**Validation Master Plan**

***Computer Systems and Software***



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# Introduction

## Purpose

The purpose of this Validation Master Plan is to describe the overall strategy, approach, and responsibilities for validation of computer systems and software. The Validation Master Plan also includes an overview of the processes that support validated systems and software.

## Scope

Describe the scope of the systems and software covered within this Validation Master Plan. For example, the document could address systems and software within a specific function (e.g., manufacturing), a site, or an entire company. Example text:

This Validation Master Plan (VMP) addresses the computer systems and software used for GxP activities within [scope]. Specific systems are listed in Attachment B.

## Definitions, Acronyms, and Abbreviations

| **Term** | **Definition** |
| --- | --- |
|  | List abbreviations, acronyms, and VMP-specific terms used within this document |
|  |  |
|  |  |

# Validation Responsibilities

## Roles and Responsibilities

Identify the organizations with responsibilities for system and software validation. Define the responsibilities of each identified organization.

At a minimum, include the following responsibilities:

* Developing and approving Validation Plans
* Developing and approving validation documents, e.g., requirements, tests, trace matrices
* Executing and approving validation tests
* Ensuring that the systems meets GxP requirements
* Preparing and approving SOPs regarding validation and use of validated systems and software
* Supporting validated systems

# Validation Strategy

## Validation Policy

Summarize the validation policies applied to the systems and software within the scope of this VMP. Reference the SOPs containing these policies. Example text:

Computer systems and software meeting one or more of the following conditions must be validated prior to production use:

* System or software used as a medical device or as a component, part, or accessory of a medical device
* System or software used in the production of a regulated product
* System or software used in implementation of the quality system as defined in predicate rules
* System or software that creates, modifies, maintains, archives, retrieves, or transmits records required by predicate rules
* System or software that submits electronic records to a regulatory agency*,* even if such records are not specifically identified in agency regulations

The following policies are applied to validation of applications built with commercial, off-the-shelf packages:

* Applications built with any industry-common off-the-shelf packages such as word processors and spreadsheets require validation; however, the underlying off-the-shelf packages and operating systems do not require independent validation.
* Applications are re-evaluated and re-validated as necessary when the off-the-shelf package or underlying operating system is upgraded or modified.
* Output of word-processors, spreadsheets or other applications do not require validation when the output is subsequently subject to 100% human review, verification, and approval.

Details regarding these policies can be found in *SOP Computer System Validation.*

## Validation Acceptance Criteria

Summarize the validation practices regarding the use of acceptance criteria. Reference any SOPs containing policies regarding acceptance criteria. Example text:

The validation acceptance criteria for each computer system are documented in an approved Validation Plan. Systems are not used for GxP activities prior to completion of all acceptance criteria. Any exceptions to this policy are documented, justified and approved by management, per *SOP Deviations*.

Typical acceptance criteria include:

* Completion of all testing identified in the Validation Plan
* Approval of all validation deliverables identified in the Validation Plan, e.g., system requirements, designs, testing, trace matrices, reports
* Approval of the Validation Report
* Completion of support staff training on approved system operation and maintenance procedures
* Completion of user training on approved system user procedures

# Validation Approach

This section overviews the approach for validation and support of computer systems and software.

## Risk Assessment

Summarize the process used to assess the risk posed by computer systems and software. Reference the SOP(s) containing this process. Example text:

The risks posed by systems and software are assessed on two elements: criticality and complexity. The criticality level is rated based on the severity of potential impact to the patient, the product being produced for the patient, and the integrity of the data associated with patients and products. The complexity level is rated based on the likelihood of occurrence of the potential harm or defect.

Risk assessments are performed prior to development of a Validation Plan.

Details of the risk assessment process are within *SOP System Risk Assessment*.

## System Vendor Assessment

Summarize the process for system vendor assessment and describe how the assessment is used to determine the validation approach. Reference the SOP(s) containing this process. Example text:

The vendors of purchased computer systems and software are assessed according to the methodology defined in *SOP Vendor Assessment* prior to development of the Validation Plan.

When systems are purchased from vendors that do not receive an acceptable assessment result, the rating for likelihood of software failure is increased in the Risk Assessment; this results in increased validation requirements.

The frequency of vendor re-assessment is determined by the system risk level; vendors of software with a high risk level are re-assessed more frequently than vendors of software with a lower risk level.

## Validation Procedure

Summarize the computer system validation process. Reference the SOPs containing this process. Example text:

Systems and software are validated according to process defined in *SOP Computer System Validation.* Here is an overview of the major validation steps and deliverables:

* Validation Plan definition and approval
* User Requirements Specification definition and approval
* Functional Requirements Specification definition and approval
* System Design and approval
* Operational Qualification (functional testing) development, approval, and execution
* Performance Qualification (user acceptance testing) development, approval, and execution
* Installation Qualification development, approval, and execution
* Validation Report definition and approval

To mitigate system risk, the Risk Assessment is utilized in development of the Validation Plan, per *SOP Risk Based System Validation*. This SOP defines the specific validation documents and activities associated with each criticality and complexity risk level.

## System Life Cycle

Summarize the process for system and software development or configuration. Reference the SOP(s) containing this process. Example text:

Custom-built computer systems and software are developed according to the practices defined in *SOP Software Development Life Cycle*. This SOP describes a “waterfall” style of software development wherein each stage (e.g., requirements, design, development, testing, deployment, maintenance) is completed and approved prior beginning the next stage.

## Validation Failures (Deviations)

Summarize the process for handling failures encountered during validation testing. Reference the SOP(s) containing this process. Example text:

During validation, all failures to meet pre-defined expected results are recorded in the validation testing protocol (e.g., IQ, OQ, or PQ) and in a Validation Failure Report. Each failure is investigated to determine whether it was caused by the tester, the test author, a software anomaly, or another reason.

The cause of the validation failure, the correction, and the regression testing requirements are recorded on the Validation Failure Report. The failure report is approved prior to the Validation Report and retained with the validation documentation.

Details of the process are in *SOP Validation Failures.*

## Validation Training

Summarize the training required for personnel involved in validation. Example text:

Personnel with responsibilities for authoring the validation documents described in *SOP Computer System Validation*, approving validation documents, and executing validation tests (IQ, OQ, PQ) are trained in the following:

* *SOP Computer System Validation*
* *SOP System Risk Assessment*
* *SOP Risk-Based System Validation*
* *SOP Validation Failures*

## Maintenance and Support Procedures

Summarize the procedures needed for the technical support of validated systems and software. Example text:

Procedures to support and maintain validated systems are developed, approved, and trained upon prior to use of the system in GxP activities. The following topics are addressed within the procedures developed for each validated system.

* Security
* Back-up and Restore
* Disaster Recovery
* System Maintenance
* Incident Management
* Change Control
* Configuration Management

Procedures are developed and approved, per *SOP Document Management.*

A detailed list of procedures is located in Appendix A*.*

## User Procedures

Summarize the procedures needed by users of validated systems and software. Example text:

Procedures for use of validated systems are developed, approved, and trained upon prior to use of the system in GxP activities. The following topics are addressed within the procedures developed for each validated system.

* User Operation
* Audit Trail Review
* User Training Requirements

Procedures are developed and approved, per *SOP Document Management.*

A detailed list of procedures is located in Appendix A*.*

## Documentation

Summarize the documentation that is retained for each validated system. Example text:

Documentation associated with validated systems is generated and retained for the same duration as required for retention of the records within the system. The following documentation is available for each system:

* All validation deliverables identified within the Validation Plan
* The results of validation testing (IQ, OQ, PQ) and the associated evidence needed for objective verification of pass/fail testing conclusions
* All development documents required by *SOP Software Development Life Cycle*
* Maintenance and support procedures, and associated training records
* User procedures and associated training records
* Training records for personnel participating in system development and validation

# Change Management

Summarize the process for managing changes to validated systems and software. Reference the SOP(s) containing this process. Example text:

All changes to validated systems and software are managed via a formal change control process.

Changes are documented in a Change Request and assessed to identify the impact to previous validation activities. The Change Request Impact Assessment includes recommendations regarding updates to existing documentation, creation of new documentation, testing of changes, regression testing, and training. The Change Request Impact Assessment is reviewed and approved, per *SOP Change Management*.

All activities identified within the Change Request Impact Assessment are completed prior to implementing the change for production use.

# Periodic Review

Summarize the process for periodic review of the VMP and of the validated systems. Reference the SOP(s) containing these processes. Example text:

The Validation Master Plan is reviewed and updated every 6 months to ensure that it accurately describes the current strategy, approach, and responsibilities for validation of computer systems and software.

Validated systems are periodically reviewed to ensure that they remain in a validated state. This includes review of validation documentation, change requests, system incident records, and the GxP regulations associated with the functions performed by the system.

The frequency of periodic review is determined by the system risk level; systems with a high risk level are reviewed more frequently than systems with a lower risk level.

The periodic review process and frequency is described in *SOP Periodic Validation Review*.

# System Retirement

Summarize the process for retirement of validated systems. Reference the SOP(s) containing these processes. Example text:

The retirement of validated systems is documented in an approved System Retirement Plan. The primary purpose of this plan is to ensure access to the records within the system for the length of time required by regulations.

The system retirement process is described in *SOP System Retirement*.

# VMP Revision History

|  |  |  |  |
| --- | --- | --- | --- |
| **Document Version Number** | **Document Revision Date** | **Revisions Made By:** | **Revision Summary**  *(Reference section[s] changed)* |
| 1.0 |  |  | Original Version |
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# Approvals

Signature(s) below indicate agreement that the contents of this Validation Master Plan are an accurate representation of strategy, approach and responsibilities for validation of computer systems and software within [scope].

|  |  |  |  |
| --- | --- | --- | --- |
| Document Prepared by: | | | |
| Function | Name | Signature | Date |
|  |  |  |  |

Signatures below additionally signify approval of this Validation Master Plan.

At minimum, include the Quality Assurance person responsible for software validation and the Technical (e.g., IT, Engineering) person in charge of computer systems and software.

| Document Approvals: | | | |
| --- | --- | --- | --- |
| Function | Name | Signature | Date |
| Head of Quality Assurance |  |  |  |
| Head of Information Technology |  |  |  |
| Head of Engineering |  |  |  |
|  |  |  |  |

**\*\*\*END OF DOCUMENT\*\*\***

**ATTACHMENT A**

Validation and Supporting Procedures

List all of the procedures specifically referenced within the VMP and the procedures supporting the VMP requirements, such as SOPs for Back-Ups, Security, and Training.

|  |  |  |
| --- | --- | --- |
| Procedure ID | Procedure Title | Effective Date |
| Procedure identifier | Name of Procedure | Date procedure went into effect |
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**ATTACHMENT B**

Computer System and Software Inventory

List all of the computer systems and software associated with GxP activities within the scope of the VMP.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| System/  Software Name | Version | GxP Functionality | Risk Level | Validation Status | Last Validation Date | Next Validation Date | Next Periodic Review Date |
|  | Version number | Briefly describe the regulated function performed or supported by the system (e.g., part inspections, training management, testing) | Risk level from Risk Assessment document | Validated or Not Validated | Date (or quarter) of last completed validation | Date (or quarter) of next planned validation | Date (or quarter) of next planned periodic validation review |
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