COBBLESTONE

COURSE ID 2875

Cleanroom, Microbiology, and Sterility Assurance Practices

DIRECTED BY

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12 HOUR

ACCREDITED COURSE

Course Topics Include:

- Regulations, Classifications, Background, and Design
- Qualification, Validation, Routine Monitoring, Excursion Investigation
- Fundamentals of Environmental Monitoring Program
- Personnel Aseptic Practices, Behavior, Gowning
- Personnel Material, Product, Equipment Practices, Training
- Entry and Exit Policy
- Contamination Control/Cleaning/Disinfection Program
- Basics of Physical and Chemical Sterilization Processes

about the course

This intensive, 12- Hour course provides attendees a comprehensive knowledge about the A-Z of Sterility Assurance which is based on regulatory requirements, FDA guidance, compliance expectations, and industry practices. Key elements of sterility assurance and contamination control starts from creating a robust and compliant cleanroom design, validation/qualification, operations, environmental monitoring program requirements, microbiological processes/methodology, cleanroom cleaning/disinfection, trafficking, gowning requirements, and contamination control will be extensively discussed.

Other key aspects of achieving product sterility such as a good understanding of the basics of sterilization processes–physical and chemical processes and the various examples of sterilization equipment and their specific process parameters will also be discussed. Critical regulations affecting Sterility Assurance requirements such as 21 CFR Part 211, ISO 14644 (various parts), ISO 11135, 11137, 11138, 14160, 14937, 17664, 17665, FDA Guidance for Industry, and other regulations guiding these critical topics will be covered.

Discussions will include the criticality of aseptic processing and other key contamination control evaluators during the manufacture and testing of products.

who should attend

This training will benefit those involved in the manufacturing, processing, testing, and release of sterile and non-sterile products within various industries such as Pharmaceuticals, Biotechnology, Drug, Biologics, Medical Device, Compounding Pharmacies, Cell Therapy, and In-vitro Diagnostics Product Manufacturing. It will be especially beneficial to personnel and management in:

- Quality Assurance/Control
- Validation
- Sterility Assurance Manager
- Shipping and Receiving
- Sterilization Professional
- Manufacturing
- Regulatory Affairs
- Engineering
- Facility and Maintenance
- Analytical Chemist/ Microbiologist

learning objectives

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

- Explain the detailed requirements of the various cleanroom classifications per ISO 14644 and expectations based on the regulations and guidelines
- Apply best practices in the design of a new cleanroom through qualification/validation, operation and routine environmental monitoring program
- List FDA and regulatory guidance and expectations on aseptic and personnel health practices, gowning and trafficking patterns within a cleanroom
- Apply industry guidance and the requirements of how to create a robust cleanroom cleaning/disinfection and contamination control programs to achieve a high degree of sterility assurance.
- Explain in details the two types of sterilization processes with detailed description of each type, parameters as well as their advantages and disadvantages

course outline

Review of Learning Objectives

Module 1

- Guidelines, Regulations and Definitions
- Key Areas of Cleanroom Technology and Classifications
- ISO and USP Limits for Microbial Contamination
- Design Considerations and Guidelines
- Location, Make-up Air, Cleanroom Walls- Surfaces
- Materials of Construction: Ceilings, Doors, Floors
- HVAC & Filtration Systems, Airflow

Module 2

- Principles and regulations guiding Cleanroom Validation (OQ/PQ) and Operation testing
- Effectiveness Verification Tests Data in a PQ Process
- Performance Qualification (PQ) Protocol and Report
- Environmental Monitoring (EM) Program, Limits, Requirements, Excursion Investigation and Data Trending
- Correlation between Contamination Control and Environmental Monitoring
- Causes of Adverse Trends

Module 3

- Principles of Aseptic Practice regulation
- Setting up an Aseptic Environment
- Cleanroom Practices - Personnel Health and Cleanliness, Personnel Practices
- Workstation and Equipment Cleaning and Disinfection
- Process flow/Trafficking Patterns for Equipment, Materials, Personnel, Supplies and Waste
- Q&A

Module 4

- Cleaning/Disinfection Program Guidance and Regulations
- Microbiology and Contamination Control and Mitigation
- GMP Cleanroom Cleaning /Cleanroom Contaminants
- Gowning Guide, Degowning, ISO Classification
- Sterilization Processes and Methods
- Thermal (Heat) Sterilization
- Dry Heat Sterilization (Hot air oven, Flaming (AKA Red Hot Sterilization), Incineration, Dry Heat Tunnels, Infra-red Radiation
- Moist Heat Sterilization Pasteurization, Boiling, Tyndallization, Autoclave/Steam Sterilizer.

Module 5

- Advantages and Disadvantages of sterilization processes
- Ionizing and non-ionizing Radiation including microwave Radiation, Ultraviolet Radiation, Gamma Rays/Gamma Sterilization
- Chemical Sterilization such as Phenolic, Hydrogen Peroxide, Halogens, Chlorine and Alcohols, Heavy Metals, Quaternary, Peroxygens and Aldehydes

Module 6

- Gaseous Method such as Ethylene Oxide, Formaldehyde, and Glutaraldehyde Sterilization
- Filtration and various types of Filters
- Monitoring of Sterilization Processes, Steam Sterilizers Test Results
- Installation & Repair Testing and Process Monitors
- Review of Case Studies (FDA's Form 483)

Question and Answer Session
Assessment Opportunity

course instructor

Charity Ogunsanya has more than 30 years of extensive experience within the Biologics, Pharmaceuticals, Radiopharmaceuticals, Biotechnology and Medical Device Industries and has been the Microbiology, Sterility Assurance, Contamination Control, Aseptic processing, Quality Control Subject Matter Expert (SME) for multiple fortune 100 companies.

She has a Bachelor of Science degree in Microbiology from the University of Benin-Nigeria and has a Master's degree from the Advanced Academic Master's Biotechnology Program at the Johns Hopkins University with concentration in Biotechnology/Biodefense. She is the CEO/ Owner of her consulting firm named Pharmabiodevice Consulting LLC. Her consultancy provides support to Biologics, Pharmaceuticals, Radiopharmaceuticals, Biotechnology and Medical Device Industries.

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 12 contact hours, or 1.2 CEUs. For further information, visit www.iacet.org