

Designing and Sustaining New and Existing Product Stability Testing Program...

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Organizer : New York Media Technologies LLC in association with METRICSTREAM INC

Venue :

Location : San FranciscoSan Francisco, CAUnited States,
San Francisco, CA , US, ZIP: United States



Description

Designing and Sustaining New and Existing Product Stability Testing Program

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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.

Seminar Fee Includes:Lunch
AM-PM Tea/Coffee
Seminar Material
USB with seminar presentation
Hard copy of presentation
Attendance Certificate
\$100 Gift Cert for next seminar

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

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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, handling and utilizing the data, setting the shelf life as well as the applicable regulatory requirements.

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.

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

Event Categories :