# Topic: cGMP Controlled Raw Material Testing Program

**Location: New Brunswick, NJ**

**Date: December 13 and 14, 2018**

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

**Detailed Agenda:**

**Course Description**

cGMP raw materials are the most critical ingredient of any product manufacturing step hence they must be controlled as stipulated in 21 CFR110.80 *Processes and Controls* as well as applicable FDA regulations. Raw material control is a very critical part that ensures drug product quality, purity and potency. Drug product manufacturers must have a defined procedure that clearly shows how raw materials are received, stored, labeled, quarantined, tested, qualified, tracked, used, and discarded at the end of expiry.

This training will provide guidance to the process of ensuring that there all the steps are followed to avoid producing an adulterated product as defined by the 21 CFR110.80 *Processes and Controls*. This seminar contains a lot of technical content, case studies, practical discussions and an exciting learning environment.

**Who Should Attend:** This seminar will benefit those involved in manufacturing, using, testing and Validating pharmaceutical gas systems in various industries such as the Pharmaceutical, Biotechnology, Drug, Biologics, Medical Device and In-vitro Diagnostics Product Manufacturing Industries, especially:

* Quality Assurance Personnel 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 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 training, you will be able to describe the appropriate ways to design the processing of all cGMP Controlled raw materials, List the steps that every drug product manufacturer should follow in order to process all incoming cGMP controlled raw materials and develop defined procedures for receiving, storing, labeling, quarantining, testing, qualifying, tracking, and discarding controlled raw materials

**Seminar Day 1**

**08:00: Registration**

**8:30am-9:00am (Breakfast)**

**9:00am–10:00am**

* Regulatory Requirements Guiding cGMP Controlled Materials:
* Examples of cGMP Controlled Materials
* How to Assess and Determine the Criticality of the cGMP Controlled Materials
  + Level I cGMP Controlled Materials
  + Level 2 cGMP Controlled Materials
  + Level 3 cGMP Controlled Materials
* Handling, Receipt and Storage of cGMP Controlled Materials

**10:00am-10:15am (Break)**

**10:15am–11:00am**

#### New Incoming cGMP Controlled Materials

#### Content of a New cGMP Controlled Material Test Specification

* + - Example of a cGMP Controlled Material Specification

#### Processing the cGMP Controlled Material Test Specification

### Approving the cGMP Controlled Material Test Specification

### Issuing the cGMP Controlled Material Test Specification

**11:00am-12:00pm**

* Testing Requirements for all cGMP Controlled Materials

### Performing the Testing of New and Unqualified Controlled Materials

### Processing New and Unqualified cGMP Controlled Materials

### Steps of Initial Qualification Testing of cGMP Controlled Materials

* + - Documenting and Approving Initial Qualification Testing of cGMP Controlled Materials
    - Releasing cGMP Controlled Material after Performing Initial Qualification Testing
  + Performing Routine Testing of Already Qualified cGMP Controlled Materials

### Processing already qualified cGMP Controlled Materials

### Steps of Routine Testing of cGMP Controlled Materials

* + - Documenting and Approving cGMP Controlled Materials after Routine Testing
    - Releasing cGMP Controlled Material after Performing Routine Testing

**12:00pm-1:00pm (Lunch)**

**1:00pm–2:00pm**

### cGMP Controlled Materials Yearly Confirmatory Testing Process

### Comparison Criteria Used in the Confirmatory Yearly Testing

### Performing Yearly Evaluation and Confirmatory Testing for Suppliers and Manufacturers of cGMP Controlled Materials

### Evaluation of Suppliers and Manufacturers of Controlled Materials after Approved Specification Changes

### cGMP Controlled Material Specification Testing Parameters

### How to Perform Disqualification of Testing Parameters

**2:00pm–3:00pm**

### How to Document Processed cGMP Controlled Materials

### Document Review of Controlled Materials

### Processing Failed cGMP Controlled Materials

### Investigating Out of Specification (OOS) Test Results Associated with Failed

### Handling Rejected Raw Materials

**3:00pm-3:15pm (Break)**

**3:15pm-4:00pm**

* Review of Case Studies Case Studies - FDA Form 483’s Inadequate Handling of cGMP Controlled Materials

**4:00pm – 5:00pm**

* Questions/Answers

**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.