**Seminar Date**:  **November 16, 2018**

**Seminar Time:** **11:00am – 12:30pm**

**Background:** This Live Webinar will help the attendee gain a better understanding of the requirements of the FDA’s Drug Stability Guidelines stipulated for new, existing and modified drug products. This webinar will provide a knowledge base to existing personnel within the Biologics, Pharmaceutical, Biotechnology or Medical Device industries with a current stability testing program to allow for the best path in maximizing the use of their product stability test data to set or extend their product’s expiration date amongst others. This webinar will also provide the detailed requirements applicable to FDA’s and 21CFR 514.1(b)(5)(x) expectations which states that *“an applicant should submit data from stability studies that have been completed as well as information about studies that are underway to substantiate the request for a specific expiration date and provide information on the stability of the drug products”***.** For this reason, it is important to have clarity and a good understanding of how to apply the various regulations to a Stability Testing Program prior to the initiation of a new program. This includes the proper way to design a Stability testing Protocol, Product Storage Temperature/Conditions, Sampling Plan, Sample Handling, Testing Process/Test Method, Storage, Data Management, Trending and Expiration date extrapolations and expectations for products in a new or existing IND or NDA application process.

**Importance of Webinar Topic:** New or existing modified drug Stability Testing Program’s regulations/requirements stipulated by the FDA, 21 CFR or other regulations may sometimes creating an overwhelming situation based on the type of product that is being manufactured. Hence, some manufacturers of new drug products have made inadvertent mistakes in the design of their new drug stability testing program. Such mistakes may ultimately delay the new, existing or modified product IND or NDA application process due to the data that was presented to the FDA (i.e. Relevant aspects of the stability testing program requirement may have been omitted by the drug manufacturers). It is better to understand, follow and apply the full requirements of a new product stability testing requirement from the onset or to correct an existing stability testing program so as to avoid future pitfalls and delayed IND or NDA submission process by the FDA.

Having produced a new or existing product, knowing the appropriate way to design and perform the stability testing of the new product which is a prerequisite for setting the product’s expiration date and possible extension of the expiration date is critical. Some drug product manufacturers have made mistakes in the past whereby a new product that was manufactured appropriately did not have a good stability testing plan or program hence it delayed the product’s ability to have an approved IND or NDA submission. A mistake of this sort has also been made by drug manufactures that resulted in a 483 or Warning letter by the FDA. Knowing how to approach the design of a new product stability program at the onset of the new product design or during an existing product testing is important and will save a company time and cost in moving the product to the next phase.

**Areas within the Webinar Sessions:** This Webinar will provide a great resource to Pharmaceutical, Biotechnology, Diagnostics, Cell Therapy, Drugs, Biologics, OTC, Radio-pharmaceutical, Pharmacies and Medical Device Industries in understanding the effective way to establish a new or modified product stability testing program. This program is an important part of a product’s regulatory filing requirements as well as the determination of the shelf life or expiration date of the product. This is an important part of every business final bottom line or indirectly relationship to their supply and warehouse chain (how long the product can be stored before it can be discarded). Understanding how to design and implement an effective stability testing program following the regulatory guidelines will allow the product to be manufactured, tested, released, adequately stored and effectively tested for stability and ultimately used through its actual end point based on the product’s potency. This will eliminate potential loss of product and business income by manufacturers of product (i.e. when a potent product is inadvertently discarded due to a poorly designed stability testing program) which ends up impacting the products’ regulatory filing status or a product’s Regulatory Filing/Application. The focus of this webinar will create a detailed process that will guide the attendees in the right direction in the planning of a new or existing product’s stability testing plan, program, protocol, handing and utilizing the data, setting the shelf life as well as the applicable regulatory requirements:

1. **Introduction of a Stability Testing Plan and Program.**
   1. Applicable Regulation and Requirements.
2. **General Stability Considerations applicable to a New product (I.e. Potency)**
3. **Storage Conditions**
   1. Shelf Life Duration of Studies and Expiration Dates
   2. Container Closure Requirements
4. **Sample Size**
   1. Sampling Plan
   2. Handling and Analysis of Samples
5. **Stability Schedule (Suggested Schedules for Conducting Stability Studies)**
   1. Pre-approval and Post Approval Studies
   2. Stability Tests
   3. Reformulated Products
   4. Accelerated Temperature Studies
   5. Test Schedule Information
      1. Suggested Time Points and Expiration dates based on testing time points
      2. Solid Dosage Forms Suggested Test Schedule
      3. Liquid and Semi-solid Types Products Suggested Test Schedule
      4. Reconstituted Products Suggested Test Schedule
   6. Temperatures of Studies based on the product type
      1. Room Temperature Studies
      2. Elevated Temperature
      3. Refrigeration
      4. Freezing Temperature
      5. Special Humidity Considerations
6. **Analytical Testing Considerations**
   1. Quality Control Release Assays and Methods
   2. Criticality of the Choice of Test that are Stability Indicators
      1. Choice of methods with meaningful data or stability indicator
      2. Method Attributes
   3. Method Attributes
7. **Stability Testing Protocol Design**
   1. How to Design a Protocol and a Report
8. **Stability Testing Data Management and Trending** 
   1. Trending Data
   2. Expiration Dating Extrapolation using Data
9. **Manual versus Automated Data Management**
   1. Advantages and Disadvantages

**Who will benefit: / Target Audience:** This topic applies to personnel/companies in the Pharmaceutical, Biotechnology and Medical Device Industries. The employees who will benefit most include:

* Quality Control Analyst and Management
* Senior Management,
* Manufacturing Associates and management
* Shipping and Distribution Personnel
* Stability Testing Department Personnel and Management
* Regulatory Affairs, and
* Quality Assurance Analyst and Management
* Process Design Personnel and Management
* Drug Packaging Personnel and Management

However, if you are already familiar with the Designing and Sustaining New and Existing Product Stability Testing Program you may recommend this webinar to anyone in your company that has questions about the subject.

**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.