COBBLESTONE

COURSE ID 2900

REVISED!

Computer System Validation and Part 11 Compliance

(CSV)

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Avoiding 483s and Warning Letters
- Operational System Checks
- Risk-based Validation
- SOPs for Computer System Validation

about the course

Today, the FDA performs both GxP and Part 11 inspections, the Europeans have released an updated Annex 11 regulation that expands Part 11 requirements and companies must update their systems and processes to maintain compliance.

This 90-minute accredited training course will explore proven techniques for reducing costs associated with implementing, using, and maintaining computer systems in regulated environments. Many companies outsource IT resources and are involved in Software as a Service (SaaS) and cloud computing.

These vendors are not regulated, and therefore, this course will enable regulated companies to ensure compliance for both infrastructure qualification and computer system validation to avoid FDA form 483s and Warning Letters.

who should attend

This course is intended for professionals from the Pharmaceutical, Biologics, Medical Device and related industries who work in the following areas:

• Quality Assurance/Quality Control	• System Validation
• Project Management	• Engineering
• Information Technology	• Manufacturing

Anyone from the above departments that enters data in a computer system, that pulls reports from a computer system, that operates equipment that stores data, engineers, QA and QC analysts, equipment operators, maintenance personnel will find this course beneficial

learning objectives

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

- Restate Part 11 requirements
- Apply Part 11 requirements to Computer System Validation
- Evaluate current SOPs for Computer System Validation
- Implement improved security controls through validation

course outline

Review of Learning Objectives

Module 1: What is expected in Part 11 and Annex 11 inspections?

- Methods of limiting system access to authorized individuals
- Effective use of operational system checks
- Proper use of authority and device checks

Module 2: Avoiding 483s and Warning Letters

- Efficiently creating an Audit Trail
- Proper methods of copying records
- Effective Record Retention

Module 3: Implementing a computer system using risk-based validation to gain maximum productivity and reduce cost by as much as two thirds

- Impact the systems have on your ability to meet predicate rule requirements
- Impact those systems have on the accuracy, reliability, integrity, availability, and authenticity of required records and signatures
- Determination of the potential of the system to affect product quality and safety, and record integrity

Question and Answer Session

Assessment Opportunity

course instructor

Joy McElroy, has 10 years of experience as a consultant, and over 20 years total experience in the pharmaceutical and biotech industries, Ms. McElroy has gained extensive knowledge of Quality Assurance, Process and Cleaning Validation, and Equipment Qualification. She has written and executed Equipment Qualification and Validation Protocols for numerous Companies. Ms. McElroy specializes in Equipment Qualification, Sterilization, Cleaning Validation, and GMP Compliance Auditing. In 2019 Ms McElroy started her own company, McElroy Training and Consultancy. She currently works with Easi.

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 1.5 contact hours, or .2 CEUs. For further information, visit www.iacet.org