

Pharmaceutical Computer Systems Validation (CSV) Checklist 2026

Pre-Validation Planning & User Requirements

Verification of User Requirements Specifications (URS), validation strategy documentation, and definition of the system scope and intended use.

System Name and Identifier

Project Scope Overview

Validation Plan Approval Date

Criticality Level

- ☐ Low
- ☐ Medium
- ☐ High
- ☐ Critical

Applicable Regulatory Standards

- ☐ 21 CFR Part 11
- ☐ EU Annex 11
- ☐ GxP
- ☐ ALCOA+

Approved User Requirements Specification (URS)

 [Upload File](#)

Project Manager Approval

Risk Assessment & Impact Analysis

Evaluation of GxP impact, data integrity risks, and complexity assessment to determine the required level of testing (IQ/OQ/PQ).

GxP Impact Level

- ☐ High Impact
- ☐ Medium Impact
- ☐ Low Impact

Risk Description

Write something...

Risk Severity Score

- ☐ 1 - Negligible
- ☐ 2 - Minor
- ☐ 3 - Major
- ☐ 4 - Critical

Identified Risk Areas

- ☐ Data Integrity
- ☐ Patient Safety
- ☐ Product Quality
- ☐ Regulatory Compliance

Mitigation Strategy

Write something...

Risk Assessment Document

 Upload File

Assessor Signature

Installation Qualification (IQ)

Verification of hardware components, software installation, network connectivity, and ensuring the environment meets predefined specifications.

Hardware Serial Number/ID

Installation Completion Date

Hardware Components Verified

- ☐ Server/Workstation
- ☐ Network Interface Card
- ☐ Peripherals (Printers/Scanners)
- ☐ Storage Units

Software Version Verified

- ☐ Version Match with URS
- ☐ New Version/Upgrade

Installation Log/Evidence

 Upload File

IQ Performed By

Operational Qualification (OQ)

Testing of functional requirements, security access controls, error handling, and system boundary testing under worst-case scenarios.

Functional Test Areas Verified

- ☐ User Access & Permissions
- ☐ Audit Trail Functionality
- ☐ Data Entry & Retrieval
- ☐ Security & Authentication
- ☐ System Alert & Notification
- ☐ Data Backup & Recovery

Test Case ID Reference

Write something...

Test Execution Status

- ☐ Pass
- ☐ Fail
- ☐ In Progress
- ☐ N/A

Description of Observed Deviations

Write something...

Execution Date

Enter date...

Tester Signature

Supporting Evidence/Screenshots

 Upload File

Performance Qualification (PQ)

Verification that the system performs consistently under real-world operating conditions and meets end-to-end business process requirements.

Test Case Reference ID

Write something...

Observed Performance Results

Write something...

Test Outcome

☐ Pass

☐ Fail

☐

☐ N/A

Date of Execution

Enter date...

Tester Signature

Supporting Raw Data/Evidence

 Upload File

Data Integrity & Security Controls

Assessment of audit trails, user access levels, electronic signatures (21 CFR Part 11), data backup/recovery, and data encryption protocols.

Compliance Features Verified

- ☐ 21 CFR Part 11 Compliance
- ☐ Audit Trail Functionality
- ☐ User Access Management
- ☐ Data Encryption & Security
- ☐ Electronic Signatures
- ☐ Data Backup & Disaster Recovery

Audit Trail Configuration Details

Write something...

Description of Security Incident Management Procedure

Write something...

Last Security Audit Date

Enter date...

Evidence of Access Control Logs

 Upload File

Data Integrity Officer Verification

Traceability Matrix (TM) Review

Ensuring a complete link between User Requirements, Functional Specifications, and the actual test cases executed.

Traceability Status

- ☐ Complete
- ☐ In Progress
- ☐ Pending Updates
- ☐ Incomplete - Critical Gaps Found

Requirement ID Reference

Write something...

Verified Traceability Components

- ☐ URS to Functional Specs
- ☐ Functional Specs to Design Specs
- ☐ Design Specs to Test Scripts
- ☐ Test Scripts to Test Results

Traceability Review Date

Traceability Gaps or Observations

Updated Traceability Matrix Document

 Upload File

Reviewer Authorization

Testing Documentation & Deviation Management

Review of test scripts, recording of all testing results, and formal management of any deviations or non-conformances encountered during validation.

Date of Deviation Discovery

Deviation Severity Level

- ☐ Critical
- ☐ Major
- ☐ Minor

Detailed Deviation Description

Write something...

Root Cause Analysis (RCA) Summary

Write something...

Corrective Actions Implemented

- ☐ Retesting Performed
- ☐ Software Patch Applied
- ☐ Personnel Retraining
- ☐ Document Update

Supporting Evidence/Evidence Logs

 Upload File

Quality Assurance Approval Signature

System Release & Final Validation Summary Report

Final review of the Validation Summary Report (VSR) and formal authorization for the system to enter live production use.

Report Completion Date

Validation Summary Report Reference ID

Final Validation Status

- ☐ Approved
- ☐ Approved with Deviations
- ☐ Rejected

Approved Deliverables Included

- ☐ IQ Report
- ☐ OQ Report
- ☐ PQ Report
- ☐ Traceability Matrix
- ☐ Deviation Log

Summary of Residual Risks

Write something...

Upload Signed Validation Summary Report

 Upload File

Quality Assurance Approval Signature

Post-Implementation & Periodic Review

Establishing maintenance schedules, change control procedures, and a plan for periodic re-validation and system monitoring.

Next Scheduled Periodic Review Date

Enter date...

Review Frequency

- ☐ Quarterly
- ☐ Bi-Annually
- ☐ Annually
- ☐ Every 2 Years

Review Scope Areas

- ☐ Audit Trail Review
- ☐ User Access Audit
- ☐ Backup/Restore Success Rate
- ☐ System Incident Log Review
- ☐ Hardware/Software Patch Levels

Summary of Findings & Continuous Improvement Notes

Write something...

Upload Periodic Review Report (PRR)

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Quality Assurance Approval

< Previous

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✓ Finish

 **Generate Sample Report**