditions that have to be met. (2) Generally the first in a series of specification documents. It provides a high level description of the user's expectation of the project scope, with emphasis on product parameters and process performance parameters. (3) A description of the requirements of the facility in terms of product to be manufactured, required throughput and conditions in which the product should be made.

Verification (ISO) (1) (ASTM) (2)

(1) Confirmation, through the provision of objective evidence that specified requirements have been fulfilled. (2) A systematic approach to verify that manufacturing systems, acting singly or in combination, are fit for intended use, have been properly installed, and are operating correctly. This is an umbrella term that encompasses all types of approaches to assuring systems are fit for use such as qualification, commissioning and qualification, verification, system validation, or other.

5.2 Acronyms and Abbreviations

CQA	Critical Quality Attribute
EHS	Environmental Health and Safety
FEFO	First Expired First Out
FIFO	First In First Out
FMEA	Failure Mode and Effect Analysis
GxP	Any regulatory mandated requirement for Good Practice GMP (Good Manufacturing Practice)
GLP	Good Laboratory Practice
HPR	Highly Protected Risk
ICH	International Conference on Harmonisation
IFC	Issued for Construction (Drawing and Specification issue)
MTBF	Mean Time Between Failures
MTTR	Predicted Mean Time To Replacement
P&ID	Process and Instrumentation Diagram
PM	Preventative Maintenance – performed on equipment and components to mitigate failure and failure consequences

QMS	Quality Management System
RCA	Root Cause Analysis
RCM	Reliability Centered Maintenance
ROI	Return on Investment
SOP	Standard Operating Procedure

6 Appendix 3 – References

1. *Quality Risk Management – Q9,* International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), www.ich.org.

2. IEC 61160 Formal Design Review

3. ISO 9001:2000 Quality management systems – Requirements.

4. *ISPE Baseline® Pharmaceutical Engineering Guide, Volume 5 – Commissioning and Qualification,* International Society for Pharmaceutical Engineering (ISPE), First Edition, March 2001, www.ispe.org.

5. *GAMP® Good Practice Guide: Calibration Management,* International Society for Pharmaceutical Engineering (ISPE), First Edition, December 2001, www.ispe.org.

6. GAMP/JETT Web site, www.ispe.org/jett.

ISPE Good Practice Guide: Good Engineering Practice
Introduction to the Attachments

Introduction to the Attachments

The attachments to the ISPE Good Practice Guide: Good Engineering Practice include a group of documents contributed by organizations active in pharmaceutical manufacture. They are a sample of what currently exists as Good Engineering Practice and have not been modified, other than to provide anonymity for the donor organizations.

Their development precedes the production of this Guide and may not be fully aligned. The content of the attachments is not endorsed by ISPE.

Attachment A Principles of Good Engineering Practices

This document outlines expected practice in engineering areas peripheral to GMP, allowing a more appropriate level of control.

It demonstrates a risk-based approach, scaling the control appropriate to the regulatory (and patient) risk.

Attachment B Project Quality Planning

This document originates from the same set of guidances as Attachment A. It provides a common method for organization and control of the quality aspects of a project. In addition, it provides a forum for knowledge capture using the attachments, and promotes scalability of the plan according to the project size and type.

Attachment C Project User Requirements Specification (URS)

This document is an example of a basic approach to requirements definition. The function of this Project URS is to provide a simple clear definition of the scope of the project, to ensure that all parties involved have a common understanding. It sets expectations and acceptance criteria and excludes budgetary and schedule issues. The expectation is that this is part of a hierarchy of documents with an increasing level of detail.

Attachment D Project Risk Analysis

This document originates from the same set of guidances as Attachment A. It provides guidance for high level risk analysis as it relates to project engineering. This introduces an early assessment of risk and management of that risk throughout a project life cycle.

Attachment E Cost Management and Reporting

This document originates from the same set of guidances as Attachment A. This document provides an approach to cost management and reporting allowing key data to be compared across projects, which facilitates organization and control.

Attachment F Site Development Plan

This is an example of key aspects of a site development plan, reduced for publication.

The document provides a good example of the typical contents of such a document, with the 'softer' architectural issues described, as well as a clear definition of the regulations with which a site work must comply.

Attachment G Project Execution Plan

This document provides the required table of contents for a typical Project Execution Plan. It provides a useful list of points to consider.

Attachment H Project Change Control

This document originates from the same set of guidances as Attachment A. The document establishes key aspects of change control.

Attachment I System User Requirements Specification (URS)

This document is from the same source as the Project URS and is an example of a URS with a more detailed focus. The function of this URS is to define the performance requirements for the system, to ensure that the end user and the designer have a common understanding. This document is also a useful tool to allow these requirements to be categorized facilitating design reviews, value engineering, design qualification, commissioning, and qualification (verification).

Attachment J Design Review

This is an example of a 'GEP' design review approach extracted from a company design review guide. It provides examples of design challenges in categories related to key project stages.

Attachment K Maintenance Test Certification

This is an example of a test record and checklist for a new electrical installation, which provides certification and a record of installed condition. It demonstrates organization and control.

Attachment L Facility Commissioning

This document originates from the same set of guidances as Attachment A. It provides a common template for commissioning of door and lighting control as well as facility finishes

Attachment M Project GMP Assessment

This document originates from the same set of guidances as Attachment A. It provides a risk based determination of whether a project is treated as GMP requiring rigorous documentation and control or if it may be managed as GEP. In addition, it promotes partitioning of projects along these lines as an efficient practice.

Attachment N Setting System Boundaries

This document is an example of a procedure for defining systems according to perceived sensitivity and risk. There are clear benefits to be gained depending where the system boundaries are placed.

Attachment O Commissioning Plan

This document is a basic template for generation of a Commissioning Plan and provides consistency of approach and a variety of points to consider.

Attachment P Commissioning Plan Compressed Air Supply

This Commissioning Plan is an example of a more complex approach to documenting GEP. It shows a way of introducing GEP to an environment that has previously only accepted GxP documentation.

Attachment Q PM Completion Checklist

This document is provided for the use of technicians performing routine maintenance activities and is intended to provide a continuous improvement mechanism. It encourages the user to constructively consider the value and merit of the activity and correct any inconsistencies and errors.

Attachment R Audit Template

This document has been derived from a document used to evaluate project and engineering organizations against pre-determined criteria. It provides a list of points to consider.

Attachment S Supplier Quality Questionnaire

This document is an example of a questionnaire for a postal audit of a supplier's Quality Management Systems. Such audits can reduce or eliminate the need for follow up or provide the focus for an on-site review.

Attachment A
Principles of Good Engineering Practices

"Company A" Guidance Document

Subject: Principles of Good Engineering Practices Issue Date: dd/mmm/yyyy Supersedes: None	Guidance No. yy,yyyy DRAFT	Version No. n dd/mmm/yyyy Page 1 of 6

1 Purpose

The purpose of this document is to describe Good Engineering Practices (GEPs) as defined in Worldwide Quality Standard xx,xxx – "Management of GMP Projects." It also provides guidance for the development, review, approval, modification, and control of guidelines designated as Good Engineering Practices.

2 Scope

2.1 This guidance document applies to:

"Company A" Divisions

• Global Supply Chain	• Global Quality
• Global Specialty Operations	• "Company A" Research

2.2 Good Engineering Practices are methods and standards applied to the engineering activities described in Worldwide Quality Standard xx,xxx – "Management of GMP Projects." These methods and standards may differ from those prescribed for Good Manufacturing Practices as required by the Worldwide Quality Standards. GEPs may be proposed as Worldwide Guidance Documents as defined by Worldwide Quality Standard zz,zzz – "Administration of Worldwide Quality Standards and Worldwide Guidance Documents." Otherwise, they serve as recommendations.

2.3 Other engineering project activities not having a GMP impact (e.g., estimating, schedule management) will be considered Project Controls and will be out of the scope of this Guidance.

2.4 Good Engineering Practices as described herein are for use in "Company A" projects and facilities regulated by current Good Manufacturing Practices (cGMP) as issued by the US Food and Drug Administration (FDA). They are specifically recommended for use on those projects required to comply with Worldwide Quality Standard xx,xxx.

2.5 In addition, Good Engineering Practices provide suitable guidance for projects and facilities not within the scope of Worldwide Quality Standard xx,xxx.

2.6 Sites should not establish GMP SOPs governing Good Engineering Practices. Project procedures may be accepted in lieu of site procedures when approved in a Project Execution Plan or memo to file.

3 Definitions

3.1 **GMP Project** – Capital projects that provide or modify facilities, systems and/or equipment that are expected to have a direct impact on product quality. The project is limited to those activities preceding the turnover to the User group for operation and maintenance.

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3.2 **GMP Documents (project)** – Documents generated during the project with the purpose of delivering and providing GMP compliance. They require to be formally approved and archived but are not normally retained within Validation Protocols. Examples include GMP Design Reviews, System Impact Assessments, User Requirement Specifications, and Project Quality Plans. These are Lifecycle GMP Documents, as defined by Worldwide Quality Standard vv,vvvv – "Lifecycle GMP Documents – Preparation and Control."

Note: Not all documents referred to in this Guidance are GMP documents.

3.3 **Good Engineering Practices (GEPs)** – Established engineering methods and standards that are applied throughout the project lifecycle to deliver appropriate cost-effective solutions (ISPE).

3.4 **GEP Documents** – Documents including, but not limited to, those described in Worldwide Quality Standard xx,xxx which are not designated as GMP documents. These include drawings, specifications, submittals, etc. which are included in the life-cycle of a project up to Equipment Qualification.

3.5 **Project Controls Documents** – Documents pertaining to project activities not having a GMP impact but necessary to achieve the project's business objective (e.g., estimating, schedule management).

3.6 **Major Project** – A capital project above the financial threshold requiring the oversight of Global Engineering Services, as defined by "Company A" Finance Manual nnnn.

3.7 **Worldwide Guidance Document (WGD)** – A document that provides scientific, technical, and procedural guidance to assist sites in implementing the requirements of the Worldwide Standards but do not establish the actual requirements.

4 Guidance

4.1 Initiation, Approval, and Control

4.1.1 Management of Good Engineering Practices are the responsibility of Global Engineering Services (GES). Suggestions for GEPs may be initiated by submittal to GES.

4.1.2 GEPs that are prepared as guidelines or recommended practices will be posted on the Global Engineering Services website as authorized by the Senior Director, Global Engineering and the Senior Director, Engineering Compliance and Validation.

4.1.3 Initiation and control of Worldwide Guidance Documents are governed by WQS aa,aaa. They must be sponsored by a global "Company A" organization and are subject to approvals as prescribed in Worldwide Quality Standard zz,zzz.

4.2 General Principles

4.2.1 Good Engineering Practice (GEP) documents are guidelines that relate to engineering activities including: design, procurement, construction, installation, commissioning, maintenance, and facility/utility operation.

4.2.2 Basic principles of good engineering are as follows:

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4.2.2.1 Projects must encompass professional and competent project management, engineering design, procurement, construction, installation, and commissioning under the direction of "Company A" Global Engineering Services or the assigned site Engineering group.

4.2.2.2 Project Scope, including regulatory requirements, must be clearly defined and approved prior to the finalization of funding and schedule.

4.2.2.3 The Project must have written procedures to ensure that the requirements of Stakeholders are met and that appropriate reviews and approvals are obtained.

4.2.2.4 The Project must have written procedures for Change Management including design changes and field changes.

4.2.2.5 Design should take full account of GMP, Worldwide Quality Standards, safety, health, environmental, ergonomic, operational, maintenance, recognized industry guidance, and statutory requirements.

4.2.2.6 The Project should consider environmental impact as well as hazardous operation (HAZOP) analysis.

4.2.2.7 Project must ensure the coordination of disciplines by providing for cross-disciplinary review of drawings and specifications as well as interdisciplinary coordination meetings.

4.2.2.8 Drawings, specifications, and calculations must be checked by a professional qualified in the same discipline (e.g., architecture, process, electrical) as the preparer.

4.2.2.9 Drawings used for construction must be stamped by an architect or engineer duly licensed within the jurisdiction of the project as required by local law.

4.2.2.10 Drawings should follow accepted conventions and standards approved by the project team and should be consistent with or convertible to the site drawing management system.

4.3 Documentation Practices

The following applies only to engineering documents and not to GMP documents.

4.3.1 Creation of Documents

4.3.1.1 Written entries must be clear and legible using an indelible medium (i.e., ink) that can be photocopied and read.

4.3.1.2 Information or data should be accurately recorded on a prescribed and controlled book, form, sheet, or electronic template at the time each action is taken or observation is made.

4.3.1.3 Compliance of observed condition or status to pre-approved specifications may be indicated by ✓, **X**, or other recognizable symbol (i.e., a checklist). Expected results need not be pre-printed on the form as long as the reference is indicated.

4.3.1.4 Quantifiable data should be recorded as observed, rather than indicating only that specifications are met.

4.3.1.5 Temporary records such as Post-it® notes, stickies, scrap paper, etc., are not to be used.

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4.3.1.6 A copy is required for unstable media (e.g., thermal paper) in addition to the original record.

4.3.1.7 Records containing photocopied information must reference the original source. (Note: Source of the photocopy may be annotated manually).

4.3.1.8 All pages and printouts from instruments or data acquisition systems should have a unique traceable identifier and page number.

4.3.1.9 Pages should be numbered; "pg. x of y" method is preferred. When documents are in sections, each section may begin a new numbering sequence.

4.3.1.10 Blank spaces may be filled in with "NA," slash, dash, or other recognizable symbol. It is not necessary to initial or date blanks.

4.3.1.11 Records are to be signed and dated by the person performing the function. It is not necessary to sign, initial or date each entry. Checklist or data sheet must be signed and dated upon completion.

4.3.1.12 The concept of "if it isn't documented, it isn't done" applies, because evidence of proper execution is necessary. It is permissible to transcribe documentation after the fact, provided that it is signed by the person who performed the function. (It must be dated on the day signed and annotated to indicate the date performed. Original data sheets should be maintained.)

4.3.1.13 Data superseded by a subsequent test or inspection (e.g., after a repair or correction) may be deleted. The final record should be annotated to indicate if a repair or correction has been made.

4.3.1.14 All plans, forms, specifications, and drawings used to construct, purchase, install, or commission facilities, equipment, and systems must be approved according to a Project Execution Plan or project procedures. Pre-approval of SAT, FAT documents is preferred.

4.3.1.15 Control of pre-executed forms is not required. Control of completed forms should be defined by the Project Execution Plan or project procedures.

4.3.2 Review and Approval of Documents

4.3.2.1 Approvers must have the education, training, or experience or any combination thereof to review and/or approve the record.

4.3.2.2 Delegation of authority to a designee must be indicated in project procedures or documented in a memo to file as defined in the Project Execution Plan or project procedures.

4.3.2.3 Review and approval of a major document (specification, report, drawing, etc.) requires full signature and date. Initials may be used for review and approval of calculations, data sheets, and checklists.

4.3.2.4 Signature and initials of reviewers must be clearly identifiable and documented according to project procedures (e.g., a signature log).

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4.3.2.5 Copies of approved documents (e.g., drawings) may contain printed reviewer/approver names or initials in lieu of signatures if they are identifiable.

4.3.2.6 Faxes must contain a clear and identifiable signature. Emails are acceptable if clearly identified as to originator and date. It is recommended that e-mail transmittals be verified by a second means (e.g., telephone).

4.3.3 Correcting Records

4.3.3.1 Corrections may be made by a single-line cross out. No initials, date, or explanation are required as long as entry is clear and unambiguous.

4.3.3.2 The entry must not be altered, obliterated or over written. The use of correction fluid, correction tape, etc., is not permitted.

4.3.3.3 It is permissible to transcribe data from one form to another (e.g., printed tabular summary of manual entries). Transcribed data must be signed and dated. Date of actual data must be included. Original data sheets and checklists must be available for review until such time that the transmitted document has been accepted and approved.

4.3.3.4 Changes to approved documents require approval by representatives of the original approving groups.

4.3.3.5 Major corrections which change the scope, design concept or test/inspection conclusion require notification of Project Manager and may be subject to project change management procedures.

4.3.4 Disaster Recovery

There should be a system in place to handle the reconstruction of records. All measures should be taken to recover the original document. For a record that is lost or destroyed and not recoverable a copy of the original record is acceptable as the official copy, which should be approved by Management.

4.3.5 Retrieval and Retention of Documents

4.3.5.1 Projects will establish procedures for retention and retrieval of records as required to carry out the project. Documents superseded by subsequent revisions should be clearly marked.

4.3.5.2 Project turnover procedures will dictate which records and documents will be turned over to the site at the completion of the project.

4.3.5.3 Sites and Global Engineering Services will establish internal methods of document storage, as dictated by company policies and procedures and in a manner that allows them to be located and retrieved within a reasonable time period, as required.

4.3.6 Destruction of Documents

Sites and GES will determine destruction methods in compliance with "Company A" policies and procedures.

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4.3.7 Electronic Records

Electronic records of engineering documents are permissible and not subject to any specific regulation. Records should be controlled in a manner to ensure that they are secure and their integrity is maintained.

5 Responsibilities

5.1 Engineering

Engineering (may be site Engineering or Global Engineering Services) is responsible for specification, design, construction, installation and commissioning of systems and equipment. They may also share responsibility for Equipment Qualification. There may be more than one Engineering group supporting a project. Division of responsibilities must be clearly delineated by a Project Execution Plan or project procedures. Engineering is responsible to maintain and control GEP documents and to make them available as required to support operations, maintenance and as a reference for future design.

5.2 Global Engineering Services (GES)

Global Engineering Services is responsible for managing all aspects of major capital projects as outlined in Worldwide Quality Standard xx,xxx. They are also responsible for developing GEP project documents and GEP guidelines.

5.3 Global Technical Services (GTS)

Global Technical Services is responsible to provide technical support to projects and sites for the transfer of technology for new and existing products, for the selection of manufacturing equipment and the review of designs related to GMP operations.

5.4 Global Quality Operations (GQO)

Global Quality Operations is responsible for the review and approval of GMP activities and documents related to capital projects. Their role is to ensure that requisite WQS and regulations have been complied with and that appropriate documentation practices have been used.

Remainder of Attachment A example document omitted from ISPE GEP Good Practice Guide.

Attachment B
Project Quality Planning

"Company A" Good Engineering Practice

Subject: Project Quality Planning Issue Date: dd/mmm/yyyy Supersedes: Version n-1	Practice No. GEP n	Version n Page 1 of 7

1 Purpose

The purpose of this document is to provide guidance for the preparation of Project Quality Plans as required by Worldwide Quality Standard xx,xxx – "Management of GMP Projects."

Quality planning is necessary to ensure that projects meet all stated requirements, applicable standards, codes, and regulations and stakeholder expectations. The purpose of the Quality Plan is to assist in developing and executing an effective quality program.

2 Scope

This guideline is for use on all projects related to the design, construction, installation, commissioning, and qualification of facilities and equipment. Project Quality Plans are required for all Major Projects. It is also considered good practice for smaller projects.

3 Definitions

3.1 **GMP Project** – Capital projects that provide or modify facilities, systems, and/or equipment that are expected to have a direct impact on quality of pharmaceutical products or active pharmaceutical ingredients (API).

3.2 **Project Stakeholder** – An individual or group that is impacted by or has responsibility for the project. Stakeholders are responsible for operation, support, validation, or ownership of the project. Typical stakeholders may include, but are not limited to Production, Engineering, and Validation. The System Owner (User) and the Quality Unit must always be project stakeholders.

3.3 **Project Manager** – Normally representing the Business, the Project Manager is designated on an approved Request for Concurrence (RFC). He/she is responsible for ensuring that the project meets the intent stated in the RFC.

3.4 **Engineering Project Manager** – The Engineering Project Manager is responsible for managing all aspects of the project including specification, design, construction, installation, and commissioning of systems and equipment. The Engineering Project Manager is responsible for the generation, review, approval, and maintenance of the Project Quality Plan.

3.5 **GMP Documents** – Documents generated during the project with the purpose of demonstrating GMP compliance. They are required to be formally approved and archived. Examples include GMP Design Reviews, System Impact Assessments, and User Requirements.

3.6 **System** – An organization of engineering components which have a defined operational function (e.g., piping, instrumentation, equipment, facility, computer hardware, computer software, etc.).

3.7 **Project Quality Plan** – A document that defines and communicates the relevant standards, procedures, and the specific activities required to ensure that the project is completed successfully to the required level of quality.

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3.8 **Good Engineering Practices (GEP)** – Established engineering methods and standards that are applied throughout the project life cycle to deliver appropriate cost-effective solutions (ISPE).

Note: GEP Documents are not GMP documents nor are they GMP records.

3.9 **Project Quality Assurance** – Planned and systematic activities implemented to provide confidence that facilities, systems, and documentation will fulfill the stakeholder expectations and meet all requirements.

3.10 **Major Project** – A capital project having an estimated value above the threshold requiring the oversight of Global Engineering Services, as defined by "Company A" Finance Manual xxxx.

3.11 **Project Assurance Team (PAT)** – For Major Projects, a group or individual assigned by the Project Manager with responsibility for establishing and implementing the project quality system. Works closely with the site Quality Unit regarding all GMP-related matters. Depending upon the size of the project, this may be one or more individuals. For smaller projects, this duty may be among those of a Project Engineer. (Alternate title: Project Delivery Team.)

3.12 **User Group** – The group with primary responsibility for the project upon completion and turnover. This may be Production, R&D, Quality (e.g., for laboratories, stability areas), Materials Management (warehousing, distribution), or others. This group is usually the System Owner.

4 Responsibilities

4.1 **Project Manager** – Ensures that Scope, User Requirements, Project GMP Assessment, and Project Execution Plan are prepared and approved and that project quality is addressed by the Project Team.

4.2 **Engineering Project Manager** – Ensures that Project Team is aware of the existence, purpose, and content of the Project Quality Plan and that it should be referenced throughout the project. Assigns Project Assurance Team and identifies individuals who will approve the Project Quality Plan(s).

4.3 **Project Assurance Team** – Oversees project quality-related activities through design, construction, and commissioning and ensures that required tests, inspections, and documents are executed properly. Where Equipment Qualification is required, primary quality oversight shifts to the site Quality Unit. Responsible for preparation, maintenance, and approval of the Project Quality Plan(s). Audits Project Team and third-parties for adherence to the Plan(s) and compliance to project procedures and requirements.

4.4 **Project Engineer** – As an authorized representatives of the Engineering Project Manager may approve the Project Quality Plan. On smaller projects assumes Project Assurance responsibilities.

4.5 **Site Quality Unit** – Approves the Project Execution Plan as a stakeholder and the Project Quality Plan (if it is a standalone document). Provides oversight and guidance regarding GMP issues and "Company A" standards and procedures.

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5 Purpose and Principles of Project Quality Assurance

5.1 A well prepared and executed Project Quality Plan defines the objectives of the project from a quality perspective, and defines how they will be achieved. It is an integral part of the project management system.

On smaller projects, where a separate Project Quality Plan is not required, Project Quality Assurance systems and activities should be described in a section within the Project Execution Plan.

5.2 The underlying basic principles of project quality are:

- Quality assurance must be designed and built in. It cannot be inspected in, or added at the end of the project.
- Quality is everybody's business. It is important that every member of the Project Team understands that they have quality related responsibilities, and understand what they are.
- Quality is a state of mind. It must be considered in all activities.
- Training of Project Stakeholders and Team members is key to establishing the correct mindset and approach to project quality.
- Effective, proactive quality management ensures that Stakeholder needs and expectations are identified, communicated, and addressed during project design and execution activities. Done effectively it can positively impact the schedule, cost and ease of execution of the project.
- The concept of Right First Time helps achieve the project objectives at minimum cost. Good planning will help identify and anticipate problems.

5.3 The Project Quality Plan is used to identify and communicate the standards to be achieved and the specific quality assurance and quality control activities that should be implemented during a project. It should be reviewed and updated periodically during the life of a project to ensure that it continues to correctly define the project approach.

Similarly it may be used as a tool to audit the project to ensure that defined practices are being followed.

5.4 A well designed project quality assurance program, as described by the Project Quality Plan, will define the method and organization for checking that the project achieves the desired quality standards for every activity at each stage of the project life cycle.

6 Timing of the Project Quality Plan

6.1 For Major Projects, an outline of the Project Quality Plan that states the intended QA and QC activities should be prepared during the Preliminary Engineering Phase. As a minimum, this should describe the scope of the project, the project quality management process, the project quality organization, applicable standards and regulations, and should identify the project processes requiring quality-related activity. It should also define the design reviews considered appropriate for the project.

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6.2 Additional details should be added to the Project Quality Plan as the project develops. For example, at or near the beginning of the Design Phase, a Design Quality section or sub-plan may be added; likewise a Construction Quality section or sub-plan at or near the beginning of Construction.

6.3 A current copy of the Project Quality Plan should be issued to all project functional leads. Training should be provided (either classroom or self-reading) to all relevant project personnel on the Quality Plan and the responsibilities and obligations imposed by the plan.

7 Content and Structure of the Project Quality Plan

The Project Quality Plan should be structured as follows:

7.1 Purpose

This section describes the purpose of the Quality Plan, by defining the quality expectations associated with the project.

7.2 Project Description and Scope

The Project Description and Scope section should summarize the scope (Stakeholder Requirements/Expectations) of the project. This information is usually taken from the Project Execution Plan or Scoping documents used to obtain funding. This section shall also identify the project deliverables in terms of the quality records at the end of the project.

7.3 Definitions

This section contains definitions of terms used in the Project Quality Plan. This enables the reader to correctly interpret the contents of the Plan. It is important to include any terms that are specific to the project.

7.4 Applicable Standards and Regulations

This section should list the specific standards and regulations that need to be considered or complied with. These may range from internal standards (e.g., Worldwide Quality Standards) and procedures to National or International regulations. The team needs to be absolutely clear on this prior to defining the specific deliverables. It may be necessary to obtain clarification from local sources as to specific local regulations.

7.5 Project Organization and Responsibilities

This section should identify the Stakeholders and their specific responsibilities with respect to project quality, including consultants, contractors, and third party suppliers.

The project team needs to understand the relationships and interactions within the team. Individual names are preferred, as opposed to group designations. It is important to know precisely who will be part of the project team and what their authorities are.

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7.6 Specific Activities and Deliverables

7.6.1 This section contains the output of the project quality program, usually divided into project phases or processes. This takes the form of detailed tasks, activities, documents, and procedures that will address the specific quality needs of the project. This is best determined by a multidisciplinary team, led by the Project Quality Assurance Team. Each assigned task should identify the person or group responsible.

Flowcharts are a simple way of describing processes.

7.6.2 An effective way to begin quality planning and definition of activities and deliverables is in a workshop setting. All stakeholders, including key third-party providers (i.e., A&E firm, CM, etc.) should be represented.

7.6.3 Each of the various project processes (see Section 8 below) should be considered. For each process determine quality assurance activities, required procedures and records, and persons responsible for planning, execution, review, and approval. A responsibilities matrix is useful to document these decisions. An example is provided in Attachment B1.

7.6.4 It is permissible that certain project phases or processes be the subject of a separate Quality sub-plan (e.g., Procurement Quality Plan, Construction Quality Plan, etc.) prepared by an assigned Team Member or third-party. Details of the quality sub-plan for that phase or process should be prepared in advance of or, at least, early in the execution of that phase. (For example, a Construction Quality Plan should be prepared prior to or early in the construction phase).

7.6.5 Sub-plans may be prepared by team members or third-parties and may be added or appended to the Project Quality Plan as they are approved. For example, the A&E firm may prepare Design Quality Plan and the CM a Construction Quality Plan.

8 Project Processes

The project processes and the applicable requirements may vary from project to project. The following is a list of processes common to most projects. Specific activities may be supplemented by more detailed project procedures as required. These procedures should be listed in the Quality Plan.

For each process, a list of suggested activities that should be considered may be found in Attachment B2. (Note that these lists are not complete and should be tailored to meet the specific needs of the project).

8.1 Quality Management

This process addresses the review and approval of project documents. It also defines the responsibilities of the Project Assurance Team pertaining to planning, conducting and closing out of audits on the project.

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8.2 Document Management

This process addresses the receipt, distribution, filing and control of project documents (GMP and non-GMP), drawings, project procedures etc, including the review and approval of project documents by authorized personnel, where required.

This process may be described in the Project Execution Plan. If so, the Project Quality Plan should provide a cross reference.

8.3 Regulatory Compliance (GMP Projects)

This process considers the internal and external compliance issues associated with introducing a new GMP project onto a site. This may be an entirely new facility or the modification of an existing facility or process. Site and company change control procedures and requirements must be addressed. These are designed to adequately cover any requirements for regulatory filing. In this area, the project must work in close cooperation with the site Quality unit and with the appropriate Regulatory groups.

Other regulatory issues, such as permitting, are usually dealt with in the Project Execution Plan.

8.4 Change Management

This process addresses the management of change through the life of the project with respect to required documentation and its review, approval and close out.

This process may be included in the Project Execution Plan. If so, the Project Quality Plan should provide a cross reference.

8.5 Design

This section of the plan will describe how the design will be reviewed to ensure that it meets the project quality requirements. The design process addresses the reviews, GMP assessments and approvals to be implemented during design phase and the involvement of project Stakeholders to ensure the completeness of the design deliverables to support operation and qualification (as required).

It is permissible to separate design quality activities to specific areas, e.g., separate the normal A&E (architect/ engineer) responsibilities into a separate sub-plan from the Enhanced Design Review and computer life cycle requirements.

8.6 Procurement

This process addresses the methodologies to be used for selection and evaluation of suppliers, and the quality control of the procured items from design, through production up to delivery to site.

"Company A" Good Engineering Practice

Subject: Project Quality Planning Issue Date: dd/mmm/yyyy Supersedes: Version n-1	Practice No. GEP n	Version n Page 7 of 7

8.7 Construction

This process addresses the management and control of construction activities, documentation, and handover deliverables. This section shall also address the material management and the preservation, maintenance, and control of the equipment from the time the materials are received at site throughout the construction and commissioning phases until handover to plant operations. There are many construction quality checks which should be considered. These should be included in a Construction Quality sub-plan (or in detailed procedures) prepared by the Construction Manager. Points to consider in Attachment B2 are usually of particular interest to the Project Team, especially for GMP projects.

8.8 Commissioning

This section will define the project approach for commissioning, who will write the commissioning plan, who will prepare the test methods and who will witness testing.

Note that documentation standards and references to commissioning within qualification should be defined in the Project Validation Plan. Some of the points to consider in Attachment B2 may be included in the Construction phase and be part of the Construction Completion Dossier.

8.9 Handover/Turnover

This section will describe or list (matrix format is recommended) the project documents that will be transmitted to site care at the completion of the project. In addition, allowance should be made for archiving of selected design documents.

8.10 Equipment Qualification

Where Equipment Qualification is required, primary quality oversight shifts to the site Quality unit. This is subject to a separate Site or Project Validation Plan and is outside the scope of this guideline.

9 Attachments

Attachment B1: Partial Quality Responsibilities Matrix

Attachment B2: Quality Planning Points to Consider

Attachment B3: Typical Project Quality Model

10 References

Remainder of document omitted.

Attachment B1: Partial Quality Responsibilities Matrix

Deliverable	Project Manager	Engineering Project Manager	Project Assurance Team	Validation	Quality Unit
Project Quality Plan	R	A	P	R	A
Design Quality Plan		A	R		
Construction Quality Plan		A	R		
GMP Design Review	R	A	R	P	A
System GMP Assessments	A		A	P	A
Commissioning Plan		P	R	A	R
Validation Plan	A	A		P	A
Document Control Procedure		A	P		
Design Change Procedure		A	P		
Field Change Procedure		A	P		
Key: P = Prepare R = Review/Consult A = Approve					

These are suggested responsibility assignments only. Responsibility for these tasks should be formally delegated within the Project Execution Plan, Project Quality Plan, or other formal project document.

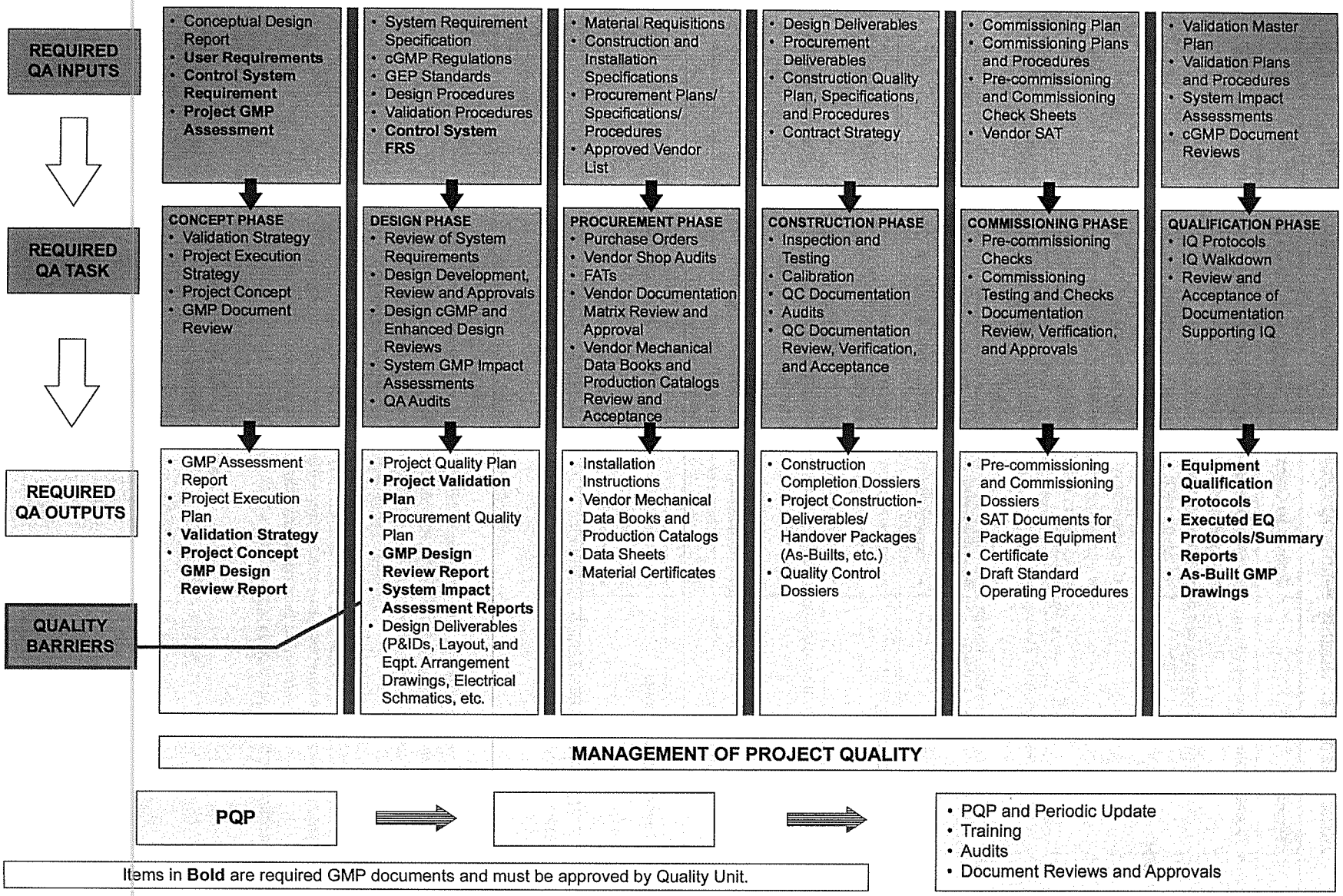
Attachment B2: Quality Planning Points to Consider

Process	Points to Consider
Quality Management	• preparation, review and approval of project quality plan and sub-plans • review and approval of project procedures • audits of quality-related activities outlined in the quality plan(s) • supplier/vendor audits • good engineering documentation practices • project team training • contractor qualification and training • quality plan updates
Document Management	• documenting decisions (e.g., minutes of meeting, telecons, email, correspondence, etc.) • archiving of superseded copies (drawings, specifications, etc.) • identification of persons with approval authority • organization/filing of documents • document security, access and retrieval
Regulatory Compliance (GMP Projects)	• site change request
Change Management	• scope changes and changes to project and system user requirements • design changes • field changes • changes to purchased equipment or systems
Design	• checking of calculations and data sheets • interdisciplinary coordination • interference checks • HAZOP reviews • environmental impact • review and approval of P&IDs, schematics, detailed design drawings • user requirements for critical systems and equipment (also part of procurement process) • review and approval of specifications • constructability assessment • enhanced design review for GMP projects and systems (includes GMP assessment and design reviews per Worldwide Quality Standard xx,xxx) • system development life cycle for computer systems (regulatory assessment, risk assessment, requirements and design) • engineering turnover/handover dossier
Procurement	• review of vendor proposals against user requirements and specifications • review and approval of vendor drawings and submittals • vendor documentation requirements to support commissioning, qualification and operation • fabrication stage inspections • material certifications • Factory Acceptance Testing (FAT) • Site Acceptance Testing (SAT) • system-related training

Attachment B2: Quality Planning Points to Consider (continued)

Process	Points to Consider
Construction	• materials and equipment receipt and inspection • hydrostatic testing • weld inspection • pneumatic testing • piping flushing/cleaning • passivation • pipe slope verification • ductwork leak testing • ductwork fabrication and cleaning • "build clean protocol" (protection of ongoing operations) • wiring continuity check • motor checks • equipment grounding • construction completion and punch list closeout
Commissioning	• construction completion dossier • instrument loop checks • instrument calibration – preliminary • HVAC test and balance • HEPA filter certifications • cleanroom certification • facility architectural checklist • mechanical system walk down • system startup and functional testing
Turnover/Handover	• designation and handling of documents to be turned over to site at completion of project • archiving/maintenance of design

Attachment B3: Typical Project Quality Model



Attachment C
Project User Requirements Specification (URS)

Site Improvement Project

Document Number: n
Effective Date: dd/mm/yyyy

1 Purpose and Scope of Document

This document is written to provide a brief description of the project scope to allow the design consultant to develop a design meeting the company's expectations.

It is not intended to revise this document.

The Basis of Design developed by the Design consultant will be reviewed and approved by the company and is considered as providing the detailed technical definition of the requirements for this project.

2 Executive Summary

The intent of this project is to upgrade portions of Building x on the company site in order to:

- comply with current corporate standards
- mitigate risk
- upgrade business critical systems that are near the end of their design life

3 Project Fundamentals

The facility is a storage and distribution building of raw materials, work in progress, and finished goods manufactured on the site.

Specific products require storage at either +2 to +8°C, -1 to -10°C or -20 to -40°C and -60 to -80°C; the building provides facilities to meet each of these requirements, and has a validated monitoring system confirming that the conditions are being maintained.

The project scope will include revising the monitoring system to cover new facilities.

All engineering systems will be commissioned and all GMP critical systems will also be validated to site standards.

4 Requirements

4.1 Freezers

Existing Freezer Rooms each hold critical product and are to be upgraded to 100% redundancy.

Freezer room 21 will be designed as a -1 to -10°C freezer for storage of ice, but must also be validated to operate at -30°C for interim storage of product if required. The unit currently operates at -10°C.

Freezer Rooms 22 and 23 are to be validated to -30°C.

Existing Freezer Room 20: does not hold critical product, only raw materials and will be designed as duty standby cooling system, with common controls (product in this room can be moved in the event of a refrigeration failure).

Freezer 18 and Freezer 19 are to be demolished and taken off site; all electrical and mechanical equipment associated with these rooms must also be removed.

Following demolition, walls and ceilings are to be patched and painted, the sprinkler system modified to cover the area, with new lighting to match the existing installed.

4.2 Cold Rooms

Cold Rooms 21 and 22 hold critical product and are to be upgraded to 100% redundancy, a door must be added to Cold Room 22 to meet exit requirements (exit through the hinged doors within the sliding doors is not permitted by local building code.

A new 5,000 sq. ft. Cold Room 23 is to be provided for critical product, designed to 100% redundancy. Racking is to be provided to match adjacent the Cold Rooms.

Fluorescent lighting shall also be provided for this room.

Cold Room 24 does not hold critical product and will be designed as duty standby cooling system, with common controls, (product in this room can be moved in the event of a refrigeration failure).

Cold Room 13 will be demolished and taken off site. All electrical and mechanical equipment associated with this room is to be removed.

Following demolition, walls and ceilings are to be patched and painted, the sprinkler system modified to cover the area, with new lighting to match the existing installed.

4.3 Refrigeration Plantrooms

Two new refrigeration plant skids are to be installed in the refrigeration room, and the existing air compressor relocated.

Overhead ductwork is to be modified as required to accommodate the new skids.

After the new skids are installed, the existing skid will be removed, and the air compressor re-installed in this location.

Additional BMS panels will be added in the same vicinity as current BMS panels (along the west wall).

The scope of work shall include removal of redundant concrete pads and ductwork, installation of concrete pads for the new skids, rerouting ductwork, patching and painting as required to leave the area in an acceptable condition.

New refrigeration plant skids are to be installed into the existing refrigeration room.

4.4 Electrical Plantrooms

Two electrical rooms are to be provided along the east wall with new access doors from the compressor room installed; the existing door to the warehouse space will be maintained.

Construction shall include new metal stud sheetrock walls, paint and two new hollow metal doors together with the supporting utilities, including HVAC and lighting.

4.5 Mechanical Yard

A new generator with a suitable sound enclosure is to be provided to the east of the existing Mechanical Yard with a new pre-cast screen wall to match the existing extended to the east to hide the new generator.

A new concrete slab with a new concrete pad will be required for the generator.

4.6 Control system

To achieve the redundancy for the refrigeration controls it is necessary to install new control cabinets.

The new PLC controls shall be Allen-Bradley SLC500 units with the installation planned to allow replacement of the existing controls for freezer rooms 20A, B, and C with new panels to the same design. Similarly the Danfoss controls for Cold Rooms 21 and 22 will be replaced.

4.7 Condenser Water System

The designer is to confirm that the current plant has adequate capacity for the new installation.

4.8 Mechanical Scope of Work

The work described above must be executed in a manner which will ensure that existing plant is kept operational.

The HVAC system shall be checked and rebalanced if required to maintain the same air flow directions.

4.9 HVAC Controls

Andover controls are currently used, these will be modified as required to suit the new equipment.

Additional refrigerant leak detectors shall be installed as required, connected to the control system.

The level of monitoring and alarm for the new units remains to be defined.

4.10 Compressed Air System

The existing compressed air system consists of an Ingersoll-Rand two-stage, nonlubricated duplex reciprocating, 15HP compressor with air receiver, coalescing air filter in parallel, air dryer and after filter. The capacity and consumption shall be reviewed and recommendations made by the project team to either re-used or replaced the current system.

4.11 Proposed Changes to Electrical System

The existing power distribution system is considered the 'A' system. An equivalent redundant 'B' system shall be created by adding a new generator, ATS, and Switchboard EB. The 'A' and 'B' systems will be inter-connected via a tie-breaker and other interlocking breakers in a fashion that with one generator in service, both groups of loads can be served. There will be two new and separate electrical rooms for the two systems.

4.12 Emergency Generator

The new generator will be a diesel engine standby type suitably rated with a sound attenuated enclosure to maintain the audible noise level down to 70 dBA level at 23'. The generator will be equipped with a sub-base fuel tank, located adjacent to the existing cooling tower. The air intake shall be oriented toward the street. The discharge air will be through the top. The exhaust flue will be extended to above the roofline to keep it away from the building intake air.

4.13 *UPS System*

Two UPS systems are to be provided for a 20-minute back-up time. Each UPS will be provided with an external maintenance bypass. The UPS output distribution boards will be standard circuit breaker panelboards.

One UPS will support the 'A' system controls and BMS, the other UPS will support the 'B' system and controls. The UPS systems will be placed in the 'A' and 'B' electrical rooms.

4.14 *Lighting*

The indoor general, non-high bay lighting is to consist of energy-efficient fluorescent fixtures. Fluorescent lamps are to be T8, 3500 degrees Kelvin color temperature, with a color rendering index (CRI) of 75 or greater.

Emergency/night lighting is to be provided by un-switched branch circuits fed from the existing emergency lighting panel.

Lighting for the new Cold room 1123 shall be T5 fluorescent suitable for low temperature use.

Existing lighting in rooms 1121 and 1122 will remain.

Any new freezer lighting is to be canopy style metal halide suitable for sub-zero temperature.

Existing freezer lighting will remain.

Illumination shall be provided at the exterior new generator area. The new luminaires will match the existing serving the adjacent space.

4.15 *Grounding*

Electrical ground wires, new generator ground, new transformer grounds, and UPS neutral ground will collect at a common ground bus inside the new electrical room. This ground bus will in turn be bonded to the nearest building steel and home run to the main electrical room ground bus.

All conduit terminations at panelboards, cabinets, and gutters will have grounding bushings with bonding jumpers interconnecting all conduits and panelboards, gutters, etc.

All parts of the power distribution system will be provided with an equipment ground conductor sized per NEC Article 250.

4.16 *Voice System*

The company will provide all cables and outlets under a separate contract. The electrical contractor shall provide all of the necessary back boxes and conduits with pull string.

The system will consist of the following:

- wall phone in electrical room
- wall phone and data outlet in maintenance room

4.17 *Fire Alarm System*

Design of the fire alarm system will be by others.

The existing remote annunciator will be upgraded. The Fire Alarm Contractor will provide all equipment and wiring under separate contract.

4.18 Security System

Design of the security system will be by others.

Security Contractor will provide all equipment and wiring under separate contract.

Attachment D
Project Risk Analysis

"Company A" Engineering Services Project Control Guidelines

Project Risk Analysis and Management

1 Purpose

Projects, by their nature, are unique events with inherent risks. Risks, which if not identified and managed, can have a significant adverse impact on a project's success. This guideline has been written to establish a common process for risk identification, assessment and management.

2 Scope

"Company A" Engineers shall follow the guidance given in the matrix in Attachment D1 to ascertain the scope of risk analysis and management required on any particular project.

3 Definitions

3.1 **Risk** – An uncertain event or circumstance which is perceived to have a significant impact on the achievement of a projects objectives.

3.2 **Risk Management** – The means by which all risks to a project are identified, evaluated for impact, assessed for likelihood of occurrence and quantified and their effect either eliminated, mitigated or provided for.

3.3 **Risk Register** – A schedule of information listing all the identified risks on a project, the nature of each risk, impacts and information relevant to its assessment and management.

3.4 **Project Stakeholder** – Investors, end users, and others with a real interest in the project outcome.

3.5 **Quantitative Analysis** – A quantitative measurement of the possible effects that risks may have on cost estimates and time plans (schedules) undertaken with computer simulation risk modeling software using analytical tools such as @Risk or Monte Carlo by Primavera or other analytical techniques. The objective is to generate a range of possible cost (Quantitative Cost Analysis) and/or time (Quantitative Schedule Analysis) outcomes against defined confidence levels of between 0% and 100% by applying 'ranges' to the estimate line items and schedule durations with the incorporation of events that might happen (risks) from the risk register.

4 Requirements

4.1 Preparation of Scope and Cost Estimates to support a (Budget Approval Document)

In the scope document supporting the Capital Estimate, ALL projects should identify and describe potential risks to the project, outline any mitigation strategies and identify the potential cost and schedule impact of these risks. This initial assessment should be used to support the estimate range and level of contingency requested in the *Budget Approval Document.*

4.2 Post (Budget Approval Document) Approval

All projects with an estimated value of more than US $n million shall prepare and maintain a risk register following the layout suggested in Attachment D2. In addition, all business critical projects under US $n million, or non-business critical projects that are complex, shall also have a risk register.

The risk register shall be prepared from data collected at either a Formal risk workshop or from risk questionnaires completed by Project stakeholders as Attachment D3. The project shall retain a file of completed questionnaires.

The risk register should be preceded by an introduction which summarizes the main risks to the project and the source of the data.

The risk register will form one of the key project indicators and should be maintained, updated and summarized in the regular monthly project report.

All projects exceeding **US $n million** must:

- Prepare a Risk Management Plan setting out review process, risk owners and managers and proposals for risk mitigation. Cost of mitigating risks should be incorporated into the Project Estimate of Contingency as appropriate. Refer to procedure PCG-08, Cost Management and Reporting (see Attachment E of this Guide).
- Carry out a formal risk workshop at a convenient time during the design process to identify potential project risks.
- Carry out a formal quantitative risk assessment on the project budget and project schedule.
- Repeat this workshop/assessment at milestones identified in the Risk Management Plan to ensure that evolving risks are identified and managed.

An external party should be used to facilitate the risk workshop and carry out the risk modeling of the estimate and schedule to provide an independent unbiased view and challenge the team on assumptions and issues.

Risk modeling of the estimate and schedule should be based on a Monte Carlo simulation using a minimum of 1000 iterations to determine confidence levels of achieving project costs or schedule.

The format for reporting the cost risk analysis should be similar to that shown in Attachment D4.

The format for reporting the schedule risk analysis should be similar to that shown in Attachment D5.

5 Responsibilities

Production, delivery and updating of the risk register and risk analysis shall at all times remain the responsibility of the *"Company A"* Project Engineer.

6 Specific Related Procedures

All Project Managers Project Controls Procedures.

7 Attachments

Attachment D1: Risk Analysis Matrix

Attachment D2: Risk Register Pro Forma

Attachment D3: Risk Identification and Interview Record Form

Attachment D4: Cost Risk Analysis Format

Attachment D5: Schedule Risk Analysis Format

Attachment D1: Risk Analysis Matrix

Task	Project Value <US $n MM	Project Value >US $n MM	Project Value >US $n M	Business Critical	Complex Schedule Critical
Risk Register Established	D	R	R	R	R
Formal Risk Workshop	D	D	R	D	D
Quantified cost analysis performed	D	D	R	D	D
Quantified schedule analysis performed	D	D	R	D	R
Key: R = Required D = Discretionary					

Attachment D2: Risk Register Pro Forma

"Company A"			Risk Register						Project: Project Manager: Project #:	
			Impact							
Reg ID	WBS	Description	% Cost	Time	Score	Rank	Priority	Bus Risk	Action By	Discussion Notes/ Mitigation
			75 2	2	150	High	0	Business Risk – Insert Yes if applicable and impacts Production/Output		
			50 3	3	150	High	0			
			50 2	2	100	Medium	0			
			25 3	3	75	Low	0			
			10 2	3	25	Low	0			

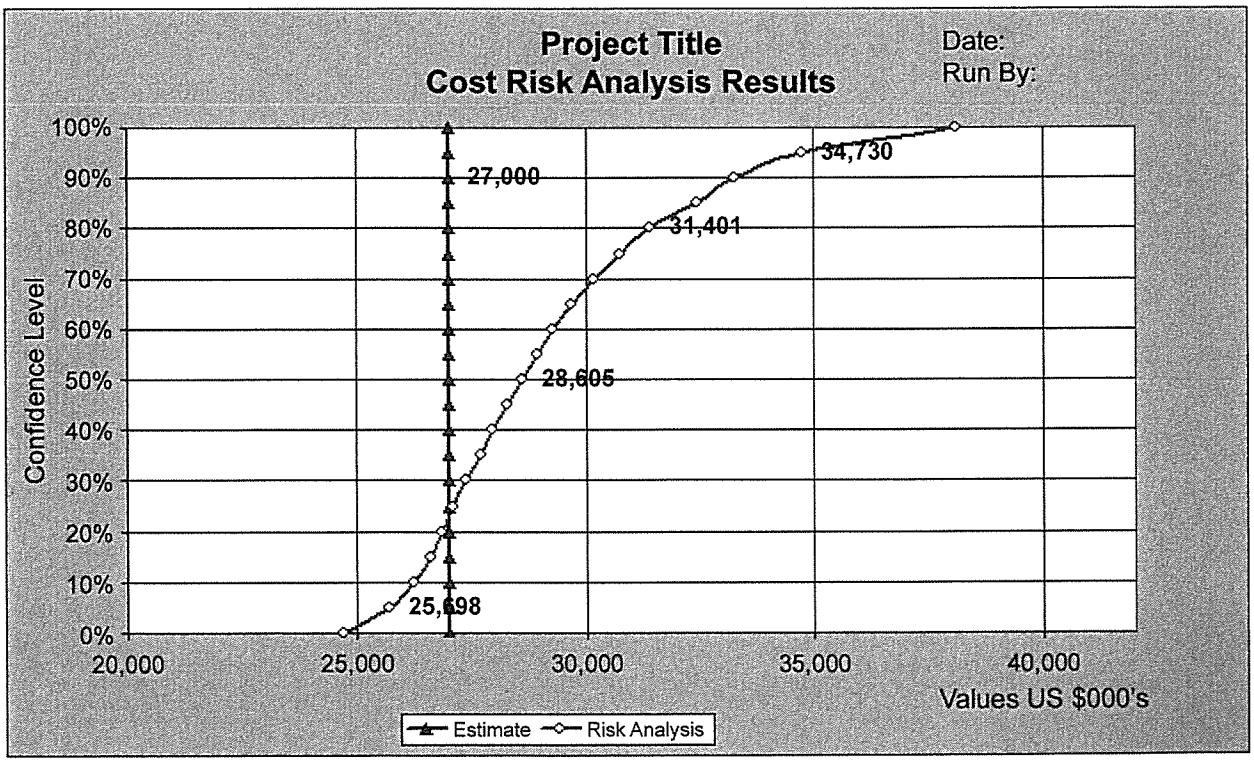
User Notes:

1. Score calculated by multiplying Probability of risk occurring x cost impact and schedule impact
2. Score to equate to High / Low should be set at outset – the norm is < 100 Low > 150 High
3. Cost impact High (3), Medium (2), Low (1) to be agreed for each project – typical above US $500k High; below US $100k Low
4. Schedule impact High (3), Medium (2), Low (1) to be agreed for each project – typical over 12 weeks High; below 4 weeks Low

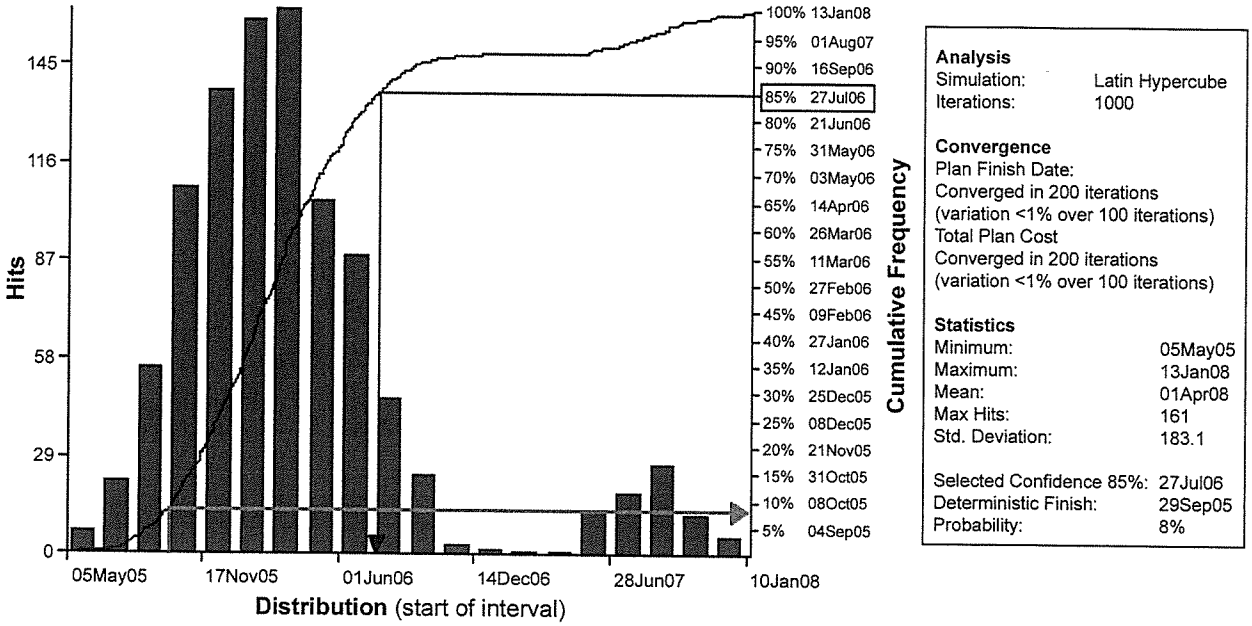
Attachment D3: Risk Identification and Interview Record Form

Risk Interview Record		Project Title:			
Interviewee:			Date:		
Item	Risk	Consequences	Likelihood %	Time Impact +/- Wks Most Likely	Cost Impact US $ Most Likely
1					
2					
3					
4					
5					
Completed By _____				Date _____	

Attachment D4: Cost Risk Analysis Format



Attachment D5: Schedule Risk Analysis Format



Analysis

Simulation:	Latin Hypercube
Iterations:	1000

Convergence
Plan Finish Date:
Converged in 200 iterations
(variation <1% over 100 iterations)
Total Plan Cost
Converged in 200 iterations
(variation <1% over 100 iterations)

Statistics

Minimum:	05May05
Maximum:	13Jan08
Mean:	01Apr08
Max Hits:	161
Std. Deviation:	183.1
Selected Confidence 85%:	27Jul06
Deterministic Finish:	29Sep05
Probability:	8%

Attachment E
Cost Management and Reporting

"Company A" Engineering Cost Management and Reporting

1 Purpose

1.1 To ensure consistency and accuracy in management and reporting of project budgets (original and revised), commitments, expenditures and forecasts to complete.

1.2 To capture and present project costs in a consistent manner for all projects, regardless of size and complexity. This consistent reporting will allow summary information to be consolidated into the Monthly Reports.

1.3 To set out common rules for the management and reporting of adjustments to budget line items and Contingency allowances through the execution of the project.

1.4 To ensure that Quarterly Capital Project Control Reports (CPCRs) and Capital Project Status Reports (CPSRs) as required by Financial Policies can be assembled accurately and easily from the data within the Cost Management system used for the day to day management of the project budgets.

2 Scope

2.1 This guideline applies to all Projects administered by *"Company A" Engineering*

2.2 Cost management shall encompass budget preparation, commitments, change order approval, cost forecasting, project tracking and final closeout.

3 Definitions

3.1 **Approval Authorization** – The single signature authority to commit company funds, resources, or equipment as specified in the Request for Concurrence (see Reference D).

3.2 **Approved Project Cost** – The original approved Request for Concurrence amount, or the most current Request for Concurrence amount reflecting supplements.

3.3 **Budget** – The funding available to complete the Scope of Work submitted as a Capital Project Cost Estimate in support of a project Request for Concurrence. The Original Project Budget may be revised through approval of Scope Changes through the course of a project. These approved changes are reflected in the Current Project Budget.

3.4 **Capital Project Control Reports (CPCR)** – A quarterly report required by Corporate Finance policy on all projects with a Total Value of US $n million or more (see Reference B).

3.5 **Capital Project Status Report (CPSR's)** – A quarterly report required by Corporate Finance policy on all projects. This report shall include a Cash Flow analysis (see Reference C).

3.6 **Commitments** – The total obligation incurred by a project, whether or not the works have been completed or invoiced. Amounts committed are reflected by contracts, purchase orders, change orders and other evidences of agreement and/or legal liability to vendors, contractors, governmental agencies and other third parties. Commitments are controlled in local currency and **must not** exceed the value of the approved Request for Concurrence. Note that any changes in the exchange rate must be reported.

3.7 **Cumulative Commitments to Date** – Represents the sum of all commitments made to date.

3.8 **Estimate of Commitments to Complete** – The best estimate of commitments over and above those already incurred to date that are required to bring the project to completion.

3.9 **Estimated Underrun/(Overrun)** – Calculated on individual budget line items and for the Total Project Cost, the estimated underrun/overrun demonstrates the amount by which the latest estimated cost is under or over the budgeted cost.

3.10 **Expenditures** – Actual project costs recorded on the books as invoiced by suppliers or contractors or as charged internally by other company departments.

3.11 **"Company A" Engineering Representative** – Engineer working for Global Engineering Services. This person is also known as the GES Engineer.

3.12 **Assumptive Scenario (Latest Estimate)** – The most current estimate of the project cost. The Assumptive Scenario is compared to the project budget and variances identified. For off-shore projects, check with the Business Unit Finance Representative regarding exchange rates to be used.

3.13 **Project Manager** – Person identified on the RFC as having overall responsibility and financial authority for the project. This financial authority may be delegated to others via the use of Approval Authorization forms.

3.14 **Project Finance Representative** – Person having responsibility for Financial compliance on the Project. This person may also be the Business Unit Financial Representative.

4 Requirements

For every project, the "Company A" engineering Representative shall create a Cost Management System that will be used to track project commitments, expenditures, and changes against the approved project budget according to the following guidelines:

Budget Preparation

4.1 Budget estimate shall be prepared and presented in accordance with PCG-05, Estimating.

4.2 Budget estimate shall be incorporated into the Cost Management System in accordance with the Project Financial Coding system.

Commitments

4.3 The "*Company A" engineering* Representative shall ensure that each Commitment (Purchase Order, Purchase Order Change, Field Change Order, etc.) is completed in sufficient detail to enable coding of each price element in accordance with the Project Financial Coding system.

4.4 The "*Company A" engineering* Representative shall confirm the terms of all commitments placed to assess whether price is firm, estimated, not to exceed or guaranteed maximum. The Cost Management system shall reflect the basis of price and enable an accurate projection of total value.

Change Orders

4.5 All proposed changes shall follow the guidance given in PCG-09, Project Change Control (see Attachment H of this Guide).

4.6 When approved, change order value shall be incorporated into the relevant Contract or Purchase Order as a commitment, referenced to the relevant Financial Cost Codes.

4.7 Verbal changes given by any member of the project team, including the Project Manager, shall not be recognized as a change to commitment until formalized in writing.

4.8 Pending change orders shall be reflected in the forecast prior to finalization and approval of the change request.

Cost Forecasting

4.9 The forecast shall be prepared and translated to *"Company A's"* Project Financial Cost Coding so that the project can easily be monitored by Project Stakeholders.

4.10 The forecast of total cost should be updated, preferably as commitments and invoices are entered into the Cost Management system. Alternatively, the forecast of total cost shall be maintained current and reported monthly.

4.11 The forecast shall be clear, logical and apparent to any observer.

4.12 In addition to the value of commitments made, the forecast shall reflect:

- Known elements of the project scope not yet purchased
- Elements of items to be purchased that were excluded from the order (e.g., freight charges, sales tax, spare parts, training, commissioning support)
- Items that may be added to the scope but are not fully defined
- Escalation from budget preparation to purchase
- Pending change orders and forecast additions and omissions
- Expected invoice total above the committed value (e.g., T&M contract) or where commitment will be underspent
- Design development allowances and construction risks

4.13 Where the forecast is below the current level of commitment or invoiced value, due to reduced scope or anticipated backcharge (for example) the reason for the reduced forecast shall be clearly shown with the Cost Management system.

4.14 A Change Log as described in PCG-09 (see Attachment H of this Guide) shall be maintained to categorize and monitor the reasons for changes to forecast by period over the project duration.

Project Tracking

4.15 Earned Value and Performance factors shall be generated by third party providers for each major activity based on planned hours, measured percentage complete and actual hours expended. This will enable the *"Company A" engineering* Representative to predict future trends and institute corrective action as necessary.

4.16 The *"Company A" engineering* Representative shall complete the Capital Project Status Report (Reference C) on a quarterly basis and forward to *"Company A" engineering* management for their review.

4.17 If required, the *"Company A" engineering* Representative and the Project Finance Representative will complete a Capital Project Control Report (Reference B) on a quarterly basis. Requirement of this report will be determined by the Project Finance Representative.

5 Responsibilities

5.1 Responsibility for Cost Management shall be defined in the Project Execution Plan.

6 References

Remainder of Attachment E example document omitted from ISPE GEP Good Practice Guide.

Attachment F
Site Development Plan

Site Development Plan Sample

1 Overview

1.1 Introduction

The Client Campus Expansion project constitutes the second phase in the development of the Master Plan for the campus. The first phase, consisting of a research and development building was completed in 1998.

The expansion project is intended to provide replacement space for functions currently housed in Buildings x, y, and z plus additional space for research expansion and consolidation of some functions currently located off site. Prior studies of Buildings x, y, and z have determined that these facilities have surpassed the end of their useful life as laboratories, and would require total renovation in order meet contemporary requirements for laboratory facility systems and design. Anticipated renovation costs, the lack of any available facilities for staging of present building occupants while renovation was undertaken, and the overall campus Master Plan led the Client to the decision to move forward with construction of the next phase of the campus.

This phase of work consists of a research and development facility, Building N, a central utility plant expansion, Building A, and a parking structure, Building C. The parking structure is being designed and constructed as a separate project and is not included as a part of this report.

1.2 Client Goals and Objectives

The following is a summary of Goals and Objectives that have been developed for the Campus Expansion project. This summary combines information from various sources including the Master Plan, Building T Schematic Design Narrative, and various discussions that have taken place over the course of the preliminary planning for this project.

This list is intended to assist Client and the design team in the development of an appropriate building solution, and also to serve as the basis for evaluation of the development of the later phases of the project as the design advances and construction is completed.

Client Goals and Objectives:

- Provide a world class facility as a symbol of Client's growth and to use as a recruitment tool.
- Consolidate currently site activities into a single, integrated, and interactive campus.
- Promote communication through interdisciplinary interaction.
- Enhance cross-pollination of groups while supporting separate facility requirements.
- Look for opportunities to improve flexibility of work environments to allow group restructuring while improving efficiency of space utilization.
- Blend Art and Science. Provide quality environments for scientists supporting an overall strategic vision for the site Master Plan. An "unorthodox" approach is desired.

Specific Goals Gathered from Lessons Learned:

- Improve the functionality of the offices.
- Improve office lighting.

- Provide more functional and consistent tech workstations.
- Resolve atrium noise issues.
- Provide additional storage space for lab areas.

1.3 Methodology

The project initially began in July of 2000 as a concept design study to determine the overall project scope, preliminary building occupants and program, concept design for all buildings, and anticipated construction costs. At this time the project scope included the following elements:

- Building N – research and development building
- Building A – central utility plant expansion
- administrative building
- employee services and conferencing
- structured parking
- associated site infrastructure, landscaping and utilities

Initial efforts focused on development of a preliminary program which attempted to define the probable occupants for each building and their general space requirements, leading to definition of the overall scope for the administrative building, employee services and building N.

At the time that the program was being developed, design studies were also under way with the architect. These investigations focused on the overall organization of the building floor plans and review of lessons learned from the past Building T project. After a number of iterations, a successful concept was developed that combined program requirements, master plan conformance, lessons learned, and maintained the strong architectural character of the campus.

The scope of the design was agreed and the concept design phase was completed at the end of November 2000 and documents were issued for pricing. The concept design, preliminary program, and cost estimate were presented for approval to the Client Board of Directors on 9 February 2001. After a one month review period, the project was approved for design and construction in March 2001. The client authorized the design team to proceed with development of the project shortly thereafter.

1.4 Project Team

The project team selected by Client to implement the expansion of the Emeryville campus consists primarily of the same team members that participated in the original project. This was done primarily to take advantage of the past experience and knowledge of the previous team members. Team members that have participated to date in the development of the project include the following:

- owner
- design architect
- executive architect, programming, and lab planning
- structural engineering

- MEP design
- civil
- landscape design
- code consulting
- atrium code consulting
- environmental consulting
- geotechnical consultant
- process consultant
- preconstruction services, estimating
- welding testing and inspection

A directory of contact information and key project participants follows.

1.5 Project Schedule

Client's objective is to occupy the new Building N as quickly as possible while not incurring excessive costs to accelerate the design or construction process. One key determinant of the overall project schedule is the timing for completion of the parking structure, which will free up parking on the Client Campus and allow the parking spaces on the Building N site to be vacated. Planning for the parking structure construction has indicated that spaces can be made available to.

In order to support the earliest possible start date, the project schedule has been developed to include a number of early packages. Multiple packages are anticipated as follows:

Package	Timing
Mass Excavation/Underpinning	Mid-January 2002
MEP Pre-Order Package	Late February 2002
Foundation/Steel/Enclosure	Late March 2002
Interior/Lab/MEP/Final Steel Package	Early June 2002

The objectives of the early packages is to allow the start of the design and permitting for the excavation and shoring, allowing the maximum time for the development of the other packages.

Refer to the attached Project Completion Schedule on the following pages for additional information regarding the anticipated activities to support the proposed construction start dates.

1.6 Outstanding Issues

The following is a summary of unresolved design issues that will require further investigation and/or development during the early stages of the Design Development phase.

Issue	Responsibility
• Atrium and office configuration on Floors N-5	

2 Architectural Description

2.1 Building Description

Building N is the second phase in the development of the Master Plan for the Client campus. Building N abuts the north wall of Building T, separated by a seismic joint. When completed, Buildings N and T are intended to function as a single building. The overall building character and materials are intended to generally match Building T.

2.2 Area Summary

Concept Phase Area Summary		
Floor Level	Program Area (NSF)	Overall Area (GSF)
Basement	29,000	58,000
Level 1	17,000	57,000
Level 2	27,500	45,000
Level 3	28,000	55,000
Level 4	32,500	50,000
Level 5	31,000	50,000
Level 6	16,000	36,000
Level 7 (Penthouse)	0	6,000
Total Area	181,000	357,000
Overall Building Efficiency (GSF/NSF)		50.7%

Area Summary		
Floor Level	Program Area (NSF)	Overall Area (GSF)
Basement	29,000	58,000
Level 1	17,000	57,000
Level 2	27,500	45,000
Level 3	28,000	55,000
Level 4	32,500	50,000
Level 5	31,000	50,000
Level 6	16,000	36,000
Level 7 (Penthouse)	0	6,000
Total Area	181,000	357,000
Overall Building Efficiency (GSF/NSF)		50.7%

2.3 Code Summary

A summary of code requirements and specific application to this building is included in the drawing set. Overall code assumptions and information are summarized on the following table.

Applicable Codes	California Building Code 1998 California Fire Code, 1998 California Energy Code, 1998 CABO/ANSI A117.1
Building Function	Research and Development Laboratories, Animal Care Facility, associated Administrative Offices
Occupancy Classification	B Occupancy Incidental additional occupancy areas include HN and H7 in Pharmacy area on first floor
Class of Construction	Type I
Fire Protection	Fire Sprinklers Required
Approximate Total Area	N66,800 GSF Building Area (Building N) plus 285,000 (Building T) = 651,800 GSF Total Unlimited area allowed for Type I Construction Classification
Approximate Area of Largest Floor	58,000 (Building N) plus 50,000 (Building T) = 108,000 GSF
Overall Height	Six Stories above grade, plus One Story Mechanical Penthouse on Roof and one Basement level below grade.
Highest Laboratory Floor	Fifth Floor, approximately 58' Above Grade
Highest Occupied Floor	Sixth Floor, approximately 7T Above Grade
Code Population	Approximately 1,100 code occupants, based on: Laboratories 200 SF/person Animal Areas N00 SF/person Offices 100 SF/person Mechanical Rooms N00 SF/person Storage Rooms N00 SF/person Conference Rooms 15 SF/person Seminar Rooms 15 SF/person
Actual Population	Approximately T00 Occupants

2.4 Lessons Learned Summary

Over the course of the initial development of the project, numerous meetings were held with Client user groups, facilities management, and maintenance in order to determine elements of the existing Building T that should be addressed differently in the development of Building N. As is often the case, these meetings focused most directly on features of the building configuration and operation that were less than desirable, however many positive aspects regarding the overall character of the building, were also noted.

The following is a compilation of comments received from various sources, organized roughly into the various components of the building.

Building T Lessons Learned

General

1. Atrium character and the light that is introduced into the building are much appreciated, however, the Atrium space itself does not support any specific functions and is consequently not well used.

2. Atrium acoustics are very disturbing. Noise generated in the atrium travels throughout the area and into the offices, and the acoustic properties of the atrium make it difficult to hear group conversations or presentations within the space.

3. The building should respect and support campus circulation routes. One example is the north entry from the parking area, which was not designed to respect the amount of traffic entering at that location.

4. Natural light is appreciated throughout the facility.

5. Building efficiency is lower than desired.

6. Building finishes are easily damaged and difficult to repair, especially the textured wall finishes of the atrium and "public" corridors.

7. Toilet room locations are too remote from most areas of the building.

8. Service elevator location adjacent to the offices creates disruption, and requires that materials, chemicals, waste, etc. be moved through the "public" corridors and in front of the offices.

9. Building security is difficult to achieve with the extensive use of the glass doors.

Offices

1. Glass office door issues: vision, acoustics, security, privacy.

2. Office sizes are too small. Offices should accommodate seating for two guests if possible.

3. Office lighting is too low.

4. Office locations conflict in some areas with public areas, functions, i.e. offices next to the mail room, across from the service elevator, etc.

5. There are no private spaces anywhere in the building for private conversations, contemplation, resting, etc.

6. Second floor space utilization, character is very different than the remainder of the facility.

Laboratories

1. Laboratory light and views appreciated.

2. Laboratories generally function well.

3. Storage space is insufficient, and closet space originally provided for lab storage has been utilized or mechanical and security equipment.

4. Chemical waste and general waste storage is not adequately addressed in the design.

5. Laboratory access.

6. Distance from labs to offices.

7. Office to lab windows not beneficial.

2.5 Architectural Materials and Systems Narrative

2.5.1 Exterior

Exterior Walls

Exterior walls at the first and second floor consist of precast concrete panels with integral colored concrete, cast in forms lined with rough sawn cedar boards. Panels typically have deep returns at windows and one-piece corners requiring two pours for some panels. First and second floor panels are treated with anti-graffiti coating.

Exterior walls for floors three through five consist of precast concrete panels with cast-in brick veneer. Panels typically have deep returns at windows, arched openings and one-piece corners, often requiring two pours. Brick faced panels utilize a special casting process to achieve a narrow, groutless joint of approximately 1/8" between bricks. Brick veneer is 1" thick units with dovetail grooves on the back face. Brick units are special sizes laid in a modified Flemish bond pattern.

Interior faces of exterior walls at the backs of arched openings are finished with hand set brick set using thin set adhesive over cement board on metal studs. Backs of parapet panels on lower floors where visible from the building are finished with hand set brick applied directly to the back of the concrete panels using thin set adhesive.

Exterior walls at the sixth floor are typically EIFS, with areas of brick-faced precast panels matching the lower floors as indicated on the building elevations. EIFS systems utilize special large aggregate size and multiple custom finish colors.

Intake air louvers at first and second floors are 6" deep drainable blade with bird screen and blank-off panels for areas not used. Louvers at exhaust penthouse areas are 4" deep drainable blade with bird screen and blank-off panels for areas not used.

Exterior Doors and Windows

- Exterior windows appear as frameless fixed window units...

2.5.2 Roofing

- Roofing is four ply...

2.5.3 Interior Construction

Partitions

- Interior Partitions: 5

Interior Doors and Frames

Wall Finishes

- Public Areas

Floor Finishes

- Office Areas: Carpet, glue down...

Stair Construction

- Stairways consist of...

Ceiling Finishes

- Public Areas

Specialties

- Toilet partitions...

2.5.4 Conveying Systems

- Passenger Elevators (2)
  - Geared traction elevators
- Service/Passenger Elevators (2)
  - Geared traction elevators

2.5.5 Equipment

Laboratory Furnishings

- Typical lab furnishings consist of...

Miscellaneous Equipment

- Residential appliances:
- Coffee areas in lab suites (1/floor, Floors 1 and 2; 2/floor, Floors N-5): undercounter Projection screens:
- Conference rooms (2/floor for floors one through six): Recessed electric projection screen in drywall pocket.

2.5.6 Furnishings

Office Furnishings

- Offices: Furnishings at typical laboratory offices are semi-custom, built-in. Refer to typical office drawings for configuration.
- Workstation: modules adjacent to the labs have custom built-in workstations, typically...

Casework

- Coffee areas in lab suites (2/floor): Vertical grain oak base and tall cabinets with stainless steel countertops and backsplash.

- Mail Rooms (1/floor): Vertical grain oak base cabinets, tall cabinets, and mail slots. Oak countertops.
- Kitchen/Vending Areas (1/floor): vertical grain oak base and tall cabinets with stainless steel countertops and backsplash.

Window Treatment

- Laboratory Areas: Manually operated solar control shades (Mecho Shades) in drywall ceiling pocket at all exterior windows.
- Conference Rooms:

2.5.7 Special Construction

- Complete window washing equipment package provided
- Environmental Rooms:
- Provide...

3 Structural Narrative

3.1 Introduction

The following report describes the design parameters, loads, material strengths, and structural systems selected for incorporation into the design of the Client Building N Lab Facility.

3.2 Scope of Bldg N

At the present time the project consists of a seven story structure of about N59,000 overall GSF.

The first floor level is a foundation/slab-on-grade level at elevation 100', of approximately 60,000 GSF. This level will support mechanical equipment, Pilot Plant and miscellaneous laboratory and officing functions.

3.3 Design Criteria References

3.3.1 Governing Building Code

1998 California Building Code

3.3.2 Industry Reference Standards

SEAOC 1999 Recommended Lateral Force Requirements and Commentary (Bluebook), Appendix I – Performance-Based Seismic Engineering.

SEAOC Vision 2000 Performance Based Seismic Engineering of Buildings

SEAOC Recommended Provisions for Buckling-Restrained Braced Frames, 2001

FEMA N5N Recommended Specifications and QA Guidelines for SMF Construction for Seismic Applications

ACI N18 "Building Code Requirements for Reinforced Concrete"

ACI N15 "Details and Detailing of Concrete Reinforcement"

ACI N15R "Manual of Engineering and Placing Drawings for Reinforced Concrete Structures"

CRSI "Manual of Standard Practice" and "Placing Reinforcing Bars"

AISC "Specifications for the Design, Fabrication, and Erection of Structural Steel for Buildings," 1997.

AISI "Specifications for the Design of Cold-Formed Steel Structural Members"

AWS "Structural Welding Code"

SDI "Design Manual for Composite Decks, Form Decks, and Roof Decks"

AISC "Seismic Provisions for Structural Steel Buildings," 1997

3.4 Structural Computer Software

Gravity Loads	RAM Steel 2000 Release
Seismic Loads	ETABS Release 7.22
	MATHCAD Spread Sheet Program

3.5 Design Loads

1. Floor Dead Loads

Typical Structure Weight ("N" composite steel deck, 5" NW concrete and steel framing)	95 psf
Superimposed Dead Loads	MEP, Clg, Lights T5 psf
	(25 psf EQ mass)
Third floor additional paving material at Atrium, and Terrace	T0 psf
Exterior Cladding Allowance, per SF of exterior wall surface	50 psf
	(100 psf system applied to 50% of wall surface)

2. Roof Dead Loads

Typical Structure Weight	65 psf
Superimposed Dead Loads	MEP, Clg, Lights 60 psf
	(25 psf for EQ mass)
Roof terrace additional paving material	60 psf

3. Floor Live Loads

Offices (includes 20 psf for partitions)(reduce as permitted by code)	100 psf

4. Roof Live Load

Typical Roof Area (Ponding @ 8 inches)	T0 psf
	(plus 2000 lb. concentrated load)

5. Wind Loads

Exposure	C
Basic Wind Speed	70 mph
Wind Load Pressure – Primary Frame	26 psf
- Elements and Components	Per Code
Overhangs, Canopies, etc. (both directions)	50 psf

6. Earth Loads (Equivalent Fluid Density)

(Not applicable to building. May be applicable to sitework elements)

Cantilever Walls	T0 pcf
Restrained Walls	55 pcf

3.6 Material Strengths

1. Concrete (Minimum F'c @ 28 days (60 days where noted))

2. Reinforcing Steel (Fy)

Rebar	60,000 psi
Welded Wire Fabric	65,000 psi

3. Structural Steel (Fy)

Gravity System WF Beams (A572 or A992 GR 50)	50,000 psi
Gravity Columns and HP Piles (A572 or A992 GR 50)	50,000 psi

4. Lightgage Steel (Fy)

Roof Deck	30,000 psi

5. Foundations

(Refer to Geotechnical Report No...)	0.T5

3.7 Seismic Approach and Loads

a. The Seismic System will...

3.8 Seismic Design Criteria for Unbonded Braced Frames (UBF) Seismic System

Utilize Concept of Vision 2000 Document, as further refined by 1999 Bluebook Appendix I

Use Enhanced Objective 1 as a performance framework for the Seismic System Structural Design Criteria

Performance to be not less than 1998 California Building Code minimums

EQ-2 Level – Operational Behavior (Elastic Limit) – 72 year average EQ recurrence interval

EQ-N Level – Occupiable Behavior – T75 year average EQ recurrence interval

EQ-T Level – Life Safe Behavior – 950 year average recurrence interval

Code Required EQ Level Check

- Comply with City of Emeryville Building Code/1998 California Building Code.
- Force Level for Code Compliance Check:

3.9 Seismic Analysis Model

A ND non-linear analysis of the entire structure using site-specific time history data for EQ-1, EQ-2, EQ-N, and EQ-T was performed.

3.10 Foundation System – Gravity Loads

The proposed deep foundation system will use...

3.11 Foundation Systems – Seismic Loads

The proposed deep foundation system...

3.12 Soil Retention System

3.13 Basement Walls

3.14 First Slab on Grade

The slab is proposed to...

3.15 Floor Gravity Loads System

Floor Slab: 5 inches thick

3.16 Roof Gravity Loads System

Due to high seismic...

3.17 Vibration Assessment and Criteria

Vibration Assessment of floor systems includes dynamic analysis...

3.18 Mechanical Access Walkways Above Vivarium

3.19 Exterior Cladding Allowance and Criteria

An exterior cladding system weighing not more...

3.20 Future Expansion Provision

4 Pilot Plant Dexription

4.1 Pilot Plant Interior Finish Materials Narrative

4.2 Glasswash/Reagent Prep Interior Finish Materials Narrative

Attachment G
Project Execution Plan

Project Execution Plan – Table of Contents

Attachment H
Project Change Control

"Company A" Engineering Project Control Guidelines

1 Purpose

1.1 Change is inevitable during the design and execution of a Capital project. As well as Budget and Schedule, changes can impact other elements of the project like Safety, GMP Compliance, and Capacity.

1.2 To ensure that all proposed changes to the Approved Design receive proper evaluation, assessment and control prior to the approval of the change.

1.3 To ensure that any cost, schedule, or compliance implications of changes are identified and approved prior to the authorization to proceed.

1.4 To ensure that a complete log of changes is maintained within the Project records.

2 Scope

2.1 This guideline applies to all Projects administered by "Company A" Engineering irrespective of size.

2.2 This procedure does not cover changes arising through design development or construction risk, which are addressed in PCG-08, Cost Management and Reporting (see Attachment E of this Guide).

3 Definitions

3.1 **Budget** – The funding available to complete the Scope of Work submitted as a Capital Project Cost Estimate in support of a project Request for Concurrence. The Original Project Budget or Plan may be revised through approval of Scope Changes through the course of a project. These approved changes are reflected in the Current Project Budget or assumptive scenario (latest estimate).

3.2 **Project Manager** – Person identified on the RFC as having authority and responsibility for the project.

3.3 **Project Finance Representative** – Person having responsibility for Financial compliance on the Project. This person may also be the Business Unit Financial Representative.

3.4 **Business Unit Representative** – Person nominated by the Project Manager to represent the interests of the Business Unit in the design and execution of the project. In most cases, this person is the Project Manager.

3.5 **Change** – A modification, deletion or addition to an agreed design that may or may not alter the original intent of the project.

3.6 **Contingency** – An allowance applied against the project estimate as a whole to reflect the risk profile to the project of "unknown unknowns." Contingency is not provided to cover Scope changes that alter the original intent/scope of the project. Examples of "unknown unknowns" could include the discovery of asbestos during site enabling works, better process definition that requires additional equipment to meet the original user intent, etc.

3.7 **Design Development** – These are allowances applied against each prime element or job code line item of an estimate for the consideration of "known unknowns." Used to cover inaccuracies and uncertainties in design scope/ definition and estimating inaccuracies, these allowances will be adjusted through the project as the scope becomes fixed and bids replace estimates.

3.8 **"Company A" Engineering Representative** – Engineer working for "Company A" Engineering Services. This person is also known as the Project Engineer.

3.9 **Scope Change** – A change in the agreed project scope that may affect factors such as quality, cost or time for completion of projects.

3.9.1 **Major Scope Change** – A major scope change requires approval of all parties who approved the original Request for Concurrence.

3.10 **Design Change** – A change to the agreed upon Approved Design that may affect factors such as quality, cost or time for completion of projects. A design change is not normal design development changes but rather a fundamental, far reaching design change made necessary by regulatory, safety, environmental or other similar changes or by design errors or omissions.

3.11 **Field Change** – A change to the agreed upon Approved Design resulting from field initiated changes that may affect factors such as quality, cost or time for completion of projects. Field changes instigated by field orders (e.g., to resolve an interference) are not considered changes in the context of this guideline.

4 Requirements

4.1 The "Company A" Engineering Representative shall establish written Change Control procedures at the commencement of Detailed Design. These procedures should be included as part of the Project Execution Plan and approved by the Business Unit Representative. A change form shall be generated by the Project Engineer for each change (see Attachment H2 for a typical form).

4.2 All applications for Change must be accompanied by supporting documentation and justification appropriate to the magnitude and extent of the change being requested. The Business benefit must be clearly identified and supported with calculations where appropriate.

4.3 Change Control procedures shall ensure that all aspects that may be affected by the change are considered and adequately documented prior to implementation.

Consideration should be given to:

- impact on safety (process, occupational and/or construction)
- impact on regulatory compliance (i.e., change to a direct impact system)
- change to an approved drawing (P&ID, loop diagram)
- other documents affected (i.e., plot plans, instrument lists, etc.)

Consideration should be evident through the use of clear Yes/No statements completed by the "Company A" Engineering Engineer or Authorized party (i.e., Safety representative). For example:

- Does this proposed affect change alter Direct Impact/GMP Systems? – Yes/No

Where the answer is Yes, then the effect and proposed actions to deal with the effect must be assessed by the "Company A" Engineering Representative and documented on the change form.

4.4 Once the impact on the project design basis has been considered, change to the Budget and/or Project Schedule shall be assessed and the basis of this assessment identified.

4.5 The source of any additional funding shall be clearly identified (Development, Contingency or Additional RFC)

4.6 The Change Form shall be approved according to the Project Procedures, which shall make due reference to financial authorization limits and special restrictions applicable (i.e., Contingency use only with VP Approval).

4.7 Only once the change is fully approved shall the "Company A" Engineering Representative authorize the work to proceed.

4.8 The Project Engineer shall maintain a Project Change Log similar to the example shown in Attachment H3.

- All changes and potential changes shall be tracked until such time that they are approved by the Business Area Expense Center Manager and the Business Area Finance Manager as described in PCG-08, Cost Management and Reporting (see Attachment E of this Guide).

- The process for dealing with changes occurring as a result of normal design development is described in PCG-08, Cost Management and Reporting (see Attachment E of this Guide).

4.9 Field Changes which are instigated by field orders (e.g., to resolve a clash) are not considered Changes in the context of this Guideline.

4.10 All changes to the approved design shall be referenced to the appropriate WBS codes indicating any budget transfers or revisions necessary.

4.11 Once a Change has been completed, the Project Change Form should be formally closed. Closure of the form indicates that all necessary documentation affected by the change has been suitably amended and that the change is complete. The "Company A" Engineering Engineer is responsible for ensuring that Changes are closed and that the Project Change log is updated

5 Responsibilities

5.1 The "Company A" Engineering Engineer is responsible for the development and application of appropriate Change Control Procedures

5.2 The responsible "Company A" Engineering Director shall review and concur with the Change Control Procedures.

5.3 The "Company A" Engineering Engineer is responsible for ensuring that Changes are closed and that the Project Change log is updated.

6 Attachments

Attachment H1: Typical Project Change Control Flow Chart

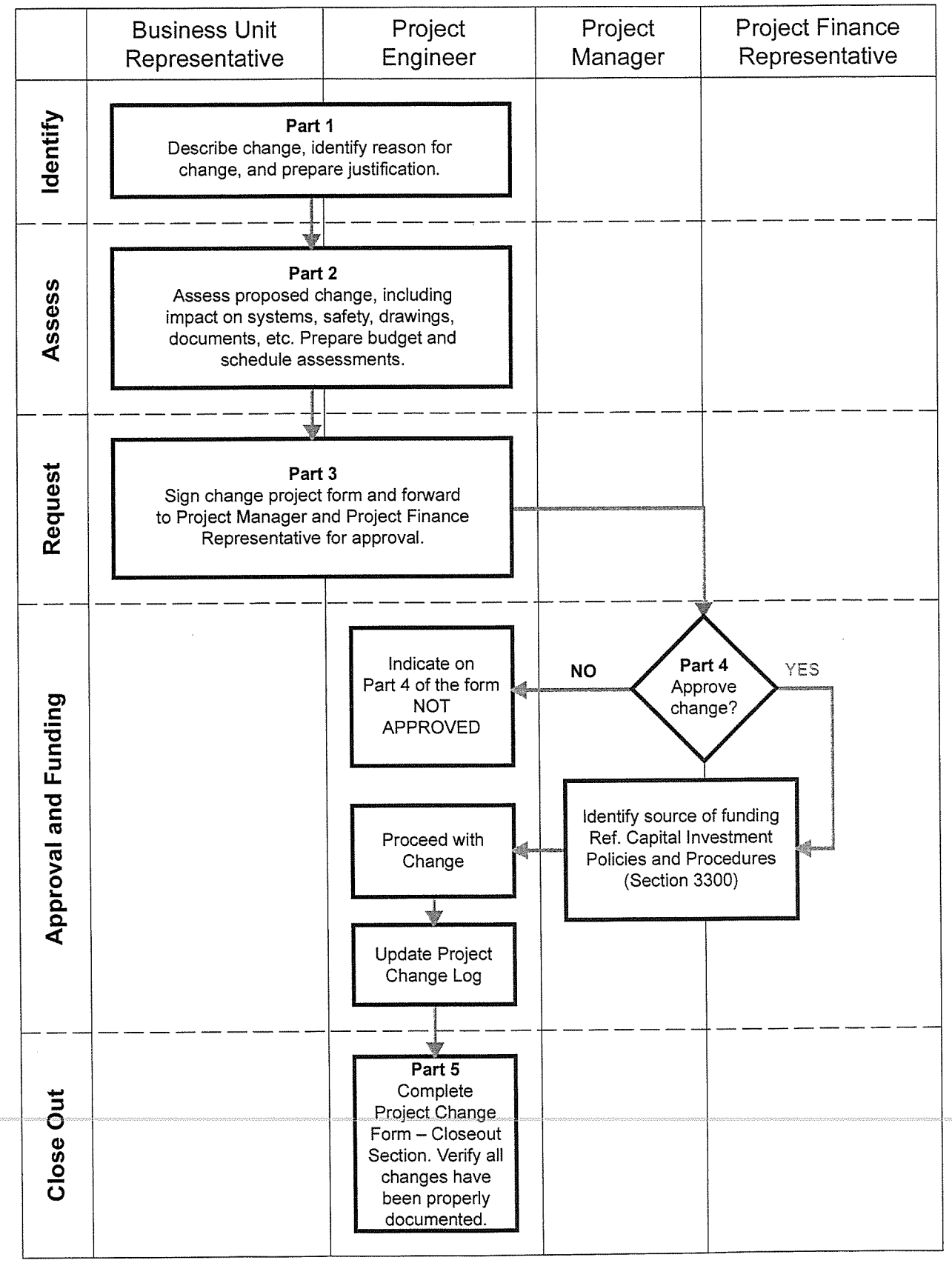
Attachment H2: Typical Project Change Form

Attachment H3: Typical Project Change Log Summary

7 References

PCG-08, Cost Management and Reporting (see Attachment E of this Guide)

Attachment H1: Typical Project Change Control Flow Chart



Attachment H2: Typical Project Change Form

Part 1 - Details

Project Name: _____ **Project Number:** _____
Change Initiated By: _____ **Change Number:** _____
Department: _____

Description of Change: _____

_____

_____

_____ Check If Additional Pages Attached: ☐

Type of Change: Scope ☐ Design ☐ Field ☐

Reason for Change:

1. Business Need ☐
2. Process Change ☐
3. Error/Omission ☐
4. Safety Compliance ☐
5. Regulatory Compliance ☐
6. Rick Management Compliance ☐
7. Security Compliance ☐
8. Other* (*Describe) ☐

*Describe: _____

_____

Justification for Change: _____

_____

_____

_____ Check If Additional Pages Attached: ☐

Part 2 – Assessment of Change

Design Basis Assessment: Does the proposed change affect or alter:

- Safety (Process and/or Construction)? Yes ☐ No ☐ *If yes, explain how change is to be addressed
- Direct Impact or GMP System? Yes ☐ No ☐ *If yes, explain how change is to be addressed
- Approved Drawings (P&ID, Loop Diagrams, etc.)? Yes ☐ No ☐ *If yes, explain how change is to be addressed
- Other Documents? (Plot Plans, Instrument Lists, etc.) Yes ☐ No ☐ *If yes, explain how change is to be addressed
- Other Systems? (Non-GMP, Indirect Systems, etc.)? Yes ☐ No ☐ *If yes, explain how change is to be addressed

*Explain: _____

_____

_____ Check If Additional Pages Attached: ☐

Project Budget and Schedule Assessment:

Budget Change	Local Currency	US $
Current Approved Budget	_____	_____
This Change Request	_____	_____
Revised Budget	_____	_____

Schedule Change	Current Date	Revised Date
Preliminary Engineering	_____	_____
65% Design	_____	_____
95% Design	_____	_____
Construction Start	_____	_____
Construction End	_____	_____
Commissioning	_____	_____
Turnover	_____	_____

Supporting Attachments:

- Process Enhancement/Change Description ☐
- Statutory or Regulatory Documentation ☐
- Internal Procedure Change Notification ☐
- Other ☐ Explain: _____
- Estimate ☐
- Drawings ☐
- Engineering Reports ☐

Attachment H2: Typical Project Change Form (continued)

Part 3 – Request for Change

Based on the information provided above, it is requested that this change be approved.

Business Unit Representative	Date	*"Company A" Engineering* Representative	Date

Part 4 – Approval and Funding

Approval:

Change is Approved ☐ Change is Not Approved ☐

Project Manager	Date	Project Finance Representative	Date

Additional funding for this change will come from:

Design Development: ☐ Contingency: ☐ Supplemental RFC: ☐

Date: _____ (Month/Day/Year) **Change Request Number:** _____ **Revision:** _____

Entered Into Project Change Log: ☐ **By:** _____ **Date:** _____

Part 5 – Closeout

Change Has Been Completed ☐ Verified By: _____

The following has been amended to reflect change:

Design Drawings: ☐ P&IDs: ☐ Loop Diagrams: ☐
Project Specifications: ☐ Instrument List: ☐ Other*: (*Explain) ☐

*Explain: _____

_____

_____ Check If Additional Pages Attached: ☐

Attachment H3: Typical Project Change Log Summary

Change Order Number	Brief Description	Initiated On	Approved			Reason for Change	Design Dev. Funding	Use of Contingency Required	Additional Funding Required	Change Complete	Date Complete
		Date	*N*	*Y*	*Date*	*1 to 8*	*US $*	*US $*	*US $*	*Y/N*	*MMDDYY*
						Totals					

Reason for Change:

1. Business Need
2. Process Change
3. Error/Omission
4. Safety Compliance
5. Regulatory Compliance
6. Risk Management Compliance
7. Security Compliance
8. Other

Attachment I
System User Requirements Specification (URS)

System User Requirements Specification Sample

Cold Storage Areas

XXX Project

Document Number: n
Effective Date: mm-yyyy

System User Requirements Specification		Document Number:
Cold Storage Areas		Rev: 0
Project:	Completed By:	Date: dd/mmm/yyyy
Location	Supersedes: None	Page: 1 of xx

Review and Approval

Role	Name	Department	Signature	Date
Project Manager				
Operations				
Quality Assurance				

Revision History

Version	Changes	Complied by	Date
0	New document		

1 Introduction

1.1 Purpose and Scope of this Document

- The scope of this project applies to the Cold Storage Areas (2 - 8°C).
- This System User Requirements Specification (URS) serves as a foundation bringing together multi-discipline system requirements into a single document to support system design, construction, commissioning, qualification, validation and ongoing operation/ maintenance for the Cold Rooms.
- The cold room systems have been assessed as Direct Impact systems, refer to the Impact Assessment section of the Project Validation Plan, document # .
- A System User Requirement is a condition that must be satisfied in order for a system to meet its intended purpose from the perspectives of all stakeholders. User Requirements Specifications focus on what is required without being prescriptive as to how the requirements are met.
- The cGMP requirements of the Systems URS are captured in specified sections of the URS document. All other miscellaneous requirements (e.g., business drivers, safety, etc.) are segregated from the cGMP requirements.

- The cGMP requirements of the Systems URS shall be incorporated into the design and verified during design qualification, installation, commissioning, and qualification activities.
- This document shall be maintained as a living document during the course of the project and is controlled under change management as new requirements are realized and existing ones enhanced or removed.
- Following project completion, update and maintenance of this document will be a site operations responsibility, managed through the site change control procedure.

1.2 Project Description Overview

The project scope is the installation of new cold storage rooms to hold finished product with a storage temperature requirement of 2 to 8°C.

This URS will provide the rationale for the cold storage system validation acceptance criteria.

All goods are received on pallets at the goods receipt area in accordance with appropriate procedures.

The goods are stored in the proper refrigerated or freezer storage areas in accordance with appropriate procedures.

1.3 General Requirements

The cold storage system must be developed in compliance with all relevant Federal, State and local codes and regulations as well as adhere to the companies Corporate Engineering Design Standards and Specifications.

1.4 Definitions and Abbreviations

cGMP	Current Good Manufacturing Practice
DQ	Design Qualification
IQ	Installation Qualification
IV	Installation Verification
OQ	Operation Qualification
PQ	Performance Qualification
RV	Receipt Verification
URS	User Requirements Specification

2 System Requirements

The systems user requirements are defined in distinct sections in the table below. Regulatory requirements specific to the specific system are also referenced in the system tables.

User Requirement Specifications for Cold Rooms

Item	Parameter/Subject Matter	Sub-Item	Requirement	Source of Requirement
1	Performance			
	External Design Conditions	1.1	The system should be designed to operate with external design conditions of -2.8 to 36.7°C (27 to 98°F).	Operational Requirement
	Internal Performance Conditions	1.2	The unit shall maintain temperature between 2 to 8°C (Acceptance Criteria), with a design performance of 3 to 7°C (expected results).	Regulatory Requirement
	Security	1.3	The cold room must have access control, such as a card reader.	Regulatory Requirement
2	Operational			
	Performance	2.1	All units should maintain temperature between 2 to 8°C with the doors held fully open for at least 2 hours.	Desirable Feature
	Redundancy	2.2	The refrigeration system must have 100% redundancy.	Operational
	Sequence of Operation	2.3	The duty unit should automatically change over with the standby unit every 24 hours at a pre-defined time.	Operational
	Electrical Power Source	2.4	All refrigeration systems must be capable of operating with main or standby power, automatically restarting when power removed then re-applied to the refrigeration system and controls.	Operational
	Functional	2.5	Racking to be laid out as existing units with finish suitable for cleaning agents.	Operational
3	Automation			
	Functional	3.1	Each refrigeration system must have an independent control panel.	Operational
		3.2	Failure of the primary refrigeration system should automatically initiate the standby refrigeration system.	Operational
		3.3	Increased temperature above the expected operating limit of 7°C will independently initiate the standby system.	Operational
		3.4	The control must operate reliably in an environment normally 20 to 25°C, exceptionally 15 to 40°C (up to 24 hours) environment with no humidity control the environment is non-condensing.	Operational
		3.5a	All automation equipment shall provide complete continuous diagnostics for each hardware component.	Operational

User Requirement Specifications for Cold Rooms (continued)

Item	Parameter/Subject Matter	Sub-Item	Requirement	Source of Requirement
		3.5b	Diagnostics shall cover communications, processor performance, engineering data storage and hardware faults.	Operational
		3.6	Diagnostics shall cover communications, processor performance, engineering data storage and hardware faults.	Operational
		3.7	The automation design shall ensure that all elements of the control system shall recover from power failure to a normal operating state.	Operational
		3.8	An approved method of software back up and restore shall be provided.	Operational
	Monitoring/Alarms	3.9	The monitoring probes utilized for GMP record purposes must be separate from the control sensors.	Regulatory Note: This function is provided by the EMS as an independent system. All alarms listed here are engineering alarm functions.
		3.10	A minimum of two probes must be used to monitor each refrigeration system.	Regulatory
		3.11	Alarms must be configured so that they are easily distinguishable based on their present condition – i.e., unacknowledged/ acknowledged, etc.	Operational
		3.12	All alarms shall be provided with an individual delay timer which must complete (i.e. time out) before the alarm becomes active.	Operational
		3.13	Alarm annunciation shall be audible and visual, acknowledging the alarm will silence the local annunciation.	Operational
		3.14a	There must be an engineering alarm if the system temperatures exceed pre-defined limits, outside the normal operating range.	Operational
		3.14b	There must be an engineering alarm if the refrigeration plant fails, or develops a fault.	Operational
		3.14c	There must be an engineering alarm if the standby cooling unit has to operate.	Operational
		3.15	Any alarm from the control panel will give a hardwired common trouble alarm to the BMS.	Operational
	Data Recording	3.16	The HMI should maintain an alarm history file (capacity will be based on the preferred unit)	Operational

User Requirement Specifications for Cold Rooms (continued)

Item	Parameter/Subject Matter	Sub-Item	Requirement	Source of Requirement
	Security	3.17	A user must be logged in and have the proper security privileges to in order to issue commands, or change set points/values. (Note: the system is not required to comply with CFR 21 Part 11).	Operational
		3.18	The system must have an automatic log off feature with a configurable time out.	Operational
		3.19	When no user is logged in, the OIT's will display data in read only mode, but no control actions can be initiated.	Operational
	Expandability	3.20	The system shall be designed with 20% spare I/O capacity per I/O type and 20% spare controller capacity per controller.	Operational
		3.21	Each major component of the automation system shall be supplied with 20% spare capacity for all elements of the system configuration.	Operational
4	Installation			
	Material of Construction	4.1	Material of construction must be suitable for the environment.	Operational
		4.2	Internal finishes must be resistant to the cleaning and sanitizing materials which may include hypochlorite solution.	Regulatory
	Door Specifications	4.3	There must be a self opening door adequate for a fork truck carrying a standard pallet for Cold. Door to match existing in adjacent location – see drawing xx.	Operational
		4.5	Door gaskets for all doors should be designed for easy replacement to facilitate maintenance.	Operational
	Dimensions Cold Rooms	4.6a	Cold Room 1121: storage area approx. 4787 sq.ft.	Operational
		4.6b	Cold Room 1122: storage area approx. 5014 sq.ft.	Operational
		4.6c	Cold Room 1123: storage area approx. 4941 sq.ft.	Operational
5	Miscellaneous			
	Maintenance	5.1	The system must have a design life of 12 years.	Operational
		5.2	The equipment must be designed for ease of maintenance. Noninvasive preventative maintenance is preferred.	Operational

User Requirement Specifications for Cold Rooms (continued)

Item	Parameter/Subject Matter	Sub-Item	Requirement	Source of Requirement
		5.3	Provision for maintenance of refrigeration system inside cold room required.	Operational
	Fire Protection	5.4a	The system materials of construction and design requirements must meet Factory Mutual (FM) requirements.	Corporate
		5.4b	The fire protection external to and within the unit must meet FM requirements.	Corporate
6	Desirable Features			
	Equipment Protection	6.1a	The refrigerated storage area should have protective bollards on either side of the truck access doorway.	Operational
		6.1b	Bollards must also be at either side of the control cabinets.	Operational
		6.2	The refrigerated storage area should have a door height indicator.	Operational
7	Notes and Other Requirements			
	Relative Humidity	7.1	Non-critical – the product is packed	N/A
	Level of Oxygen	7.2	Non-critical – the product is packed	N/A
	Lighting	7.3	All Cold Rooms: UV intensity of <0.01w/m²	N/A
	Particulates – Viable and Non-Viable	7.4	Non-critical – the product is packed	N/A
	Emergency Systems	7.5	There must be an emergency egress door with panic bar release.	Safety
		7.6	There must be emergency lighting	Safety

3 Attachments

Remainder of Attachment I example document omitted from ISPE GEP Good Practice Guide.

Attachment J
Design Review

Extract From a Set of Design Review Challenges

This is an extract from a set of design review challenges, intended to provide a means of ensuring compliance with GMP requirements, and act as a means to capture project experiences, by adding challenges.

The system would be used by the project team, who would take the entire list of challenges, and edit to suit the project scope, they may then review the design challenges (the concept is that the questions challenge the design team to demonstrate compliance with the requirement), with the design authority, alternatively the design team could present their responses to the challenges to the relevant members of the project team.

Where there are company "standard" design solutions these have been shown by adding guidance in the response column.

Initial Action	Response
Define the scope of the project, the product type, and activities within each building.	

1 Introduction

The design review for a facility is different from system design reviews in that many important concepts are developed in the early stages of the facility design, hence it is important to review the concept design in more detail than is the case with other systems. The facility design review template has been structured into sections starting at a macro level, and going into smaller sub divisions, i.e.:

- Site
- Building
- Area – (by type)

It is considered a good practice to define the project scope, and the activities within each building, so that the relevant sections of the review template can be identified, e.g., warehousing, maintenance, admin – general, admin GMP, Laboratories, Manufacturing (type).

1.1 Site Challenges

Challenge	Response	Resolution
Are any hazardous materials going to be stored in bulk on the site?		
Does the proposed layout consider minimum spacing requirements for known hazards – dust control system explosion venting, solvent storage, etc.?		
Does the proposed layout allow for access for emergency vehicles –fire tenders, ambulances, etc.?		
Does the site layout allow for safe (unidirectional?) traffic flow for the largest anticipated vehicle?		

Challenge	Response	Resolution
Is parking adequate/outside the site security boundary?		
How does the layout impact opportunities for expansion of manufacturing/warehousing administration/utilities distribution?		
Is there a building numbering convention which has been followed?		
How will the utilities be distributed – is there a concept which will facilitate the site expansion?		
How are the underground services to be distributed – water supply, drainage segregated into surface water, sewerage, and production drainage?		
Are there any requirements for water catchment/ containment?		
For a new site: How will the design concepts relating to site expansion be captured to allow their use in future? For an existing site: Has the design considered any pre-existing expansion plans or strategies?		

1.2 *Building Challenges – Non-Production Area*

Challenge	Response	Resolution
Has account been taken of the following risks: Earthquake, flooding, structural movement both major and local, local extremes of conditions – rain, wind, heat?		
Does the design consider personnel/material flows and departmental interactions?		
Is there a requirement for security in the building – if so how is it managed?		
What access control provision is there for services rooms? Is it adequate?	May be electronic control, suited keys, etc.	
Does the design incorporate local custom and practice for storage of outer clothing?		
Are fire escape routes in compliance with local code and the insurer's requirements?		
How does the design achieve the fire resistance required?		
How is the fire compartmentalization arranged internally, are materials used non combustible and insurer approved?		

Challenge	Response	Resolution
Are there any windows – are they specified to be approved by the insurance authority?		
Have specific hazards been identified, and fire protection measures defined – food preparation areas, computer rooms, record retention areas, gas cylinders or tanks?	If any stored records are considered irreplaceable – then dual fire protection systems may be required.	
How does the design minimize the risk of ingress of insect/rodents/other pests?	Typically by minimizing openings, specifying high quality doors, rapid roll doors with weather seals for warehouse loading bays, and the use of airlocks with insectocutors between the doorways where possible.	

1.3 Building Challenges – Production Area

Challenge	Response	Resolution
Has account been taken of the following risks: Earthquake, flooding, structural movement both major and local, local extremes of conditions – rain, wind, heat?		
How does the design provide good insulation from the external environment, using non-combustible construction elements?		
Does the design consider personnel/material flows and departmental interactions?		
Is there a requirement for security in the building – if so how is it managed?		
What access control provision is there for services rooms? Is it adequate?	May be electronic control, suited keys, etc.	
Does the design incorporate local custom and practice for storage of outer clothing?		
Are fire escape routes in compliance with local code and company requirements?		
How does the design achieve the fire resistance required?		
How is the fire compartmentalization arranged internally, are materials used non-combustible insurer approved?		
Are there any windows – are they specified to be approved by the insurance authority?		

Challenge	Response	Resolution
Have specific hazards been identified, and fire protection measures defined – solvent stores, computer rooms, record retention areas, gas cylinders or tanks?		
How does the design minimize the risk of ingress of insects?	Typically by minimizing openings, specifying high quality doors, rapid roll doors with weather seals for warehouse loading bays, and the use of airlocks with insectocutors between the doorways where possible.	
Are emergency egress doors sealed with alarms on them?		
How does the design separate production areas from non-production areas?		
Is there a maintenance access philosophy to facilitate maintenance access with the minimum need to enter a manufacturing area?		
Are there facilities to show visitors around the facility, minimizing the need to access production areas, and change – e.g., separate viewing corridors?		
Are separate areas or means of segregation provided for: Receipt, identification, sampling, quarantine of incoming materials, quarantine before release of API, intermediates, or finished product, laboratory areas		

1.4 Area Challenges – Non-Manufacturing Area

Challenge	Response	Resolution
Is the cleaning method defined? What internal finishes are specified – are they easily cleaned and resistant to the cleaning agents which will be used? How is the durability/repair ability of the finishes demonstrable?	• Wall finishes • Floor Finishes • Ceiling Finishes • Doors • Windows	
Is wall/door protection required/specified?		
What finish is specified for door accessories (locks, hinges, and handles)?	Should be stainless steel; 304 can be use for general, 316L for aseptic production areas.	

Challenge	Response	Resolution
How will the standard for the finishes be defined, and monitored?	It is good practice to produce samples to be accepted by SP, or nominate one room in the facility as the sample room, used to contain mutually agreed finishes standards, for large projects a "sample room" may be built.	
Have process flows been established for the following, and are they acceptable, i.e., generally unidirectional? How can it be shown that the layout is the optimum?	• Materials • People • Waste materials	
Has adequate storage space and racking been defined for: documentation, cleaning materials?		
Are there adequate bathroom facilities with hot and cold water, or equivalent, air dryers, given the possible split between sexes locally?		
How are environmental conditions monitored, and alarms provided, e.g., T, RH, differential pressure?		
How is it known that the drainage is adequately sized, and what will prevent potential backflow?		
What is the maximum size/weight of any replaceable part for the utility or process equipment? How will it be replaced/maintained? Are doors and corridors large enough – is lifting equipment required?		
How are utilities distributed in the facility, and what would be the impact of leakage? Is this an optimum solution, allowing for expansion?		
What lighting levels are specified for the facility, normal and emergency, are they adequate?		
How will the light fittings be maintained, is this acceptable?	Top access with flush fitting glass internally is best for aseptic areas, with bottom access for lower risk areas.	
What is the maximum size piece of Utility and processing equipment? How will it be installed – are doors and corridors big enough?		

1.5 Area Challenges – Manufacturing Area

Challenge	Response	Resolution
Is the cleaning method defined? What internal finishes are specified – are they easily cleaned and resistant to the cleaning agents which will be used? Are the finishes durability/repair ability demonstrable?	• Wall finishes • Floor Finishes • Ceiling Finishes • Doors • Windows	
Is coving correctly specified for floor/wall, and wall/ceiling joints?	Should have both for production areas, and other rooms in the production area, for secondary packing there should be floor/wall coving, but can do without wall/ ceiling coving.	
How does the design provide protection against risks of internal shedding or cracking?		
Is wall/door protection specified?		
Are doors, windows in doors, and windows in the production area walls flush fitting, with minimum crevices?		
What finish is specified for door accessories, (locks, hinges, and handles)?	Should be stainless steel; 304 can be used for general, 316L for aseptic production areas.	
How is the sealing of the rooms covered, including electrical conduits, piped services, and ductwork penetrations?	This is necessary to ensure that room pressure differentials/airflow directions can be maintained.	
How will the standard for the finishes be defined, and monitored?	It is good practice to build a "sample room," or nominate one room in the facility as the sample room, used to contain mutually agreed finishes standards.	
Have process flows been established for the following, and are they acceptable, i.e., generally unidirectional? How can it be shown that the layout is the optimum?	• Raw Materials • Manufacturing Process • Packaging Components • Equipment (portable or parts) • Finished Goods • People • Quality Samples • Waste Materials • Laundry	
Is there a defined area for each process step?	There should be!	

Challenge	Response	Resolution
How has it been established that there is adequate space to install, clean, maintain, and operate the process and utility equipment? What is the maximum size replaceable part for the utility equipment, and the manufacturing equipment? How will it be taken out? (How is the equipment going to be taken in, are doors and corridors big enough?)		
Has adequate storage space and racking been defined for: Samples, test equipment, batch records, qualification documentation, facility, utility, and equipment spare parts, raw materials, labels, packaging components and finished goods?		
Has there been a formal assessment for ease of Maintenance and a cross contamination risk assessment considering the option of local storage of specific tools?		
Have separate controlled access areas been provided for label storage, reject labels, reject materials, product awaiting final release?		
Has adequate space been identified for quality control laboratories, and IPC testing, does the design consider workflow within the test area?		
Are there adequate equipment wash bays, with suitable finishes, tanking (bunding), drainage arrangements, and unidirectional flow?		
Is there a dedicated room or space for the storage of clean equipment?		
Is there a dedicated room for equipment parts or tooling?		
Are areas of different classifications separated by airlocks for people and material flow?		
Are controlled manufacturing areas separated by airlocks for people and materials flow?		
Are there primary and secondary change facilities for each different area classification, and product type?	Note that an airlock is required to separate the change area from the manufacturing area.	
Are there adequate bathroom facilities with hot and cold water, or equivalent, air dryers, given the possible split between sexes locally?		
Is there provision for storing cleaning materials, calibration equipment, and any dedicated maintenance tools in the area?		

Challenge	Response	Resolution
What access control provision is there for services rooms, production and storage areas? Is it adequate?	May be electronic control, suited keys, etc. Some segregation with controlled access is required by the regulations for: Labels, including reject labels. Reject materials.	
How are areas labeled, and status of them shown, e.g., clean, or in used batch 2003/03?		
How is the packaging area laid out in order to minimize risk from decarding, and separate primary from secondary packaging?	A separate decarding area is preferred, with primary packaging in a dedicated room, having airflow of the appropriate classification on the product.	
How are packaging lines separated?	Spatially is a minimum requirement, with a physical barrier to the floor of at least 3 feet (1 meter) tall being preferred?	
How is cross contamination being prevented?	Airflow directions, airlocks, with interlocked doors?	
How are environmental conditions monitored and local alarms provided, e.g., t, RH, differential pressure?		
How are utilities distributed in the facility, and what would be the impact of leakage? Is this an optimum solution?		
How is it known that the drainage is adequately sized, and what will prevent potential backflow?		
What lighting levels are specified for the facility, normal and emergency, are they adequate? Is color rendering specified/required?		
How will the light fittings be maintained, is this acceptable?	Top access with flush fitting glass internally is best for aseptic areas, with bottom access for lower risk areas.	
How are the interfaces from the utilities to the production equipment specified, will the meet GMP?		
Is the product in a category which requires segregation – if so how is this achieved for the facility and relevant utilities?		
Is there an airlock separating an elevator from any classified area?		

Attachment K
Maintenance Test Certification

Completion and Inspection Certificate

Particulars of the Electrical Installation

Department: _____ Date: _____

Name of Installation	Circuit Ref.		Plant ID No (if applicable)	

_____

_____

Type of Installation	New	Alteration	Addition to Existing Installation
(indicate as appropriate)			

Type of Earthing	TN-C	TN-S	TN-C-S	TT	IT
(indicate as appropriate)					

Characteristics of supply at **origin** of the installation:
Nominal voltage _____ V Frequency _____ Hz Number of phases _____

	Ascertained by Enquiry	Determined by Calculation	Measured
Prospective Short Circuit Current _____ kA			
Earth Fault Loop Impedance (Ze) _____ ohms			

Maximum Demand _____ A

Overcurrent Protective Device Type BS _____ rating _____ A
Main Switch or Circuit Breaker Type BS _____ rating _____ A No of poles _____
(if an Residual Current Device (RCD) is fitted, rated residual operating current _____ mA)

I/We being the persons responsible for the Design/Construction/Installation of the electrical installation, **CERTIFY** that the said work for which I/We have been responsible is to the best of our knowledge and belief in accordance with the Statutory Regulations for Electrical Installations.

The extent of the liability of the signatory is limited to the work described above as the subject of this certificate.

For the <u>Design of the Installation</u>
Name (block letters): _____
For and on behalf of: _____
Signature: _____ Date: _____

For the <u>Construction of the Installation</u>
Name (block letters): _____
For and on behalf of: _____
Signature: _____ Date: _____

For the <u>Inspection and Test of the Installation</u>
Name (block letters): _____
For and on behalf of: _____
Signature: _____ Date: _____

I RECOMMEND that this installation be further inspected and tested after an interval of not more than _____ years (5)

Schedule of Items Inspected

Tick items inspected. Delete items that are not applicable.

	connection and identification of conductors		connection of single pole device in phase conductor only
	routing of cables		correct connection of socket outlets and lamp holders
	selection of conductors in accordance with design		presence of fire barriers
	presence of appropriate device for isolation		adequacy of access to switchgear and equipment
	presence of under voltage devices		presence of danger and other warning notices
	labelling of installation, circuit, fuses, switches, terminals		diagrams, instructions, and similar information
	choice and setting of protective and monitoring devices (for protection against indirect contact and/or overcurrent)		
	Method of Protection against Direct Contact		
	by insulation of live parts		by obstacles
	by barriers and enclosures		by placing out of reach
	Methods of Protection against Indirect Contact		
	presence of protective conductors (used to connect together conductive parts, main earthing terminal, earth electrodes, the earthed point of the source)		presence of main equipotential bonding conductors
	supplementary protection by residual current device		presence of supplementary bonding conductors
	Schedule of Items Tested		
	Prior to Turning On Power		
	Continuity of Phases		
	Polarity		
	Continuity to Earth/Ground		
	Insulation Resistance Phase to Phase		_____ M ohms
	Insulation Resistance Phase to Earth		_____ M ohms
	Insulation Resistance Neutral to Earth		_____ M ohms
	After Power On		
	Loop Impedance Zs		_____ ohms
	Earth Fault Current Measured		_____ Amps
	R.C.D. Trip Test 1/2 Trip Current		
	R.C.D. Trip Test 1 × Trip Current		
	R.C.D. Trip Test 5 × Trip Current		
	R.C.D. Disconnection Time		_____ s
	Load Current		_____ A

Circuit Design Details

Circuit Ref.				
Plant ID No. (if applicable)				
Origin of Circuits				
Destination of Circuits				
Installation Method	Table 4A			
Cable Type				
Route Length (meters)	L	M		
Design Voltage		V		
Design Current	Ib			A
Grouping Factor	Cg			
Ambient Temp. Factor	Ca			
Required Current Carrying Capacity	Iz			A
Circuit Conductor CSA		mm2		
Tabulated Current Carrying Capacity	It			
Type of Protective Device		BS		
Rating of Protective Device	In			A
Volt Drop		V		
Earth Loop of Circuit	R1+R2+Ze	ohms		
Fault Current at Protective Device				A
Protective Device Disconnection Time	t			s

Comments: _____

_____

_____

_____

_____

_____

Designer: _____ Date: _____

Schedule of Test Results

			Circuit Conductors				Overcurrent Device		Residual Current		Insulation Resistance			
Circuit	Service	No.			Live	CPC			Device		Phase/			Loop
Ref.	Plant ID No (if applicable)	of points served	Cable Type	Length Meters	CSA mm2	CSA mm2	Type BS	Rating in A	Rating mA	Trip Time MS	Phase/ Neutral M ohms	Phase/ Earth M ohms	Neutral/ Earth M ohms	Imped-ance Zs ohms

Test equipment used + S Nos: _____

Comments: _____

Attachment L
Facility Commissioning

"Company A" Good Engineering Practice

Subject: Facility Commissioning Issue Date: dd/mmm/yyyy Supersedes: Version n-1	Practice No. GEP n	Version n Page 1 of 2

1 Purpose

The purpose of this document is to define a recommended method to commission the layout and finish aspects of a facility.

2 Scope

The document is specifically intended for GMP manufacturing areas, but may be used for all facility commissioning. Where sections are not used, these may be marked as N/A. Additional sections may be added as appropriate to suit the required application and scope of the project.

All structural and dimensional checks of the building and associated openings should be carried out at the appropriate stage of construction and are not expected to be covered under this guideline.

This document does not address the qualification requirements necessary for equipment and critical utilities. Worldwide Quality Standard qq,qqq – "Equipment Qualification" should be adhered to for qualification of such systems. Safety and Operational issues have also incorporated into this document.

3 Definitions

3.1 **Good Engineering Practices (GEP)** – Proven and accepted, cost-effective, engineering methods and practices that ensure the effective satisfaction of Stakeholder's requirements. They are established engineering methods and standards that are applied throughout the project lifecycle to deliver appropriate cost-effective solutions (ISPE). (Note that Good Environmental Practices are also known as *GEP.* The use of this acronym should be in context and with care).

3.2 **Facility** – As it pertains to this GEP, a facility is a defined structure or building where manufacturing or support operations are carried out. This does not include any installed or associated mechanical or electrical equipment

4 Recommended Practice

4.1 Sites and project teams may use the templates in the attachments for the appropriate facility to be commissioned. Modifications to the template can be made as required to suit the project need.

4.2 Specifications for finishes can be taken from purchase orders, design and functional specifications or drawings as appropriate. (Note: The finishes specified in this document are examples only).

4.3 Fill in the "building/room/area/location" field to identify which area of the facility is being commissioned. (Note: Where specifications are similar, multiple areas of the facility may be combined).

4.4 Using Attachment L1, area finishes can be verified by a combination of facility "walk-through," and a review of facility drawings or manufacturers specifications.

"Company A" Good Engineering Practice

Subject: Facility Commissioning Issue Date: dd/mmm/yyyy Supersedes: Version n-1	Practice No. GEP n	Version n Page 2 of 2

4.5 The checklist in Attachment L2 should be completed by a "walk-through" of the facility and verification (either by visual inspection or documentation check) that the facility is constructed according to architectural specifications and to an acceptable quality.

4.6 Any comments regarding the tests should be recorded in the comments section. If there are no comments, this section should be signed and marked as N/A.

4.7 Any discrepancies observed during completion of the checklist should also be recorded in a Project Punch List (a sample format for such a list is included as Attachment L3). Where the inspector considers that any such issue is acceptable then he may write a memo to the facility owner explaining the issue, together with a rationale for accepting current installation. The owner must confirm that the change is acceptable by signing agreement on the memo. All such memos will be attached to the checklist.

4.8 The facility checklist should be signed off by the Engineering Function and the Area Owner indicating that the area complies with the required architectural finishes and facility layout.

4.9 The signed-off checklist should be filed in accordance with the Project Turnover/Handover Procedure.

4.10 Documentation requirements are outlined in GEP-n *Principles of Good Engineering Practices*.

4.11 All forms must be completed using blue or black indelible ink.

5 Responsibilities

5.1 **Engineering** (Global Engineering Services or site Engineering Department) is responsible for day to day management of the project, assurance that facilities meet specifications and turnover of all systems to the User group. Engineering has primary responsibility for preparation and execution of the facility commissioning checklists.

5.2 **Global Quality Operations (GQO)** is responsible for the review and approval of GMP activities and documents related to capital projects and to ensure compliance with requisite "Company A" Standards and procedures. They may audit commissioning documents to ensure that appropriate inspections have taken place and discrepancies suitably resolved.

5.3 **Area Owner/User** is responsible for review of the facility commissioning documentation prior to final acceptance. They will work with Engineering to resolve any apparent discrepancies.

6 References

6.1 Worldwide Quality Standard xx,xxx – "Management of GMP Projects"

Attachment L1

(Enter building/room/area/location here) Source: _____

Description	**Specified** *(examples only – sites will enter specifics)*	**Complies** *(✓ as appropriate)*	**Comments**
Drawing No./Schedule of Finishes	*1234\ML\56*	Yes ☐ No ☐	
Floor	*Anti Static Polyurethane Terrazzo*	Yes ☐ No ☐	
Skirting/Coving	*Terrazzo Coving*	Yes ☐ No ☐	
Wall Finish	*Mipolam*	Yes ☐ No ☐	
Ceiling	*Gyproc/Epoxy Paint*	Yes ☐ No ☐	
Door No. (Location)	*D12 Door from centrifuge room to corridor*	Yes ☐ No ☐	
Door Type (Open In/Out)	*Double Hinged (electro-magnetic hold open*	Yes ☐ No ☐	
Door Finish	*SS faced door within a painted mild steel channel frame*	Yes ☐ No ☐	
Door Hardware • Hinge (Location) • Door Handle • Vision Panel	 *St, steel ball bearing hinge on LHS of door looking from room 131* *Hinge Lock Handle* *Double Glazed Flush Finish*	 Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐	
Lighting • Intensity • Switch Operation	 *e" 300 lux @ 1 meter above floor level* *Single toggle switch by on the LHS of door 34 turns lights on and off.*	 Yes ☐ No ☐ Yes ☐ No ☐	
Windows	*Double Glazed Flush Finished*	Yes ☐ No ☐	

Completed By:_____ Date: _____

Checked By: _____ Date: _____

Attachment L2

(Enter building/room/area/location here) Area Architectural Verification – FLOORS Source: _____

Item	Description	Complies *(✓ as appropriate)*	Comments
1	The floors are visually flat, smooth, and free from cracks and crevices.	Yes ☐ No ☐ N/A ☐	
2	All floor surfaces are accessible for cleaning.	Yes ☐ No ☐ N/A ☐	
3	Floor is free from stains and marks.	Yes ☐ No ☐ N/A ☐	
4	The interface between the floor and wall is coved.	Yes ☐ No ☐ N/A ☐	
5	Floor penetrations are sealed (e.g., transfer pipes, service lines) with the finish smooth and crevice free.	Yes ☐ No ☐ N/A ☐	
6	The floor is sloped for self draining where applicable.	Yes ☐ No ☐ N/A ☐	
7	Floor drains are capped and sealed where required.	Yes ☐ No ☐ N/A ☐	

Completed By:_____ Date: _____

Checked By: _____ Date: _____

Attachment L2 (continued)

(Enter building/room/area/location here) Area Architectural Verification – DOORS Source: _____

Item	Description	Complies *(✓ as appropriate)*	Comments
8	The doors are smooth, free from cracks and crevices and are suitable for cleaning.	Yes ☐ No ☐ N/A ☐	
9	Doors with vision panels are sealed.	Yes ☐ No ☐ N/A ☐	
10	Door alarms are operational.	Yes ☐ No ☐ N/A ☐	
11	Doors open in the correct direction without obstruction and close freely – Fully open door, release, door should close smoothly and the latch engage.	Yes ☐ No ☐ N/A ☐	
12	Door locks (access control systems) and interlocks are operational and manual/safety over-rides are operational.	Yes ☐ No ☐ N/A ☐	
13	Roll doors open automatically if they hit something	Yes ☐ No ☐ N/A ☐	
14	Roll doors do not close if object is blocking the path sensor.	Yes ☐ No ☐ N/A ☐	
15	Door light indicators, where applicable are operational.	Yes ☐ No ☐ N/A ☐	

Completed By:_____ Date: _____

Checked By: _____ Date: _____

Attachment L2 (continued)

(Enter building/room/area/location here) Area Architectural Verification – WALLS/WINDOWS Source: _____

Item	Description	Complies *(✓ as appropriate)*	Comments
16	The walls are smooth, free from cracks and crevices.	Yes ☐ No ☐ N/A ☐	
17	Wall penetrations are sealed (e.g., extract grilles, service lines).	Yes ☐ No ☐ N/A ☐	
18	All surfaces are accessible for cleaning.	Yes ☐ No ☐ N/A ☐	
19	Bumper rails for wall protection are present.	Yes ☐ No ☐ N/A ☐	
20	Walls are free from stains and marks.	Yes ☐ No ☐ N/A ☐	
21	Coving is present between wall and ceiling interface.	Yes ☐ No ☐ N/A ☐	
22	Windows are sealed to prevent opening during routine operations.	Yes ☐ No ☐ N/A ☐	
23	Windows are flush mounted or with sloped reveals where required.	Yes ☐ No ☐ N/A ☐	

Completed By:_____ Date: _____

Checked By: _____ Date: _____

Attachment L2 (continued)

(Enter building/room/area/location here) Area Architectural Verification – CEILINGS Source: _____

Item	Description	Complies *(✓ as appropriate)*	Comments
24	The ceilings are smooth, free from cracks and crevices.	Yes ☐ No ☐ N/A ☐	
25	Sprinkler heads are recessed and capped.	Yes ☐ No ☐ N/A ☐	
26	Ceiling penetrations are sealed (e.g., HVAC grilles, transfer lines, alarm beacons, lights).	Yes ☐ No ☐ N/A ☐	
27	Ceiling is free from stains and marks.	Yes ☐ No ☐ N/A ☐	

Completed By:_____ Date: _____

Checked By: _____ Date: _____

Attachment L2 (continued)

(Enter building/room/area/location here) Area Architectural Verification – GENERAL Source: _____

Item	Description	Complies *(✓ as appropriate)*	Comments
28	Exposed surfaces of pipes/ducts/fixtures/cables are cleanable.	Yes ☐ No ☐ N/A ☐	
29	All piping is suitable for its purpose and is of appropriate finish for the area in which it is located.	Yes ☐ No ☐ N/A ☐	
30	All piping and associated supports is run vertically where practical and all surfaces including bracketing are accessible for cleaning and inspection.	Yes ☐ No ☐ N/A ☐	
31	All equipment external surfaces are fully cleanable.	Yes ☐ No ☐ N/A ☐	
32	All lines, utilities, equipment, and rooms are labeled as appropriate.	Yes ☐ No ☐ N/A ☐	
33	Non-installed furniture (mobile furniture) is of appropriate material, smooth and cleanable.	Yes ☐ No ☐ N/A ☐	

Completed By:_____ Date: _____

Checked By: _____ Date: _____

Attachment L3: Punch List

No.	Comment/Observation	Responsible Party	Sign	Corrective Action Completed By

Note: By signing the Punch List, the signatory confirms that the corrective action has been completed satisfactorily.

Checked By (Area Owner): _____ Date: _____

Approval Page

Good Engineering Practice approved for posting and use by:

Remainder of Attachment L example document omitted from ISPE GEP Good Practice Guide.

Attachment M
Project GMP Assessment

"Company A" Good Engineering Practice

Subject: Project GMP Assessment Issue Date: dd/mmm/yyyy Supersedes: Version n-1	Practice No. GEP n	Version n Page 1 of 3

1 Purpose

The purpose of this document is to provide guidance related to Project GMP Assessment required by "Company A" Worldwide Quality Standard xx,xxx – "Management of GMP Projects."

2 Scope

This guideline applies to Major Projects, as defined by Worldwide Quality Standard xx,xxx, to determine whether they are GMP Projects. It is understood that in most cases this assessment may seem obvious. There are, however, a sufficient number of projects where this is not so clear. In any case, the assessment must be documented.

In addition, this Good Engineering Practice provides suitable guidance for projects and facilities not within the scope of Worldwide Quality Standard xx,xxx.

3 Definitions (from Worldwide Quality Standard xx,xxx)

3.1 **Good Engineering Practices (GEP)** – Established engineering methods and standards that are applied throughout the project lifecycle to deliver appropriate cost-effective solutions (ISPE). (Note that Good Environmental Practices are also known as *GEP.* The use of this acronym should be in context and with care).

3.2 **GMP Project** – Capital projects that provide or modify facilities, systems and/or equipment that are expected to have a direct impact on product quality. The project is limited to those activities preceding the turnover to the User group for operation and maintenance.

3.3 **Project Stakeholder** – An individual or group that is impacted by or has responsibility for the project. Stakeholders are responsible for operation, support, validation or ownership of the project. Typical stakeholders may include, but are not limited to Production, Engineering or Validation. The project manager, system owner (User) and the Quality Unit must always be project stakeholders.

3.4 **GMP Documents** – Documents generated during the project with the purpose of delivering and proving GMP compliance. They are required to be formally approved and archived but are not normally retained within Validation Protocols.

4 Recommended Practice

4.1 The Assessment Process

4.1.1 The Project Stakeholders should use a systematic assessment process for determining if the Project is a GMP Project and for separating the GMP and non-GMP components of the Project.

4.1.2 The assessment must be approved by the key Project Stakeholders including the Project Manager (sponsoring group), the Project Engineering Manager and the Quality unit.

"Company A" Good Engineering Practice

Subject: Project GMP Assessment Issue Date: dd/mmm/yyyy Supersedes: Version n-1	Practice No. GEP n	Version n Page 2 of 3

4.1.3 For many projects, the determination is straightforward and may be documented and approved in the Project Conceptual Design Report or Project Execution Plan (or other early stage project document). In this case, supplementary checklists may not be needed.

The GMP Assessment should be documented as early in the project as possible.

4.1.4 Attachments M1 and 2 are examples of appropriate documentation for the GMP Assessment process. The project team may use these or document decisions in the Project Execution Plan. In any case, the principles of these checklists should be applied.

4.1.4 Attachment M1 is a simple questionnaire to assess the project. It is particularly useful in those cases where there is some question about GMP applicability (for example, in a developmental facility).

4.1.5 Attachment 2 is an optional addition and serves to indicate the major sections or areas of the project (e.g., manufacturing area, labs, warehouse, office space) which might be separated into GMP and non-GMP. This is particularly useful if non-GMP areas (e.g., office building, waste treatment facility) can be clearly segregated from GMP areas, allowing for these project segments to be exempt from project GMP requirements.

4.1.6 If the project is to be segmented into GMP and non-GMP, it is recommended that all aspects of the work (i.e., design, construction, commissioning, etc.) be segmented (i.e., run the segments as virtual separate projects). It is very difficult to apply two sets of rules within one project.

4.2 Documentation of Project GMP Assessment

4.2.1 The Project GMP assessment should be documented in the Project Conceptual Design Report, Project Execution Plan, in another early stage project document (e.g., Project User Requirements) or as a stand-alone document. If Attachments are used, they should be included.

4.2.2 Any document containing the Project GMP Assessment must be approved by the Project Manager (sponsoring group), the Project Engineering Manager and the Quality unit, as a minimum.

5 Responsibilities

5.1 Project Engineering Manager/Director

The Project Engineering Manager or Director is responsible for managing all day to day aspects of major capital projects including specification, design, construction, installation and commissioning of GMP systems and equipment. The Project Engineering Manager will initiate and approve the GMP Assessment of the project and ensure that the approved documentation is controlled according to project procedures.

5.2 Project Manager

The Project Manager represents the project owner or primary user and is responsible for overall success of the project. The Project Manager provides input on the intended use and requirements of the project and approves the GMP Assessment.

"Company A" Good Engineering Practice

Subject: Project GMP Assessment Issue Date: dd/mmm/yyyy Supersedes: Version n-1	Practice No. GEP n	Version n Page 3 of 3

5.3 Global Quality Operations (GQO)

Global Quality Operations is responsible for the review and approval of GMP activities and documents related to capital projects. They will review and approve the GMP Assessment to ensure that applicable Corporate Quality Policies, Worldwide Quality Standards and regulations have been considered and that proper documentation practices have been employed. The usual Quality representative is from the site. For new ("green field") sites, the Quality representative may be appointed from another Global Quality Operations group.

6 Attachment

Attachment M1: Project GMP Assessment Form (Parts A and B)

7 References

7.1 Worldwide Quality Standard xx,xxx – "Management of GMP Projects"

Attachment M1: Project GMP Assessment Form

"Company A" Global Supply Chain	
Project GMP Assessment	Page 1 of 3
Project Name or Description:	
Project No:	RFC No.:
Site:	
Project Sponsor:	Project Manager:
Approvals Project Manager:_____ Date: _____ Name: Title: Project Engineering Manager:_____ Date: _____ Name: Title: Quality Unit:_____ Date: _____ Name: Title:	

Attachment M1: Project GMP Assessment Form (continued)

"Company A" Global Supply Chain		
Project GMP Assessment		Page 2 of 3
Part A. Assessment		
Do the facilities, equipment or systems proposed:		**Yes or No**
1	Manufacture, process, package or hold drug product or active pharmaceutical ingredient (drug substance) for commercial use in humans or animals or for clinical use in humans or do they directly control or monitor any of these functions?	
2	Manufacture, process, package or hold chemical intermediates produced from starting materials as defined in Worldwide Quality Standard zz,yyy – "Active Pharmaceutical Ingredient (API) Manufacture" or do they directly control or monitor any of these functions?	
3	Directly impact testing, approval or release of product, API, intermediates or other GMP materials and components or the associated documentation?	
4	Directly impact required regulatory, clinical, or consumer information for commercial or clinical product (e.g., stability, labeling)?	
5	Provide, modify or otherwise directly impact utilities that are in direct contact with product (e.g., water, pure steam) or directly impact critical GMP conditions (e.g., room temperature, relative humidity, equipment cleanliness)?	
6	By the consensus of the Project Stakeholders, need to be managed as a GMP Project?	

GMP Assessment Conclusion	**Yes or No**
This project is a GMP Project. (Answer Yes if the response to any of the questions 1 thru 6 above is Yes. Answer No only if the response to all of the questions 1 thru 6 above is No.)	

Attachment M1: Project GMP Assessment Form (continued)

"Company A" Global Supply Chain	
Project GMP Assessment	Page 3 of 3
Part B. Project Information (optional)	
Provide a brief project description: _____	
If the project can be *clearly* segmented into GMP and non-GMP areas, indicate the segments below:	
Segment	**GMP? (yes or no)**
e.g., Warehouse	
Process Area	
Fill/Pack Area	
Office Building	
Waste Treatment Plant	
Etc.	

Approval Page

Good Engineering Practice approved for posting and use by:

Remainder of Attachment M example document omitted from ISPE GEP Good Practice Guide.

Attachment N
Setting System Boundaries

Setting System Boundaries

The project scope of work must be divided into discrete systems to facilitate project development by;

- allowing impact assessment of the system and associated components[1]
- providing a clear definition of the system for Design Qualification
- providing a clear definition of what will be included in the construction turnover packages

A system is defined as an organization of engineering components that have a defined operational function.

The boundaries of each system will also need to be defined carefully, to ensure that there are no components caught "between systems."

For example the pipe connecting the Purified Water system to a piece of Manufacturing Equipment must be part of either the Purified Water system or of the Manufacturing equipment system.

Other factors to consider include:

- Is the system a Direct Impact system?

  There may be benefits from combining equipment with similar functions where they are not GMP, to simplify (and reduce the cost of) the construction documentation. An example of this would be combining three nominally independent fume hoods within a laboratory.

- The extent of the system which will require validation:

  Using a compressed air system as an example, it may be a good idea to provide a system break (e.g., a non return valve and receiver) and dedicated product contact distribution sub-system fed from this receiver, to minimize the extent of the system requiring qualification, and the number of test points for ongoing monitoring.

- The part of a system which is most likely to be modified in future:

  Using a Purified Water system as an example, it may be better to split the plant into two sub-systems: a "Generation System," and a "Storage and Distribution System."

The advantage of a split like this will be apparent when the distribution system is modified, for example to add more outlets. The scope of re-qualification work will be reduced.

A few examples of system boundary definitions are given below:

HVAC System

The system boundaries are defined as follows:

All plant and ductwork from the air inlet louver to the connections on the terminal filter boxes. The scope includes the heating/cooling coils together with all associated control valves and pipe fittings up to the isolation valves on the flow and return of the service feeding the coil. The scope would typically also include the relevant control sensors.

---

[1] Note that in this application components can be defined as items, sub systems, processes or instruments.

Purified Water System

The system boundaries are defined as follows:

The entire system from the potable water feed isolation valve up to the distribution loop outlet valves, together with the associated flow controller, and pipe section to the isolation valve on the equipment being fed, or outlet pipe if the system is not connected to any equipment.

The scope includes:

The heating/cooling heat exchangers together with all associated control valves and pipe fittings, up to the isolation valves on the main flow and return lines of the service feeding the exchanger.

The drainage pipework up to the air-break between the drain pipe, and the drain, note that checking and documenting the air break will be included in the documentation for the purified water system.

The System Tree (optional)

A "system tree" may be used as a simple pictorial way of showing the project scope, and the systems considered to be Direct Impact. This is an aid in describing the scope of work and the impact assessment process to an auditor.

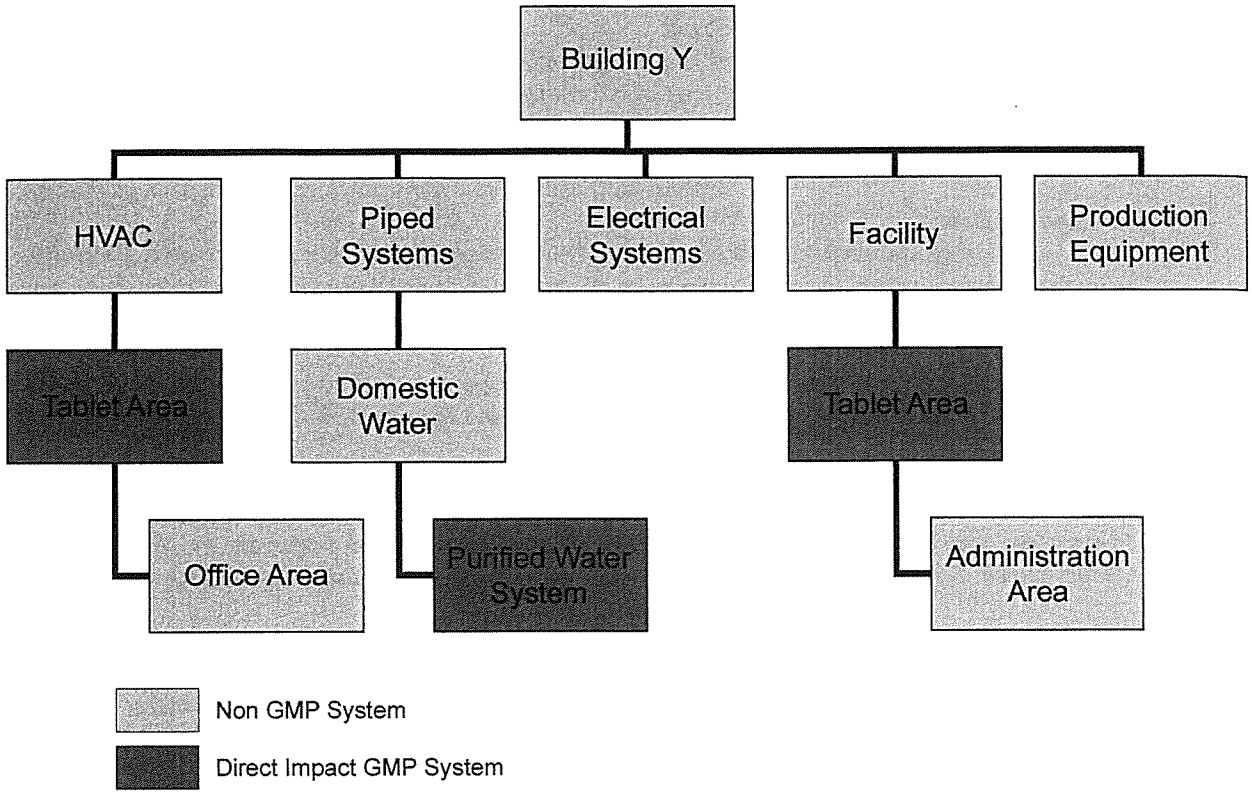
Indirect impact of no impact (to product quality) utility systems typically include:

Chilled water, plant steam, non-product contact process heating/cooling systems, HVAC systems, chilled/hot water systems, and non-product contact compressed gases, vacuum systems (designed too prevent the potential of reverse flow to contact product), electrical systems, including emergency generators.

Direct impact utilities typically include:

Purified water, Water for Injection (WFI), pure steam, HVAC systems serving controlled environments, product contact compressed gases, and Clean in Place (CIP) systems.

Figure N1.1: System Tree



Attachment O
Commissioning Plan

Commissioning Plan

1 Version History

Rev No.	Date	Summary of Changes
0	dd/mmm/yyyy	Issued for Approval

2 Approvals

Written By:

Name: _____

Signature: _____ Date: _____

Approval Signatures

The following parties have reviewed and approved this document:

Name (Project Manager): _____

Signature: _____ Date: _____

Name (Construction Manager): _____

Signature: _____ Date: _____

Name (MEP Design Manager): _____

Signature: _____ Date: _____

Name (Client Technical Representative): _____

Signature: _____ Date: _____

3 Purpose and Scope

Project Scope

Document Purpose

This commissioning plan will:

- Define the role of the commissioning authority in terms of the witnessing and verification of commissioning activities performed by subcontractors.
- Define the role of the commissioning authority in terms of the verification of the construction quality assurance activities for the utilities, equipment, systems, and facilities.
- Define the role and responsibilities of the commissioning authority in terms of the commissioning of the utilities, equipment, systems, and facilities.
- Define the role and responsibilities of the commissioning authority in terms of Turnover Package Review.

The document will also define the tests to be carried out, and the documentation to be produced by the commissioning authority.

References

4 Commissioning Strategy

The Building systems need to be put to work in a timely manner, with performance verified as being in accordance with the design specifications, and accurate as-built engineering records obtained to ensure that accurate data is entered into the building maintenance system.

Definition

Commissioning Elements

This Commissioning Plan addresses the following items:

- commissioning roles and responsibilities
- commissioning safety
- pre-commissioning verifications (in-process inspections)
- startup and commissioning
- commissioning report test format and content
- review of turnover packages

Commissioning Authority Responsibilities

5 Commissioning Safety

Definition

Implementation of appropriate safety controls and procedures during commissioning is essential for protection of personnel and equipment. Safety controls may consist of the following, as applicable:

- detailed safety evaluation of equipment, systems, testing, and startup procedures
- safety procedures
- safety training
- determination of required PPE
- evaluation and implementation of MSDS requirements
- lockout/tagout training and implementation
- The specific requirements for each system will be written in the Startup Procedures by the Commissioning Authority.

Responsibilities

Documentation

6 Commissioning

6.1 Scheduling

Commissioning Schedule

6.2 Pre-commissioning

Commissioning Prerequisite

Pre-commissioning Inspections

Mechanical Completion

Definition

Phased Commissioning

Safety Review	

6.3 *Startup and Formal Commissioning*

Special Pre-Startup Checks	
Software Functional Testing	Where specified, or considered beneficial Software functional bench testing will be carried out either with the system empty or on a test rig to detect any software flaws. After any discrepancies are corrected, Software functional testing will be carried out documented in the commissioning test report.
Startup Procedures	Procedures for the initial and ongoing start-up of systems and equipment shall be developed for all systems. These procedures shall be pre approved by the Client Representative.
Setting to Work and Initial Shake-down	The setting to work process may include initial run-in of mechanical components, adjustments to mechanical or control settings, loop tuning, etc. The commissioning report will include steps outlining and recording the results of these activities.
Functional Testing	Functional testing will include the following: • Demonstration that systems operate within required specified tolerances across the design operating range. • alarms and interlocks • sequence of operations • confirmation of software title and version • software back up and restore • power failure and recovery • HMI displays and controls Functional tests will be specified in the commissioning report. It is expected that problems will be uncovered during commissioning, which must be corrected and appropriate retests performed and documented following GEP.
Specialty Testing	

6.4 Commissioning of Authority Having Jurisdiction (AHJ) Systems

AHJ Systems	Definition
General Approach	
Code Inspections	
Responsibilities	

7 Commissioning Documentation and Turnover Packages

Commissioning Tests	
Commissioning Summary Report	A commissioning summary report shall be submitted by the Commissioning Authority to summarize the results of the commissioning effort, and highlighting any problems, resolution, operational limitations discovered, etc. The finished commissioning report will include the following: • introduction • summary • signature register • system description/control description (from design documents) • system flow diagram/P&ID schematic • system status recording any minor outstanding works (punch list) • system test requirements/expected results/acceptance criteria • test results – component tests • functional tests • performance tests • test method statements • list of all variable settings, including PID set points • copy of all test equipment calibration certificates • approval section

Commissioning summary report shall be approved by the "Company A" site representative and the "Company A" technical lead.

Turnover Packages Turnover packages are the repository of all project documents, including commissioning documentation.

Attachment O1: List of Project Team Members

Title	Company	Representative

Attachment O2: List of Systems to be Commissioned

System #	System Description	Phase

Attachment O3: List of Specifications

Attachment O4: Commissioning Pre-Startup Checks

Attachment O5: Commissioning – Functional Test

Remainder of Attachment O example document omitted from ISPE GEP Good Practice Guide.

Attachment P
Commissioning Plan Compressed Air Supply

xyz ref	Compressed Air Supply Commissioning Plan	Company X

Commissioning Plan Review and Approval

	Name	Signature	Date
Prepared by:			

The Pre-Approval section must be completed prior to execution of this plan. When executing a pre-approved plan, ensure that you use a controlled copy.

Pre-Approval			
Role	**Name**	**Signature**	**Date**
Project Manager			
Engineering Manager			

Post-Approval			
Role	**Name**	**Signature**	**Date**
Project Manager			
Engineering Manager			

Revision	Date	Author	Modified Sections	Description
00	dd/mmm/yyyy	A N Other	All	Original

1 Commissioning Plan

When successfully executed, this Commissioning Plan protocol will verify that the Compressed Air Supply has been fully commissioned and satisfies GEP Ltd's Requirement Specification and the supplier's Functional Design.

2 Instructions

2.1 Pre-Approval

The pre-approval section at the head of this document must be completed prior to execution.

2.2 Roles

The Tester will execute the Commissioning Plan tests in sequence following the instructions provided in the Commissioning Plan test sheets. He/she will record required data and sign and date the sheets (together with any supplementary sheets such as data sheets, screen shots, etc.) at the time of execution.

2.3 Commissioning Plan Acceptance Criteria

- A test ***Pass*** can only be recorded if the test results meet all specified acceptance criteria.
- A test ***Fail*** will be recorded if the test results do not meet the stated acceptance criteria. A test discrepancy *must* be recorded.

2.4 Test Runs

Each Commissioning Plan test script is identified as "TSnn," where "nn" is the sequential test number. The test sheets also have a "Run No." field, which is incremented by the Tester each time a test is executed. Every test that fails will have a discrepancy log entry. The test identifier and the run number must be recorded in the relevant log entry.

The discrepancy log allows for recording corrective actions. The test must be repeated, incrementing the sequential run number, to prove that the correction has been effective.

2.5 Test Equipment

All test equipment used must be recorded in Attachment P2.

2.6 Summary Reporting

Upon completion of all tests the summary results table must be completed and a Commissioning Plan Summary Statement must be recorded.

The final status of the commissioning plan may be an unconditional **Pass** (no open discrepancies system available for use), a conditional **Pass with Discrepancy** (open discrepancies but system may conditionally be used) or a **Fail** (the system cannot be used).

2.7 Post-Approval

Once testing is either successfully completed or abandoned for whatever reason, the Commissioning Plan document together with its discrepancy log and all attachments shall be submitted for post-execution review and approval.

3 Summary of Results

To be completed after all tests have been executed to conclusion.

Test No.	Title	No. of Runs	Final Result (Pass or Fail)	Initials
1.	Design Review Record			
2.	Vendor Assessment Record			
3.	Operation and Maintenance Documentation Summary Record			
4.	Pressure Test Verification			
5.	Installation Drawing Check			
6.	Safety Inspection			
7.	Air Quality – Dryness			
8.	Air Quality – Oil			
9.	Air Quality – Particulates			

	Name	Signature	Date
Completed by:			

4. Commissioning Plan Summary Statement

Summary Statement			
Commissioning Plan Completion Date			
Final Status	*Pass*	*Pass with discrepancy**	*Fail*
	Circle the applicable status		
Reservations and Conditions to be Addressed Prior to Production Use			

	Name	Signature	Date
Completed by:			

Attachment P1: Test Scripts

Test Identifier	TS01 Design Review Record	Run No.	
Objective	To provide documented evidence that the proposed design is considered suitable and is in compliance with the users requirements.		
Procedure	Record the details of the design documents and verify version.		
Acceptance Criteria	An approved design review record is available for the system.		

Document Reference	Record Version	Approved (Y/N)	Initial
00343/URS/PR200704 "User Requirements"			
00343/SUPPLIER.DS/PR200704 "Design Specification"			
00343/DR/PR200704 "Design Review Record"			

Observations	*Any observations or comments shall be recorded here. If there are none write "NONE."*		
Result	*Pass* *Fail* *Circle the applicable status*	Discrepancy No.	

	Name	Signature	Date
Tester:			

Attachment P1: Test Scripts (continued)

Test Identifier	**TS02 Vendor Assessment Record**	**Run No.**	
Objective	To provide evidence that a satisfactory vendor assessment has been completed, documented, and archived.		
Procedure	Record the details of the vendor assessment and identify any limitations it specifies.		
Acceptance Criteria	A satisfactory vendor assessment is available for the system.		
Document Reference	**Record Version**	**Approved (Y/N)**	**Initial**
00343/VA/PR200704 "Vendor Assessment"			
Limitations	*Any limitations specified in the assessment record/report should be summarized below. If there are none write "NONE."*		
Result	***Pass*** ***Fail*** *Circle the applicable status*	**Discrepancy No.**	

	Name	**Signature**	**Date**
Tester:			

Attachment P1: Test Scripts (continued)

Test Identifier	TS03 Operation and Maintenance Documentation Summary Record	Run No.	
Objective	To provide evidence that sufficient documentation is available to enable the proper operation and maintenance of the system.		
Procedure	Record details of the system Operation and Maintenance (O&M) manual(s) and verify that the content includes: Description of Operation, Maintenance Schedules, Spare Parts List, Bill of Materials, Component Data Sheets, Component Certification, and Record Drawings.		
Acceptance Criteria	Sufficient documentation is available to enable the correct operation and maintenance of the system.		

Document/Drawing Reference and Title	Record Version	File Location	Initial

Observations	*Any observations or comments shall be recorded here. If there are none write "NONE."*		
Result	*Pass* *Fail* *Circle the applicable status*	Discrepancy No.	

	Name	Signature	Date
Tester:			

Attachment P1: Test Scripts (continued)

Test Identifier	TS04 Pressure Test Verification	Run No.	
Objective	To provide evidence that sufficient documentation is available to demonstrate that the system has been pressure tested beyond its working pressure.		
Procedure	Verify that the vendor has supplied the pressure test certificate, record its reference number and verify that the company's insurers have accepted its validity.		
Acceptance Criteria	Pressure vessel certification has been provided by the vendor and is acceptable to GEP Ltd's insurers.		

Test Certificate Reference	Test Date	File Location	Date Accepted by Insurers	Initial

Observations	*Any observations or comments shall be recorded here. If there are none write "NONE."*

Result	*Pass* *Fail* *Circle the applicable status*	Discrepancy No.	

	Name	Signature	Date
Tester:			

Attachment P1: Test Scripts (continued)

Test Identifier	TS05 Installation Drawing Check	Run No.	
Objective	To provide documented evidence that the system has been installed in compliance with design drawings.		
Design Reference	Drawing GEP/PR200704/CompressedAir (latest version)		
Procedure	Take a copy of the required drawing, mark it with the commissioning plan document reference and test number, and sign and date it. Compare the drawing with the installation and mark the drawing to clearly indicate areas or items that are correct, that are incorrect or could not be verified.		
Acceptance Criteria	The installation checks demonstrate that the system has been installed as represented in the design drawings.		

Step		Expected Result	Actual Result	Record Pass or Fail	Initial
1.	Get a copy of drawing GEP/PR200704/ CompressedAir from the drawing office and record the version.	Drawing available	Version:		
2.	Compare the drawing with the installation and mark the drawing to clearly indicate areas or items that are correct, that are incorrect or could not be verified.	All items are installed as per the drawing.			

Observations	*Any observations or comments shall be recorded here. If there are none write "NONE."*

Result	*Pass* *Fail* *Circle the applicable status*	Discrepancy No.	

	Name	Signature	Date
Tester:			

Attachment P1: Test Scripts (continued)

Test Identifier	**TS06 Safety Inspection**		**Run No.**	
Objective	To provide evidence that a satisfactory safety inspection has been completed, documented and archived.			
Procedure	Record the details of the safety inspection report and whether the report findings were satisfactory. Ensure that the report has been archived.			
Acceptance Criteria	A satisfactory safety inspection report is available for the system.			
Report Reference	**Report Date**	**Safety Report is Satisfactory (Yes or No)**	**Archived (Yes or No)**	**Initial**
Observations	*Any observations or comments shall be recorded here. If there are none write "NONE."*			
Result	*Pass* *Fail*		**Discrepancy No.**	
	Circle the applicable status			

	Name	**Signature**	**Date**
Tester:			

Attachment P1: Test Scripts (continued)

Test Identifier	**TS07 Air Quality – Dryness**	**Run No.**	
Objective	To provide documented evidence that the drier associated with the compressed air system produces dry air that meets the User Requirements.		
Design Reference	00343/URS/PR200704 "User Requirements"		
Procedure	With the system in normal operation, insert a calibrated dew point meter at the test points listed below and record the result.		
Acceptance Criteria	Compressed air dew point is >= -42 °C and <-40 °C		

Dryer		**Test Point**	**Actual Result**	**Record Pass or Fail**	**Initial**
1.	Sn.0704-023	Point A2			
2.	Sn.0704-024	Point C2			
3.	Sn.0704-025	Point B2			

Observations	*Any observations or comments shall be recorded here. If there are none write "NONE."*

~~Result~~	~~*Pass*~~ ~~*Fail*~~ *Circle the applicable status*	~~Discrepancy No.~~	

	Name	**Signature**	**Date**
Tester:			

Attachment P1: Test Scripts (continued)

Test Identifier	TS08 Air Quality – Oil	Run No.	
Objective	To provide documented evidence that the entrained oil content of the compressed air supply is within the limits stated in the Requirements Specification.		
Design Reference	00343/URS/PR200704 "User Requirements"		
Procedure	With the system operating normally and using calibrated test equipment, attach a Dräger tube oil indicator and a flow meter to the test point. Sample 250 liters of air and record results below.		
Acceptance Criteria	Max. oil content 0.1 mg/m³ (Indicated by no colour change)		

	Sample Point	Actual Result	Record Pass or Fail	Initial
1.	Point A1			
2.	Point C1			
3.	Point B1			

Observations	*Any observations or comments shall be recorded here. If there are none write "NONE."*

Result	*Pass* *Fail*	**Discrepancy No.**	
	Circle the applicable status		

	Name	Signature	Date
Tester:			

Attachment P1: Test Scripts (continued)

Test Identifier	**TS09 Air Quality – Particulates**	**Run No.**	
Objective	To provide documented evidence that the particulate level within the compressed air system meets that stated in the Requirements Specification.		
Design Reference	00343/URS/PR200704 "User Requirements"		
Procedure	With the system operating normally use a calibrated particle counter attached via a diffuser to each test point and record the counts for $1m^3$ of sampled air regulated to 1 bar.		

Acceptance Criteria	**Particle Size**	**0.1 µm**	**0.2 µm**	**0.3 µm**	**0.5 µm**	**1.0 µm**	**5.0 µm**
	Maximum Count	100	24	10	4	0	0

Sample Point		**0.1 µm**	**0.2 µm**	**0.3 µm**	**0.5 µm**	**1.0 µm**	**5.0 µm**	**Record Pass or Fail**	**Initial**
1.	Point A3								
2.	Point C3								
3.	Point B3								

Observations	*Any observations or comments shall be recorded here. If there are none write "NONE."*

Result	***Pass*** ***Fail*** *Circle the applicable status*	**Discrepancy No.**	

	Name	**Signature**	**Date**
Tester:			

Attachment P2: Record of Test Equipment Used

Test Equipment

Record the make, model and serial number of each test equipment item. Record the last calibration date. Identify which tests the equipment was used in.

Make	Model	Serial Number	Last Calibration Date	Used in Tests	Initials

	Name	Signature	Date
Tester:			

Attachment P3: List of Attachments

Attachment List			
No.	**Attachment Description**	**Printed, Signed, and Dated (Y/N)?**	**Initials**

	Name	Signature	Date
Tester:			

Attachment P4: Discrepancy Log

Discrepancy No.		Test Ref.		Run No.	

Discrepancy Detail			
Recorded by:	Print Name	Sign	Date

Proposed Resolution			
Approved for Action:	Print Name	Sign	Date

Corrective Action Completed:	Print Name	Sign	Date

Attachment Q
PM Completion Checklist

PM Completion Checklist

PM Performer Review

☐ PM Performer proposes removal of this PM because this procedure does not ensure operational standards and/ or reliability in the performer's opinion (this does not apply to regulatory PMs).

☐ PM Performer recommends modifications as detailed by the red lines. The PM was completed per original procedures.

☐ PM Performer recommends modifications as detailed by the red lines. The PM was performed per the redline procedure after approval from supervision.

☐ In the opinion of the PM Performer, the existing PM Procedure was performed as written and ensures operational standards and/or reliability.

PM Performer Job Plan Recommended Improvements

Suggested job plan improvements such as parts, drawings, special tools, and detailed test equipment operational procedures are listed below:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Supervisor Review

Finished Date/Initials_____ Closed Date/Initials _____

Attachment R
Audit Template

Audit Template

Prior to carrying out an audit, the purpose of the audit should be defined and a set of audit challenges defined which will achieve the objective.

This example was developed to review a small site based project group.

1 Staff and Organization

Is there a defined organization chart?

Are roles and responsibilities clearly defined?

Are the individuals appropriately trained/experienced for the role they have?

Are there adequate support staff to suit the scale of the project in each category:

- general admin./document control
- discipline engineering
- safety
- environmental
- (either local or contract)

Is there a training plan for the staff?

2 Administration

Is there an adequate budget change control system?

Is there a project schedule of the appropriate level in relation to the scale/scope of the project?

Is there a cost control system in place?

Is there a work permit system in place covering hot work, access to heights etc?

Are site safety inspections carried out on a routine basis?

Is there a project commissioning plan?

Is there a project validation plan?

3 Documentation

Is there a Project User Requirement Specification defining the scope of the project, so that there is clear understanding for the client and project team?

Was the design developed in defined stages with cost estimates and evaluation of the viability of the project at each stage? Typical stages would include:

- concept design
- BOD
- detail design

Was the content and quality of the detail design package defined adequately to minimize risk of bid revisions?

What system was used to review the design package?

Is there a formal Bidding procedure that includes contractor pre-qualification in terms of – financial stability/ experience/available resource/references?

Is there a system to monitor construction progress?

Is there provision for O&M's/commissioning/startup spares?

Is there a formal project management guide defining the project processes?

Is there a system defining the requirements for submittals/samples?

4 Cost

Is there a process to review the budget comparing to other local projects of similar size/scope?

Is the final cost estimate broken down into categories, professionally reviewed with a risk assessment – target final cost estimate should be ± 10%.

Is there a system for cost reporting considering spend to date actual versus planned, with estimated final cost?

Are consultancy fees identified and reasonable for the well defined (?) scope of work?

Is there a system for value engineering/review of the project design?

5 Customer Satisfaction

Is there a system to measure client satisfaction with projects looking not just as cost and schedule, but softer issues such as quality and value for money?

Is there a feedback system to incorporate "lessons learnt" into the next project?

Is there a system to review changes/improvements to see if there are systemic problems with the design/ interpretation of the client requirements?

6 Quality

Is there a robust system in place to monitor installation standards and ensure that they meet client expectations?

How have the materials for construction been selected – is there an agreed project cost/design life/operating cost compromise?

How have the finishes been defined – and agreed to be fit for purpose aspects such as compliance with GMP, reparability decided – what system is used to check installed quality during construction?

Is there a system for construction quality control in place – is it adequate?

7 Safety and the Environment

Does the project have a safety officer/representative, with a safety policy and regular training/site inspections?

Is there a plan to train staff at appropriate levels on safety and environmental aspects?

Is there a system to ensure that construction staff have the appropriate personal safety equipment, and are trained in its use?

Is there a system to review the project design and construction for the potential impact on the environment, reviewing risk mitigation methods?

Attachment S
Supplier Quality Questionnaire

Commentary on the Supplier Quality Questionnaire

In order to achieve the goals of reducing risk, managing cost, and maintaining control it is good practice to assess the quality of all your potential suppliers. The following example of a Supplier Quality Questionnaire should be considered a baseline and additional sections and questions may be added as appropriate to the situation.

In collecting the baseline information you will become aware of those suppliers who inherently embrace quality in all aspects of their business, those who see quality as an 'optional extra' to be supplied only when the customer insists, and those who do not understand or see any benefit in the concept at all. This knowledge is key to reducing risk when selecting a supplier.

There are of course other reasons for selecting suppliers that may override quality considerations, these include financial viability, cost, and technical ability. These factors together with the baseline quality information can be used to assess a risk versus benefit factor for each supplier.

Information associated with standard document deliverables is often missed when comparing suppliers in a competitive tender situation. One supplier's cost may include a complete set of documentation, while another may consider these as chargeable extras. Knowledge of this prior to placing an order can prevent cost escalation and/or contractual wrangling at a later date.

All the above information will assist you in defining the contractual conditions and/or service levels you will need to put in place to maintain control over your suppliers and ensure that you get consistent service.

It should be noted that it is frustrating for a supplier to receive many separate requests for information from different people/departments within your organisation, resulting in duplication of information common to all such as company name, address, etc. To avoid this it is recommended that the Supplier Quality Questionnaire is combined with other requests for supplier information.

Supplier Quality Questionnaire

Instructions

Please read through the list of questions below and then record your responses on the sheet provided for this purpose. Please provide as much documentary evidence as you can and attach these to the response sheet. Once you have completed the questionnaire please return it to the Supplier Quality Manager, at GEP Ltd.

1 Company Details

1.1 Products and Services

Provide a list of the products and/or services that you propose to supply to us.

1.2 Name and Address

Provide your company name and the address of the office that will provide the proposed products/services.

1.3 Registration Details

Provide your company registration number, type of company, registered office address, and VAT registration number.

1.4 Organization

Provide an organization chart(s) showing the structure of the division of your company that provides the products and services defined in A.1 and how it fits into your overall organization.

1.5 Primary Contacts

Provide a list of roles, names, telephone numbers, and email addresses of your personnel you wish us to use as primary contacts.

2 Quality Management System

2.1 Type of Quality Management System

Please describe the type of quality management system you have in place (e.g., none, informal, formal, certified).

2.2 Scope of Quality Management System

Describe the scope of your quality management system. What products, services and associated processes does it cover? (e.g., project management, product development, product testing, product release, document management, drawing management, configuration management and change control, customer complaints, corrective and preventative actions, staff training, control of sub-contractors.)

2.3 Procedures and Work Instructions

Provide a list of your procedures and/or work instructions that cover the scope defined in B.2. If possible provide a few examples of key procedures to exhibit layout and content.

2.4 Self Auditing

Do you carry out regular self audits to ensure that your staff are working in accordance with your quality management system and that the records you require them to keep are being correctly maintained? If you do please provide the date and scope of your last self audit.

2.5 External Inspection and Certification

If you have a formal, certified quality management system, please provide details of the certifying body, the standard achieved, e.g., ISO 9001:2000 (see Reference 3, Appendix 3), the expiry date of your current certificate and the stated scope of certification.

2.6 Customer Audits

For critical equipment, systems and services we may decide to audit your quality management system (or your ways of working if no formal system exists) to ensure quality of supply. Please state if you are agreeable to such audits and please specify any limitations or conditions you would wish us to comply with (e.g., sign a confidentiality agreement, exclusion of proprietary design information).

3 Deliverables

3.1 Standard Documentation

Please provide a list of the documentation you would normally supply (i.e. at no extra cost and without a contractual requirement) with the product and/or as part of the service. If possible provide a few examples of key deliverables to exhibit layout and content (e.g., project plan, quality plan, factory acceptance test specification, site acceptance test specification, maintenance manuals, licenses, user guide, data sheets, as-built drawings, safety certificates, calibration certificates, warranty certificates).

3.2 Additional Documentation

Above and beyond the standard documentation you provide, customers may ask for additional documentation. Please can you provide a list of the more common additional documentation you are willing to provide (e.g., development testing records, software code reviews, design specifications, product revision history).

4 Outsourcing

4.1 Supplier Selection

Do you outsource, sub-contract or in any other way rely on any third party to supply, design, build, or document any of your products or product components? If so please provide details of how you assess and select your third-party suppliers.

4.2 Service or Quality Level Agreements

Do you establish service or quality level agreements with your third-party suppliers? If so please provide an example to exhibit layout and content.

4.3 List of Third-Party Suppliers

Please provide a list of third-party suppliers that you use in the production/delivery of the products/services that you propose to supply to us.

Question Number	Attachment Numbers	Response