COBBLESTONE

COURSE ID 2759

Understanding the Process Validation Life Cycle

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

- Stages of the Process Validation Life Cycle
- Protocols and Reports
- Process Validation Components
- Regulatory Trends in Process Validation

about the course

This 90-minute, accredited training is intended to help you better understand and get familiar with best practices for Process Validation applicable for the highly regulated biological / pharmaceutical industry. This course is further intended to discuss the life cycle of the Process Validation system. You will learn when a process should be validated, the basic components of a Process Validation (IQ, OQ, and PQ) and how to write protocols and reports.
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 online training will benefit professionals in the following industries: Pharmaceutical, Biotechnology, Medical Device, Chemical Processing, Food, Cosmetics, and Biologics

Potential job functions that would apply: Engineers, Chemists, Scientists, Formulators, Documentation Specialists, Auditors, Managers, Technicians

In departments such as: Manufacturing, Operations, QA/QC, Engineering

learning objectives

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

- Define the stages of the Process Validation Life Cycle
- Discuss what data should be included in the protocols/reports
- Analyze recent regulatory citations pertaining to Process Validation

course outline

Review of Learning Objectives

Module 1: What is Process Validation?

- Regulatory Requirements
- Key Definitions
- The Stages of Process Validation

Module 2: Process Validation Implementation

- **Installation Qualification**
  - **Drafting the Protocol, Data Gathering, Writing the Report**
- **Operational Qualification**
  - **Drafting the Protocol, Data Gathering, Writing the Report**
- **Performance Qualification**
  - **Drafting the Protocol, Data Gathering, Writing the Report**

Module 3: Case Studies

- FDA 483 Citation Review
- Warning Letter Review

Question and Answer Session

Assessment Opportunity

course instructor

Danielle DeLucy, MS, is owner of ASA Training and Consulting, LLC which provides Pharmaceutical and Biologics based companies with training and quality systems assistance in order to meet Regulatory compliance.

Prior to this role, Danielle has been in the industry for 20 years serving in numerous Quality Management Roles at Sanofi Pasteur, such as the Director of Product Quality, the oversight of Sterility Assurance practices and provided QA oversight of numerous filling and packaging operations. Danielle began her QA career as a Quality Control Pharmaceutical Microbiologist at a contract laboratory where she performed various tests for their clients.

In the years after, she has held positions in the Quality management arena while increasing her responsibility. She has helped to lead many Regulatory Health Inspections and was instrumental in the coaching process of her peers prior to any inspection. She has worked with companies such as Johnson & Johnson, Novartis, and Glaxo SmithKline to name a few. Currently, Danielle assists companies who are faced with warning letters, consent decrees and those wishing to improve compliance establish more robust quality systems so that the company can succeed.

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