COBBLESTONE

COURSE ID 2803

Cleaning Validation

Best Practices

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- FDA Requirements and Industry Standard Practices
- Evaluate Industry Cleaning SOPs
- Evaluation of Cleaning Agents
- Laboratory Issues in Cleaning
- Microbiological Aspects of a Cleaning Validation Program for Manufacturing Equipment

about the course

Cleaning Validation is one of the many GMP requirements critical to the production of a drug product or medical device. Unfortunately, product recalls due to inadequate cleaning still occur indicating that implementation of an effective and compliant program is lacking in some companies. Because costly regulatory actions can have a significant negative impact on a company, a better understanding is needed.

This 90-minute accredited training course provides practical guidance on cleaning validation regulatory compliance, in conjunction with, risk-based, reasonable, and informed decision making and activity planning. The course will describe the requirements for establishing an effective cleaning validation program, including the development of a general policy, cleaning SOPs, and other appropriate documentation. In addition, participants will understand the requirements for maintaining a validated cleaning process.

who should attend

This online training will benefit professionals in the Pharmaceutical, Biotechnology, Medical Devices, and other regulated industries. It will be especially valuable to those working as:

- Quality Engineers
- Operators
- Quality Control
- Research & Development
- Quality Assurance
- Supervisors
- Engineering
- Validation Engineers
- Analysts
- Manufacturing
- Managers
- Auditors
- Chemists

Managers and supervisors of this personnel will also benefit from this training by learning about the challenges faced by them.

learning objectives

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

- Outline the importance and underlying principles of cleaning validation and the requirements to have adequate cleaning procedures for manufacturing equipment in contact with the product
- Explain the FDA perspectives on cleaning validation and areas of concern during regulatory inspections and become prepared to defend your own cleaning validation approach/program and avoid costly delays and/or rejections by regulatory agencies
- Write cleaning validation procedures, protocols, and final reports that meet FDA, WHO, PIC, and EU regulations

course outline

Review of Learning Objectives
Module 1

- FDA Requirements and Industry Standard Practices and Current FDA concerns about validation of cleaning processes
- How to Develop/Review your Cleaning Procedures and the Adequate Selection of Cleaning Agents and Parameters
- Discussion of answers with participants

Module 2

- Evaluate industry cleaning SOPs by participants
- Evaluation of cleaning agents by participants
- How to Implement a Robust Cleaning Validation Plan
- Participant discussion of answers

Module 3

- Laboratory Issues in Cleaning
- Participant discussion and example presentation of their laboratory issues
- Microbiological aspects of a cleaning validation program for manufacturing equipment
- Participant discussion and example presentation of their bioburden issues
- Keys to Cleaning Validation Maintenance – Remaining Compliant

Question and Answer Session
Assessment Opportunity

course instructor

Joy McElroy earned a Bachelor of Science degree in Zoology at North Carolina State University. She began working in the pharmaceutical and biologics industries in 1992 performing Environmental Monitoring and Sterility Testing. She then moved into a supervisory role where she oversaw the Quality Control Lab. Joy began working in Quality Assurance, performing GMP Compliance audits, batch record reviews, and holding annual GMP training. After working in Quality Assurance for a few years, Joy moved into Equipment Qualification and Cleaning Validation.

With 28 years total experience in the pharmaceutical and biologics industries, Joy has gained extensive knowledge of Quality Assurance, Technical Writing, Process and Cleaning Validation, Equipment Qualification, Computer System Validation and Part 11 Compliance. She has written and executed cleaning validation protocols and equipment qualifications for numerous companies.

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