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**Validation Master Plan Template!**

Computerized System Validation Master Plan

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# Introduction

Attention: This validation plan is applicable to software or computerized systems only. It is not applicable to physical equipment.

## Goal

This document is the validation master plan of ACME Company.

It defines the phases of validation and, after validation, the principles to maintain systems in a validated state. Its goal is to set the principles to:

* Bring evidences that involved processes are compliant with quality and regulatory requirements,
* Ensure the safety and integrity of critical data.

The validation of each computerized system is described in a Validation Protocol (form XXX, see template), which implements the principles of this procedure. The results of the validation are described in a Validation Report (form XXX, see template).

## Scope

This validation procedure embraces all computerized and automatized systems used by processed in the scope of ACME QMS, including text documents with macros and spreadsheet documents with macros or complex formulas.

It doesn’t include:

* Text or spreadsheet documents without macros,
* Software used in processes outside QMS scope: accounting, legal…
* The IT infrastructure (network…).

The IT infrastructure is managed through the xxx procedure (your procedure).

## Responsibilities

XXX (the QA manager for instance) is responsible for the application of this procedure. He/she is also responsible for:

* The coordination of validation tasks between all system owners (see below),
* The periodic inventory of all computerized systems of ACME Company.

Each computerized system is attributed to a system owner. The system owner is responsible for the validation of the computerized systems he manages.

He/she his responsible for:

* The creation and the maintenance of Validation Protocols,
* The follow-up of validation activities of systems he/she has is charge.

# Criteria for Selection and Classification of computerized systems

This chapter explains the principles of selection, classification of computerized systems, and their eligibility to design qualification.

Overview of steps:

|  |  |
| --- | --- |
| Step | Purpose and description |
| Step 1 – Selection | Among all computerized systems present in ACME Company, a subset doesn’t require validation. The selection is the first step to select computerized systems, which require validation. |
| Step 2 – Classification | The second step is to split selected systems in three categories:   * Low level of concern, * Medium level of concern, * High level of concern.   Depending on their categories, the validation protocol may differ:   * Low level of concern: reduced validation protocol, * Medium level of concern: IQ, OQ, PQ, with optional provisions upon justification, * High level of concern: full IQ, OQ and PQ. |
| Step 3 – Design qualification | The third set is to determine whether design qualification (DQ) is required, based on the features of the computerized system to validate |

## Step 1 – Selection

### Identification of computerized systems

For each system, the following tables allow to identify computerized systems, which require validation. Other criteria may be used to select computerized systems on a case-by-case basis.

(if the answer is yes to at least one of the question of the table below, software should be validated, unless rationale is brought)

| **#** | **Question** | **Answer** |
| --- | --- | --- |
| 1.1 | Is the computerized system used in a process for production and service provision, in a way that affect the ability of the product to conform to specified requirements? (§7.5.2 of ISO 13485) |  |
| 1.2 | Is the computerized system used in the quality management system? (§4.1.6 of ISO 13485:2016) |  |
| 1.3 | Add you own answers, based on ISO or 21 CFR part 820 (like 820.70(i)) requirements, or any other relevant regulations or standards. |  |

(if the answer is yes to at least one of the questions of the table below, electronic records are in the scope of 21 CFR part 11)

|  |  |  |
| --- | --- | --- |
| **#** | **Question** | **Answer** |
| 1.4 | Are records stored in electronic format only? |  |
| 1.5 | Are records stored both in electronic format and in paper, with electronic records preferably used rather than paper records? |  |
| 1.6 | Are electronic signatures equivalent to inked signatures? |  |

### Risk assessment on computerized systems

For each system, a risk analysis is made to assess the consequences of software failure on the process.

This risk assessment is made by seeking the following (but not limited to) sequences of events:

* For software used on or with equipment in production:
  + The consequence on the equipment it controls or supports,
  + The consequence on the conformity of the product,
  + The consequence on the patient,
* For software used for servicing:
  + The consequence on the service it controls or supports,
  + The consequence on the conformity of the product or of the service,
  + The consequence on the patient,
* For software used to process quality or regulatory data:
  + The consequence on quality documents or records,
  + The consequence on the conformity of the product,
  + The consequence on the patient.
* For all software:
  + The consequence of a security breach or attack,
  + The consequence on quality documents or records,
  + The consequence on the conformity of the product,
  + The consequence on the patient.

### Selection of computerized systems

If the answer is yes to one of the following questions, the computerized system shall be validated:

|  |  |  |
| --- | --- | --- |
| **#** | **Question** | **Answer** |
| 1.7 | Is the answer « yes » to at least one of the questions 1.1 to 1.3? |  |
| 1.8 | Are there risks, whichever the risk severity, where the system is involved in the sequence of events |  |

If the answer is yes to the following question, the computerized system shall be validated against 21 CFR part 11:

|  |  |  |
| --- | --- | --- |
| **#** | **Question** | **Answer** |
| 1.9 | Is the answer « yes » to at least one of the questions 1.4 to 1.6? |  |

## Classification of computerized systems

The classification here is based on risks. This is a example, you may use your own classification criteria. Eg if a computerized system shall be 21 CFR part 11 compliant, it cannot be in low level of concern.

If the answer is yes to the following question, the computerized system is of high level of concern:

|  |  |  |
| --- | --- | --- |
| **#** | **Question** | **Answer** |
| 2.1 | Are there risks non acceptable (use the scale in your risk management procedure) where the computerized system is involved in the sequence of events? |  |

If the answer is yes to the following question, the computerized system is of Medium level of concern :

|  |  |  |
| --- | --- | --- |
| **#** | **Question** | **Answer** |
| 2.2 | Are there risks non acceptable (use the scale in your risk management procedure) where the computerized system is involved in the sequence of events? |  |

If the answer is no to the two questions above, the computerized system is of low level of concern.

## Design qualification of computerized systems

### Characteristics of system

For each system, the origin (vendor, manufacturer…) of the system shall be identified and the degree of configuration capabilities of the system shall be assessed.

|  |  |  |
| --- | --- | --- |
| **#** | **Origin of software** | **Tick if Yes** |
| 3.1 | Software is Off The Shelf, highly configurable |  |
| 3.2 | Software is developed internally |  |
| 3.3 | Software is text document or spreadsheet with complex formulas or macros |  |

Remarks:

* 3.1 Examples of Highly configurable software:
  + ERP,
  + Software with complex configuration files like rules or workflows in XML
  + Customizable software with macros or scripts,
* 3.1 Examples of basic configuration, for which answer to question 3.1 could be “No”
  + Users/passwords settings,
  + Network settings,
* 3.2 Internally developed software includes outsourced software development based on software specifications internally defined,
* 3.3 Examples of complex formulas and macros:
  + Macros with graphical user interfaces,
  + Macros files of several kilobytes,
  + An underlying architecture is required to organize macros, eg: modules and classes,
  + Formulas with more than two levels of dependency,
* 3.3 Examples of simple formulas and macros for which answer to question 3.3 could be “No”:
  + Sum, average, percentage formulas,
  + Macros, which apply bulk presentation settings to a document.

### Design qualification of system

If the answer is yes to the following question, the design qualification of the computerized system is required:

|  |  |  |
| --- | --- | --- |
| **#** | **Question** | **Answer** |
| 3.4 | Is the answer « yes » to at least one of the questions 3.1 to 3.3? |  |

## Selection and classification Records

The inventory of all computerized systems, their selection and classification based on criteria above are recorded in the computerized systems inventory (create your own form, copy tables above and paste and fill them in the form).

# Validation protocol

The validation protocol follows the steps:

* Design Qualification,
* Installation Qualification,
* Operations Qualification,
* Performance Qualification.

Depending on the computerized system level of concern, some protocol tasks are optional or not required.

## Design qualification

### Design qualification steps

The design process shall include at minimum the following tasks and milestones:

* Project launch review,
* Software Risk assessment,
* Software specifications, including risk mitigation actions,
* Design review,
* Software verification,
* Design validation review.

The design qualification protocol contains the rationale for the chosen software verification methods (unit tests, integration tests, code reviews…).

The design qualification protocol may be adapted from a software design procedure. It may also be adapted from purchase procedure if the development is outsourced.

### Design Qualification Documentation

The table below identifies the documentation group applicable to each category of software classification.

R: Require. D: Desirable

| No | Title | Software classification | | |
| --- | --- | --- | --- | --- |
| High | Medium | Low |
| 1. | Operation & Maintenance Manual | R | R | R |
| 2. | Software Requirements Specification | R | R | R |
| 3. | Architectural Design | R | R | D |
| 4. | Detailed Design | R | D |  |
| 5. | Source Code Review and Report. | D |  |  |
| 6. | Unit Test Report | R |  |  |
| 7. | Integration Test Specification. | R | R |  |
| 8. | Integration Test Results. | R | R |  |
| 9. | Software Test Specification. | R | R | R |
| 10. | Software Test Results. | R | R | R |

## Installation qualification

### Installation qualification steps

Installation qualification aims to ensure that computerized system is properly installed in the right environment.

The scope of IQ inspections or testing includes, as applicable:

* In the case of system installed on hardware, verifying that hardware settings and features match hardware requirements,
  + Hardware installation,
  + Hardware customization or settings,
  + Network connections,
  + Peripherals (backup/restore peripherals, other peripherals),
  + Hardware maintenance contracts,
* In the case of system on the cloud, verifying:
  + Cloud servers settings and characteristics,
  + Contract with the cloud service provider,
* Verifying that software environment settings and characteristics match environment requirements:
  + Operating system versions,
  + Servers (database…) versions,
  + Virtual machines versions…
* Verifying that software documentation is available and in the right version:
  + Installation, administration and user manual,
  + When design qualification is required, DQ output documentation,
  + Specific QMS procedures and instructions, if applicable,
* Installing software, if applicable,
* Verifying that software is properly installed:
  + Software version,
  + Installation results records (log files, screen shots…),
* Migrating data, if applicable,
* Verifying that data are properly migrated:
  + Migrated datasets,
  + Data migration logs.
* Configuring software, if applicable,
* Verifying that software is properly configured:
  + Configuration settings,
  + Configuration steps logs.

### Installation qualification documentation and records

The installation qualification documentation contains:

* An installation qualification protocol containing all the verification/inspections required,
* One or more installation qualification reports containing results of installation qualification,
* Any additional record serving as evidence of installation qualification,
* Bug reports found during installation qualification.

The table below identifies the documentation group applicable to each category of software classification.

R: Require. D: Desirable

| No | Title | Software classification | | |
| --- | --- | --- | --- | --- |
| High | Medium | Low |
| 1. | IQ Protocol | R | R | D |
| 2. | IQ Report and bug reports | R | R | D |
| 3. | IQ Records | R | D |  |

## Operational qualification

### Operational qualification steps

Operational qualification aims to ensure that every function of the computerized system is working as expected.

The scope of OQ testing includes, as applicable:

* Functional and performance requirements,
  + Verifying software functions,
  + Verifying software behavior in degraded status,
* Non-functional requirements, like
  + Security, safety and privacy,
  + Backup/restore,
  + Administration functions,
  + Maintenance functions,
  + 21 Part 11 compliance.

### Operational qualification documentation and records

The operational qualification documentation contains:

* An operational qualification protocol containing all the verifications/inspections required,
* One or more operational qualification reports containing results of operational qualification,
* Any additional record serving as evidence of operational qualification,
* Bug reports found during operational qualification.

The table below identifies the documentation group applicable to each category of software classification.

R: Require. D: Desirable

| No | Title | Software classification | | |
| --- | --- | --- | --- | --- |
| High | Medium | Low |
| 1. | OQ Protocol | R | R | D |
| 2. | OQ Report and bug reports | R | R | D |
| 3. | OQ records | R | D |  |

## Performance qualification

### Performance qualification steps

Performance qualification aims to ensure that the computerized system works as expected in its target environment and with target users.

### Performance qualification documentation and records

The performance qualification documentation contains:

* Optionally, a performance qualification protocol containing verifications of user requirements,
* One or more performance qualification reports containing feedback of users, discovered bugs, …
* Optionally, any record serving as evidence of performance qualification,
* Bug reports found during performance qualification.

The table below identifies the documentation group applicable to each category of software classification.

R: Require. D: Desirable

| No | Title | Software classification | | |
| --- | --- | --- | --- | --- |
| High | Medium | Low |
| 1. | PQ Protocol | D |  |  |
| 2. | PQ Report | R | R | R |
| 3. | PQ Records | D |  |  |
| 4. | User feedbacks and bug reports | R | R | R |

## Deviations – software bugs

Deviations and software bugs are recorded in ACME company bug tracking system.

The severity of deviations in assessed with the following criteria:

* Major: Non-compliance or major risk for the patient,
* Medium:
  + Non-compliance or major risk for the patient but with a workaround,
  + Minor risk for the patient,
* Minor: No non-compliance and No risk for the patient, but software behavior is outside specifications.

Deviations that are not software bugs follow the path of non-conformities procedure:

* Identification/description of the deviation,
* Investigation and identification of the root cause of the deviation,
* Impact on qualification activities already completed,
* Proposed corrective action.

Corrective action should include, where applicable, revision of requirements and specifications, version changes to software, and re-testing.

# Validation reports

## Qualification reports

Reports are required to summarize each of the qualification phases of the validation project.

All qualification reports must address the following:

* An overall summary of the results,
* Inclusion or reference of the location of the primary data and the executed protocol,
* Discussion of all deviations, corrective actions, and resulting changes (especially bug fixes between IQ and OQ or OQ and PQ)
* A conclusion that includes conditions for use of the system.

## Final validation report

A final Validation Report is required to verify the completion of all activities required by the validation protocol.

The final validation report must address the following:

* An overall summary of the validation project,
* A list of all deliverables generated as per the Validation Master Plan and their location,
* Any deviation from the Validation Master Plan with justification,
* A clear conclusion indicating whether or not the system is suitable for use in routine operations.