COBBLESTONE

COURSE ID 2

Sterilization Professionals Certification

A 10 Part Program

DIRECTED BY

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25
Hours

ACCREDITED COURSE

- 10 Courses
- 90 Minutes each

about the course

In the FDA's Guide to Sterilization Process Controls, the FDA stated five (5) key inspectional objectives that are used by the agency during routine inspections of sterilization and sterility assurance processes. One of the key areas of concern pertains to the production and process control subsystem (including sterilization process controls) which requires that manufacturers of products must manufacture products that meet defined specifications.

Developing processes that are adequate to produce medical devices or other products that requires a defined Sterility Assurance Level (SAL) requirements, testing specifications, validating or fully verifying the results of those processes, including monitoring and controlling the processes are all steps that help assure that the result of the manufactured products meet the defined specifications.

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 483s 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.

Cobblestone's 10-Part Sterilization Professional Certification program provides detailed training on the key principals and tools required to become a Sterilization Professional which starts from the concept of understanding what a Microorganism is through the various aspects of Aseptic Process requirements, different types of sterilization systems/processes that are applied within the industries to achieve their unique or desired product SAL in conjunction with an effective Cleanroom Controls which is an integral part of the sterilization process controls. This Certification Program offers professionals a detailed and expansive training and development skills with a broader understanding in the area of sterilization which is required in order to attain a certificate of accomplishment.

who should attend

The Sterilization Professional Certification will be valuable to all individuals working within or managing sterilization and Sterility Assurance processes that supports sterile products requiring sterilization prior to release for use.

Obtaining the Sterilization Professional Certification would be beneficial to professionals in various industries such as the Pharmaceutical, Biotechnology, Drug, Biologics, Medical Device and In-vitro Diagnostics Product Manufacturing Industries, especially those within the following departments:

- Sterilization Engineers and Specialists
- Sterility Assurance Personnel
- Auditors and Quality Assurance Supplier Audits
- Quality Assurance Personal and Management
- Quality Control Personnel and Management
- Laboratory Managers
- Testing Analysts and Technicians
- Manufacturing Personnel and Management
- Suppliers and Vendors of Pharmaceutical Gas Systems
- Validation Personnel and Management
- Supplier Quality Assurance Auditors, Personnel and Management
- Regulatory Affairs Personnel and Management
- Shipping and Receiving Personnel and Management
- Facility and Maintenance Personnel and Management
- Microbiologist Personnel and Management
- Engineering Personnel and Management
- Materials Management Personnel and Management

learning objectives

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

- Interpret the various Sterilization and Sterility Assurance regulations, standards and requirements
- Apply regulatory requirements to routine operational sterilization and sterility
- assurance applications
- Plan and manage sterilization process controls to minimize product non- conformances and product sterility failures and investigations
- Train and mentor internal sterilization, manufacturing, sterility assurance and other
- critical staff on various types of sterilization process requirements including the qualification and requalification requirement
- Develop various types of Sterilization and Sterility Assurance Process Standard
- Operating Procedures (SOPs)
- Prepare and Execute IQ, OQ and PQ protocols and draft reports for various sterilization processes and systems
- Perform effective technical audits of Sterilization Process Suppliers and Vendors
- using key audit review requirements applicable to sterilization and cleanroom controls
- Represent an organization as a Sterilization and Sterility Assurance Subject Matter Expert (SME) during FDA and other International Regulatory bodies' inspections
- Interact with management, regulators and other external auditors.

certification outline

- Basics of Microbiology
- Requirements for Aseptic Techniques and Practices
- Basics of Electron Beam Sterilization Process Requirements
- Basics of Gamma Radiation Sterilization Process Requirements
- Basics of Ethylene Oxide Sterilization Process Requirements
- Basics of Vaporized Hydrogen Peroxide (VHP) Sterilization and Decontamination Practices
- Requirements of Aseptic Processing and Filtration Sterilization
- Basics of Sterilization by Heat
- Cleanroom, Microbiology, and Sterility Assurance Practices for Sterilization
- Cleaning, Sanitization, and Disinfection Practices

course instructor

Charity Ogunsanya - Owner/CEO Pharmabiodevice Consulting LLC
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 a Masters degree from the Advanced Academic Master's Biotechnology Program at Johns Hopkins University with a concentration in Biotechnology/Biodefense. She is the CEO/Owner of her consulting firm Pharma Biodevice Consulting LLC.

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 25 contact hours, or 2.5 CEUs. For further information, visit www.iacet.org

Regulatory Affairs Professional Society (RAPS)
Cobblestone is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. Cobblestone has agreed to follow RAPS-established operational and educational criteria. This course may be eligible for up to 12 credits towards a participant's RAC recertification upon full completion. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.