COBBLESTONE

COURSE ID 2959

Cleanroom, Microbiology and Sterility Assurance Practices for Sterilization Processes

Part of the Sterilization Professional Certification Program

DIRECTED BY

Charity Ogunsanya -- CEO and founder of Pharmabiodevice Consulting LLC

3 HOUR

ACCREDITED COURSE

Course Topics Include:

- ISO 14644-1 through ISO 14644-4
- Cleanroom Contamination Control program
- Basics of Microbiology and Contamination Control
- Regulatory Agencies Expectations

about the course

For products that claim a desired Sterility Assurance Level (SAL), proof of a defined SAL (specification) is achieved through the product's sterilization and sterility assurance controls. Compliance Observations cited each year by the FDA on Form 483's that relates to Sterilization and Sterility Assurance processes shows that there are deficiencies associated with these key processes that are critical to a product's sterility including inappropriately qualified and trained personnel required as key staff to implement a fully compliant sterilization process. This can potentially lead to Product Failures (Sterility Failures), product Non-conformances, Product Recalls, FDA's Warning Letters, Consent Decrees and discontinuance of commercial operations which may negatively impacts a company's profitability. FDA regulated industries that produce products with a defined SAL are obligated to have adequately trained and knowledgeable staff or Subject Matter Experts (SMEs) within sterilization and sterility assurance to provide applicable regulatory guidance with the impacted systems.

This 3-hour accredited training introduces both new and existing employees to Cleanroom Regulations and Basic Background as well as the proper way to Design, Qualify/Validate and perform routine monitoring of Cleanrooms per ISO 14644-1 through ISO 14644-4. This webinar will educate the attendees on establishing a robust Environmental Monitoring, Personnel Training, Aseptic Practices, Cleanroom Behavior, Cleanroom Trafficking and Cleanroom Gowning programs for an effective Cleanroom Contamination Control program.

This webinar will provide guidance to attendees on the basics of microbiology and how to establish a robust Cleanroom Cleaning and Disinfection Program, its application to contamination control and sterility assurance requirements as well as its role in today's manufacturing activities.

This training is part of the 10-course series required for the Sterilization Professional Certification Program.

Attend this as a step in the certification process or as a stand-alone course for personal career advancement and training.

who should attend

This online training will benefit professionals working in the Pharmaceutical, Biotechnology, Drug, Biologics, Medical Device, Compounding Pharmacies and In-vitro Diagnostics Product Manufacturing industries. It will be especially valuable for personnel and management within the following areas:

• Sterilization Engineers and Specialists; Microbiologists	• Quality Assurance; Quality Control
• Sterility Assurance Auditors; Quality Assurance Supplier Auditors	• Laboratory; Testing Analysts and Technicians
• Manufacturing; Shipping; Receiving; Facility; Maintenance; Engineering	• Validation; Regulatory Affairs
• Suppliers and Vendors of Pharmaceutical Gas Systems	• Materials Management

learning objectives

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

- Define Cleanroom Regulations and Basic Background
- Establish the proper Design, Qualification/Validation, Cleaning Validation and Routine Monitoring of Cleanrooms per ISO 14644-1 through ISO 14644-4
- Apply the requirements of Environmental Monitoring Program, Personnel Training, Aseptic Practices, Cleanroom Behavior, Cleanroom Trafficking and Cleanroom Gowning to an appropriately designed Cleanroom Contamination Control program
- Establish a robust Cleanroom Cleaning and Disinfection Program and its application to contamination control and sterility assurance requirements
- Define the Basics of Microbiology and Contamination Control program requirements
- Identify the FDA's view of an appropriate contamination control and sterility assurance program based on the review of Compliance Expectations, FDA Form 483's, and Case Studies

course outline

Review of Learning Objectives

Module 1: Basics of Cleanroom Design and Qualification Requirements

- Summary of Cleanroom Guidelines and Regulations
- Summary of Key Areas of Cleanroom Technology
- Effective Design of a Cleanroom
- Effective Cleanroom Qualification/Validation
- Cleanroom Certification Testing
- Routine Environmental Monitoring Tests

Module 2: Cleanroom Monitoring, Controls and Sterility Assurance Requirements

- Guidance and Regulations
- Contamination Control and Environmental Monitoring
- Interpreting EM Test Data Used in Trending
- Operating in an Aseptic Processing Environment
- Cleanroom Practices - Cleanroom Personnel Practices, Sterile Gloves, Sterile Gowns and Operator Technique
- Cleanroom Gowning Guide

Module 3: Basics of Microbiology and Contamination Control and FDA Compliance Requirements

- Basics of Microbiology and Contamination Control
- Importance of GMP Cleanroom Cleaning
- Cleaning and Disinfection Techniques
- Selecting Detergents
- Key Aspects of Cleanroom Controls
- Review of Compliance Expectations, FDA Form 483's, and Case Studies

Assessment Opportunity

course instructor

Charity Ogunsanya is the CEO and founder of Pharmabiodevice Consulting LLC (www.pharmabiodeviceconsultant.com). Ms. Ogunsanya has over 30 years of extensive practical and management experiences in various Fortune 100 Pharmaceutical, Biotechnology, Biologics, Cell-Therapy, Diagnostics, Food and Cosmetics, Compounding Pharmacy, Research and Development, Radio-pharmaceutical, Contract Manufacturing Organization (CMO) and Medical Device/IVD companies.

Throughout her corporate career within these diverse industries, she held various high level, high visibility and business critical roles within the Quality Control and Quality/Compliance divisions for major Fortune 100 companies both as their Subject Matter Expert (SME), Site Manager, Multi-site Manager and Director Levels respectively.

Her technical expertise includes the interpretation, administration and set up of New Cleanroom/Facility Design, Operations, Validation, Monitoring, Manufacturing Operations, Food Safety, Quality Assurance, Quality/Compliance, Quality Engineering, Aseptic Processing, Contamination Control, Regulatory Affairs, Quality Control, Microbiology, Sterility Assurance, Stability, Vaccine Development, New Product Design, Raw Material Testing, Environmental Controls, Product Release Testing and Medical Device Sterilization (Ethylene Oxide (EtO), Gamma, Radiation, VHP sterilization) processes for compliance to various regulations.

Ms. Ogunsanya's has a Bachelor of Science degree in Microbiology from the University of Benin-Nigeria and a master's in biotechnology (Biodefense Concentration) from The Johns Hopkins University Advanced Academic Program.

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 3 contact hours, or .3 CEUs. For further information, visit www.iacet.org