

Validation Package IQ OQ PQ

Assemble the qualification plan, protocols, execution records and reports for one system. Complete acceptance criteria before execution; keep actual results, signatures and stage decisions blank until recorded by authorized personnel. Copy the protocol module for each applicable stage or test group.

Complete bracketed fields with approved information. Duplicate modules and rows as needed; record the reason for any section marked not applicable.

Document [ID and revision] **Owner** [Role] **Scope** [Organization, site or product]

Effective date [Date] **Approval** [Controlled record] **Next review** [Date or trigger]

Validation plan

Plan element	System specific decision
System intended use and boundary	[System ID, components, interfaces, GxP impact and exclusions]
Strategy and applicable stages	[DQ, FAT, SAT, IQ, OQ, PQ or combined stages; approved rationale]
Risk based scope	[Method, assessment reference and critical functions]
Roles and stage gates	[Author, reviewer, executor, quality and release authority]
Governing documents	[Plan, requirements, procedures and change-control references]

Requirements and design

Requirement ID	Exact requirement and risk link	Specification and test reference
[URS ID]	[Requirement, units and criticality from approved assessment]	[FS/DS ID, DQ evidence and planned test]
[URS ID]	[Requirement]	[Specification and evidence]

Design qualification and supplier assessment

Design or supplier question	Evidence examined	Decision and open item
[Requirement or supplier capability]	[Design review, assessment or document]	[Authorized conclusion and action]

Factory and site acceptance testing

Acceptance activity	Scope and protocol	Result reference and gaps
[FAT or SAT where applicable]	[System, configuration, prerequisites and approved protocol]	[Executed report, deviations and decision]

Installation qualification

Repeatable qualification protocol

Use this module for IQ, then copy it under OQ or PQ with the stage-specific conditions. Do not split one test case across records.

Protocol setup		Complete before execution
Protocol ID objective and scope		[Stage, system/subsystem and test group]
Configuration and prerequisites		[Hardware/software versions, prior stage, approved procedures and trained roles]
Instruments and materials		[Instrument IDs, calibration status, materials and traceability]
Conditions and sampling rationale		[Ranges, worst-case conditions, sample size and approved rationale]
Recording and deviation method		[Raw-data location, evaluation method and deviation route]
Test ID and requirement	Test step	Expected result and acceptance criterion
[Test ID; URS/risk ID]	[One executable action with exact setpoint and units]	[Observable result and approved criterion]
[Test ID]	[Next action]	[Expected result and criterion]

Execution record

Test ID	Actual result and raw data	Outcome and execution record
[ID]	[Leave unexecuted until performed; record values and units]	[Pass/Fail only after evaluation; executor and date]
[ID]	[Raw-data reference and observation]	[Outcome or deviation ID]
Stage report		Executed scope deviations and decision
IQ report reference		[Executed/not executed tests, results, deviations, conclusion and authorization to proceed]

Operational qualification

Copy the protocol and execution module above. Define operating ranges and challenge conditions before execution.

OQ planning and report	Controlled record
Functions and operating limits challenged	[Test IDs, ranges, alarms, interlocks and approved criteria]
Coverage and prerequisites	[Prior-stage status, instruments and test conditions]
Executed result and conclusion	[Raw data, deviations, report and authorized next-stage decision]

Performance qualification

Copy the protocol and execution module for representative operation, process performance, cleaning or utilities as applicable.

PQ planning and report	Controlled record
Routine conditions and sampling	[Materials, personnel, runs, sampling rationale and approved criteria]
Critical parameters and attributes	[CPP/CQA IDs, limits, units and evidence]
Executed result and conclusion	[Data, variation, deviations and report; no assumed release]

Deviations and traceability

Deviation and affected test	Assessment and correction	Closure evidence and decision
[ID, observation and test ID]	[Impact, cause, action and retest rationale]	[Evidence, reviewer and status]
Requirement and risk	Test or evidence	Result and unresolved gap
[URS/risk ID]	[Protocol, test and report]	[Recorded outcome and open item]

Validation summary report

Summary question	Recorded conclusion and evidence
What was executed	[Stages, protocol versions, configurations and omitted tests with reasons]
Were acceptance criteria met	[Result summary, deviations and evidence; do not infer pass]
What remains open	[Conditions, risks, restrictions, owner and target date]
Is progression or release authorized	[Decision, authority, approval reference and operating boundary]

Maintaining the validated state

Controlled activity	Adopted rule and trigger	Evidence and responsibility
Change control	[Impact assessment, approval and requalification criteria]	[Change record and authority]
Periodic review or verification	[Frequency, inputs, method and criteria]	[Review result and actions]
Operation cleaning and maintenance	[Qualified ranges, procedure and competence]	[Logs, exceptions and review]

Glossary

Term	Meaning in this package	Source
[URS IQ OQ PQ or other term]	[Expansion and adopted meaning]	[Controlled reference]

Package completeness check

- ☐ Protocols and criteria were approved before execution and raw data is traceable.
- ☐ Actual results, deviations and decisions are recorded without prefilled outcomes.
- ☐ Traceability, open items and qualified operating limits are reviewed before release.

Review role	Date and decision	Signature or approval record
[Engineering, validation or quality authority]	[Approved or returned]	[Controlled reference and conditions]