COBBLESTONE

COURSE ID 2497

Computer System Validation: Rules and Tools

For Today's IT Professionals, Quality Staff Users

DIRECTED BY

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12 Hours

ACCREDITED COURSE

- Regulations
- Risk Assessment Tools and Techniques
- Rules and Tools
- Vendor Selection and Audit
- Data Integrity and ALCOA
- Part 11- ERES
- Validation Process
- High-tech Systems Like: Clinical Trial Software, Tomography, Voice Recognition, Surgical Systems
- 2022 FDA Draft Guidance

about the course

For decades, the FDA and International regulatory agencies have been very concerned about the increased use of computer systems for reporting, clinical trial analysis, and communication.

Early validation guidance is focused on processing and reporting. However, today the industry is dependent on the use of computer systems. Developments in areas such as Artificial Intelligence, computer-controlled processing, manufacturing, devices, and inventory systems require sophisticated computers, trained users, skilled IT professionals, and involved management.

This training will include the most recent 2022 FDA draft guidance Computer Software Assurance for Production and Quality System Software.

This program provides both national and international requirements and the techniques needed to meet today's challenging environment. Topics include FDA, GAMP, ISO, MDD, Risk analysis, and more.

This intensive, 12-hour accredited course is designed to provide an overview of the various aspects of computer validation including best practices, US and International regulations, and Industry expectations. It addresses the rules, tools, and techniques to develop and provide the basis for compliance and implementation for a single system or a company-wide program and process.

Since this training is highly interactive, those attending the live training event must have a webcam on their computer equipped with a microphone and speakers/headset to fully participate.

who should attend

This course is intended for professionals in the pharmaceutical and other life science industries working in all facets of computer systems. The course addresses the responsibilities, roles, tasks, and acceptable techniques associated with the following personnel:

- System Users
- Quality Assurance and Control Staff
- Project Managers
- Regulatory Staff
- Auditors
- IT Professionals
- System Vendors
- System Developers, Designers, and Integrators

learning objectives

Upon completion of this course, you will be able to:

- Explain regulatory requirements and how to comply
- Describe the effective use of GAMP5
- Implement the use of risk assessment tools
- Initiate the necessary steps to comply with Part 11
- Develop a validation plan
- Summarize requirements planning
- Describe and initiate a Validation SOP

course outline

Review of Learning Objectives
Overview of Regulations

- The FDA
- GAMP 5
- EU Annex

System validation

- What is Validation?
- Regulatory Definitions
- The Validation Process

Validation Process

- The Validation Tools
- Validation Master Plan
- Validation Project Plan
- Test Plans and Protocol
- IQ, OQ, PQ
- SDLC

Class exercise

- Risk Assessment-Tools, Techniques, Rationale
- Why Risk Assessment- GAMP 5, EU Annex 11, FDA
- Fault Tree, FMEA, HACCP

Testing

- What to Test (based upon Risk)
- The Test Plan/Protocol
- Testing to Requirements

Case Study

- "Qualifying"
- Vendor Qualification
- Qualifying Staff
- Design Qualification

Documentation

- What to Document?
- Can It be Electronic
- What Do the Regulators Want and Need to See?

The Validation Project

- The Validation Package
- What is next?

Question and Answer Session

Assessment Opportunity

course instructor

Phil Sax was an early thought leader for CSV. A Founder and President of Weinberg Spelton and Sax, a Computer System Validation Consultancy, he has been involved in hundreds of successful validation projects. He has trained more than 1000 professionals, including FDA staff, and has served as Vice President and Chief Regulatory and Quality Officer for 3 international companies. Phil has consulted and worked in 19 countries throughout North America, Europe, Asia, and the Middle East. Phil testified to the US House of Representatives about Computer System Validation issues. Since 2014 Phil has served as an Adjunct Assistant professor in the Masters of Regulatory Affairs and Quality Assurance Program of the Pharmacy School at Temple University. He has developed and directed courses in validation, Good Clinical Practices, and Drug Development.

Accreditations

International Accreditors for Continuing Education and Training (IACET)

Cobblestone has been approved as an Accredited Provider by the International Association for Continuing Education and Training (IACET), www.iacet.org. In obtaining this approval, Cobblestone has demonstrated that it complies with the ANSI/IACET Standards which are widely recognized as standards of good practice internationally. Cobblestone is therefore authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 12 contact hours or 1.2 CEUs.

Regulatory Affairs Professional Society (RAPS)

Cobblestone is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. Cobblestone has agreed to follow RAPS-established operational and educational criteria. This course may be eligible for up to 12 credits towards a participant's RAC recertification upon full completion. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.