COBBLESTONE

COURSE ID 2960

Cleanroom, Cleaning, Sanitization and Disinfection 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:

- Different Types of Disinfectants, Sanitizers and Sterilizing Chemicals
- Content of a Robust Cleaning, Sanitization and Disinfection Program
- Importance of cGMP Cleanroom Cleaning and Disinfection Chemistries and Frequencies
- Do's and Don'ts of Cleaning and Disinfection Based on Recent FDA Citations

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 entire process of cleaning and disinfection terminologies, practices, requirements, process steps, types of disinfectants, composition and specific roles in contamination control as it applies to cleanrooms used for manufacturing activities.

The importance of cleaning and disinfection cannot be over emphasized due to its criticality in ensuring a state of contamination control in order to prevent product contamination and potential loss of the products. This webinar will describe in detail a very robust cleaning and

disinfection program requirements that can be applied in creating a robust cleaning and disinfection Standard Operating Procedure (SOP). The webinar will also discuss a sample of FDA's issued form 483's compliance issues associated with cleaning and disinfection deficiencies as well as their resolution.

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

learning objectives

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

- Define terminologies of cleaning, disinfection, and decontamination applicable to cleanroom classifications.
- List the types and classification of different types of Disinfectants, Sanitizers and Sterilizing Chemicals
- Describe the different types of disinfectants, sanitizers and sterilizing chemicals and their applications within product manufacturing cleanrooms
- Define the content of a robust cleaning, sanitization, and disinfection program requirements
- Establish the importance of cGMP Cleanroom Cleaning and Disinfection Chemistries and Frequencies
- Demonstrate the Do's and Don'ts of cleaning and disinfection based on recent FDA's Form 483 and Warning Letter compliance citations

course outline

Review of Learning Objectives
Module 1: Introduction to Disinfection and Chemical Disinfectants

- What is Cleaning?
- What is Decontamination?
- General Rule for the Use of Disinfectants
- Types of Cleaning, Disinfection and Sterilizing Chemicals
- Disinfectant Effectiveness

- Appropriate Selection and Use of Different Types of Disinfectants

Module 2: Cleaning and Disinfection Program Defined

- Appropriate Selection and Use of Different Types of Disinfectants
- Things Impacting Disinfection and Sterilization
- Cleaning and Disinfection Program
- Regulatory Requirement and Industry Guidance
- Importance of GMP Cleanroom Cleaning and Disinfection
- Types of Cleaning Defined

Module 3: Cleaning and Disinfection Chemistries, Frequency and FDA Requirements

- Cleaning and Disinfection Chemistries & Frequency
- Factors Influencing Cleaning and Disinfection Performance
- Disinfectant Application/Application Techniques
- Recommended Frequency for Cleaning and Disinfection
- Cleaning and Disinfection SOP Development
- Cleaning and Disinfection: Resistance & Rotation
- Recent FDA Warning Letter Citations on Cleaning and Disinfection Deficiencies

Assessment Opportunity

course instructor

Instructor Name, 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