Validation of Computer System (CSV) and CFR Part 11 Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

This intensive course outlines the critical knowledge and skills required to achieve and maintain regulatory compliance in the modern life sciences industry. The curriculum focuses on the essential link between Computer System Validation (CSV) and the foundational FDA regulation, 21 CFR Part 11 (Electronic Records and Electronic Signatures). Participants will master the latest risk-based approaches like the FDA's new Computer Software Assurance (CSA) guidance, moving beyond outdated, documentation-heavy validation models. The core of this training is ensuring Data Integrity (ALCOA+ principles) across GxP-regulated computerized systems, including cloud-hosted platforms, laboratory instruments, and manufacturing controls.

The evolving regulatory landscape demands that professionals not only understand the "what" but the "how" of defensible validation. Validation of Computer System (CSV) and CFR Part 11 Training Course provides the strategic framework for implementing streamlined, lifecycle-based validation processes, thereby drastically reducing validation costs and time-to-market. By integrating the technical controls of Part 11 (e.g., secure audit trails, access controls, electronic signatures) with pragmatic CSV methodologies (GAMP 5, V-Model), attendees will gain a competitive advantage in mitigating FDA Form 483 and Warning Letter risks and successfully preparing for and defending regulatory inspections.

Programme Curriculum

Validation of Computer System (CSV) and CFR Part 11 Training Course

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Course Duration

10 days

Course Objectives

Upon completion, attendees will be able to:

1. Apply the risk-based approach to validation, specifically utilizing the Computer Software Assurance (CSA) framework.
2. Interpret the Scope and Application of 21 CFR Part 11 requirements for electronic records and electronic signatures.
3. Design and implement a robust Data Integrity (ALCOA+) program for all GxP systems.
4. Develop a compliant Validation Master Plan (VMP) and execute the full CSV Lifecycle (IQ, OQ, PQ).
5. Establish effective User Access Controls and System Security measures mandated by Part 11.
6. Critically evaluate system requirements to write defensible User Requirement Specifications (URS) and Functional Specifications (FS).
7. Manage change control and configuration management to keep systems in a perpetually validated state.
8. Validate Cloud-Hosted Systems (SaaS) and manage vendor qualification for third-party software.
9. Implement and review secure audit trails to ensure traceability of all record creation and modification.
10. Ensure electronic signatures are legally binding, secure, and uniquely linked to records.
11. Understand and apply the principles of EU GMP Annex 11 alongside Part 11 for global compliance.
12. Prepare for and successfully defend system validation during FDA inspections and regulatory audits.
13. Integrate emerging technologies like AI/ML and Robotic Process Automation (RPA) into the GxP validation scope.

Target Audience

1. Validation/CSV Engineers and Specialists
2. Quality Assurance (QA) & Compliance Professionals
3. IT/IS/Informatics Personnel (Supporting GxP Systems)
4. R&D, Clinical, and Laboratory Managers
5. Audit & Inspection Readiness Teams
6. Data Governance and Data Integrity Owners
7. Automation, Manufacturing, and Process Engineers

8. Project Managers (Implementing new GxP Systems)

Course Modules

Module 1: Regulatory Foundations and CSV Fundamentals

- Defining CSV
- Overview of the V-Model and the System Development Life Cycle (SDLC).
- GAMP 5 structure.
- Case Study Focus: Failure to Validate LIMS. A firm receives a 483 for using an unvalidated Laboratory Information Management System (LIMS), leading to questions about the reliability of QC data.
- Validation Master Plan (VMP) and Traceability Matrix.

Module 2: The Core of 21 CFR Part 11

- History, Intent, and current FDA Enforcement Policy.
- Technical controls and Procedural controls.
- Defining Electronic Records (ER) and Electronic Signatures (ES) under the regulation.
- Case Study Focus: Electronic Batch Record (EBR) Non-Compliance. An inspection cites a firm for electronic signatures not being permanently bound to the associated EBR data.
- Focus on Electronic Signature Components.

Module 3: Data Integrity: The ALCOA+ Principles

- Detailed breakdown of ALCOA+ principles
- The role of Data Governance in maintaining data integrity across the enterprise.
- Identifying and remediating common data integrity gaps
- Case Study Focus: Audit Trail Manipulation. A manufacturing system's time-stamped log is found to be editable, compromising the Originality and Contemporaneousness of data.
- Data Integrity by Design.

Module 4: Risk-Based Validation & Computer Software Assurance (CSA)

- Transitioning from CSV to CSA.
- Risk Ranking systems.
- Applying Unscripted Testing and Exploratory Testing for low-risk systems under CSA.
- Case Study Focus: Over-Validation Cost Overrun. A project is delayed and over budget due to writing and executing thousands of test scripts for a simple off-the-shelf system (OTS).
- The concept of Criticality Assessment and its impact on the validation effort.

Module 5: Requirements Management (URS, FS, DS)

- Writing clear, testable, and unambiguous User Requirement Specifications (URS).
- Translating URS into Functional Specifications (FS) and Design Specifications
- The importance of Requirements Traceability Matrix (RTM) for audit defense.
- Case Study Focus: Failed Requirement Traceability. During an OQ, a critical system function fails, but the RTM cannot trace the defect back to the original URS/FS, indicating poor planning.
- Best practices for document control and specification change management.

Module 6: Qualification Phase I: Installation Qualification (IQ)

- Verifying proper installation and connection to the infrastructure.

- Hardware setup, software installation, and configuration verification.
- Verifying and documenting the Vendor's Installation Procedures.
- Case Study Focus: Improper Installation. An investigator finds that the software version installed does not match the validated version on record, leading to a system failure.
- Importance of System Inventory and Configuration Management documentation.

Module 7: Qualification Phase II: Operational Qualification (OQ)

- Verifying system functionality as designed across its operating range.
- Developing and executing test scripts based on Functional Risk Assessment.
- Testing key Part 11 controls.
- Case Study Focus: Security Control Failure. The OQ fails to test the password aging and lockout features, which are later found to be non-compliant with Part 11 requirements.
- Requirement for Challenge Tests

Module 8: Qualification Phase III: Performance Qualification (PQ)

- Verifying the system performs consistently under real-world conditions
- Running end-to-end process tests and verifying integration points.
- Involving End-Users in the final testing phase.
- Case Study Focus: Process Integration Failure. A validated ERP system fails to properly transmit batch release data to a separate quality management system (QMS), halting product release.
- Final review and approval

Module 9: Electronic Signatures: Compliance and Controls

- Detailed review of 21 CFR 11.100 and 11.200 rules for electronic and digital signatures.
- Two-factor authentication and unique user identification.
- Ensuring signer acknowledgement and signature meaning documentation.
- Case Study Focus: Shared Login Citation. An FDA inspector issues a 483 for shared login credentials in a production system, directly violating the unique user identification rule of Part 11.
- Managing Digital Certificates and security of signature-generating components.

Module 10: Audit Trails, Access Control, and System Security

- Defining a Secure, Computer-Generated, Time-Stamped Audit Trail (SCTSAT).
- What to look for and the frequency of review
- Implementing Role-Based Access Control (RBAC) and user privilege management.
- Case Study Focus: Inadequate Audit Trail. A laboratory system's audit trail only records who logged in, not who deleted a sample result, leading to a data integrity violation.
- Validation of System Backup and Disaster Recovery processes.

Module 11: Cloud Computing (SaaS, PaaS, IaaS) Validation

- Understanding the shared responsibility model in the cloud GxP environment.
- Vendor Assessment and Qualification for Cloud Service Providers (CSPs).
- Validation requirements for Software-as-a-Service (SaaS) and configurable systems.
- Case Study Focus: Cloud Vendor Failure. A firm mistakenly relies on a cloud vendor's "Part 11 certified" claim without performing their own audit of data integrity controls.
- Using SOC 1/2 Reports and vendor validation deliverables as part of the overall compliance package.

Module 12: Change Control and System Maintenance

- Defining a robust Change Management System for GxP computerized systems.
- Performing Impact Analysis to determine the need for re-validation
- Categorizing changes and establishing re-validation triggers.
- Case Study Focus: Unvalidated Patch/Upgrade. An IT team applies a system security patch without proper change control, inadvertently breaking a critical compliance feature, resulting in an FDA citation.
- Periodic Review and Retirement/Decommissioning of Computer Systems.

Module 13: GxP Systems Validation in Practice

- Validation for specific systems.
- Validation of Automated Manufacturing Systems
- Spreadsheet Validation
- Case Study Focus: Spreadsheet Error Leading to Recall. A Quality Control (QC) decision is based on a calculation from an unvalidated spreadsheet with a faulty formula, leading to a product recall.
- Special considerations for Off-the-Shelf (OTS) and COTS software.

Module 14: EU GMP Annex 11 and Global Compliance

- Harmonization of Part 11 and Annex 11.
- Focus on Annex 11 requirements.
- Validating systems for global deployment and international regulatory submission.
- Case Study Focus: Global Audit Finding. A European audit (EMA) cites a facility for failing to implement electronic data archiving procedures compliant with Annex 11.
- Regulatory trends from international bodies (ICH, WHO) on computerized systems.

Module 15: Regulatory Inspection Readiness and Defense

- Preparing the Validation Master File (VMF) and ensuring documentation integrity.
- Protocols for preparing SMEs and IT staff for a regulatory audit.
- Strategies for responding to FDA Form 483s and Warning Letters related to CSV/Part 11.
- Case Study Focus: Inspection Day Data Access Failure. The company cannot retrieve the complete and original audit trail data during an inspection, resulting in a refusal to receive observation.
- Mock Audits and Corrective and Preventive Actions (CAPA) planning.

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org **or call** +254769199797

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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