COMPUTER SYSTEM VALIDATION FOR CLOUD AND COTS APPLICATIONS

Online Training

A seminar designed to ensure that you know what to validate, how to validate, and when to leverage vendor-supplied documentation in your validation. You will also learn the necessity and power of vendor assessments and risk-based validation.

Our Instructors

Rodrigo Perez

Rodrigo brings +35 years of experience in validation, including computer system validation, process, equipment, and others across the regulated life sciences industry. He teaches risk-based processes to not only save time and effort, but to comply with both US and international regulations.

John Gow

John has been actively working in the pharmaceutical industry for +30 years across the UK, Europe, and US. He specializes in Data Integrity and Computer System Validation and brings a wide range of experience to help students grow their validation skills and get inspection-ready.

Learning Objectives

- The many implementation models for purchased systems, e.g., COTS, Cloud, SaaS, PaaS, IaaS, as well as the appropriate validation approach for each model

- The required contents of all validation deliverables, including the Validation Plan, Requirements Specifications, Validation Tests (IQ, OQ, PQ), Trace Matrices, Test Summaries, and Validation Reports

- The importance of software vendor assessments, the methods of vendor assessment, and how these assessments impact your validation approach

- What it really takes to be 21 CFR Part 11 and Annex 11 compliant

- How to implement risk-based computer system validation practices

Course Description

Most companies today are buying, rather than building, the computer systems that they use in their GxP regulated activities. However, for pharmaceutical, biotech, medical device, and similar companies, computer system validation (CSV) is still required. But CSV responsibilities and approaches have changed.

Whether your solution is cloud-based, SaaS, COTS (commercial-off-the-shelf), or OOTB (out-of-the-box), this seminar has been designed to ensure that you leave knowing what to validate, how to validate, and when to leverage vendor-supplied documentation in your validation. You will also learn the necessity and power of vendor assessments and risk-based validation.

This computer system validation seminar incorporates FDA, ICH, and Eudralex expectations for risk-based computer system validation, and aligns with industry-wide standards, such as those defined by GAMP and PIC/S.

AGENDA

Module 1: Computer System Validation (CSV) Regulations
- CSV Purpose and Benefits
- Validation definition
- Which systems require validation
- Global CSV regulations and guidelines, e.g., FDA, ICH, EudraLex, PIC/S, WHO
- Specific COTS, Cloud, and SaaS requirements
- FDA Predicate Rules

Module 2: FDA 21 CFR Part 11
- Which systems require Part 11 compliance
- Electronic Records Requirements
- Electronic Signatures Requirements
- Closed Systems Requirements
- Open Systems Requirements
- Part 11 Guidance and Enforcement

Module 3: Annex 11
- Which systems require Annex 11 compliance
- Risk Management requirements
- Software and service provider requirements
- Validation requirements
- Data protection requirements
- Electronic signature requirements
- Business continuity requirements

Module 4: Implementation Models
- COTS and OOTB models
- Cloud models
- SaaS, PaaS, and IaaS models
- Additional models

Module 5: CSV Methodology
- Validation "V" model, e.g., GAMP
- Validation, Verification, and Qualification
- Validation approaches for COTS, Cloud, and SaaS models
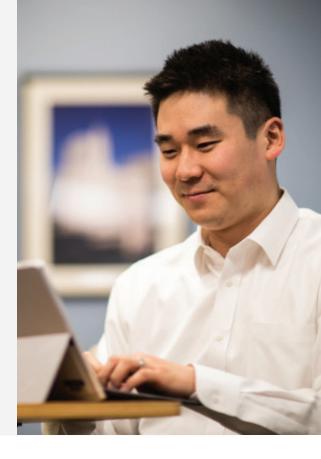- Validation Responsibilities with COTS, Cloud, and SaaS models

Module 6: Requirements
- User Requirements Specification (URS)
- Functional Requirements Specification (FRS)
- Requirements writing best practices
- URS and FRS content
- Example URS and FRS for a purchased system

Module 7: Risk Assessment and Mitigation
- Risk management terminology
- Risk assessment methodology
- Risk mitigation practices
- Risk-based computer system validation
- Example Risk Assessment for a purchased system

Module 8: Validation Plan

- QMS to support validated systems
- Scaling and sequencing validation activities
- Acceptance criteria
- Validation Plan contents
- Example risk-based Validation Plan for a purchased system

Module 9: Design and Development

- Design contents
- Design reviews and Code reviews
- Coding standards
- Example Design for a purchased system

Module 10: Validation Test Writing

- Testing techniques
- Test Plan purpose and contents
- IQ, OQ, and PQ
- IQ structure and contents
- OQ and PQ structure and contents
- Validation test writing best practices
- Example Test Plan for a purchased system
- Example IQ for a purchased system
- Example OQ and PQ for a purchased system

Module 11: Validation Test Execution

- Validation test execution process
- Validation testing documentation
- Validation test execution best practices
- Validation testing failures
- Example Validation Incident Report for a purchased system
- Example executed OQ and PQ for a purchased system

Module 12: Trace Matrices

- Trace matrices contents
- Example Trace Matrix for a purchased system

Module 13: Validation Report

- Validation Report contents
- Validation Plan deviations
- Example Validation Report for a purchased system

Module 14: Supplier Assessment

- Assessment timing
- Supplier assessment methods
- Risk-based method selection
- Supplier assessment topics
- Supplier audit process and best practices
- Leveraging audit results in risk-based validation

Module 15: Service Level Agreements

- Important of Service Level Agreements (SLAs)
- SLA role in risk mitigation
- Contents of SLAs

Module 16: CSV Failure Consequences

- FDA enforcement options
- FDA Warning Letter statistics for software
- Examples FDA Warning Letters for purchased systems

Module 17: Program Implementation

- CSV program implementation steps
- Supplier assessment program implementation steps

Who Should Attend the Computer System Validation Seminar?

IT, QA, Engineering & Business Managers and Professionals who need to:

- Manage computer system validation projects

- Approve CSV project deliverables, such as validation plans, requirements documents, validation protocols (IQ, OQ, PQ), trace matrices, and validation reports

- Audit computer system validation processes and documents

- Assess software vendors' quality assurance practices prior to purchasing systems for use in GxP activities

COMPUTER SYSTEM VALIDATION FOR CLOUD AND COTS APPLICATIONS

Registration

Single Student: $1,599

3 Students: $3,198
(Buy 2, Get one FREE)

Registration Cost Includes:

Course binder, example validation package,

Certificate of Completion**.**

Online Training

Attend from the comfort of your home or office.

Our experienced computer system validation consultants have designed a concise, yet thorough course to equip you with the information you need to validate purchased applications.

A mixture of instructor lectures, activities, and real-world examples will keep you engaged. And, there will be plenty of opportunities to get answers to your company-specific questions.

Professional Development Credits:
16 hours/PDUs

Continuing Education Units: 1.6

You will need internet access, a phone and a PDF reader.

Register online at ValidationCenter.com

or by calling our office: **+1 847.295.7160**