Design and Execution of Stability Studies for Biologics

Duration: 60 Minutes

Stability of biologics is necessary to ensure safety of products throughout their shelf life. This presentation looks at the design of stability studies in accordance with ICH guidance and regulatory expectations. Recommendations will be provided on the types of methods that should and should not be included on stability based on degradation pathways and how to set appropriate specifications. There will be a discussion of what testing is required to determine that the methods are actually stability indicating, as well as how to interpret data that is obtained during stability studies.

Instructor: Christina Vessely
Product ID: 501796

Live Session for one participant - $250.00 | Recorded Session - $375.00 | Training CD - $500.00 | Corporate Live Max 10 Participants - $1250.00 | Live + Recorded webinar - $500.00 | Live + Training CD - $625.00

Objectives of the Presentation

- To obtain a better understanding of what is required to successfully execute stability studies
- To understand what the most likely degradation pathways are for biologics
- Selecting analytical methods for the assessment of degradation across shelf life
- To learn what it means for a method to be stability indicating and how to demonstrate that the method is performing as intended
- Setting appropriate acceptance criteria to support claims of product stability at different stages of the development program
- Evaluating data obtained

Why Should you Attend

- To obtain a better understanding of what is required to successfully execute stability studies
- To understand what the most likely degradation pathways are for biologics and what analytical methods are applied to evaluate degradation across shelf life
- To learn what it means for a method to be stability indicating and how to demonstrate that the method is performing as intended

Areas Covered

- Analytics for Biologics
- Degradation pathways (Oxidation, Aggregation, Deamidation)
- The impact of product degradation on potency and safety
- Which analytical methods are used to evaluate each type of degradation
- Design and execution of forced degradation studies during analytical method development
- The evaluations of stability trends (or the lack thereof)

Who will Benefit

- Quality control managers
- Stability coordinators
- Laboratory directors
- Stability department personnel
- RandD laboratory personnel
- RandD laboratory supervisors and management
- QC laboratory personnel and management
- Protein formulation group personnel and management
- Regulatory affairs personnel
- Regulatory affairs management

Topic Background

This topic relates to regulatory expectations as outlined in the ICH guidance on stability. The topic includes further explanation of what is described in the document, as well as information not specifically covered within the guidance. The goal is to help the attendee to better understand how to align the science and regulatory requirements in order to improve safety for patients.

Instructor Profile:

Christina Vessely, Ph.D. has over 17 years of experience in the areas of analytical and formulation development within the biotechnology industry. Her work experience ranges from early stage research and development for small and start-up firms through late stage development and commercialization for mid-sized and large pharmaceutical companies. Her product experience includes insulin analogs, cytokines, monoclonal antibodies, and other therapeutic proteins, as well as virus-like particles and vaccines. She has been involved in the development and execution of CMC/Regulatory strategy for both biosimilar and novel products, including fast track programs. Her industrial experience includes the development of both liquid and lyophilized formulations for therapeutic proteins and vaccines, for both traditional and non-traditional delivery systems. In the analytical arena, Christina's areas of expertise have included method development, qualification and validation, the development of reference standards and other critical reagents, stability strategy and evaluation, and establishment of comparability and/or similarity. She is experienced with various biophysical and biochemical techniques for both the routine release and extended characterization of therapeutic proteins and biotechnology products