

Computer System Validation in FDA-regulated Industries

Course Description

This 2 day seminar includes an overview of validation tasks required by FDA Regulations and Guidelines. The course content goes beyond simply “what” needs to be done – the emphasis is on “how” to accomplish computer system validation tasks. The workshop format promotes hands-on, practical learning. Participants learn:

- A Validation Process that addresses Regulatory Requirements and Guidelines for Computer System Validation
- Regulatory action taken for non-compliance to Validation Requirements (*483s, Warning Letters*)
- Risk Management Activities
- How to develop and execute a Validation Plan
- How to perform and document Validation Tasks
- How to assess Software Development Activities for various types of software, and the impact of the development activities on the validation process
- How to develop, complete, and document Test Activities
- How to summarize, assemble, package, and maintain Validation Documentation

Schedule

February 3-4, 2004	❖	Baltimore, MD
March 30-31, 2004	❖	New Orleans, LA
June 23-24, 2004	❖	Toronto, ON, Canada
September 28-29, 2004	❖	Albuquerque, NM
December 1-2, 2004	❖	Princeton, NJ

Registration Fee

\$1195

This includes attendance both days, continental breakfasts, lunches, and breaks, an attendee binder containing slides, handouts, and activities, and 30 minutes of follow-up validation consulting that can be used within 60 days of attendance.

- Additional Sessions:** New dates/locations will be added as needed throughout the year. Check www.validassoc.com for updates. All seminars can be held at your site.
- Cancellation Policy:** A full refund of the seminar registration fee will be made for attendee cancellations made at least 2 weeks before a seminar begins. Substitutions may be made at any time.
- Registration Payment:** In addition to checks and purchase orders, we also accept the following credit cards:



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Validation Associates, Inc.
Computer System Validation Specialists
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2004

Seminar Schedule

Baltimore, MD

computer system validation
in fda-regulated industries

New Orleans, LA

auditing computer system
providers

Toronto, ON, Canada

achieving and maintaining
21 cfr part 11 compliance

Albuquerque, NM

computer system
validation overview

Princeton, NJ

 Validation Associates, Inc.

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Achieving and Maintaining 21 CFR Part 11 Compliance

Course Description

This 1 day seminar reviews the requirements, FDA guidance and industry positions on the Electronic Records & Electronic Signatures rule. The seminar addresses enabling technologies and mechanisms to ensure that the system remains compliant throughout its lifetime.

Participants learn how to:

- Evaluate new and existing systems for compliance
- Complete a Gap Analysis
- Prepare a Remediation Plan

Schedule

February 2, 2004	❖	Baltimore, MD
March 29, 2004	❖	New Orleans, LA
June 22, 2004	❖	Toronto, ON, Canada
September 27, 2004	❖	Albuquerque, NM
November 30, 2004	❖	Princeton, NJ

Registration Fee

\$595

This includes attendance, continental breakfast, lunch, and breaks, and an attendee binder containing slides, handouts, and activities.

Auditing Computer System Providers

Course Description

This 1 day seminar focuses on the activities associated with planning and completing audits of computerized system providers. The session addresses evaluating the quality of validation deliverables, and is applicable to both internally developed and vendor supplied systems.

Participants learn how to:

- Develop an Audit Checklist
- Evaluate SOPs governing System Development, Maintenance, and Support
- Evaluate System Development Deliverables in relation to SOPs and Industry Standards
- Prepare an Audit Report & address Corrective Action Follow-up

Schedule

February 5, 2004	❖	Baltimore, MD
April 1, 2004	❖	New Orleans, LA
June 25, 2004	❖	Toronto, ON Canada
September 30, 2004	❖	Albuquerque, NM
December 3, 2004	❖	Princeton, NJ

Registration Fee

\$595

This includes attendance, continental breakfast, lunch, and breaks, and an attendee binder containing slides, handouts, and activities.

Computer System Validation Overview

Course Description

This 1/2 day introductory seminar overviews the regulatory and business requirements for computer system validation in FDA-regulated industries. It includes a discussion of the issues surrounding computer system validation, and reviews the scope of required validation activities. Recent updates to existing regulations, and new FDA regulations and guidelines, are also discussed.

Schedule

This seminar can be scheduled at your location.

Consulting Services & Project Experience

Our approach to providing validation services is adaptable to fit each client's needs and company procedures, and is applicable to any computer system validation project. We can provide your organization with the following services:

- ❖ Validation Project Management
- ❖ Providing Document Templates for Validation Deliverables
- ❖ Preparation of Validation Plans and/or Protocols
- ❖ Validation Test Script and Test Data Creation
- ❖ Test Script Execution and Analysis of Results
- ❖ Preparation of Validation Summary Reports
- ❖ Evaluation/Assessment of Validation Documents
- ❖ Evaluation and/or Development of SOPs
- ❖ Evaluation of system compliance with 21 CFR Part 11 (Gap Analysis)
- ❖ Prospective and Retrospective Validation Projects
- ❖ On-Site Training and Speaking Engagements
- ❖ Performing Audits of Vendors Providing Automated Systems
- ❖ Auditing Computer Validation Practices of Service Providers (CROs, Analytical Labs)
- ❖ Performing PDA supplier audits for the Audit Repository Center (ARC)

We have a wide range of system validation project experience in FDA-regulated industries, including:

- ❖ Oracle, Access, & Lotus Notes Database Systems supporting various functional areas
- ❖ Clinical Remote Data Entry & Reporting
- ❖ Animal Facility Management Systems
- ❖ Document & Content Management Systems
- ❖ Laboratory Information Management Systems
- ❖ Clinical Trial/Data Management Systems
- ❖ Adverse Event Reporting Systems
- ❖ Environmental Monitoring Systems
- ❖ Digital Imaging Applications & Devices
- ❖ Clinical Supply & Clinical Labeling Systems
- ❖ Product Distribution and Recall Systems
- ❖ Interfaces between automated systems
- ❖ Interfaces between instruments and computerized systems
- ❖ Data conversions/migration

The Company

Since 1995, Validation Associates, Inc. has specialized in providing our clients in the pharmaceutical, biotechnology, and medical device industries with computer system validation project consulting and training services.

Our employees and teaming partner associates have been performing validation activities, and advising others on their validation efforts, for a number of years. Our backgrounds in systems development and systems quality assurance within regulated environments, as well as broad computer system validation project experience in FDA-regulated industries, provide clients with a unique mix of theoretical and practical experience and expertise.

We have delivered numerous presentations on various aspects of computer system validation, including participation at DIA, SQA, AALAS, and RAPS conferences. We have authored an article that was published in the DIA's journal, and have trained thousands of people on this topic.

We understand the regulatory requirements and guidelines for computer system validation, and have been responsible for producing many of the development life cycle deliverables as defined in the ISO and ANSI/IEEE standards for quality computerized system development.

For additional information on any of our services,
or to reserve a space at a seminar, contact us at:



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