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2-day In-person Seminar:

Designing and Sustaining New and Existing Product Stability Testing Program

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

Location 1: November 17-18, 2016 | Orlando, FL **Location 2:** February 20-21, 2017 | Atlanta, GA

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.

LEARNING OBJECTIVES

This seminar 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 seminar 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 seminar 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.

COURSE DESCRIPTION

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.

This seminar 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 seminar 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.

WHO WILL BENEFIT

The Seminar will benefit people within the pharmaceutical, biotechnology or medical device industries that currently have a stability testing program but are not savvy about maximizing the use of their data for extending their product's expiration dating. 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
- Quality Assurance Analyst and Management
- Process Design Personnel and Management
- Drug Packaging Personnel and Management

AGENDA

Day One (8:00 AM – 5:00 PM)

Breakfast and Registration: 8:00 AM – 9:00 AM

Session 1: 9:00 am – 10:15 am

- 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:
- Introduction of a Stability Testing Plan and Program.
  - Regulatory guidance associated with the requirements of a product's stability testing program.
  - Delineating the program requirement specific to a type of product.
  - Applicable Regulation and Requirements.
  - Purpose of a Stability testing Program
- General Stability Considerations applicable to a New product (I.e. Potency)
  - New product stability indicator tests
  - Rationale for choosing the test and impact to the product's shelf life.
- Storage Conditions
  - Shelf Life Duration of Studies and Expiration Dates
  - Container Closure Requirements

Session 2: 10:15 am - 11: 00 am

- Sample Size
  - Sampling Plan
  - Handling and Analysis of Samples
- Stability Schedule (Suggested Schedules for Conducting Stability Studies)
  - Pre-approval and Post Approval Studies
  - Stability Tests
  - Reformulated Products
  - Accelerated Temperature Studies
  - Test Schedule Information
    - Suggested Time Points and Expiration dates based on testing time points
    - Solid Dosage Forms Suggested Test Schedule
    - Liquid and Semi-solid Types Products Suggested Test Schedule
    - Reconstituted Products Suggested Test Schedule

11:00 am – 11:15 am (Break)

Session 3: 11:15 am - 12: 00 pm

- The relationship between choosing the right product storage temperature and impact to its shelf life.
  - Temperatures of Studies based on the product type
  - Room Temperature Studies
  - Elevated Temperature
  - Refrigeration
  - Freezing Temperature
  - Special Humidity Considerations
- Container Closure Requirements.
- Storage Temperature for various types of products.
- Performing an effective sampling plan and utilizing the appropriate sample size for a stability testing program.
- Performing a compliant sample analysis, handling and effecting the appropriate test specification for the product type.

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

Session 4: 1.00 pm - 2: 00 pm

- 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:
  - How to Conduct a Pre-approval and Post Approval Stability Testing Studies
  - Performing Various Types of Stability Tests such as Reformulated Products, Accelerated Temperature Studies and others.
  - Understanding the different Types of Stability Test Schedules Provided by Regulations Based on the following Product Types and Information:

Session 5: 2.00 pm - 3: 00 pm

- Suggested Time Points and Expiration dates based on testing time points
- Solid Dosage Forms Suggested Test Schedule
- Liquid and Semi-solid Types Products Suggested Test Schedule
- Reconstituted Products Suggested Test Schedule
- Performing Different Temperatures of Studies based on the product type such as Room Temperature Studies, Elevated Temperature, Refrigeration, Freezing Temperature and Special Humidity Considerations

3.00 pm - 3:15 pm (Break)

3.15 pm - 4:00 pm(Review of Case Studies)

- Review of Case Studies: Issues Encountered by Drug Product Manufacturers Based on a Poorly Designed Stability Testing Program
  1. Case Study #1 and Suggested Resolution

4.00 pm - 5:00 pm (Questions and Answer Session)

5:00 pm (Close of Seminar)

AGENDA

Day Two (8:00 AM – 5:00 PM)

Breakfast and Registration: 8:00 AM – 9:00 AM

Session 1: 9:00 am – 10:15 am

- 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:
  - How to Design an effective Stability Testing Program, Protocol and a Report for a New and Existing Product.
  - How to Effectively Handle, Manage Data, Utilize and Perform the Trending of Stability Testing Results and Data.

Session 2: 10:15 am - 11: 00 am

- Topic: Analytical Testing Considerations, Review of Case Studies
- Knowledge Base: Attendees will gain an understanding in the following key areas:
  - How to perform Quality Control Testing, Setting Test Specification and Assay Release Process in a Stability Testing Program.
  - 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.
  - Choice of methods with meaningful data or stability indicator
  - Analytical Assay Test Method Attributes

11:00 am – 11:15 am (Break)

Session 3: 11:15 am - 12: 00 pm

- Using the Laboratory Information Management Systems (LIMS) in a Stability Study Program
  - Data Documentation, Entry and Management (Types of Documentation Methods)
  - The Criticality of the Choice of a Stability Test Data Management System used for Data Management.
  - Considerations when choosing a Stability Test Data Management System (Manual versus Automated Data Management)
    - Advantages and Disadvantages of each type of system
  - Types of Stability Test Data Management Software (LIMS) for Stability Test Data Management

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

Session 4: 1.00 pm - 2: 00 pm

- Understanding the LIMS Stability Module Program and Statistical Analysis Tools
  - Understanding the various modules under the Stability Data Management Software in LIMS.
- Best practices when selecting Stability test data (LIMS) Vendor
- The various parts of the Stability test data management software
- Common mistakes made during the purchase of some Stability data management software.
- Choosing the best LIMS software programs used for stability test data management.

Session 5: 2.00 pm - 3: 00 pm

- Using Stability Testing Data to Generate the Product's Expiration Dating or Shelf Life.
- How to Perform the Extrapolation of a Product Shelf Life Using Data from an Ongoing Stability Testing Program
  - Great for products in clinical studies.
- Understand the different ways of performing statistical analysis of the stability test result data (manual versus automated software).

3.00 pm - 3:15 pm (Break)

3.15 pm - 4:00 pm(Review of Case Studies)

- Review of Case Studies: Issues Encountered by Drug Product Manufacturers Based on a Poorly Designed Stability Testing Program
  1. Case Study #2 and Suggested Resolution
  2. Case Study #3 and Suggested Resolution

4.00 pm - 5:00 pm (Questions and Answer Session)

5:00 pm (Close of Seminar)

Registration Form

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

Date & Location: .....

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Register for 3 and 4th person gets a free pass.

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