COBBLESTONE

COURSE ID 2957

Requirements of Aseptic Processing and Filtration Sterilization

Part of the Sterilization Professional Certification Program

DIRECTED BY

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3 HOUR

ACCREDITED COURSE

Course Topics Include:

- Filter Validation Testing
- Mechanisms of Filtration Sterilization
- Validation and Qualification Requirements
- Ultrafiltration vs. Microfiltration
- 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 3-hour accredited training introduces both new and existing employees to the requirements of aseptic processing preparation and filtration of solutions. The webinar describes the factors, steps, principles, applications and working mechanisms of filtration sterilization while comparing and contrasting the different types of filtration processes and types of filters used for filtration of solutions during sterile drug manufacturing process.

The attendees will also gain an understanding on the process steps required to validate the filters used for sterile filtration of products as defined by regulations using Brevundimonas diminuta. This webinar will provide attendees detailed regulatory agencies' expectations on the use and validation of different types of filters and their respective roles in today's manufacturing activities.

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

learning objectives

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

- Describe the objectives and requirements of aseptic processing preparation and filtration of solutions
- Establish the process steps for filter validation testing
- Define the factors, steps, principles, applications and working mechanisms of filtration sterilization
- Compare and contrast the different types of filtration processes and types of filters used for filtration
- Establish the validation and qualification requirements of sterile filtration of products
- Compare and contrast the requirements of Ultrafiltration and Microfiltration
- Define the regulatory agencies expectations of filtration sterilization process requirements

course outline

Review of Learning Objectives
Module 1: Aseptic Processing Requirements Applicable to Sterile Filtration

- Aseptic Processing – Overview
- Objectives of Aseptic Processing
- Cleanroom/Manufacturing Environment
- Aseptic Processing Requirements – From A to Z
- Useful Publications

Module 2: Factors, Steps, Principles, Applications and Working Mechanisms of Filtration Sterilization

- Introduction to Filtration Sterilization
- Advantages and Disadvantages of Filtration Sterilization
- Introduction and Steps Involved in Filtration Sterilization
- Principles and General Theory of Filtration
- Classification, Types and Materials of Filters
- Applications of Filtration
- Filtration Sterilization of Liquids and Gases

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

- Removal of Insoluble Products by Microfiltration and Ultra Filtration
- Validation and Qualification of Sterile Filtration Processes of Products
- Eight (8) Elements of a Sterile Filtration Validation
- Sterile Filter Compatibility
- Retention – Defining the Worst-case Conditions
- Extractables and Leachables: What are the Requirements?
- Regulatory Agencies Expectations

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