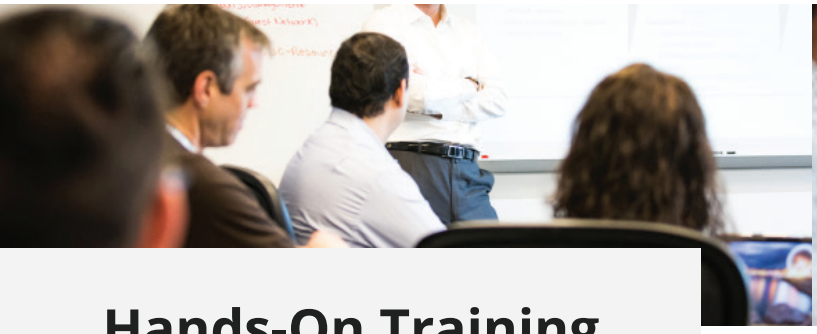
COMPUTER SYSTEM VALIDATION BOOT CAMP®



Hands-On Training

A course designed to completely immerse you in computer system validation. This course delivers comprehension of the regulations impacting your systems and hands-on practice writing validation documents. You will leave ready to lead efficient, effective, inspection–ready validation projects.

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

- 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

Course Description

Boot camp is tough and challenging. It's a week of complete immersion in the validation process. Participants will work in focused teams to complete hands-on validation activities through instruction, exercises, and case scenarios.

The course moves quickly and participants will change gears often to keep interest high and accommodate multiple learning styles. A balance of instructor lectures, reading materials, hands-on activities, and competitions keeps energy levels high and challenges the participants.

AGENDA - Day 1

Module 1: Therac 25 Case Study
- Lessons for today
- Impact on CSV regulations

Module 2: Introduction to the FDA
- FDA history, regulations, and enforcement
- Predicate rules
- Case Study: FDA enforcement

Module 3: Regulation for CSV
- FDA regulations and guidance
- Eudralex Annex 11, 20, and III
- ICH Guidelines
- PIC/S Guides
- Exercise: Exploring the regulations

Module 4: Principles of Software Quality
- Validation roles and responsibilities
- Software quality principles
- Exercise: Using FDA.gov

Module 5: Method and Models
- Common SDLCs
- Validation, verification, and qualification
- COTS, Cloud, SaaS, PaaS, IaaS
- Which systems require validation
- Which features require validation

Module 6: GAMP
- Validation "V" Model
- GAMP 4 and 5

Module 7: 21 CFR Part 11
- Which systems require Part 11 compliance
- Electronic records requirements
- Electronic signatures requirements
- Closed system requirements
- Open system requirements

AGENDA – Day 2

Module 8: FDA Guidance Documents
- Quiz: FDA Guidance
- 21 CFR Part 11 Guidance
- FDA Software Validation Guidance

Module 9: Risk-Based Validation
- Risk terminology
- Risk assessment
- Risk-based validation
- Risk-based procedures

Module 10: Software Quality Assurance
- SOPs for software quality
- Quality audits

Module 11: Requirements
- Requirements development
- User Requirements Specification (URS)
- Functional Requirements Specification (FRS)
- Exercise: Requirements Development

Module 12: Requirements Documents
- Requirements best practices
- Exercise: Requirements Interviews
- Exercise: URS and FRS writing

AGENDA – Day 3

Module 13: System Design and Development
- Quality assurance in design
- Quality assurance in development
- Exercise: Application and Design
- Exercise: Risk Assessment

Continued...

Module 14: Validation Plan
- Validation Plan purpose and contents
- Exercise: Validation Plan writing

Module 15: Preparing to Test
- Validation testing process
- Testing process best practices

Module 16: IQ, OQ, PQ Overview
- IQ purpose and contents
- OQ purpose and contents
- PQ purpose and contents

AGENDA – Day 4

Module 17: Testing Plan
- Principles of validation testing
- Testing techniques
- Testing Plan purpose and contents
- Exercise: Testing Plan writing

Module 18: IQ, OQ, PQ Protocols
- Protocol structure and contents
- Objective evidence
- Test writing best practices
- Test structure best practices
- Exercise: OQ/PQ writing
- Exercise: IQ writing

Module 19: Trace Matrices
- Trace Matrix purpose and contents
- Exercise: Trace Matrix writing

Module 20: Test Execution
- Test execution best practices
- Validation failure documentation
- Exercise: Validation test execution

Module 21: Test and Validation Reports
- Test Summary purpose and contents
- Exercise: Test Summary writing
- Validation Report purpose and contents
- Exercise: Validation Plan writing

Module 22: Change Management
- Maintaining validation status
- Change control processes
- Impact assessments

AGENDA – Day 5

Module 23: System Retirement
- Record retention
- Retirement challenges
- Module 24: Spreadsheet Validation
- 21 CFR Part 11 challenges
- Validation approach

Module 25: FDA Warnings Letters
- Most frequent computer Warnings
- Most frequent validation Warnings
- Trends and examples
- Exercise: Be the Consultant

Module 26: CSV Exam
- Activity: Exam Preparation
- Final Exam

We have used our real-world experience to design a computer system validation course that not only meets FDA, ICH, and Eudralex expectations for risk-based validation, but also prepares you to implement these practices in your company. The standard operating procedures and validation templates used in class have already been proven at other companies.

We are focused on your comprehension and application of the CSV techniques that will result in efficient, effective, and inspection-ready validation initiatives.

Who Should Attend Computer System Validation Boot Camp?

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

- Manage or participate on computer system projects requiring validation
- Create or approve CSV project deliverables, such as requirements documents, validation protocols (IQ, OQ, PQ), Test Plans, and Test Reports.
- Understand the process of computer system validation
- Author, implement, or upgrade CSV policies and procedures that utilize a risk-based approach to meeting the latest regulatory expectations
- Understand the FDA and international regulatory landscape around CSV

Testimonials from Past Students

"A great hands-on approach to learning" – Natalie

"The class is more than a class. It is a walking talking instructional manual to be able to effectively and efficiently complete tasks." – Byron

"I was able to develop a detailed understanding of how I will apply these principles at my company" – Rachael

"The training course is very informative and leaves you with a good sense of the entire validation process" – Angie

"ProPharma Groupnot only gave a clear and concise explanation of the best practice on the methodology of validation, but the tools necessary to implement them into our environment." – Christina

"Excellent overall experience. This class handles all aspects of system validation and you will walk away well prepared to implement."

– Christine

COMPUTER SYSTEM VALIDATION BOOT CAMP®

Registration

Single Student: $3,195

3 Students: $6.390
(Buy 2, Get one FREE)

Registration Cost Includes:

- Pre-work packet
- Course binder
- Validation deliverable and SOP Templates package
- Certificate of Completion

Professional Development Credits:
36 hours/PDUs

Continuing Education Units: 3.6

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

Register online at ValidationCenter.com

or by calling our office: +1 847.295.7160

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