COBBLESTONE

COURSE ID 2686

REVISED!

Introduction to Validation Principles, Practices and Requirements

DIRECTED BY

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12 Hours

ACCREDITED COURSE

- Developing a Validation Plan
- Cosmetic Validation GMPs
- Food GMP Validation
- Data Validation
- Case Studies
- Interactive Environment
- 21 CFR Part 11- ERES
- 21 CFR 820 (QSRs)
- 21 CFR 211

about the course

FDA-regulated industries utilize several types of validation to help ensure their products' quality and comply with FDA and international regulations and requirements.

This 12-hour, accredited training course provides an overview and introduction to Validation principles and requirements. Process validation, Data Validation, Computer System Validation, Cleaning Validation, Methods Validation, Qualifications, and validation project Management are discussed in detail during this program.

The course is designed to provide a basic understanding of 4 classifications of validation that are generally recognized throughout the industry and by regulators. The program provides an effective and efficient transition to more advanced and specialized validation programs and responsibilities. To further enhance the lecture material, case studies discussions, protocol review and interactive exercises will be employed.

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 to fully participate.

who should attend

This course is designed for professionals in the Pharmaceutical, Food, Cosmetics Quality, Regulatory and Medical Device industries who have validation responsibilities, who have a need to understand validation requirements, who desire to conduct and manage validation functions and who have a desire to understand validation types and requirements.

The course will be especially beneficial to professionals in the **Quality**, **Regulatory**, **Engineering** and **Auditing areas**.

learning objectives

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

- Explain and understand basic validation concepts
- Implement FDA validation guidance and regulations
- Define the meaning of words within the validation vocabulary
- Describe the basic concepts of:
    - Process Validation
    - Data Validation
    - Computer System Validation
    - Cleaning Validation
    - Methods Validation
    - Qualifications

course outline

Review of Learning Objectives

Define Validation

- What is validation?
- Why is it necessary?
- What are the benefits?
- Who requires validation?

FDA Regulations and Guidance

- Review FDA guidance on process validation
- Validation requirements of 21 CFR 211 (cGMPs)
- 21 CFR 820 (QSRs)

Validation classifications

- Retrospective Validation
- Prospective Validation
- Hybrid projects

Process Validation

- Review validation protocol
- Validation plan
- IQ, OQ, PQ- Qualifications

Computer System Validation

- What is computer validation?
- 21 CFR part 11- ERES
- GAMP 5

Cleaning Validation

- Why cleaning validation?
- Regulatory requirements

Methods Validation

- What is Methods Validation?
- Regulatory requirements
- Class Develop a Validation Plan

The Validation Project

- Staffing
- Management
- Tasks
- Responsibilities

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 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