COBBLESTONE

COURSE ID 2955

Basics of Ethylene Oxide (EtO) Sterilization Process Requirements

Part of the Sterilization Professional Certificate Program

DIRECTED BY

Charity Ogunsanya — CEO and founder of Pharmabiodevice Consulting LLC

2 HOUR

ACCREDITED COURSE

Course Topics Include:

- Ethylene Oxide Sterilization Regulations
- Ethylene Oxide Sterilization IQ/OQ/PQ Validation Requirements
- Compliance Requirements of Ethylene Oxide Sterilization Process
- Ethylene Oxide Sterilization FDA Compliance Issues

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 the requirements of ISO 11135 and other applicable regulations. The role of Ethylene Oxide (EtO) sterilization used for certain manufactured products, supplies and ancillary systems cannot be overemphasized. Having a clear understanding of the detailed requirements of EtO sterilization process and its impact on a product's material of composition is critical to determining the suitability of the application process.

This webinar discusses the regulations, process steps, validation requirements, routine processing and compliance requirements applicable to EtO sterilization process used for the sterilization of Medical Device and other products. The webinar will address auditors review and verification requirements and FDA's Compliance Observations and Case Study review applicable to EtO requirements.

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

learning objectives

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

- Apply the regulations and steps associated with routine EtO sterilization process
- Define the basic process steps associated with routine EtO sterilization
- Describe the Installation, Operational and Performance Qualification (IOQ/PQ) Validation requirements for EtO sterilization process
- Define the process for maintaining process effectiveness and manufacturing controls for products requiring EtO sterilization
- Verify the compliance requirements of EtO sterilization process using a defined audit review verification process.
- Discuss EtO Sterilization FDA compliance citations and review requirements for compliance.

course outline

Review of Learning Objectives

Module 1: Rules, Regulations and Process Steps of Ethylene Oxide Sterilization

- Rules, Regulations and Guidance for Ethylene Oxide Sterilization Processes – Key Elements of ISO 11135:2014 and ISO 10993-7:2008(R-2012)
- Step-by-Step Process of Ethylene Oxide Sterilization Validation – Qualification of Equipment/Process and Cycle Development

Module 2: Ethylene Oxide Sterilization Validation and Compliance Requirements

- Step-by-Step Process of Ethylene Oxide Sterilization Validation, continued…
- Handling Routine Process for Ethylene Oxide Sterilization
- Flow Chart of Ethylene Oxide Sterilization Process
- Auditor's Review of Ethylene Oxide Sterilization Facility's Quality Management System (QMS)
- Auditor's Review of Ethylene Oxide Sterilization Validation Routine Process and Controls

Module 3: Auditors and FDA's Compliance Expectations on Ethylene Oxide Sterilization

- Auditor's Review of Ethylene Oxide Sterilization Validation Routine Process and Controls, continued…
- FDA's Inspectional Guide on Sterilization Process Controls
- FDA Warning Letter Citations – Ethylene Oxide Sterilization
- FDA Warning Letter Citations-EtO Sterilization - Case Studies

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