# Topic: Designing and Sustaining New and Existing Product Stability Testing Program

**Location: Orlando, FL**

**Date: September 28 and 29, 2018**

**Time: 10:00 a.m. – 4:00 p.m.**

**Background:**

This Conference/Webinar will help the attendee gain a better understanding of the requirements of the FDA’s Drug Stability Guidelines that is stipulated for new, existing and modified drug products that have an existing or new IND or NDA submission. This webinar will also benefit people within the Pharmaceutical, Biotechnology or Medical Device industries that are currently have a stability testing program but do not know how to maximize the use of their data for extending their product’s expiration dating. This webinar will provide the detailed requirements applicable to the 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”* **FDA’s Guidance for Industry.** For this reason, it is important to have clarity and understanding of how to apply this regulation prior to the initiation of a new product stability testing program which includes the protocol design, testing, storage, data management, trending and expiration dating extrapolations and expectations for products in a new or existing IND or NDA application process.

**Importance of Conference 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 4 Sessions:**

This conference 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 virtual conference/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.

**Detailed Agenda:**

**10:00 a.m. – 10:15 a.m.** Introduction of a Stability Testing Plan, Program, Applicable Regulation and Requirements.

**10:15 a.m. – 11:15 am - Session 1:**

**Topic: General Stability Considerations Applicable to a Product’s Stability (I.e. Potency), Storage Conditions, Sampling Plan and Sample Handling**

**Knowledge Base:** Attendees will gain an understanding in the following key areas:

1. Regulatory guidance associated with the requirements of a product’s stability testing program. Delineating the program requirement specific to a type of product.
2. New product stability indicator test, rationale for choosing the test and impact to the product’s shelf life.
3. The relationship between choosing the right product storage temperature and impact to its shelf life.
4. Container Closure Requirements and Storage Temperature for various types of products.
5. Performing an effective sampling plan and utilizing the appropriate sample size for a stability testing program.
6. Performing a compliant sample analysis, handling and effecting the appropriate test specification for the product type.

**11:15 a.m. - 11:30 p.m. Break**

**11:30 a.m. - 12: 30 p.m. Session 2**

**Topic: Designing and Conducting Effective Stability Testing Program Using the Suggested Schedules for Various Product Types**

**Knowledge Base:** Attendees will gain an understanding in the following key areas:

1. How to Conduct a Pre-approval and Post Approval Stability Testing Studies
2. Performing Various Types of Stability Tests such as Reformulated Products, Accelerated Temperature Studies and others.
3. Understanding the different Types of Stability Test Schedules Provided by Regulations Based on the following Product Types and 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
		5. Performing Different Temperatures of Studies based on the product type such as Room Temperature Studies, Elevated Temperature, Refrigeration, Freezing Temperature and Special Humidity Considerations

**12:30 p.m. - 1:30 p.m. Lunch**

**1:30 p.m. - 2:30 p.m. Session 3**

**Topic: Stability Testing Protocol Design, Data Management and Trending. Comparative Analysis of Using a Manual versus Automated Data Management**

**Knowledge Base:** The Attendees will gain an understanding in the following key areas:

1. How to Design an effective Stability Testing Program, Protocol and a Report for a New and Existing Product.
2. How to Effectively Handle, Manage Data, Utilize and Perform the Trending of Stability Testing Results and Data.
3. Using Stability Testing Data to Generate the Product’s Expiration Dating or Shelf Life.
4. How to Perform the Extrapolation of a Product Shelf Life Using Data from an Ongoing Stability Testing Program – Great for products in clinical studies.
5. Understand the different ways of performing statistical analysis of the stability test result data (manual versus automated software).
6. Understand the Advantages and Disadvantages of both systems.

**2:30 a.m. –2:45 p.m. Break**

**2:45 p.m. - 3:45 p.m. Session 4**

**Topic: Analytical Testing Considerations, Review of Case Studies**

**Knowledge Base:** Attendees will gain an understanding in the following key areas:

1. How to perform Quality Control Testing, Setting Test Specification and Assay Release Process in a Stability Testing Program.
2. Detailed Reasons why the Choice of a Quality Control Test Method, Specific Assays and Tests Specifications are Critical to the Success of a Product’s Stability Testing Program and Shelf Life Determination.
3. Choice of methods with meaningful data or stability indicator
4. Analytical Assay Test Method Attributes
5. **Review of Case Studies on Pharmaceutical Stability Testing - FDA’s Warning Letters to Companies:** Issues Encountered by Drug Product Manufacturers Based on a Poorly Designed Stability Testing Program:
6. **Stability Testing Compliance Issues - Case Study Category #1**

Failure to have a written testing program designed to assess the stability characteristics of drug products in order to determine appropriate storage conditions and expirations dates [21 C.F.R. § 211.166(a)].

1. **Stability Testing Compliance Issues - Case Study Category #2**

Failure to thoroughly investigated any unexplained discrepancy or the failure of a batch or any of its components to meet its specifications whether or not the batch has already been distributed [21 C.F.R. § 211.192].

1. **Stability Testing Compliance Issues - Case Study Category #3**

Failure to ensure your container closure system provided adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product [21 C.F.R. § 211.94(b)].

**3:45 p.m. – 4:00 p.m. 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.