Procedure: Computer System Validation

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# Purpose

The purpose of this procedure is to describe the systems, provides instructions and identify responsibilities for validation of computer systems at [Company] ensuring compliance with Regulatory and GxP requirements.

The SOP defines the validation strategy to ensure that all computer systems that have an impact on product quality are formally validated.

# Scope

The scope of this procedure includes all forms of computerised systems used as part of a GMP regulated activities. A computerised system is a set of software and hardware components which together fulfil certain functionalities.

Excluded from this procedure are:

* GMP manufacturing processes, equipment, utilities, cleaning and laboratory validation (ref. to *QP710 – Validation of Processes and Equipment*)
* Embedded process control systems in manufacturing equipment

# Responsibilities

Amend this section to reflect your organisational structure.

|  |  |
| --- | --- |
| Role | Responsibility |
| Quality Manager | * Identifies validation requirements. * Ensures that staff are trained in the content of this document. |
| Validation staff | * Complete and document validation activities and documentation. |
| IT Manager | * Review, provide input and approve validation documents as required |

# Procedure

This validation procedure is based on GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems and current industry practices.

Computer system validation (CSV) at [Company] is managed by [insert who is responsible for CSV] reporting directly to the [insert reporting structure]. The CSV department is responsible for the management, coordination and maintenance of all computer system validation activities.

[Management of and responsibility for validation differs between companies and may report to Quality, Production, Engineering, etc. It is important to define the approach at your company.]

There should be close cooperation between all relevant personnel such as Process Owner, System Owner, Authorised Persons and IT. All personnel should have appropriate qualifications, level of access and defined responsibilities to carry out their assigned duties.

## General validation requirements

Validation is a documented programme that provides a high degree of assurance that a computer system will consistently produce a product meeting pre-determined specifications. Validation provides a business benefit in that understanding of processes and products increases patient safety, minimises waste and product non-conformance and facilitates more reliable continuity of supply.

All GxP computer systems must be validated to demonstrate fitness for intended use and to satisfy regulatory requirements.

Any proposed changes made to a computer system must be assessed to determine the impact and associated risk to the product / patient. If the proposed change could impact product quality then it must be validated.

Where a computerised system replaces a manual operation, there should be no resultant decrease in product quality, process control or quality assurance. There should be no increase in the overall risk of the process.

## Project lifecycle approach

The lifecycle approach is used as a basic structure for projects undertaken by [Company]. The V-model, which is outlined in GAMP 5, is used on site for all validation projects and defines the project lifecycle from the planning stages, right through to the operation and maintenance of the validated state.

User Requirements Specification

Functional Specification

Design Specification

IQ

OQ

PQ

Build / purchase

Commission equipment

Verifies

Design Review

Validation Plan

Validation Report

Testing

Verifies

Verifies

## Identification of validation

The validation department [or IT, dependent upon company structure] is responsible for reviewing all computer systems to identify those that require validation. This is initially assessed using a Risk Assessment or a System Impact Assessment as outlined below in Section 4.4. Production and IT staff may be required to assist with the review.

## Risk management

Validation is undertaken using a risk-based approach. During the planning and specification stage an assessment of the risk to product quality, purity and data integrity must be made. The result of this assessment enables the validation requirements and extent to be determined. This is documented in the project Validation Plan (VP).

Risk management should be applied throughout the lifecycle of the computerised system taking into account patient safety, data integrity and product quality. As part of a risk management system, decisions on the extent of validation and data integrity controls should be based on a justified and documented risk assessment of the computerised system.

An initial risk assessment will be performed at (or before) the beginning of the project phase based on an understanding of business processes and business risk assessments, user requirements, regulatory requirements and known functional areas. The initial risk assessment comprises the following:

### GxP determination

[The initial risk assessment should include a decision on whether the system is GxP regulated (i.e., a GxP assessment).]

### System impact

[The initial risk assessment should determine the overall impact that the computerized system may have on patient safety, product quality, and data integrity due to its role within the business processes.] Ref. FP710-2 – System Impact Assessment.

### Need for further assessments

[The amount of information available when performing the initial risk assessment depends on both the business process and on the GAMP category. For simpler systems the initial risk assessment may be sufficient for all relevant risks to be identified, assessed, and controlled. However, more complex systems may require further, more detailed assessments as the system is developed.]

The [Computer System Name] has been assessed for its GAMP computerised system categorisation. The conclusion is that the [Computer System Name] system is GAMP category [X], and is a GxP system.

## Computer systems validation

Computer software is validated according to GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems.

Where a software malfunction could result in product nonconformity, the computer software controlling the production process must be validated prior to initial use. This includes software used in QC inspection equipment (or otherwise in monitoring and measurement of specified requirements).

Where possible, production software developed and supplied under contract is validated by the contractor, in accordance with acceptance procedures which should be specified in the contract. Completed validation documentation should be supplied with the software.

Standard, off-the-shelf software for use in production processes and software that is included with standard manufacturing equipment is only purchased from approved suppliers and in accordance with Procedure QP704: Supplier Evaluation and Monitoring and Procedure QP706: Procurement.

The competence and reliability of a supplier are key factors when selecting a product or service provider. The need for an audit should be based on a risk assessment.

Supplier approval includes gathering and evaluating information regarding the supplier's software validation program. Only suppliers who have a robust QMS may be placed on the Approved Supplier List.

Documentation supplied with commercial off-the-shelf products should be reviewed by regulated users to check that user requirements are fulfilled.

An up to date listing of all relevant systems and their GMP functionality (inventory) should be available for inspection at all times. For GMP critical systems, an up-to-date system description detailing the physical and logical arrangements, data flows and interfaces with other systems or processes, any hardware and software pre-requisites, and security measures should be available.

# Validation deliverables

Validation activities must be carried out in accordance with approved protocols. Protocols must specify critical steps and contain pre-defined acceptance criteria for all checks, tests and supporting documentation. After completion of the validation, a report must be written that summarises the results and draws conclusions and makes any necessary recommendations. The validation documentation and reports should cover the relevant steps of the life cycle.

A formal release is required following satisfactory qualification / validation. This is typically achieved by the approval of the validation summary report or by the issue of an approved for release document, or as stipulated in the project VP. Protocols and reports must be reviewed by appropriate manufacturing, engineering, development and supporting staff and approved by QA. Validation documents are controlled as part of the site quality management system.

As part of the validation activities, the following documents will be produced, and will form the validation package that will be maintained for the life of the system. This document set will be available for audit by regulators or customers and will demonstrate that the [Computer System Name] has been implemented in accordance with current regulatory expectations and local policies and procedures.

The table below provides a list of deliverable project documents and responsibilities for preparation, review and approval.

Note that for some change control activities, only a subset of this suite of documents may be required or alternatively there may be several iterations of a document type (e.g. IQ, OQ, PQ). This is managed and justified by the specific validation plan.

[Computer System Name] Validation Documents:

| Document Deliverable Description | Author | Reviewer(s) | Approver(s) |
| --- | --- | --- | --- |
| Insert or delete as required | Complete | Complete | Complete |
| Initial Risk Assessment |  |  |  |
| User Requirements Specification |  |  |  |
| Supplier Assessment and Report |  |  |  |
| Validation Plan (this document) |  |  |  |
| Detailed Risk Assessment |  |  |  |
| Functional Specification |  |  |  |
| Design Specification |  |  |  |
| Source Code Review |  |  |  |
| Design Review |  |  |  |
| Requirements Traceability Matrix |  |  |  |
| Design Qualification Protocol & Report |  |  |  |
| Supplier validation documentation (Reviewed & Approved) |  |  |  |
| Installation Qualification Protocol & Report |  |  |  |
| Operational Qualification Protocol & Report |  |  |  |
| Performance Qualification Protocol & Report |  |  |  |
| Data Migration Plan / Report |  |  |  |
| Validation Summary Report |  |  |  |

## Validation Plan

The Validation Plan (VP) or equivalent (e.g. Validation Master Plan, Project Validation Plan) details the validation methodology to be used, activities required and standards to be met within a project. The VP:

* must be initiated and authorised at the earliest practicable stage
* must be reviewed and updated throughout the life-cycle of the work, so that it remains an accurate description of the validation intent
* must include documented rationales to justify the validation approach to be taken

## User Requirements Specification

The high level user requirements must be clearly defined in a User Requirements Specification (URS). Where third parties are involved, the URS should form the basis of any contractual agreement between the parties. This is a key validation document and should be updated as required during the life of the item or software being validated.

The URS should describe the required functions and attributes of the computerised system and be based on documented risk assessment and GMP impact. The attributes may be in the form of functional or performance requirements, and only those requirements that have relevance to the critical functions of the system, or safety of the system, will be formally qualified.

User requirements should be traceable throughout the life-cycle (ref. Section 5.4).

The URS may also contain functional and design specifications if these are not documented in separate documents.

The Functional Specification (FS) describes in more detail how the user requirements will be met at a functional level. This is a more technically detailed document to the URS and therefore should provide a more detailed description of how the user requirements are to be met at a functional level. For small or simple projects the functional requirements may be included in the URS document.

The Design Specification (DS) detailed more than the FS how the user requirements will be met in terms of design or build of the item, software or facility. It is typically required for engineering and for software coding projects. For simple systems or equipment the design requirements may be included in the URS.

## Supplier assessment and report

All reasonable steps should be taken to ensure that the system has been developed in accordance with an appropriate quality management system. The supplier should be assessed appropriately.

The supplier of the [Computer System Name] system will be sent a quality assessment for their Quality Assurance representative to complete. The result of the assessment and any conclusions will be added to a report, created as one of the project deliverables.

If deemed necessary by the Quality Manager, an on-site audit may be required.

## Requirements Traceability Matrix

The Requirements Traceability Matrix (RTM) links the individual requirements in the URS, through to the specification documents that define how the system will meet these requirements (FS or DS) and then onto the individual test cases where the testing is performed.

## Source Code Review

[In most cases this section will be not applicable as this is typically only required for the validation of GAMP Category 5 systems. It is an important part of the SDLC but should be carried out by the supplier as part of their QMS as often the software is proprietary and unavailable for customer review. The supplier assessment should indicate whether the supplier has appropriate procedures in place and whether the review has been carried out satisfactorily by the supplier and hence determine whether additional testing or review is required during validation.]

## Design Review & Design Qualification

The system design must be reviewed by personnel with the appropriate knowledge and experience to ensure that all product quality/regulatory requirements have been included in the design. The outcome of the Design Review(s) (DR) must be documented, clearly stating if the quality of the design is acceptable; listing any deficiencies together with details of planned remedial action.

Design Qualification (DQ) is the formal, documented evidence that quality has been built into the design and the systems shall be fit for purpose.

Design Qualification will be performed for all new computer hardware and software associated with the system.

DQ assessment will verify that the [Computer System Name] user requirements and functional requirements are adequately addressed in the Design Specification document.

As DQ is the final step to formally review and document the proper design of the system, the protocol must enable the reviewers to verify that all quality-critical attributes and essential technical attributes of the system have been incorporated in the design. When the DQ report is approved, the system is ready for fabrication and construction.

The design qualification assessment cannot start until the user requirements specification, functional requirements and design specification have been approved, and the DQ protocol has been pre-approved.

## Qualification protocols

Generally speaking, qualification consists of the following distinct phases:

* Design Qualification (ref. Section 5.6)
* Installation Qualification (ref. Section 5.7.1)
* Operational Qualification (ref. Section 5.7.2)
* Performance Qualification (ref. Section 5.7.3)

The objective is to ensure that an appropriate risk based approach to the completion and documentation of qualification activities is undertaken for all GMP computer systems.

Not all testing and qualification stages will apply to every validation exercise conducted and therefore the approach must be justified in pre-approved rationales and be based on good scientific/technical argument and documented fact.

For simple equipment, IQ, OQ and PQ may be combined in one protocol as long as the resulting document addresses the requirements for testing installation, operation and performance qualification. This approach should be documented in the project VP.

### Installation Qualification

Installation Qualification (IQ) will be performed for all new or upgraded computer hardware and software associated with the system.

* Hardware components will be tested to record their details, to confirm correct installation and to verify they meet the minimum performance requirements of the [Computer System Name] application.
* IQ testing will verify that the system software and other related or important applications, such as anti-virus and back-up, have been installed, are the correct versions and have been configured as detailed in the pre-approved specification(s) [cross reference the applicable documents].
* The IQ protocol will also identify what training and operating procedures are required for the [Computer System Name] system to allow it to enter live production.

IQ testing cannot start until the Design Qualification testing has been completed and approved for IQ phase handover and the IQ protocol has been pre-approved.

Results of IQ testing may be documented within the IQ protocol or in a separate report.

### Operational Qualification

The [Computer System Name] system will be tested at Operational Qualification (OQ) to verify that it operates as specified in the pre-approved specification(s) throughout all specified operating ranges. The testing will focus on the following critical areas:

* Security
* Operator data entry
* Functionality – correct configuration of calculations
* Critical alarms
* Reporting
* Data back-up and restoration.

Evidence of appropriate test methods and test scenarios should be demonstrated. Particularly, system (process) parameter limits, data limits and error handling should be considered. Automated testing tools and test environments should have documented assessments for their adequacy.

The OQ testing cannot start until the Installation Qualification testing has been completed and approved for OQ phase handover and the OQ protocol has been pre-approved.

Results of OQ testing may be documented within the OQ protocol or in a separate report.

### Performance Qualification

[Describe how PQ will be carried out. It may or may not be possible to duplicate the live environment so PQ may need to be carried out after the system is in use. Also, discuss any post go-live monitoring that may be required and how the results of such monitoring will be reported e.g. an interim summary report prior to PQ testing followed by an additional VSR.]

The [Computer System Name] system will be tested at PQ to verify that it operates as specified in the end environment, using the approved procedures. The PQ will incorporate stress testing, which will simulate higher levels of data entry and processing than are likely to be encountered during production and confirm handling of exceptions and fault situations are appropriately managed.

The PQ will include a test to confirm that all system-related procedures have been approved for use in live production. The PQ protocol will be used to verify that adequate user training has been performed to allow the system to enter live production.

The PQ testing cannot start until the Operational Qualification testing has been completed and approved for PQ phase handover and the PQ protocol has been pre-approved. Results of PQ testing will be documented in a separate PQ Report (PQR).

## Data Migration Plan / Report

[If applicable. This is required when existing data is to be transferred to the ‘new’ system, such as in the case of a system upgrade.]

If data are transferred to another data format or system, validation should include checks that data are not altered in value and/or meaning during this migration process.

A data migration plan will be written for this project to document the approach required to assure the quality and content of data transferred from the old system to the new system.

## Validation Summary Report

Following the completion of the PQ Report(s), a Validation Summary Report (VSR) shall be prepared. The VSR must be produced to reconcile, summarise and conclude on the validation activities described in the validation plan. The VSR includes a clear statement that the objective of the validation exercise as stated in the VP has been achieved.

The VSR should summarise the results of all testing and document any failures, incidents, deviations, changes to the original plan, limitations found, and a statement of fitness for purpose.

Where release of either part of the system, or the system with a reduced scope is required prior to the full completion of pre-defined validation activities, the scope of the release and its justification must be documented and approved within an interim VSR.

The summary report must be approved by a representative of the Quality organisation.

## Recording of test results and raw data

All test results shall be:

* recorded in real-time at the time of testing
* signed off by the tester to confirm that the requirements were, or were not, met
* traceable back to the test plan and the relevant specification document (e.g. FS)

Once all tests have been completed and signed off, an independent check must be carried out to verify that all testing is satisfactory, and the test stage can be considered complete and having met all acceptance criteria.

All raw data generated during testing must be retained as part of the validation documentation. Raw data may be in electronic or paper format and, where possible, must be attached to the PQ report. If not attached, reference must be made as to the location of the raw data (e.g. database location).

# Acceptance Criteria

[Describe how the system will be formally released for use. Include how any significant deviations or incidents will be handled. e.g.]

The system will be considered ready for release into live production use when:

* all tests have been successfully completed and approved
* all related incidents have been closed or otherwise justified as acceptable
* the system has been reviewed and assessed as fit for its intended purpose
* the [QA manager] (or delegate) has approved the system for live production
* the system has been formally released by the authorisation of a system release form

# Validation maintenance

Validation activities encompass the entire life of the computer system, from requirements definition through to decommissioning. Computer systems must be maintained in a constant state of compliance throughout their lifecycle.

For the validation of bespoke or customised computerised systems there should be a process in place that ensures the formal assessment and reporting of quality and performance measures for all the life-cycle stages of the system.

## Change control

Change control is the primary mechanism by which validation is maintained.

The Change Control process evaluates potential effects of all proposed changes.

All changes (including replacements and system configurations) made to a validated computer system, both planned and unplanned (malfunction/breakdown), must be approved by a representative of the Quality organisation (or performed as part of a Quality approved process) and the potential impact on the computer system validation status determined prior to commencement of the change.

This is carried out in accordance with Procedure QP703: Change Control.

All changes to an active validation project are also controlled and approved using the site change control procedure; Procedure QP703: Change Control.

The Quality Manager is responsible for overseeing the change control system, issuing and controlling the completion of change control forms, the risk management of each change and the validation activities that may be required.

Once in a validated state, the computer system will be maintained under change control. All changes must be evaluated to determine the impact on product quality, purity and data integrity, ensure compliance with GMP and establish any need to revalidate the computer system affected.

## Validation review

Computerised systems should be periodically evaluated to confirm that they remain in a valid state and are compliant with GMP. Such evaluations should include, where appropriate, the current range of functionality, deviation records, incidents, problems, upgrade history, performance, reliability, security and validation status reports.

# Documentation management

SOPs and validation deliverables are generated as required in accordance with the site QMS and follow Procedure QP401: Document Control. Updates or changes to existing documents will be managed under the site change control system documented in Procedure QP703: Change Control.

Review, approval, issue, change, storage and retirement are controlled according to Procedure QP401: Document Control.

# Training

Participants involved in validation must be trained in this validation procedure and should be familiar with the project VP. Only personnel who are trained in use of the computer system should be allocated validation activities. All training must be complete, documented and approved before validation tasks are undertaken.

Persons writing validation documents will be trained in GMP, Good Documentation Practices (GDP) and validation and will either be familiar with the computer system or will have direct access to those who are.

# Incident observation and deviation reporting

During protocol execution, an incident or a deviation from the protocol may occur. All incidents and deviations must be recorded on the incident/deviation Form FP710-1 Validation Exception Report and describe the incident and the steps taken to address it. The actual or potential impact on the test and the computer system must be assessed and documented. Each incident must be assigned a unique number which is noted in the protocol at the relevant step, and the outcome is discussed in the validation report.

Depending on the frequency and seriousness of any incidents or deviations, a decision may be required as to the direction taken to complete the validation. Any such decisions will be documented as part of the validation documentation. A QA representative must sign off on all validation incidents & deviations.

If a test incident, deviation or failure occurs, testing should be stopped and brought to the attention of the project manager and QA. The issue is then evaluated to confirm what action is required. A minor deviation such as a correction to a typographical error in the protocol can be corrected by hand, initialled and dated by the person making the change and testing continued. Each project shall generate a register of such incidents so that they can be referenced in the documentation and tracked through to completion. All testing incidents are then summarised in the validation summary report.

Examples of incidents and deviations include:

* protocol errors and omissions
* test failures
* equipment problems
* unexpected events or outcomes
* deviations from the steps described in the protocol

[Note that if an exception is reported during a PQ batch, this may constitute a deviation to be reported under *QP805 – Managing Deviations* as this deviation may have occurred on a live batch. In this event QA would need to advise as to the course of action.]

# Project management

A project plan should be developed and maintained throughout the duration of the project. This should cover all aspects of the validation, project management, timetable, resources, budget and risk management.

# Decommissioning a validated system

When a validated computer system is removed from operational service it must be decommissioned in a controlled manner.

Work must be performed to demonstrate that at the time the system was removed from routine operational use that it was operating in compliance with specified requirements, and fit for purpose. Details to be recorded to provide confirmation that equipment is fit for purpose at the time of decommissioning include:

* Confirmation that the computer system was within its validation review period at the time of decommissioning,
* Confirmation that equipment had been adequately maintained / backed-up until final routine use.
* Confirmation that the computer system was functioning correctly prior to removal.

A decommissioning exercise must be documented and approved by a representative of the Quality Organisation.

These operations provide assurance that any decision or material made up to the date of a GMP critical computer system being decommissioned was made according to the validated process using qualified equipment.

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term or abbreviation | Definition |
| --- | --- |
| CSV | Computer System Validation |
| Design Qualification (DQ) | Design qualification refers to the documented verification that the proposed design of the facility, system and / or equipment is suitable for the intended purpose. Design Review and DQ may be used interchangeably; this involves a planned and systematic review of specifications, design and development throughout the life cycle. |
| Design Specification (DS) | Details how the user requirements will be met in terms of design or build of the system, software or facility |
| FMEA | Failure Mode and Effects Analysis |
| Functional Specifications (FS) | Describes the detailed functions of the equipment or system and what it will do. |
| GAMP | Good Automated Manufacturing Practice |
| GxP | Includes:  Good laboratory practice (GLP)  Good manufacturing practice (GMP)  Good documentation practice (GDP) |
| Installation Qualification (IQ) | Documented verification that a system / equipment is installed according to written and pre-approved specifications. |
| Operational Qualification (OQ) | Documented verification that a system / equipment operates according to written and pre-approved specifications throughout all specified operating ranges. |
| Performance Qualification (PQ) | Documented verification that a system / equipment is capable of performing or controlling the activities of the processes it is required to perform or control, according to written and pre-approved specifications, while operating in its specified operating environment. |
| PQR | Performance Qualification Report |
| QMS | Quality Management System |
| RTM | Requirements Traceability Matrix |
| SOP | Standard Operating Procedure |
| User Requirements Specification (URS) | This describes what the equipment or system is needed or supposed to do, and is normally written by the user. The User Requirement Specification is a design input that describes the requirements of the system as described in AS/NZSISO9001:2015 – published Sept 2015 section 7.3.2. |
| VP or VMP | Validation Plan or Validation Master Plan |
| VSR | Validation Summary Report |

Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
|  |  |  |  |
|  |  |  |  |

Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP401 | Document Control |
| QP703 | Change Control |
| QP704 | Supplier Evaluation and Monitoring |
| QP706 | Procurement |
| FP710-1 | Validation Exception Report |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
|  |  |

List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

DOCUMENT END