COBBLESTONE

COURSE ID 2951

Basics of Microbiology

Part of the Sterilization Professional Certification Program

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- History and Definitions
- Microorganisms
- Infections and Disinfection

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 basics of Microbiology with emphasis on the history, various microbiological era's and specific discoveries within each Era. Attendees will gain full knowledge of the detailed study, principles and characteristics of microorganisms and how they relate to cleanroom contamination, asepsis and infection including its applicability in product manufacturing activities. This course will describe the various types of disinfection and sterilization processes as well as the impact on contamination control within the manufacturing cleanrooms.

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

Attend this as part of 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
• 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:

- Describe the history, various Microbiology Era's and specific discoveries within each Era
- Summarize the detailed study and principles of microbiology
- List the characteristics of the major groups of microorganisms
- Describe causes of asepsis and its relationship with the infection process
- List the various aspects of disinfection and sterilization and its impact on contamination and infection control processes

course outline

Review of Learning Objectives
Module 1: Microbiology and Its History

- The 4 Eras of Microbiology
- Spontaneous Generation versus Biogenesis
- Earliest and Important Discoveries
- Koch's Postulates
- Harmful and Useful Forms of Microorganisms
- Harmful Microorganisms Causing Diseases
- How Microorganisms Spread; Prevention
- Effects on Human Beings
- Why Study Microbiology as a Subject?

Module 2: Microorganisms

- Types, Characteristics and Composition
- Principles of Microbiology-Specifically Bacteria
    - Cell Structure
    - Cytoplasm
    - Chromosomes, Plasmids/Episomes
    - Cell Wall
    - Cell Chemistry

- Principles of Microbiology-Specifically Bacteria
  - Gram Classification
  - Gram Reaction
  - Peptidoglycan/Murein
  - Gram Positive/Negative Cell Wall
  - Teichoic Acid
  - Acid Fast Envelop; Stain-Process
- Microbial Growth and Factors Affecting

Module 3: Infection and Disinfection

- Chain of Infection
- Causative Agents/Infectious Agents
- Portal of Exit
- Mode of Transmission
- Direct and Indirect Transmission
- Portal of Entry; Susceptible Host
- Important Terminologies
- Agents used in Sterilization & Disinfection
- Physical and Chemical Methods of Sterilization
- Testing of Disinfectants
- Quiz and Review
- Summary

Question and Answer Session
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