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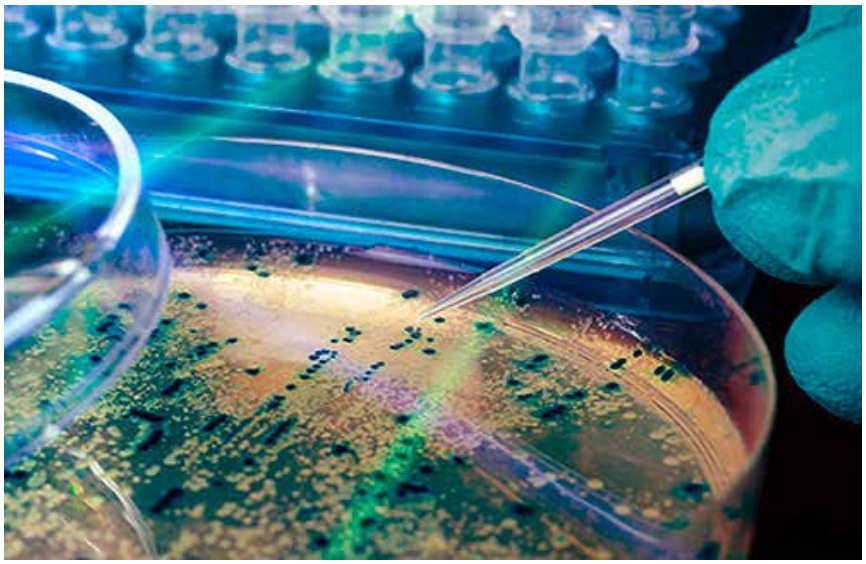
2-Day In-Person Seminar

Cleanroom, Microbiology and Sterility Assurance Practices for Drug and Device Manufacturers

By: **Charity Ogunsanya,** CEO and Founder, Pharmabiodevice Consulting LLC

Location: Dallas, TX | May 28-29, 2020



SPEAKER

Charity Ogunsanya, CEO and Founder, Pharmabiodevice Consulting LLC

Charity Ogunsanya, is the CEO and founder of Pharmabiodevice Consulting LLC. Ms. Ogunsanya has over 23 years of extensive practical and management experience in various Fortune 100 pharmaceutical, biotechnology, biologics, cell therapy, diagnostics, research and development, radio-pharmaceutical, Contract Manufacturing Organization (CMO) and medical device/IVD companies.

She has been a much sought after SME 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 other regulatory bodies' inspectional findings. Her remediation work has constantly resulted in several successful national and international regulatory bodies' inspections, re-inspections and new product approvals.

Her technical expertise covers and goes beyond 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.

She has a keen working knowledge of 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.

She is a member of the Parenteral Drug Association (PDA), American Society of Microbiologists (ASM), and other Scientific Forums and Industry Expert Network. She has a Bachelor of Science degree in Microbiology from the University of Benin-Nigeria and she is currently attaining her Masters in Biotechnology (Biodefense Concentration) at the Johns Hopkins University Advanced Academic Program.

COURSE DESCRIPTION

This course will educate you about various key elements of sterility assurance and contamination control such as Cleanroom Regulations, Classification, Sources and types of particles, Design Requirements, Validation/Qualification, Operations, Environmental Monitoring Program requirements, Excursion investigations, DataTrending, Microbiological processes/methodology, Cleanroom cleaning/disinfection. The types of micro-organisms, typical mitigation steps in ensuring an effective contamination control through Personnel Training (Aseptic Practices, Cleanroom Behavior and Contamination Control Procedures),Gowning Controls, Personnel Training, Cleanroom Trafficking (Cleanroom Personnel Material, Product and Equipment Transfer Practices and Training (Entry and Exit Policy), Cleanroom Gowning, Contamination Control, Cleaning and Disinfection Program and the Basics of Sterilization Processes- Physical and Chemical Processes will also be discussed. The various regulatory bodies' requirements such as 21 CFR Part 211 (mostly relevant 211.113 "Control of microbiological contamination", ISO 14644 (Various Parts), FDA Guidance for Industry: Sterile Drug Products Produced By Aseptic Processing - Current Good Manufacturing Practice") amongst others and the criticality of aseptic processing and other key contamination control evaluators during the manufacture and testing of products are important to the quality determination and release of the finished manufactured products.

The seminar will consist of two (2) Parts for a total of 6 Modules.

There are seven (7) key topics that will be discussed on Day 1 and Day 2 of the Seminar are as follows:

- Cleanroom Regulations, Classifications, Basic Background and Design Considerations
- Cleanroom Qualification, Cleaning Validation (IOQ/PQ), Routine Monitoring and Excursion Investigation
- Environmental Monitoring Program (Monitoring, Excursion Investigation and Trending of Data)
- Personnel Training (Aseptic Practices, Cleanroom Behavior and Contamination Control Procedures)
- Cleanroom Trafficking (Cleanroom Personnel Material, Product and Equipment Transfer Practices and Training (Entry and Exit Policy)

- Cleanroom Gowning, Contamination Control, Cleaning and Disinfection Program
- Basics of Sterilization Processes- Physical and Chemical Processes

Bonus: Compliance Expectations, FDA Form 483's and Case Studies

LEARNING OBJECTIVES

- Discuss Cleanroom Classification, Regulations and Guidelines
- Summarize how to Perform Cleanroom Design, Validation/Qualification, Operation, Environmental Monitoring Program and ensuring a state of control
- Describe Aseptic Practices, Personnel Health Practices, Gowning and Trafficking Patterns in a Cleanroom
- Establish and describe the Requirements of Cleanroom Cleaning/Disinfection and Contamination Control Practices
- Summarize various Sterilization Processes, Advantages and Disadvantages –both Physical and Chemical
- Describe the Sterilization Processes and Controls

AGENDA

Day 1 (8:30 AM – 4:30 PM)

08.30 AM - 09.00 AM: Breakfast and introduction

9:00 AM – 11:00 AM: Module 1

- Cleanroom Guidelines, Regulations and Definitions
- Summary of Key Areas of Cleanroom Technology and Classifications
- Define the EU, ISO and USP Recommended Limits for Microbial Contamination
- Cleanroom Design and Initial Design Considerations
- Cleanroom Design Guidelines - Facility Layout, Airlocks or Anteroom, Windows and Speaking Diaphragms, Pass-through and Gowning Rooms
- Cleanroom Design Guidelines - Cleanroom Location, Make-up Air, Cleanroom Walls- Seamless, Non-porous Surface

11:00 AM – 11:15 AM: Break

11:15 AM – 12.00 PM: Module 2

- Review Cleanroom Design Guidelines (Material of Construction for Cleanroom Ceilings), Cleanroom Doors and Cleanroom Floors
- Discuss the Design Guidelines (HVAC & Filtration Systems) and the types of Cleanroom Airflow

12:00 PM – 01:00 PM: Lunch Break

01:00 PM – 02.30 PM: Module 2

- Summary of the principles and regulations guiding Cleanroom Validation (OQ/PQ) and Operation testing
- Performing Cleanroom Effectiveness Verification Tests and utilizing Cleanroom Cleaning Validation Data in a PQ Process
- Designing a Cleanroom Performance Qualification (PQ) Protocol and Report
- Applying the Fundamentals of Environmental Monitoring (EM) Program, Limits, Requirements, Excursion Investigation and Data Trending
- Perform a correlation between Contamination Control and Environmental Monitoring
- Understand the Causes of Adverse Trends

02:30 PM – 02:45 PM: Break

02:45 PM – 04.00 PM: Module 3

- How to Use the principles of Aseptic Practice regulation to set up an Aseptic Environment and for the manufacturing of a product
- Cleanroom Practices - Personnel Health and Cleanliness, Personnel Practices (Sterile Gloves, Sterile Gowns and Operator Technique)
- Step-wise approach in performing workstation and Equipment Cleaning and Disinfection
- Process flow/Trafficking Patterns for Equipment, Materials, Personnel, Supplies and Waste within a Cleanroom

04:00 PM – 05.00 PM: Question and Answers

Day 2 (8:30 AM – 4:30 PM)

08:30 AM – 09:00 AM: Breakfast

09:00 AM – 11.00 AM: Module 1

- Cleaning/Disinfection Program Guidance and Regulations
- The Basics of Microbiology and Contamination Control and Mitigation
- GMP Cleanroom Cleaning and Primary Cleanroom Contaminants
- Cleanroom Gowning Guide, Garment Recommendations, Gowning/Degowning and Requirements by ISO Classification

11:00 AM – 11:15 AM: Break

11:15 AM – 12.00 PM: Module 2

- Sterilization Processes and Methods (Physical and Chemical)
- Terminologies and factors influencing Thermal (Heat) Sterilization
- Examples of Dry Heat Sterilization (Hot air oven, Flaming (AKA Red Hot Sterilization), Incineration, Dry Heat Tunnels, Infra-red Radiation
- Moist Heat Sterilization and Examples - Pasteurization, Boiling, Tyndallization, Autoclave/Steam Sterilizer.

12:00 PM – 01:00 PM: Lunch Break

01:00 PM – 02.30 PM: Module 2

- Advantages and Disadvantages of various types of dry heat and moist heat sterilization processes
- How to Differentiate between Ionizing and non-ionizing Radiation including microwave Radiation, Ultraviolet Radiation, Gamma Rays/Gamma Sterilization
- Use and Disadvantages of Ionizing Radiation-Gamma Radiation
- Chemical Sterilization Methods using various types of liquid sterilants such as Phenolic , Hydrogen Peroxide, Halogens, Chlorine and Alcohols, Heavy Metals, Quatenary, Peroxygens and Aldehydes

02:30 PM – 02:45 PM: Break

02:45 PM – 03.45 PM: Module 3

- Chemical Sterilization using Gaseous Method such as Ethylene Oxide, Formaldehyde and Glutaraldehyde Sterilization
- Sterilization by Filtration and various types of Filters
- Monitoring of Sterilization Processes using Mechanical and internal chemical Indicators
- Routine Monitoring of Steam Sterilizers and Ethylene Oxide Sterilizers - Bowie Dick Type Tests and Test Results
- Installation & Repair Testing and Sterilization Process Monitors

03:45 PM – 04.45 PM: Review of case studies

04:45 PM – 05.00 PM: Question and Answers

WHO WILL BENEFIT

This training will benefit those involved in the manufacturing, processing, testing and release of sterile and non-sterile products. It will provide the attendee an understanding of the basic concept of microbiology, microbiological and contamination control practices, cleanroom design, routine testing, qualification/validation and use of cleanrooms as well as the typical sterilization processes (Physical and Chemical) within various industries such as the Pharmaceutical, Biotechnology, Drug, Biologics, Medical Device and In-vitro Diagnostics Product Manufacturing Industries, especially personnel and management in:

- Quality Assurance
- Quality Control
- Manufacturing
- Validation
- Supplier Quality Assurance
- Regulatory Affairs
- Shipping and Receiving
- Facility and Maintenance
- Engineering
- Materials Management
- Analysts
- Analytical Chemists

Registration Form

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Written cancellations through fax or email (from the person who has registered for this conference) received at least 10 calendar days prior to the start date of the event will receive a refund — less a $300 administration fee. No cancellations will be accepted — nor refunds issued — within 10 calendar days from the start date of the event. On request by email or fax (before the seminar) a credit for the amount paid minus administration fees ($300) will be transferred to any future ComplianceOnline event and a credit note will be issued. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after distributing to other attendees. In case it is not available we will send the material after the conference is over. In the event ComplianceOnline cancels the seminar, ComplianceOnline is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

Seminar Topic: Cleanroom, Microbiology and Sterility Assurance Practices for Drug and Device Manufacturers

Date & Location: .Dallas, TX | June 18-19, 2020 .....

Attendee Details Registration Fee $1899.00:

	Name	Title	Email
Attendee 1			
Attendee 2			
Attendee 3			
Attendee 4			

Email address (so you can receive order acknowledgements, updated news, product information and special offers)

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Organization .....

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Payment Options

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C ☐ Charge to: ☐ Visa ☐ MasterCard ☐ American Express

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Expiration date .....

Total amount $ .....

Signature .....
(Signature required on credit card and bill-me orders.)

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