COBBLESTONE

COURSE ID 3027

Computer System Validation: Regulatory Overview

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

- FDA oversight
- GAMP – providing guidance on risk-based approach
- MHRA – guidance on data integrity
- ISO – standards that correspond to regulations
- MDD – FDA is not the only regulatory body

about the course

The ever-increasing use of computers within the life science industries draws the attention of the FDA and international regulatory agencies. In recent years we have moved from simple record-keeping systems to computer-controlled processing, manufacturing, devices, and inventory systems. As we look forward to the increasing use of artificial intelligence, we will require increasingly sophisticated computers, trained users, skilled IT professionals, and involved management.

This 90-minute accredited course is designed to provide an introduction and overview of key topics, regulations, tools, guidance, and foundational principles that guide computer system validation.

Topics include:

FDA, GAMP, MHRA, ISO, and MDD.

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

who should attend

This course is intended for professionals in the life science industries working in all facets of computer system validation. The course addresses the regulatory requirements and industry guidance that should drive the CSV efforts in the life science industries for the following personnel:

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

An overview and introduction for professionals who manage staff in any of these areas would also benefit from this course by gaining a better understanding of the current regulations and most recent issues.

learning objectives

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

- Identify regulatory requirements and current guidance on Computer System Validation
- Describe Key Elements of FDA Part 11 and EU Annex 11
- Describe the effective use of GAMP5
- Identify Data Integrity Guidance and Describe Key Elements of data integrity

course outline

Review of Learning Objectives

Module 1:
Overview of Regulations

- Electronic Records and Electronic Signatures
  - 21 CFR Part 11
  - EU Annex 11

Data Integrity

- FDA
- MDRH

GAMP 5

- Risk-based approach

Module 2:
System validation

- What is Validation?
- Regulatory Definitions
- Practical Translation
- Guiding Principles to Remember
- Risk-Based Approach (GAMP 5)
- Least Burdensome Approach
- Think it Through
- Deliver on Promises

Module 3:
Critical Concerns

Why these matters

- Regulatory Findings (e.g., 483, Warning Letter, Consent Decree)
- Responding and Remediating takes time energy and money

CSA is coming

Question and Answer Session

Assessment Opportunity

course instructor

Phil Sax is 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 as 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, He maintains an active compliance and regulatory affairs consultancy.

Accreditations

International Accreditors for Continuing Education and Training (IACET)
Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. 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. For further information, visit www.iacet.org