COBBLESTONE

COURSE ID 2958

Basics of Sterilization by Heat

Part of the Sterilization Professional Certification Program

DIRECTED BY

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2 HOUR

ACCREDITED COURSE

Course Topics Include:

- Requirements of Both Dry and Moist Heat Sterilization Processes
- Operational Requirements of Dry and Moist Heat Sterilization Equipment
- Installation/Operational/Performance Qualification (IO/OQ/PQ) protocol requirements
- 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 2-hour accredited training introduces both new and existing employees to sterilization by heat which includes Dry Heat and Moist Heat Sterilization processes. The role of sterilization by heat used for certain manufactured products, supplies and ancillary systems cannot be overemphasized. Having a clear understanding of the detailed requirements of the various types of sterilization by heat processes and their key impact on product material of composition is critical to determining the suitability of the application process to be employed.

This webinar describes the various types of dry and moist heat sterilization processes, types of equipment, functionality, operational ranges, validation requirements and the FDA's inspection approach to sterilization process controls.

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	• Materials Management
• Suppliers and Vendors of Pharmaceutical Gas Systems	• Validation; Regulatory Affairs

learning objectives

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

- Explain the basic principles and requirements of both dry and moist heat sterilization processes
- List various examples of dry and moist heat sterilization equipment and their operational requirements.
- Compare and contrast dry and moist heat sterilization with other types of sterilization processes
- Describe the Installation/Operational/Performance Qualification (IO/OQ/PQ) protocol requirements of dry and moist heat sterilization validation processes
- Define internal auditors' and FDA's inspection approach to terminal sterilization processes controls

course outline

Review of Learning Objectives

Module 1: Basics of Dry Heat Sterilization Process

- Definition of Sterilization
- Source of Contaminants
- Usefulness of Sterilization
- Sterility Assurance Level
- Key Essentials of a Sterilization Process
- Methods of Sterilization

Module 2: Dry Heat Sterilization Validation Requirements

- Introduction to Dry Heat Sterilization Validation
- Types of Dry Heat Sterilizers
- Validation of Dry Heat Sterilizers
- Steps in the Validation of Dry Heat Sterilization Process
- Biological Process Validation in Sterilization Cycles
- Examples of Dry Heat Sterilization Equipment and their Operational Requirements

Module 3: Validation and Qualification Requirements of Sterile Filtration Processes of Products

- Basic Understanding of Moist Heat Sterilization Process
- Advantages/Disadvantages of Moist Heat Sterilization
- Advantages/Disadvantages of Autoclave Steam Sterilization
- Categories of Moist Heat Sterilization
- Validation of Moist Heat Steam Sterilization –IQ/OQ/PQ
- FDA's Inspection Approach to Terminal Sterilization Processes Controls

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 2 contact hours, or .2 CEUs. For further information, visit www.iacet.org