

Validation Plan

Purpose

This document represents the Validation Plan (VP) for **xxxx**

Scope

This VP covers all qualification & validation activities required for **xxxx**..

References

xxxx

Approvals

	Print Name	Signature	Approval Date
Author			
QA/RA			
Manufacturing			

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Validation Strategy

- overall strategy for validating this process or item.
- major activities, techniques, and tools that are to be used.
- prospectively or retrospectively
- discuss Risk based approaches

Installation Qualification

- State if an IQ will be performed.
- Justify if an IQ is not needed, for example by referencing existing documents

Operational Qualification

- State if an OQ will be performed.
- Discuss sampling plans
- Justify if an OQ is not needed, for example in the case that there are only non-adjustable set-points and/or no critical process parameter. If existing OQ documents will be used, reference the document

Performance Qualification

- State if a PQ will be performed.
- Discuss sampling plans
- Justify if a PQ is not needed, for example in the case of low impact changes

External Validations

- Identify any external validations to be done, i.e. at suppliers (molding, extrusion, ...) or service providers (testing, sterilization,.....)
- Clarify responsibilities and requirements for review and approvals

Validation Training

- Identify specific training that must be conducted as part of the validation activities.
- Participants may need to be trained to validation specific topics, like, but not limited to:
 - sample build protocols in order to use worst case settings
 - pre- and post validation activities like calibration or material preparation
 - defect awareness training