



Computerised System Validation (CSV) and CSA Training: Risk-Based GxP Software Assurance



Computerised System Validation (CSV) and CSA Training: Risk-Based GxP Software Assurance

Introduction:

Computerised System Validation CSV and CSA training on risk-based GxP software assurance is a 5-day course for quality assurance, IT and validation engineering staff in pharmaceutical, medical device and laboratory organisations, ending with a Computerised System Validation Plan and Risk-Based Test Strategy for a case LIMS and SaaS rollout. Organisations lose time and inspection credibility when every LIMS, MES, ERP or chromatography data system screen gets heavy scripted testing while high-risk functions and cloud updates go unexamined. Nominees already specify, test or release GxP software and analyse case documents. CoreConcept Training Center delivers this computerised system validation course.

Course Objectives:

- Classify GxP computerised systems by intended use, GAMP 5 software category and impact on patient safety, product quality and record trustworthiness
- Assess software suppliers and SaaS providers through questionnaires, audits and reuse of vendor test evidence
- Write user requirements and functional specifications with a traceability matrix that links each requirement to its assurance activity
- Select scripted IQ, OQ and PQ testing or CSA unscripted, ad hoc and exploratory testing according to function risk
- Specify electronic record and electronic signature controls, change control, periodic review and system retirement steps for the operational phase
- Produce a Computerised System Validation Plan and Risk-Based Test Strategy for a LIMS and SaaS rollout

Target Audience:

- Quality assurance staff responsible for approving validation plans, test evidence and validation summary reports
 - Validation engineering staff responsible for writing requirements, risk assessments and test protocols for GxP software
 - IT and infrastructure staff responsible for hosting, configuring, patching and backing up regulated applications
 - Laboratory informatics staff responsible for LIMS, chromatography data systems and instrument software
 - Manufacturing systems staff responsible for MES, batch execution and ERP quality modules
 - System owners and business process owners responsible for the intended use of a computerised system
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Course Outline:

Day 1: CSV Foundations, Intended Use and System Inventory

- Computerised System Definition Covering Software, Hardware, People and Process
- GxP Impact Assessment of LIMS, MES, ERP and CDS
- Validation Lifecycle From Concept Through Operation to Retirement
- System Owner, Process Owner and Quality Unit Roles
- Computerised System Inventory and Validation Status Gap Review

Day 2: GAMP 5 Lifecycle Model, Software Categories and Supplier Assessment

- GAMP 5 Software Categories 1, 3, 4 and 5
- GAMP 5 Specification and Verification Model for Configured Products
- Supplier Questionnaire and Postal Audit for Software Vendors
- SaaS and Cloud Provider Qualification and Service Level Agreements
- Leveraging Supplier Documentation and Vendor Test Evidence

Day 3: Requirements, Risk Assessment and Assurance Testing in Practice

- User Requirements Specification Writing With Testable Acceptance Criteria
- Functional and Configuration Specification for a Configured LIMS
- Function-Level Risk Assessment Using Severity, Probability and Detectability
- Scripted IQ, OQ and PQ Protocol Design and Execution
- CSA Critical Thinking With Unscripted and Exploratory Testing

Day 4: Electronic Record Controls, Operational Phase and Problem Cases

- Part 11 and Annex 11 Electronic Signature Control Mapping
- Access Management, Backup, Restore and Disaster Recovery Testing
- Change Control Impact Assessment for Patches and SaaS Releases
- Periodic Review Checklist and Revalidation Trigger Decisions
- System Retirement, Data Migration and Archive Verification

Day 5: Case Study on a LIMS and SaaS Validation Plan

- Case Organisation Brief for a Multi-Site LIMS Rollout
 - Case System Categorisation and Supplier Assessment Findings
 - Case Requirement Risk Ranking and Traceability Matrix Build
 - Case Test Strategy Balancing Scripted and Unscripted Assurance
 - Computerised System Validation Plan and Test Strategy Completion
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Skills You Will Gain:

- GxP Impact Assessment
- Software Categorisation
- Supplier and SaaS Qualification
- Requirements Traceability
- Function Risk Ranking
- Assurance Test Design
- Electronic Signature Control Review
- Validated State Maintenance

Why Attend This Course:

- Deliver a Computerised System Validation Plan and Risk-Based Test Strategy to the quality head and system owner for approval before the next rollout
- Decide which software functions need scripted protocols and which can rely on unscripted testing or vendor evidence
- Avoid duplicated vendor testing, late inspection findings and stalled SaaS upgrades caused by unclear validation scope
- Coach business process owners, testers and IT administrators on requirement writing, test evidence and change control records

Conclusion:

Back at work, the participant gives the Computerised System Validation Plan and Risk-Based Test Strategy to the quality head, the system owner and the IT service lead. They use it to agree validation scope, assign testing effort by function risk and accept supplier or SaaS evidence before a LIMS, MES or ERP release goes live. After the first release or periodic review under the plan, the unit should check test effort against defects found, change requests raised and review findings, then adjust the risk criteria.

Frequently Asked Questions FAQ:

What should participants know before a computerised system validation CSV and CSA course?

Participants should already work with GxP software as testers, quality reviewers, IT administrators or system owners. Familiarity with standard operating procedures and change control helps. Bringing an anonymised requirement, risk assessment or test script makes the case work closer to their own systems.

How does computerised system validation CSV and CSA differ from a data integrity or equipment qualification course?

This course concentrates on the software lifecycle: categorisation, supplier assessment, requirements, risk-based testing and the operational phase. Data integrity courses focus on record practice and audit trail review, while equipment qualification courses cover physical plant and utilities.

Why is CSA presented alongside computerised system validation CSV?

CSA keeps the CSV goal of fitness for intended use but directs effort to high-risk functions. Lower-risk features can be covered by unscripted or exploratory testing and supplier evidence, reducing paperwork without weakening assurance where patients or product quality could be affected.

What do participants take back from the computerised system validation CSV and CSA course?

Participants take back a Computerised System Validation Plan and Risk-Based Test Strategy for a case LIMS and SaaS rollout, with categorisation, supplier findings, a traceability matrix and a test mix, ready to adapt to their own systems.
