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.

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

Tel: +1 215.354.1720

Fax: +1 215.354.1725

E-mail: info@validassoc.com

Web: www.validassoc.com

Mail: Validation Associates, Inc.
305 E. Pennsylvania Blvd.
Feasterville, PA 19053-7846

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:

Validation Associates, Inc.
Computer System Validation Specialists
305 E. Pennsylvania Blvd.
Feasterville, PA 19053-7846

www.validassoc.com

Need assistance with Computer System Validation

We can help!

Since 1995 we have provided computer system validation training and project consulting to our FDA-regulated clients.

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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 how to:

- Use a Validation Process that addresses the Regulatory Requirements and Guidelines for Computer System Validation
- Develop a Validation Plan and perform and document Validation Tasks
- Assess Software Development Activities and how to develop, complete, and document Test Activities
- Summarize, assemble, package, and maintain Validation Documentation

Registration Fee: $1195. 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.

Schedule: See www.validassoc.com for public sessions. Call for pricing to hold this seminar at your location.

Computer System Validation Overview

Course Description

This ½-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.

Registration Fee: $295. Includes attendance, breaks, and an attendee binder containing slides and handouts.

Schedule: See www.validassoc.com for public sessions. Call for pricing to hold this seminar at your location.

Risk Management

Course Description

This 1-day seminar reviews the FDA regulations and industry guidance on risk assessment including GAMP, NIST, and ISO. The seminar addresses the process to complete Risk Assessment and Risk Mitigation activities as applied to computer system validation.

Registration Fee: $595. Includes attendance, continental breakfast, lunch, and breaks, and an attendee binder containing slides, handouts, and activities.

Schedule: See www.validassoc.com for public sessions. Call for pricing to hold this seminar at your location.

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
- Prepare an Audit Report & address Corrective Action Follow-up

Registration Fee: $595. Includes attendance, continental breakfast, lunch, and breaks, and an attendee binder containing slides, handouts, and activities.

Schedule: See www.validassoc.com for public sessions. Call for pricing to hold this seminar at your location.

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

Registration Fee: $595. Includes attendance, continental breakfast, lunch, and breaks, and an attendee binder containing slides, handouts, and activities.

Schedule: See www.validassoc.com for public sessions. Call for pricing to hold this seminar at your location.

Certified Software Quality Engineer (CSQE)

Course Description

This 2-day seminar reviews the Body of Knowledge for the American Society for Quality (ASQ) Certified Software Quality Engineer (CSQE). The course provides an overview in the basic principles, concepts, and application of software quality, and provides a refresher for individuals planning to take the ASQ CSQE exam.

Schedule: See www.asqphilly.org for public sessions. Call for pricing to hold this seminar at your location.

Consulting Services & Project Experience

Our approach to providing validation services is adaptable to 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
- ❖ Document Templates for Validation Deliverables
- ❖ Preparation of Validation Plans and/or Protocols
- ❖ User Requirements Specification Development
- ❖ Validation Test Script and Test Data Creation
- ❖ Test Script Execution and Analysis of Results
- ❖ Traceability Analysis & Traceability Matrix Preparation
- ❖ Preparation of Validation Summary Reports
- ❖ Evaluation/Assessment of Validation Documents
- ❖ Evaluation and/or Development of SOPs
- ❖ Risk Management Activities & Documentation Preparation
- ❖ Part 11 Gap Analysis and Remediation Plan Development
- ❖ Prospective and Retrospective Validation Projects
- ❖ On-Site Training and Speaking Engagements
- ❖ Vendor Audits of Technology Providers

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

- ❖ Database Systems supporting various functional areas
- ❖ Clinical Remote Data Entry & Reporting
- ❖ Animal Facility Management Systems
- ❖ Document & Content Management Systems
- ❖ Customer Relationship 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