COBBLESTONE

COURSE ID 2952

NEW!

Requirements for Aseptic Techniques and Practices

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:

- Proper Aseptic Practices
- Cleanroom Contamination and Controls Microbiological Requirements
- Four (4) Pillars of Aseptic Techniques
- Cleanroom/Cleanzone Behaviors and Practices

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 the basic requirements and steps of proper aseptic practices and sources of contamination within cleanrooms and Quality Control testing environments. This webinar provides preliminary understanding of the basics of microbiology and the requirements of cleaning & disinfection as it relates to contamination control requirements. Participants will be able to apply the 4 Pillars of Aseptic Techniques, Cleanroom Behaviors and Practices within product manufacturing and testing Cleanrooms and Cleanzones.

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

learning objectives

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

- Summarize the requirements of proper aseptic practices within cleanroom and testing operations
- Define the basic microbiological requirements as it affects cleanroom contamination and controls
- Apply the basics of cleaning and disinfection to proper aseptic practices and contamination control
- Identify and apply the four (4) pillars of aseptic techniques
- Distinguish between aseptic techniques and cleanroom/cleanzones behaviors and practices

course outline

Review of Learning Objectives
Module 1: Aseptic Practices and Basics of Microbiology and Contamination Control

- Background and Microbiology Basics
- Contamination Control, sources of contamination and cleaning & disinfection
- History & Milestones of Aseptic Techniques
- Regulatory Requirements of Good Aseptic Practices
- Contamination Control
- Types of Cleaners/Disinfectants

Module 2:

- What is Aseptic Technique and Aim of Aseptic Technique?
- Items Requiring Sterilization - Applicable to Aseptic Technique
- Methods of Sterilization

- General Principles of Aseptic Technique
- Example of a Typical Transfer Process

Module 3: Cleanroom, Cleanzones and Aseptic Filling Suites Behaviors and Practices

- Definitions
- Sterile Drug Products Produced by Aseptic Processing (FDA)
- Scope and Responsibilities Associated with Cleanroom Control
- Cleanroom, Cleanzones and Aseptic Filling Suites Behaviors and Practices
- Cleanroom Behavior and Practices
- Cleanzones Behavior
- Aseptic Filling Suite Behavior

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