**Topic Title:** **How to Achieve a Compliant and Effective Cleanroom Design and Facility**

**Validation**

**Speaker: Charity Ogunsanya (CEO, Pharmabiodevice Consulting LLC)**

**Course Duration: 90 Minutes**

**Q&A Duration: 10 Minutes**

**Date: March 27, 2018**

**Time: 10 am PST (1 pm EST)**

**Background:**

An effective product manufacturing Cleanroom design helps in facilitating a compliant facility validation, disinfection program, routine monitoring, Cleanroom controls and a continuous microbial state of control. The criticality of ensuring a state of control within a product manufacturing Cleanroom facility cannot be over emphasized. A well designed product manufacturing Cleanroom is a key critical starting point in preventing future design-related compliance issues. I.e. Clean room microbial bioburden leading to aseptically manufactured sterile drugs, pharmaceutical, biotechnology, vaccines, cell therapy and other product contamination.

Other related issues arising from a poorly designed cleanroom includes but not limited to persistent environmental monitoring excursions, inability to validate the cleanroom for routine process use, product cross-contamination from ineffective airflow and cleanroom controls and so much more.

A constant high level of facility micro-organisms based on environmental monitoring test results may be impacting to the drug or product manufacturing process, loss of the batch of an aseptically manufactured product, high cost of environmental monitoring excursion investigation, delayed product release, loss of sales, product complaints, redesign issues, revalidation, impact to other cleanroom utilities and a host of other issues…..

**Why should you attend:**

This 90-minute training will provide an understanding of the regulations guiding cleanroom facilities, what constitutes an effective design, cleanroom classification, how a cleanroom validation should be structured as well as the routine monitoring of cleanrooms after the facility validation has been completed. The attendees will also gain an understanding of the different classifications and limits specific to the requirements stipulated by the USP, EU and ISO. The ways and types of materials of construction to be used within a cleanroom during the design and construction for an effective design and continuous contamination control will also be discussed. Designing an effective cleanroom facility validation protocol and report, when and how to transition into the routine environmental monitoring processes and how to maintain a state of control within the cleanroom and the routine environmental monitoring and excursion investigation processes will be discussed.

**Areas Covered in the Session:**

**Module#1 (Basics Background of a Clean room Regulation, Classification and Design)**

* Summary of the Regulations Guiding Clean room Technology, Design and Validation
* Types of Clean room Classifications and Requirements
  + EU Vs. ISO Vs. USP Requirements and Classification
* Types and Sizes of Clean room Particles
* Typical Uses of Various Levels of Clean room Classifications
* How to Ensure an Effective Design of a Clean room
  + Initial Consideration and Roles
  + What Constitutes an Effective Cleanroom Design
  + What Materials of Construction to Use in the Design
  + Specific Design Concept Applicable to Processes
  + Planning a Cleanroom Design
    - Who Should be Involved/Roles
  + Process Steps in the Design of a Clean room

**Module#2 (Cleanroom Cleaning Validation, Routine Monitoring and Excursion Investigation)**

* Summary of Clean Room Validation Process
* Process Steps Applicable to Clean Room Validation
  + Clean Room Facility Validation Protocol-Content
  + Cleanroom Validation Report-Content
* Role of Various Departments During the Validation Process
  + Facility Engineers in the Process
  + Validation in the Process
  + Quality Control in the Process
  + Quality Assurance in the Process
* Utilizing Clean Room Validation Data for Routine Environmental Monitoring Program
  + Routine Environmental Monitoring Programs Applicable to Cleanroom
  + Testing Types
* Typical Clean Room Environmental Monitoring Excursions
* Investigating and Correcting Cleanroom Environmental Monitoring Excursions

**Module#3 (Contamination Control and Disinfection Processes)**

* Clean Room Contamination Control and Disinfection Processes
  + Mitigating Particulate Contaminants
    - Cleanroom HEPA Filtration
    - Cleanroom cleaning, sanitization and/or disinfection process
    - Other Best Practices - Control of Clean room Contaminants:
      * Cleanroom Personnel Training
      * Basic Aseptic Practices
      * Gowning Practices and Personnel Qualification
      * Personnel Clean room behavior

**Question and Answer Session**

**Learning objectives: (Optional)**

* Discuss the basic background, types of clean room classification, various regulations, applications and particulate levels associated with clean room facilities.
* Discuss the clean room design consideration, planning, roles, materials of construction, effective design and execution processes prior to the validation.
* Describe clean room validation process steps not limited to roles, consideration, planning, execution, protocol and report content and validation process steps.
* Discuss the transitional process steps from facility validation into routine clean room environmental monitoring processes.
* Discuss roles and consideration during these processes as well as how to maintain a state of continuous environmental control and investigations associated with a clean room monitoring excursion.

**Who will benefit:**

This webinar will provide a great resource to personnel involved within the following departments in the Pharmaceutical, Biotechnology, Diagnostics, Drugs, Cell Therapy, Biologics and Medical Device industries:

* Quality Control
* Manufacturing/Production
* Senior Management
* Regulatory Affairs
* Quality Assurance
* Compliance
* Design Engineers
* Facility, Maintenance and Engineering
* Test Contractors

However, if you are already familiar with how to achieve a Compliant and Effective Cleanroom Design and Facility Validation you may recommend this webinar to anyone in your company that may require additional knowledge about this subject.

**Target audience (Job tittle or job function):**

This webinar is targeted mainly to:

* Quality Control
* Manufacturing/Production
* Senior Management
* Regulatory Affairs
* Quality Assurance
* Compliance
* Design Engineers
* Facility, Maintenance and Engineering
* Clean Room Testing Contractors
* Environmental Monitoring Technicians

Target Companies/Industries: (New)

1. Pfizer
2. Amgen
3. Johnson and Johnson
4. GSK
5. MedImmune
6. Roche
7. Sanofi Pasteur
8. Genzyme (Roche)
9. Abbott Laboratories
10. Pharmaceutical
11. Biotechnology
12. Biologics (Vaccine)
13. Cell Therapy
14. Diagnostics
15. Medical Device
16. Drugs
17. Radio-pharmaceuticals

**Keywords: (optional)**

Facility, Validation, Cleanroom, Technology, Design, Environmental Monitoring, Aseptic Processing, Classified Areas, Contamination Control, Clean Room Technology, Disinfection, Facility Validation

**Tuition and Registration**

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

**Instructor Profile:**



**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.