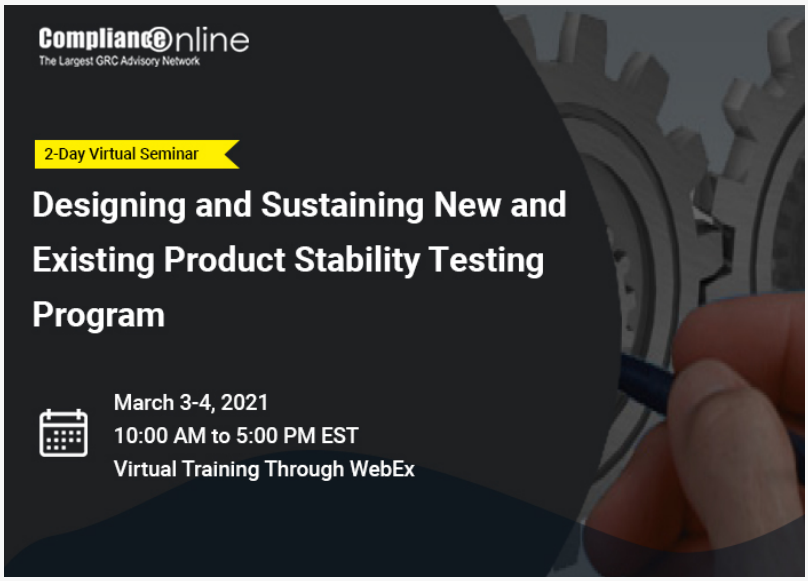
ComplianceOnline: Charity Ogunsanya Explains How to Design and Sustain New & Existing Product Stability Testing Program

"Designing and Sustaining New and Existing Product Stability Testing Program" Seminar has been added to ComplianceOnline.com's offering.



Designing and Sustaining New and Existing Product Stability Testing Program

SAN JOSE, CA, USA, February 19, 2021 /EINPresswire.com/ -- ComplianceOnline, the largest GRC advisory network, has officially launched registration for the Seminar 'Designing and Sustaining New and Existing Product Stability Testing Program'. The seminar will be held on March 3-4, 2021 (10:00 AM to 5:00 PM EST) and will be presented by Charity Ogunsanya, CEO and Founder, Pharmabiodevice Consulting.

New or existing modified drug Stability Testing Program's regulations/requirements stipulated by the FDA, 21 CFR or other regulations may sometimes create 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 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 a 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 Virtual 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 indirect 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 endpoint based on the product's potency. This will eliminate potential loss of product and business income by manufacturers of the 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.

Learning Objectives:

This Virtual 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. It will also benefit people within the Pharmaceutical, Biotechnology, or Medical Device industries that 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 Virtual 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 before 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.

Who Will Benefit:

The Virtual 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

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: March 3-4, 2021 (10:00 AM to 5:00 PM EST)

About the Speaker:

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.

About ComplianceOnline.com:

ComplianceOnline is a leading provider of regulatory compliance training programs for companies and professionals in regulated industries. ComplianceOnline has successfully trained over 55,000 professionals from 15,000 companies to comply with the requirements of regulatory agencies. ComplianceOnline is headquartered in Palo Alto, California, and can be reached at http://www.complianceonline.com. ComplianceOnline is a MetricStream portal. MetricStream (www.metricstream.com) is a market leader in Enterprise-wide Governance, Risk, Compliance (GRC), and Quality Management Solutions for global corporations.

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