Computer System Validation for Cloud and COTS Applications

2 Day Instructor led Training Course

Who Should Attend

- Information Technology Analysts
- Information Technology Developers and Testers
- Software Quality Assurance Professionals
- QC/QA Managers and Analysts
- Analytical Chemists
- Compliance and Audit Managers
- Laboratory Managers
- Automation Analysts
- Manufacturing Specialists and Managers
- Supply Chain Specialists and Managers
- Regulatory Affairs Specialists
- Regulatory Submissions Specialists
- Risk Management Professionals
- Clinical Data Analysts
- Clinical Data Managers
- Clinical Trial Sponsors
- Computer System Validation Specialists
- GMP Training Specialists
- Business Stakeholders/Subject Matter Experts
- Business System/Application Testers
- Vendors responsible for software development, testing and maintenance
- Vendors and consultants working in the life sciences industry who are involved in computer system implementation, validation and compliance

Advancements in technology have forced organizations to rethink business models. Once controlled and orderly, these organizations are now more chaotic and complex, serving patients and customers that are better informed and with higher expectations than ever before. Work practices and tools must change to meet these challenges.
The approach to developing software, performing validation and maintaining a system in a validated state through its entire life cycle should be carefully considered in order to meet changing needs. This webinar will include a comparison of the agile and waterfall methodologies, along with the pros and cons of each. There may not be one size that fits all, and so it is important to understand what needs to be considered when making such a determination.

Why Should You Attend

The attendee will learn about FDA's approach to modernizing technology, and how that will benefit both the Agency and industry. We will discuss ways to modernize the System Development Life Cycle (SDLC) approach to Computer System Validation (CSV) by using automated testing tools that will result in a continuous validation of software products. This approach is amenable to the agile software development methodology, which can be adapted for use in validation. We'll discuss the pros and cons of each approach, and industry best practices for success.

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AGENDA

Day 1:

Module 1: CSV Methods and Models

- GxP Systems
- Computer System Validation (CSV)
- Common SDLC Methodologies
- GAMP®5 "V" Model
- Computer System Validation (CSV) vs. Computer Software Assurance (CSA)
- Critical Thinking
- Waterfall vs. Agile Methodology

Module 2: Software and Services

- Computer Off-the-Shelf (COTS) Software
- Cloud Systems
- Software as a Service (SaaS)
- Platform as a Service (PaaS) & Infrastructure as a Service (IaaS)
- Single Sign On (SSO)
- Medical Devices using Software.
- Software-as-a-Medical Device (SaaMD)
- Mobile Devices
- Spreadsheet Validation

Module 3: CSV Planning

- Validation Plan
- Rationale for Validation Testing
- GAMP®5 System Categorization
- Risk Assessment and Mitigation

Module 4: System Requirements and Design

- Requirements Development
- User Requirements Specification (URS)
- Functional Requirements Specification (FRS)
- System Design/Configuration Management Specification (SDS/CMS)

Module 5: IQ, OQ, PQ Test Planning & Execution

- Validation Protocols - IQ, OQ, PQ
- Validation Test Execution
- Validation Test Summary Report

Module 6: Test and Validation Reports

- Requirements Traceability Matrix (RTM)
- Validation Summary Report
- System Acceptance and Release Notification
- Day 1 Q&A Session

Day 2:

Module 7: CSV Operations and Maintenance

- Maintaining a System in a Validated State
- Disaster Recovery Planning
- Business Continuity Planning
- Incident Reporting, Investigation, and

Module 8: CSV Supporting Components

- Good Documentation Practices (GDPs)
- Training
- Organizational Change Management (OCM)
- Validation Policies and Procedures

Module 9: Managing FDA-Regulated Data

- 21 CFR Part 11 Guidance
- Electronic Records/Signatures (ER/ES) Requirements
- Data Integrity: ALCOA+ Principles
- Data Life Cycle Approach
- Data Governance
- Data Privacy: HIPAA, GDPRs, et al

Module 10: Vendor Audit

- Audit Preparation
- Audit Execution
- Post-Audit
- Vendor Contracts and Service Level Agreements (SLAs)

Module 11: FDA Trends

- Regulatory Influences
- Regulatory Trends
- Current Compliance and Enforcement Trends

Module 12: Inspection Preparation

- FDA Inspection Readiness
- Industry Best Practices

Day 2 Q&A Session

Module 13: CSV Exercises

- Exercise 1: CSV
- Exercise 2: Validation Plan (VMP) Writing
- Exercise 3: Risk Assessment
- Exercise 4: FDA Requirements for ER/ES
- Exercise 5: Interviews and URS/FRS Writing.....

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FACULTY CAROLYN TROIANO

35 YEARS OF EXPERIENCE IN COMPUTER SYSTEM VALIDATION AND COMPLIANCE

Our trainer is a Award winning FDA Compliance Speaker for Validation, 21 CFR Part 11 (Electronic Records/Signatures) and Data Integrity. Her experience includes computer system validation and compliance in the pharmaceutical, medical device, tobacco and other FDA-regulated industries. She is currently an independent consultant, advising companies on computer system validation and large-scale IT system implementation projects.

Our trainer successes include building and managing teams and business units at multiple “greenfield” sites in the pharmaceutical, biotechnology and IT consulting industries, as well as in the public sector. I have weathered numerous layoffs, mergers and acquisitions, and demonstrated my very strong leadership skills in helping staff get through difficult times.

REGISTRATION FORM

Name _____

Email _____

Position_____ Phone _____ Mobile _____

Terms And Condition

- Registration shall be reconfirmed only once payment has been made prior to the course.
- Cancellation of participant/s shall be submitted in writing to WCS ten days (10 days) before the course. There is a 50% liability on all bookings once made.
- WCS reserves the right to make alterations to the conference/executive briefing content, timing, speakers without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of WCS. If such a situation arises, we will refund your registration fee or we will try to reschedule the event

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