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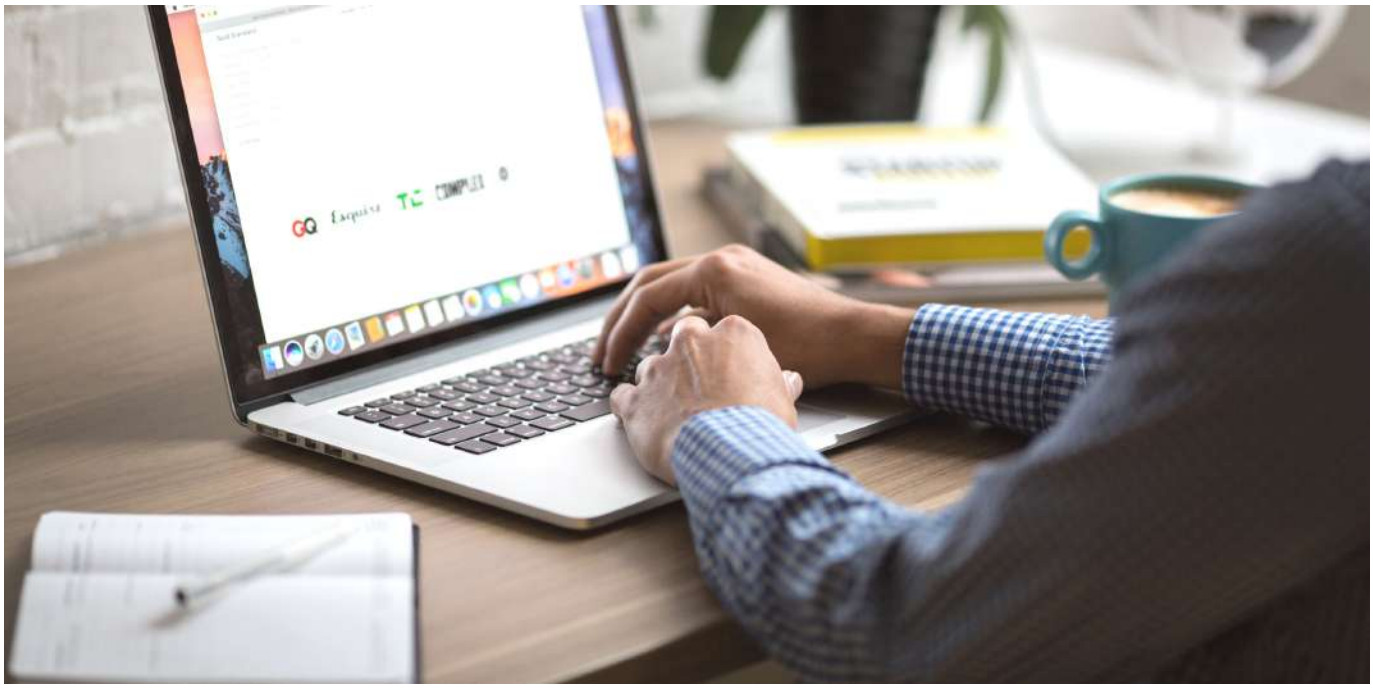
COMPUTER SYSTEM VALIDATION (CSV)



December 13-15, 2021

12:30 PM -05:00 PM EDT | 09:30 AM - 02:00 PM PDT

3-Day Seminar 12 hrs plus Training

THIS SESSION WILL BE HELD VIA FACULTY VIDEO CONFERENCE OVER THREE SUCCESSIVE DAYS WITH BOTH AUDIO AND PRESENTATION.

LEARNING OBJECTIVES

- Understanding of how to comply with key FDA and international CSV regulations and guidance, such as 21 CFR Part 11 and Annex 11
- ·The purpose of each validation deliverable and hands-on practice creating each deliverable, including the Validation Plan, Requirements Specification, Test Plan, Validation Tests (IQ, OQ, PQ), Trace Matrix, Test Summary, and Validation Report
- Comprehension of risk-based validation techniques and how to leverage these techniques to create efficient yet compliant validation approaches
- Appropriate validation strategies for many types of applications, including Cloud/SaaS, COTS, spreadsheets, and custom developed systems
- Awareness of best-practices and inspector expectations for computer system validation and software quality assurance (SQA) programs

Computer System Validation Professional Certificate Course

This course is designed to completely immerse you in the principles, methods, and best practices of Computer System Validation (CSV). You will learn about the regulations that impact your systems and gain hands-on practice writing validation documents. You will leave ready to lead efficient, effective, inspection–ready validation projects, whether you choose to follow a traditional waterfall or agile methodology.
Boot camp is tough and challenging. It is a three-day complete immersion in the validation process, including industry best practices and more recent advances in technology.
Participants will complete hands-on validation activities through instruction, exercises, and case scenarios.

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

AGENDA

AGENDA - Day 1

Module 1: Computer System Validation (CSV) Regulations 12:30 PM EDT

- FDA Regulations and Guidance
- Other Regulations and Guidance (EMA, ICH, EU, MHRA, PIC/S)
- Exercise: Exploring the Regulations using the fda.gov website

Module 2: Computer System Validation Method and Models 1:30 PM EDT

- Validation, verification, and qualification
- Common SDLCs
- GAMP 5 "V" Model
- COTS, Cloud, SaaS, PaaS, IaaS
- Spreadsheet Validation

Break 02:45 PM EDT 15 mins

Module 3: 21 CFR Part 11 - 03:00 PM EDT

- 21 CFR Part 11 Guidance
- Electronic records/signatures requirements
- Exercise: FDA Guidance for ER/ES

Data Integrity and Governance - 04:00 PM EDT

Session End Time : 05:00 PM EDT

FACULTY CAROLYN TROIANO

Award winning FDA Compliance Speaker for Validation, 21 CFR Part 11 (Electronic Records/Signatures) and Data Integrity. My experience includes **34+ years in IT/ Business, Marketing & Compliance** leadership and management roles at a variety of Fortune 100 companies, across multiple industries.

AGENDA – DAY 2

Module 4: Validation Planning - 12:30 PM EDT

- Validation Strategy Document
- Validation Strategy Components
- Rationale for Validation Testing...

Module 5: Risk-Based Validation - 02:15 PM EDT

- Risk assessment
- Risk mitigation
- Exercise: Validation Plan writing

Break - 03:00 PM EDT

Module 6: Requirements - 03:15 PM EDT

- Requirements development
- User Requirements Specification (URS)
- Functional Requirements Specification (FRS)

Module 7: System Design and Development - 03:40 PM EDT

- System Design Configuration (SDS)
- Configuration Management Specification (CMS)

Module 8: IQ, OQ, PQ Protocols and Execution - 04:00 PM EDT

- Validation testing process
- IQ purpose and contents
- OQ purpose and contents...

Module 9: Validation Testing Plan

- Principles of validation testing
- Testing techniques
- Testing Plan purpose and contents...

Module 10: IQ, OQ, PQ Protocols

- Protocol structure and contents
- Objective evidence
- Test writing best practices
- Test structure best practices...

Module 11: Test Execution

- Test execution best practices
- Validation failure documentation
- Exercise: Validation test execution

Session End Time : 05:00 PM EDT

AGENDA – DAY 3

Module 12: Requirements Traceability Matrix (RTM) 12:30 PM EDT

- Trace Matrix purpose and contents
- Exercise: Trace Matrix writing

Module 13: Test and Validation Reports - 12:45 PM EDT

- Test Summary purpose and contents
- Validation Report purpose and contents
- Exercise: Validation Summary Report writing

Module 14: Change Management 01:00 PM EDT

- Maintaining validation status
- Change control processes
- Security and Access
- Audit Trail Review
- Incidence Reporting
- Periodic System Review

Module 15: System Retirement 02:00 PM EDT

- Record retention
- Retirement challenges

Break at 02:30 PM EDT 15 mins

Module 16: FDA Warnings Letters 02:45 PM EDT

- Current Trends in Compliance and Enforcement
- Case Study: FDA enforcement
- Exercise: Be the Consultant

Module 17: Q/A Session & CSV Exam 04:00 PM EDT

- Activity: Exam Preparation
- Final Exam
- Q/A Session with the Course Instructor

Session End Time : 05:00 PM EDT

COMPUTER SYSTEM VALIDATION (CSV)
3 DAY VIRTUAL SEMINAR

Registration

Early Bird
One Dial-in One Attendee
Live: $1295

Group-Max. 5 Attendees -
Live + 12 month access :
$3995

Registration Cost Includes

- Checklist of documents and the direction for how to create
- Course binder
- Many exercises on Validation Plan, the Requirements Traceability Matrix, and the Validation Summary Report.
- Training Certificate

Please bring a laptop to boot camp. You will need internet access, spreadsheet and word processing applications and a PDF reader.

Register online at www.worldcompliianceseminars.com

or by calling our offi ce : 844-267-7299