Procedure: Validation of Processes and Equipment

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Table of Contents

[1. Purpose 3](#_Toc407095947)

[2. Scope 3](#_Toc407095948)

[3. Responsibilities 3](#_Toc407095949)

[4. Procedure 3](#_Toc407095950)

[4.1. General validation requirements 4](#_Toc407095951)

[4.2. Project lifecycle approach 4](#_Toc407095952)

[4.3. Identification of validation 5](#_Toc407095953)

[4.4. Risk management 5](#_Toc407095954)

[4.5. Facility, utilities and services validation 5](#_Toc407095955)

[4.6. Equipment validation 5](#_Toc407095956)

[4.7. Process validation 5](#_Toc407095957)

[4.8. Cleaning validation 7](#_Toc407095958)

[5. Validation deliverables 7](#_Toc407095959)

[5.1. Site Validation Master Plan 7](#_Toc407095960)

[5.2. Validation Plan 8](#_Toc407095961)

[5.3. User Requirements Specification 9](#_Toc407095962)

[5.4. Design Review and Design Qualification 9](#_Toc407095963)

[5.5. Commissioning and qualification protocols 9](#_Toc407095964)

[5.6. Validation Summary Report 12](#_Toc407095965)

[5.7. Recording of test results and raw data 12](#_Toc407095966)

[6. Validation maintenance 13](#_Toc407095967)

[6.1. Change control 13](#_Toc407095968)

[6.2. Periodic equipment re-qualification 13](#_Toc407095969)

[6.3. Validation review and re-validation 13](#_Toc407095970)

[7. Control of validation batches 14](#_Toc407095971)

[8. Documentation management 14](#_Toc407095972)

[9. Training 14](#_Toc407095973)

[10. Incident / observation and deviation reporting 14](#_Toc407095974)

[11. Project management 15](#_Toc407095975)

[12. Decommissioning a validated system 15](#_Toc407095976)

[Appendix 1: Three stage validation lifecycle approach 16](#_Toc407095977)

[Appendix 2: Validation Process Flow 17](#_Toc407095978)

# Purpose

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

The SOP defines the validation strategy to ensure that all facilities, services, laboratories, equipment and processes that have an impact on product quality are formally validated.

# Scope

The scope of this procedure includes:

* GMP manufacturing processes
* Process equipment (& embedded control systems)
* Labelling and packaging
* Facilities, utilities & services
* Cleaning
* Laboratory equipment

Excluded from this procedure are:

* computer systems and/or process control systems that are not embedded into process equipment (ref. to *QP718 - Computer System Validation*)
* laboratory test methods

# 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. |
| Department managers | * Review, provide input and approve validation documents as required |

# 

# Procedure

Validation at [Company] is managed by [insert who is responsible for validation] reporting directly to the [insert reporting structure]. The validation department is responsible for the management, coordination and maintenance of all 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.]

## General validation requirements

Validation is a documented programme that provides a high degree of assurance that a facility, equipment or operation 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 equipment and processes must be validated to demonstrate fitness for intended use and to satisfy regulatory requirements.

Any proposed changes made to equipment or a process must be assessed to determine the impact and associated risk to the product. If the proposed change could impact product quality then it must be validated.

## 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 is responsible for reviewing all manufacturing processes, equipment and control 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 engineering 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 patient safety 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).

Equipment is assessed using a System Impact Assessment which will define equipment as either Direct, Indirect or No Impact in its ability to impact product quality (ref. to *Form FP710-2: System Impact Assessment*). All Direct Impact equipment must be validated.

## Facility, utilities and services validation

The objective of facility validation is to ensure the appropriate design, construction, functionality, preventative maintenance and calibration are in-place to support the manufacturing processes.

The objective of utilities and services validation is to ensure that the design, construction and operation are appropriate for the intended use. Each utility and service should be assessed for the risk that it imparts on the final product; ‘GMP-critical’ utilities and services will be qualified / validated and ‘Non GMP-critical items’ will be commissioned according to GEP (Good Engineering Practice) as described in the ISPE Baseline Guide for New and Renovated Facilities, Volume 5, Commissioning and Qualification.

## Equipment validation

The objective of equipment validation is to ensure that the design, construction, installation and operation of equipment are appropriate for the intended use. The level of validation will depend upon its criticality in the process (is the system Direct/Indirect/No Impact) and the criticality of individual components within the equipment system.

The appropriateness of the equipment for its intended use is confirmed during Design Qualification and its correct installation is verified during Installation Qualification.

Critical functionality of systems and processes is tested in the Operational Qualification phase to ensure that it meets the functional requirements for the system.

The application of various processes will be validated in the Performance Qualification phase to ensure that when used as intended, the equipment design and functionality results in product meeting all quality/user requirements. Performance Qualification also ensures that hand-over to routine production occurs in a documented and controlled manner.

## Process validation

Process Validation (PV), sometimes executed as Performance Qualification, is the means of ensuring and providing documentary evidence that processes (within their specified design parameters) are capable of repeatedly and reliably producing a finished product of the required quality.

All new and modified processes shall be validated in accordance with current regulatory requirements. Validation plans and protocols shall be written and executed to demonstrate that a specific process will consistently produce a product that meets pre-determined specifications and quality attributes.

Process validation testing is typically carried out a minimum of three times to verify repeatability of results. There are three recognised approaches to validation:

* Prospective validation – must be used for all new equipment, process, system & method validation
* Concurrent validation – batch by batch release may be used when justified and approved by Quality Manager.
* Retrospective validation – only used in exceptional circumstances to validate existing systems but must be fully justified and approved.

### Three stage validation lifecycle approach

[Note that this PV approach has been adopted by regulatory agencies internationally and is now an expectation in some markets. This practice should be adopted as soon as practicable as it will become industry standard.]

Validation of commercial manufacturing processes must be based on a product / process lifecycle approach which must be defined and built into the validation plan. Refer to **Appendix 1 – Three stage validation lifecycle approach**.

The lifecycle approach incorporates the following:

**Process Design (Stage 1):**

The commercial manufacturing process is defined during this stage based on knowledge gained through laboratory / pilot scale development, scale-up studies and/or successful manufacturing history in the case of legacy products.

A Product Control Strategy (PCS), which accounts for the potential sources of variability at the commercial scale, is a required output from this stage which is then taken into formal process validation.

**Process Qualification (Stage 2):**

During this stage the process design is evaluated, on qualified systems, to verify that the process is capable of reproducible commercial scale manufacturing. The objective of Process Qualification is to gather accumulated, documented, knowledge and data to verify the process design and that the control strategy (at commercial scale) results in an output in accord with the defined specification. The following are required of Stage 2:

* The number of batches required to demonstrate that the PCS is capable of routinely producing material of the appropriate specification must be justified.
* The level of sampling in Process Qualification must be sufficient to confirm the expected quality both within and between batches;
* The rationale and plan to achieve this must be documented.

**Continued Process Verification (Stage 3):**

During Continued Process Verification (CPV), products / processes are assessed to provide assurance that the product control strategy continues to produce product of the appropriate quality. This is gained via statistical analysis of batch data such that any out of control symptoms are predictive of potential batch failure.

## Cleaning validation

Cleaning validation is performed to demonstrate and document that cleaning procedures successfully and consistently remove from product contact surfaces any cleaning agents, remaining intermediates, final products or breakdown products that may adversely impact on the quality of subsequent product.

# 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. 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 validation plan. Protocols and reports must be reviewed by appropriate manufacturing, engineering, development and supporting staff and approved by Quality Assurance. Validation documentation is controlled as part of the site document management system.

The documentation requirements for validation projects can vary depending on the size, nature and complexity of the project. For small projects, much of the information can be incorporated into the key documents, whereas larger projects may require a full complement of validation documents. In each case, the validation approach and deliverables must be documented and approved.

Refer to **Appendix 2 – Validation Process Flow** for an overview of a “typical” validation project. Note that the deliverables for each validation project must be assessed on a case by case basis.

## Site Validation Master Plan

The Site VMP is a high level overview that identifies the major site validation activities, processes and resourcing requirements. The Site VMP is prepared to capture the following functional areas (or each area may have its own VMP):

* Production stream(s), including services
* Computer / IT
* Laboratories
* Cleaning

Site (or area) VMPs are updated at least every 12 months and include the following information:

* References to governing policies, procedures, and guidelines providing reference to the standards followed, ensuring that validation is planned, co-ordinated and performed in a controlled and compliant manner.
* References lower level stream and project VPs as required.
* Responsibilities, specifying who is responsible for the validation activities.
* High level overview of validation activities for all systems within scope.
* Schedules and progress.
* Approvals – the Site VMP must be approved by the head of the business unit and the Quality Manager.

## 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
* should define Critical to Quality Attributes (CQA) and Critical Process Parameters (CPP)

### System Impact Assessment

An initial assessment of potential impact, and therefore risk, of a system to product quality must be performed prior to, or in conjunction with, the preparation of a VP. The outcome of this assessment is a key factor in determining the validation activities required for that system, whereby the system will be designated as Direct, Indirect or No Impact.

* The System Impact Assessment must be accurately and thoroughly documented to ensure clarity of the decision making process. The impact assessment may be documented within the VP or as a stand-alone document.
* Similarly to the VP, the Impact Assessment must be reviewed and updated if there are changes to the system or if more information becomes available to ensure that the Impact Assessment is current.
* Direct Impact systems are further assessed to identify ‘critical’ and ‘non-critical’ components of the system.

### Supplier Assessment

Processes must be in place to ensure that systems and services from external suppliers are fit for purpose.

The approach to the assessment of suppliers must be documented. The outcome of the supplier assessment (including any required audit activities) must be reported together with details of how any supplier or system deficiencies will be managed in the VP.

## 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 system, facility or software being validated.

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 system, software or facility. It is typically required for engineering and for control systems and may be split into Hardware or Software Design Specifications (HDS or SDS). For simple systems or equipment the design requirements may be included in the URS.

## Design Review and 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.

All deliverables required as part of the Design Qualification and impacting the design decision are to be included in the VP and would typically include reference to:

* Basis of design documents – URS, FDS/HDS/SDS
* Validation Plan (or equivalent) including impact assessments / criticality assessments
* FMEA / Risk Analysis
* Requirements Traceability Matrix
* Supplier Assessments
* Design Reviews

## Commissioning and qualification protocols

Generally speaking, commissioning and qualification consists of the following distinct phases:

* Design Qualification (ref. Section 5.4)
* Commissioning (ref. Section 5.5.1)
* Installation Qualification (ref. Section 5.5.2)
* Operational Qualification (ref. Section 5.5.3)
* Performance Qualification or Process Validation (ref. Section 5.5.4)

The objective is to ensure that an appropriate risk based approach to the completion and documentation of commissioning and qualification activities is undertaken for equipment, services and facilities.

All manufacturing facilities and equipment must be commissioned in accordance with Good Engineering Practice (GEP). The level of qualification performed must be appropriate to the assessed level of risk (e.g. by system impact and component criticality assessment).

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.

Process and cleaning validation protocols describe all of the testing required to verify the manufacturing or cleaning process being validated. Therefore, IQ, OQ and PQ protocols do not apply as all of the testing is carried out in the one protocol and the results are reported in a validation report.

Therefore, the following sections typically apply only to equipment, utilities, facility and computer systems validation.

### Commissioning

Commissioning is a well-planned, documented and managed engineering approach to the start-up and handover of equipment, services and facilities to the end user, resulting in a safe and functional environment that meets established design requirements and stakeholder expectations. Commissioning is generally executed as Factory Acceptance Testing (FAT) and/or Site Acceptance Testing (SAT).

Commissioning exercises are applied to:

* equipment, services or facilities if determined to be an Indirect Impact or No Impact system
* Direct Impact systems however components identified as GMP Critical in the Device Criticality Assessment shall also undergo formal qualification. Components identified as non-critical in Direct Impact systems may be managed by commissioning under GEP
* all systems according to a documented testing rationale, utilising commissioning protocols and check sheets as appropriate to the exercise. Commissioning protocols, reports and any raw data will be approved/ reviewed by engineering personnel and by the Quality function if deemed necessary.

### Installation Qualification

Installation Qualification (IQ) is documented verification that equipment, services and facilities have been properly installed according to pre-approved protocols and acceptance criteria. The IQ may include an IQ report or the report may be written as a separate document.

The scope of the IQ includes, but is not limited to, verification of:

* Drawings
* Documentation (manuals, spares, etc.)
* Correct installation of components and recording of component details
* Hardware & software versions / configurations
* Connection of plant services
* Product contact parts / chemicals
* Maintenance and calibration routines

Phase handover from IQ to OQ must be controlled and receive approval from the Quality Manager or delegate.

### Operational Qualification

Operational Qualification (OQ) is documented verification that equipment, services and facilities have been properly tested according to pre-approved protocols and acceptance criteria and functions as intended across all specified operating ranges. The OQ typically addresses the testing of specific critical functionality.

The OQ may include an OQ report or the report may be written as a separate document.

The scope of the OQ includes, but is not limited to, verification of:

* Critical functionality (including boundary testing if applicable)
* Alarming and safety features
* QMS documentation, training, procedures

Phase handover from OQ to PQ must be controlled and receive approval from the Quality Manager or delegate.

### Performance Qualification

Performance Qualification (PQ) is a documented programme to demonstrate that an operation or operations, when carried out within defined parameters, will consistently perform its intended function to meet pre-determined acceptance criteria. The selection of critical parameters studied during this phase must be supported by the risk assessment process performed during the design phase and must be pre-established in OQ prior to commencing PQ.

PQ is a confirmatory exercise that must only be undertaken when products/processes are capable, understood and controlled e.g. critical to quality attributes (CQA) and critical process parameters (CPP) have been identified and operating limits/ranges specified. The successful completion of PQ indicates that product/materials may be commercialised.

Testing and qualification exercises must be justified in pre-approved rationale(s). The rationale(s) must be based on good scientific/technical argument and documented fact.

PQ protocols must:

* be product specific and only carried out on a defined process after development and optimisation work has been completed and documented
* demonstrate that the specified process and equipment as a combined system will meet the agreed criteria during routine operation
* sample / test sufficiently to provide evidence that a process, when used routinely, will produce product that will meet its pre-determined quality attributes
* be documented and approved prior to execution

For both process and cleaning validation, the number of batches required to undergo PQ must be pre-defined and rationalised. The number of batches studied must be sufficient to show that the critical process limits identified can be routinely met when all sources of process variation is taken into account. It may also include more frequent In-Process-Checks (IPCs), and / or release testing against a tighter specification limit.

The following applies to PQ test results:

* A Performance Qualification Report (PQR) must be prepared for each validation exercise summarising and assessing results against acceptance criteria and defining success or otherwise of the validation exercise.
* For prospective exercises, a single PQR may be prepared to capture all PQ batches as defined in the PQ Protocol, or PQRs for individual PQ batches may be prepared to facilitate batch release for concurrent validation provided this approach has received prior approval from the Quality Manager.

## 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. lab test reference, database location).

# Validation maintenance

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

## 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) made to a validated system, both planned and unplanned (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 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 equipment, process or system will be maintained under change control. All changes must be evaluated to determine the impact on product quality, ensure compliance with GMP and establish any need to revalidate the process, system or equipment affected.

## Periodic equipment re-qualification

Where regulations specify the requirement, some systems are subject to periodic requalification, e.g. sterilising autoclaves, Steam-In-Place and HVAC systems serving aseptic areas. Systems assessed and identified as requiring periodic requalification and the schedule for re-qualification are documented in the Site VMP (ref. Section 5.1).

The requalification of these systems is executed under pre-approved PQ Protocols and the results of the exercise reported in a PQR. Any deviations are recorded and investigated.

## Validation review and re-validation

Validation reviews are a periodic review of validated systems and are conducted to provide formal confirmation and justification of an ongoing validated state or identify required re-qualification or re-validation. A report is generated for each validation review with a clear statement as to the cumulative effect of change upon the validated state of the system.

The Site VMP defines:

* the validation review period for all equipment (should not exceed three years)
* the validation review schedule for all equipment
* the content of the validation review

# Control of validation batches

The control and release of validation batches must be managed to ensure that batches subject to validation are assessed to have met their validation acceptance criteria and regulatory expectations prior to commercial release.

[The restriction of validation batches to prevent premature release to market must be managed by systems within the site. Prior to batch release by QA, batches that have undergone validation must be identified and prevented from unauthorised release.]

# Documentation management

Standard operating procedures (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 as per 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 staff who are trained in use of the equipment, process or computer system should be allocated validation activities. All training must be complete, documented and approved before validation tasks are undertaken.

Staff writing validation documents will be trained in GMP, Good Documentation Practices and validation and will either be familiar with the process, equipment or computer system or 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 system/process/equipment 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 to be 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/PV 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 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:

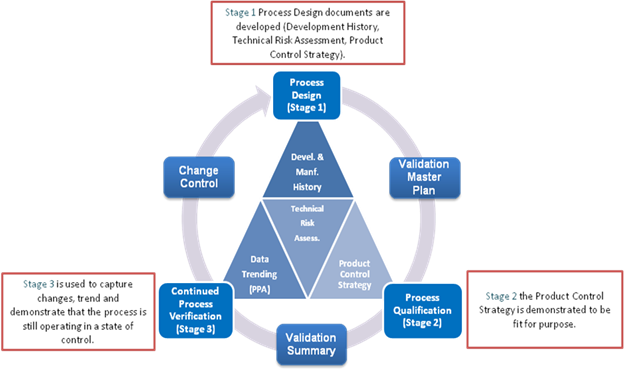
* Details of the last production batch manufactured / packed using the equipment,
* Confirmation that the batch was suitable for release and system challenges were satisfactory (e.g. Start-up tests, IPCs),
* Confirmation that the equipment was within its validation review period at the time of last batch production,
* Confirmation that equipment had been adequately maintained / calibrated up until the final use in routine production.

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 Direct Impact system being decommissioned was made according to the validated process using qualified equipment.

Appendices

# Appendix 1: Three stage validation lifecycle approach



# Appendix 2: Validation Process Flow



**Appendix 2 – Validation Process Flow (contd.)**



Definitions

Amend as required or delete.

| Term or abbreviation | Definition |
| --- | --- |
| CQA | Critical to Quality Attribute |
| CPP | Critical Process Parameter |
| CPV | Continued Process Verification |
| 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 |
| FAT | Factory Acceptance Testing |
| 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) |
| IPC | In-Process-Checks |
| 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 |
| Process Validation (PV) | The means of ensuring and providing documentary evidence that processes (within their specified design parameters) are capable of repeatedly and reliably producing a finished product of the required quality. |
| PCS | Product Control Strategy |
| SAT | Site Acceptance Testing |
| 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/NZS ISO9001:2015 – 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 |
| QP718 | Computer System Validation |
| FP710-1 | Validation Exception Report |
| FP710-2 | System Impact Assessment |

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