

Pharmaceutical Validation Checklist Template

 Show only Checklist

Display Style
Default 

Planning & Scope Definition

Defining the scope, objectives, and critical aspects of the validation project.

Project Objective

Write something...

Scope Description (Inclusions & Exclusions)

Write something...



Validation Type (e.g., Prospective, Concurrent, Retrospective)

- Prospective
- Concurrent
- Retrospective

Project Start Date

Enter date...

Estimated Completion Time (in days)

Enter a number...

Critical Process Parameters (Initial Assessment)

Risk Assessment

Identifying and assessing potential risks associated with the process/equipment.

Process/Equipment Description

Write something...

Potential Hazards/Failure Modes

Write something...

Likelihood of Occurrence (1-5)

Enter a number...

Severity of Impact (1-5)

Enter a number...

Risk Score (Likelihood x Severity)

Enter a number...

Risk Level (Low, Medium, High)

- Low
- Medium
- High

Control Measures/Mitigation Strategies

Write something...

Effectiveness of Control Measures (Adequate/Inadequate)

- Adequate
- Inadequate

Design & Specification Review

Verifying that the design and specifications meet requirements and are adequately documented.

Describe the intended function of the equipment/process.

Write something...

Upload design drawings or schematics.

 Upload File

Specify critical operating parameters (e.g., temperature, pressure).

Enter a number...

Does the design meet relevant regulatory requirements (e.g., GMP, FDA)?

Yes

No

Not Applicable

Explain any deviations from standard designs and justification for these deviations.

Write something...

Date of Design Specification Review

Enter date...

Reviewer Signature

Installation Qualification (IQ)

Confirming that the equipment/system is installed correctly and according to specifications.

Equipment Name

Manufacturer

Serial Number

Installation Date

Detailed Description of Equipment and Location

Write something...

Utilities Connected (Select All That Apply)

- Electricity
- Water
- Compressed Air
- Nitrogen
- HVAC

Installation Vendor

Installation Technician Signature

Operational Qualification (OQ)

Demonstrating that the equipment/system operates within defined parameters.

Operating Temperature (Minimum)

Enter a number...

Operating Temperature (Maximum)

Enter a number...

Pressure (Minimum)

Enter a number...

Pressure (Maximum)

Enter a number...

Date of First OQ Run

Enter date...

Start Time of First OQ Run

Enter time...

Equipment Status After OQ

- Operational
- Requires Calibration
- Requires Repair

Observations During OQ Runs

Write something...

OQ Execution Signature

Performance Qualification (PQ)

Verifying that the equipment/system consistently performs as intended under actual operating conditions.

Batch Number(s) Tested

Enter a number...

Start Date of PQ Runs

Enter date...

End Date of PQ Runs

Enter date...

Number of PQ Batches/Runs Completed

Enter a number...

Summary of PQ Results and Observations

Write something...

PQ Criteria Met?

- Yes
- No
- N/A

Attachment: PQ Data Reports/Charts

 Upload File

Signature of PQ Reviewer

Documentation & Records

Ensuring complete and accurate record-keeping throughout the validation process.

Validation Protocol Reference Number

Write something...

Validation Protocol Document

 Upload File

Protocol Creation Date

Enter date...

Protocol Review Date

Enter date...

Protocol Reviewer Signature

Summary of Findings/Deviations

Write something...

Report Approval Signature

Number of Pages in Report

Enter a number...

Change Control

Establishing procedures for managing changes to the validated system.

Date of Change Request

Enter date...

Description of Change

Write something...

Justification for Change

Write something...

Impact Assessment (High/Medium/Low)

High

Medium

Low

Estimated Implementation Time (Days)

Enter a number...

Affected Systems/Equipment

- Equipment A
- Software B
- Process C
- Documentation D

Requestor Signature

Approval Date

Enter date...

Approval Signature

Review & Approval

Formal review and approval of validation protocols and reports by qualified personnel.

Review Date

Enter date...

Reviewer Name

Write something...

Review Comments

Write something...

Approval Status

- Approved
- Rejected
- Conditional Approval

Approval Reason (if rejected/conditional)

Write something...

Approver Signature

Approval Date

Enter date...