# Topic: Understanding the Basics of Ethylene Oxide Sterilization Requirements and ISO 11135 Regulations

**Location: San Diego, CA**

**Date: April 12 and 13, 2018**

**Time: 8:30am-5:00pm.**

**Detailed Agenda:**

**Background**

This Conference/Webinar will guide the attendee in gaining a better understanding of the regulations/requirements guiding Ethylene Oxide sterilization validation/qualification and re-validation/requalification processes. The attendees will understand the process steps associated with effectively addressing the initial and re-qualification of new or modified ETO sterilization Chamber and applicable Cycle parameters during ETO validation per ISO 11135.

**Detailed Agenda**

**Seminar/Training Day 1**

**9am-9:30am (Breakfast and Registration)**

**9:30 am– 10:00 am - Session 1**

* Understand the rules, regulations and guidelines for Ethylene Oxide Sterilization
  + ANSI/AAMI/ISO 11135-1:2007 Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
  + ANSI/AAMI/ISO TIR11135-2:2008Association for the Advancement of Medical Instrumentation Sterilization of health care products — Ethylene oxide — Part 2: Guidance on the application of ANSI/AAMI/ISO 11135-1
  + AAMI TIR14:2009 Association for the Advancement of Medical Instrumentation Contract sterilization using ethylene oxide
  + ANSI/AAMI/ISO 11138-2:2006/(R)2010 Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes.
  + AAMI TIR28:2009 Association for the Advancement of Medical Instrumentation Product adoption and process equivalence for ethylene oxide sterilization
  + ANSI/AAMI/ISO 10993-7:2008 Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals
  + AAMI TIR16:2009 Association for the Advancement of Medical Instrumentation Microbiological aspects of ethylene oxide sterilization.
  + AAMI TIR15:2009 Association for the Advancement of Medical Instrumentation Physical aspects of ethylene oxide sterilization
* **Describe the Basics of Ethylene Oxide sterilization requirements.**
  + Overview of Ethylene Oxide (EtO) sterilization process
  + Why perform EtO Sterilization Process on Products
    - Products Suitable for EtO Sterilization Processes

**10:00 a.m. – 11:00 am - Session 2**

* **Understanding the Typical EtO Treatment Conditions**
  + The Basics of EtO Processing Steps
    - Preconditioning/conditioning
    - Sterilization cycle
    - Aeration
* **EtO Cycle Development Process**
  + Equipment/Process qualified by contract sterilizer
  + Sterilization cycle development
* **Sterilization Load Pattern**
  + Developed maximum load pattern

**11:00am – 11:15am (Break)**

**11:15am – 12:00 pm - Session 3**

* **Example of EtO Qualification**
* **Steps in the Qualification of Ethylene Oxide Qualification**
  + How to Establish the Qualification Process
  + How to Establish the Revalidation Requirements
* **How to Determine Packaging Bioburden**

**12:00pm – 1:00pm (Lunch)**

**1:00pm – 2:00 pm - Session 4**

* **How to Perform Bioburden Determination**
  + Bioburden determination of the product per ISO 11737-1:2006
* **Performing Load Preconditioning**
* **Performing Microbial Challenge using Biological Indicators (BIs)**

**2:00pm – 3:00 pm - Session 4**

* **Survival Cycle**
  + Demonstrate capability to recover BIs
  + Survival cycle identical as full cycle except the EtO gas exposure time is less
  + Single cycle
  + Survivors support recovery process

**3:00pm – 3:15 pm (Break)**

**3:15pm – 4:00 pm (Case Studies)**

* FDA issued 483’s and Warning Letter Compliance Citations associated with EtO Validation – **Case Study #1**
* FDA issued 483’s and Warning Letter Compliance Citations associated with EtO Validation – **Case Study #2**
* FDA issued 483’s and Warning Letter Compliance Citations associated with EtO Validation – **Case Study #3**

**4:00pm – 5:00 pm (Questions and Answer Session)**

**5:00pm (End of Day #1)**

**Seminar/Training Day 2**

**9am-9:30am (Breakfast and Registration)**

**9:30 a.m. – 10:00 am (Session 1)**

* **Half Cycle**
  + Half cycle identical as full cycle except the EtO gas exposure time is half
  + Run in triplicate
  + Challenges
  + Half cycle used to support a SAL of 10-6

**10:00 a.m. – 11:00 am (Session 2)**

* Understanding the Process of Qualification of an ETO sterilization cycle parameters
* Understanding how to validate a new chamber for ETO sterilization
* **Full Cycle**
  + Full Cycle Primarily used to support product and packaging integrity
  + Run in triplicate
  + Challenges
* **Re-sterilization**
  + Samples exposed to multiple cycles at worse case locations
  + Challenges associated with Re-sterilization

**11:00am – 11:15am (Break)**

**11:15 a.m. – 12:00 pm (Session 3)**

* **Revalidation/Requalification**
  + Re-qualification program established
  + Change Control
  + Product Change

**12:00pm – 1:00pm (Lunch)**

**1:00pm – 2:00pm (Session 4)**

* **Routine Processes**
  + Contract Sterilizers/Manufactures Responsibilities
  + Critical parameters
  + Use of Biological Indicators (BIs) versus Non-use of BIs

**2:00pm – 2:15 pm (Break)**

**2:15pm – 3:00 pm (Case Studies)**

* FDA issued 483’s and Warning Letter Compliance Citations associated with EtO Validation – **Case Study #4**
* FDA issued 483’s and Warning Letter Compliance Citations associated with EtO Validation – **Case Study #5**
* FDA issued 483’s and Warning Letter Compliance Citations associated with EtO Validation – **Case Study #6**

**3:00pm – 4:00 pm (Questions and Answer Session)**

**4:00pm (End of Day #2 Closing Comments and Adjournment)**

**Tuition and Registration**

**TUITION\*– Single Rate:** U.S.**$1,295.00 per person Group Rate:** U.S.**$1,245.00 per person\*\***

Register at www.pharmabiodeviceconsultant.com. For Questions and Information call Customer Service at 240-678-2020.

Please Note: Multiple participants are not authorized to share access provided to a single registrant, a single dedicated seat license must be purchased for each individual. Pharmabiodevice Consulting LLC reserves the right to cancel access or collect the group rate payment if this requirement has been violated. Only registered participants will receive accreditation.

System Requirements: PC-based attendees: Windows(R) 7, Vista, XP or 2003 Server/Macintosh(R)-based attendees: Mac OS(R) X 10.4.11 (Tiger(R)) or newer

**Online Training Course/Courses of interest**

1. Basic Requirement of the Bacterial Endotoxin Testing (BET) or LAL Program–An Online Course. The course ID# 2567
2. CAPA: A Critical Quality System Requirement–An Online Course. The course ID# 2570
3. Clean Room Operations in a Nutshell–An Online Course. The course ID# 2662
4. Designing an Effective Environmental Monitoring Program–An Online Course. The course ID# 2765
5. Environmental Monitoring (EM) Program Basics–An Online Course. The course ID# 2663
6. Out-of-Specification (OOS) Result Investigation–An Online Course. The course ID# 2581
7. Performing an Effective, Robust and Compliant Sterility Failure Investigation: How to Avoid Common Mistakes–An Online Course. The course ID# 2766
8. Standard Operating Procedure (SOP) and Standard Test Method (STM) Requirements–An Online Course. The course ID# 2584

**Course Director**



**Charity Ogunsanya (CEO, Pharmabiodevice Consulting LLC**

Charity Ogunsanya has over 26 years of extensive experience within the Pharmaceutical, Biotechnology, Biologics, Cell-Therapy, Diagnostics, Research and Development, Radio-pharmaceutical, Contract Manufacturing Organization (CMO) and Medical Device companies.

Throughout her corporate career within these diverse industries, she held various high visibility and business critical roles within the Quality and Compliance division in major Fortune 100 companies both as a Subject Matter Expert (SME), Site Manager, Multi-site Manager and Director Levels receptively.

She has been a sought after expert and have been consistently hired after several competitive efforts by major fortune 100 companies to assume key roles specifically related to remediation and difficult Quality and Compliance related deficiencies associated with FDA’s Consent Decree, FDA’s Warning Letters and difficult regulatory bodies inspectional findings which is always achieved with a successful outcome. She has also been a sought after expert by various companies requesting her expertise as a known industry expert to specifically assume roles in order to perform a total overhaul, restructure, compliance remediation, re-organization, start-up processes related to Quality Systems improvements and/or enhancements. In all cases, her remediation work resulted in several successful National and International regulatory bodies’ inspections, re-inspection and new product approvals.

Her technical expertise are not limited to the interpretation, administration and set up of Quality Assurance, Quality/Compliance, Quality Engineering, Aseptic Processing, Contamination Control, Quality Control, Microbiology, Sterility Assurance, Stability, Vaccine Development, New Product Design, Product Release Testing and Medical Device Sterilization (Ethylene Oxide (EtO), Gamma, Radiation, VHP sterilization) systems and operations for compliance to various regulations.

Ms. Ogunsanya is vast in the requirements and regulations guiding new and existing products from planning through design, proof of concept, research and development, technology transfer, pre-clinical, clinical, commercial manufacturing, supply chain, regulatory filings, pre-approval inspections, licensure, government affairs, commercialization and post-approval inspections. Her expertise has been sought after by several Fortune 100 Pharmaceutical, Biotechnology, Biologics and Medical Device companies as a Quality and Compliance SME during critical national and international regulatory bodies’ routine and new product approval inspections.

She is the CEO of Pharmabiodevice Consulting LLC (www.pharmabiodeviceconsultant.com) targeted towards Quality and Compliance related remediation, enhancements and consultant services for various companies within the industry. She is a well sought after high level consultant for several international professional expert networks such as Gerson Lehrman Group, Zintro Expert Network and Intota Expert Network. She is a member of the Parenteral Drug Association (PDA), American Society of Microbiologists (ASM), and other Scientific Forums and Industry Expert Network.

Ms. Ogunsanya’s technical industry expertise is recognized based on numerous invitations that she receives to speak at national and international conferences, seminars and webinars hosted by very reputable conference and seminar organizations such as Center for Professional Advancement (www.cfpa.com), Institute for Validation Technology (http://www.ivtnetwork.com), Compliance Online (http://www.complianceonline.com), International Pharmaceutical Academy (IPA) and others.

She has a Bachelor of Science degree in Microbiology from the University of Benin-Nigeria and her Masters in Biotechnology (Biodefense Concentration) at the Johns Hopkins University Advanced Academic Program.