

# Standard Operating Procedure

## Title: Validation – Concept and Procedure

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Materials used in the Operational Qualification should be those to be used at the normal running of the process.

Compiling and Filing of the entire documentation. Approval of the results of the test program.

At the conclusion of the Operational Qualification phase, the following documentation must be available:

- SOPs for operation and cleaning.
- Training manual or appropriate documentation.

When all the Operational Qualification tests have been conducted and results are deemed to be acceptable the information is compiled into an Operational Qualification Report. The OQ Report is reviewed and the test results are evaluated to ensure that the proposed qualification program and requirements have been fulfilled. This OQ Report is then reviewed for approval by the Validation Committee.

Once approval by the Validation Committee has been given a "Provisional Approval for use by Production" (with a 6 month expiry) is applied to the equipment/system/process.

### 7.2.5. Performance Qualification (PQ)

The Performance Qualification phase consists of additional Validation tests, or the results of extended testing may be included as part of the equipment/systems Performance Qualification. All results obtained during the Performance Qualification must be recorded, even those not meeting the requirements.

#### **Confirmation testing for Production Process (Process Validation)**

Three consecutive successful production batches should be documented to demonstrate conformity to specification.

At the time commencing process validation, other related elements of validation should be in place:

- Facilities, systems, services and equipment to be used should be qualified and calibrated.
- Analytical testing methods should be validated.
- Specifications, materials and suppliers should be established.
- Trained personnel taking part in the validation work.
- The rationale for commencing Process Validation prior completion of the required elements should be formally documented and approved.

### 7.3. Validation Report

A Validation Report must be issued by the Validation Team when specified acceptance criteria given in the protocol are met. This report must address the Validation requirements stipulated in the Validation Plan and include references to the Qualification Tests conducted (both in the Operational and Performance Qualification stages), results and observations obtained from the testings and state the required revalidation program required. The report is then to be reviewed by the Validation Committee (this must be within 6 months of the original Provisional Approval for use by Production).

### 7.4. Revalidation

Based on the validation results and the type of subject a revalidation plan must be established. Revalidation is further required if the finding of the in-process and quality control results indicate the need.

The revalidation programme is to be included in the Revalidation Master Plan.