Designing and Sustaining Drug Stability Testing Programs

Agenda

10:00 a.m. – 10:15 a.m. Introduction to the Virtual Conference

10:15 a.m. – 11:15 a.m. **Session 1**
General Stability Considerations Applicable to a Product's Stability (I.e. Potency), Storage Conditions, Sampling Plan and Sample Handling

Attendees will gain an understanding in the following key areas:

- Regulatory guidance associated with the requirements of a product's stability testing program. Delineating the program requirement specific to a type of product.
- New product stability indicator test, rationale for choosing the test and impact to the product's shelf life.
- The relationship between choosing the right product storage temperature and impact to its shelf life.
- Container Closure Requirements and 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.

11:15 a.m. – 11:30 a.m. **Break**

11:30 a.m. – 12: 30 p.m. **Session 2**
Designing and Conducting Effective Stability Testing Program Using the Suggested Schedules for Various Product Types

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:

- 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

12:30 p.m. – 1:30 p.m. **Lunch**

1:30 p.m. – 2:30 p.m. **Session 3**
Stability Testing Protocol Design, Data Management, and Trending. Comparative Analysis of Using a Manual versus Automated Data Management

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.
- 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).
- Understand the Advantages and Disadvantages of both systems
- Key documents to have ready to print out and produce at a moment's notice

2:30 a.m. – 2:45 p.m. **Break**

2:45 p.m. – 3:45 p.m. **Session 4**
Analytical Testing Considerations, Review of Case Studies

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
- **Review of Case Studies**: Issues Encountered by Drug Product Manufacturers Based on a Poorly Designed Stability Testing Program
    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)].
    2. Failure to have 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].
    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**

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