SiTec PharmaBio

Stability Testing for Protein Drug Products & Substances

A Life-cycle Approach

19-20 September 2016

Parc Científic de Barcelona

Baldiri Reixac, 10 - 08028 Barcelona - Spain

Course Topics Include:

- FDA and EMA Regulatory Expectations
- Protocols and Reports
- Out of Specification (OOS) and Out of Trend (OOT) Results
- Case Studies/Workshops

Who Should Attend

This course is designed to serve the needs of professionals working on Innovator and Biosimilar Protein and Peptide stability during development, for approval, and for postmarketing studies. Because of its comprehensive content, this course will be valuable to personnel in:

- Stability departments
- Research and Development
- QA and QC
- Regulatory Affairs
- Production

Professionals who are involved in planning, conducting, reviewing, supervising, or managing stability testing activities to determine shelf lives and retest dates of pharmaceutical proteins and peptides would benefit greatly from this training.

Learning Objectives

Upon completion of this course, you will be able to:

- Explain the FDA and EMA regulatory expectations, ICH Guidelines and technical issues surrounding protein and peptide stability testing
- Establish, carry out, audit, and review Stability Programs which determine and monitor the shelf lives of Innovator and Biosimilar protein and peptide drugs.
- Recognize key structural and functional instabilities of proteins and peptides to facilitate planning your testing program, and know why these instabilities are important for safety and efficacy.
- List the elements of Stability Protocols and Stability Reports and have the expertise to write and review them.
- Handle Out of Specification (OOS) and Out of Trend (OOT) stability results and review the compliance and noncompliance of how others have dealt with these always present issues.

Course Description

This 2-day intensive course provides comprehensive and up-to-date knowledge of developing and executing compliant and effective stability programs for protein and peptide biopharmaceuticals and biologics. The course covers both US FDA and EU EMA regulatory and technical expectations and activities to fulfill those expectations, with the guidelines of the International Conference on Harmonization (ICH) receiving special attention. The approach of the course is practical as well as theoretical so that attendees will be able to plan, accomplish and review stability studies and programs.
Attendees will have the opportunity to apply what they have learned during a workshop in which participants join the instructor in planning model stability programs for relevant product types.

Course Director

Dr. Pardeep Gupta is Professor at College of Pharmacy, University of the Sciences in Philadelphia. He holds the Burroughs-Wellcome Endowed Chair and is Director of Industrial Pharmacy Lab. He holds a PhD in Pharmaceutics from University of Wisconsin, USA, and has over 25 years experience in academic teaching and research. He teaches courses in controlled drug delivery, pharmaceutical solutions, drug stability, drug diffusion and pharma processes. His academic research focuses on delivery of proteins, peptides and poorly soluble drugs, he is currently involved in nanoparticle-based protein delivery, use of amphiphilic peptides as stabilizers of nanosuspensions, and design of peptide drugs. Dr. Gupta has over 100 research publications, patents, presentations, symposia and book chapters. He serves on the editorial board of Remington-The Science and Practice of Pharmacy, and also authored several chapters. Dr. Gupta has been a consultant and technical expert for over 30 pharma companies and intellectual property law firms. He has taught courses in the area of drug formulations and stability to scientists from pharma and biotech companies. He belongs to several professional organizations such as AAAS, ACS, AAPS and CRS.

Course offered by CfPA
THE CENTER FOR PROFESSIONAL ADVANCEMENT
FOUNDED 1967

COURSE OUTLINE

FIRST DAY

8:30-9:00

Registration

Regulatory and Technical Foundations of Protein and Peptide Stability Programs

Review of Learning Objectives/ Course Introduction

- Course Overview
- Discovery of participant learning needs
- Stability Terminology and Definitions
- Drug Substance v. Drug Product Stability
- Stability Goals and objectives during a product's lifecycle

FDA and EMA Regulations and Expectations for Stability Programs

- FDA: 21CFR parts 58, 210, 211, and 600—680
- EMA: Volume 4 and Annex 13
- International (ICH) Stability Guidance Documents Q5, Q1, et al.: How and when to use them
- The applicability to protein and peptide drug substances of ICH Q7/EMA Vol. 4 Part 2
- Differences between EMA and FDA expectations
- Differences for products on an accelerated approval track

Scientific and Technical Foundations of Stability Programs

- Crucial Drug Substance and Drug Product characterization activities
- Reading a protein or peptide structure for more effective study design and data interpretation
- Stress Testing and Forced Degradation studies to determine degradation pathways, rates, and products
- Analytical methods: physical/chemical and biological potency
- Microbiological aspects of protein and peptide stability
- Sterility testing and container/closure integrity
- Accelerated stability testing for proteins and peptides?

Stability Programs for Early to Middle Development Phases

- Stability studies for Pre-clinical Development
- Stability Programs for Phase 1 Clinical Studies
- Stability Studies for Phase 2 Clinical Studies

Getting Ready for Pivotal (typically clinical Phase 3) Stability Studies

- Identification and mapping of impurities and degradants
- Validation of the stability-indicating potential of analytical methods
- Validation of stability chambers and rooms
- Ancillary stability studies for laboratory reagents, reference materials and excipients

SECOND DAY

9:00-17:00

Stability Programs for Approval/ Licensure/Marketing Authorization Applications and Beyond

Primary Stability Studies for BLAs, NDAs, and MAAs

- Essentials elements a Compliant and Effective Stability Protocol
- Effective handling of deviations, discrepancies, and changes (planned and unplanned)
- Analysis and presentation of Stability Data
- Writing the Stability Report

Post-marketing Stability Studies

- Fulfilling the Stability Commitment
- Stability and process consistency studies
- Annual Stability Batches
- Stability Testing as Part of Comparability Exercises

Reviewing and Auditing Stability Studies and Programs

- Review of common stability-related Regulatory Deficiencies
- Checklist for reviewing Stability Protocols
- Checklist for reviewing Stability Reports
- Checklist and tricks of the trade for auditing Stability Programs
- Preparing for regulatory inspections

Stability Case Studies and Workshop

- Stability Program for a model peptide
- Stability Program for a model monoclonal antibody
- Stability Program for a model rDNA glycoprotein

Course wrap-up and Conclusions

Assessment Opportunity

TUITION AND PAYMENT

Early registration:
(received before July 15th, 2016) - Euro 1700+VAT/1530+VAT (group discount*)

Regular registration:
(received after July 15th, 2016) - Euro 1900+VAT/1710+VAT (group discount*)

(Fee includes course materials, lunches and coffee breaks)
Participants are responsible for their own hotel reservations.

*Group discount is for two or more enrollments from the same company.

Payable by bank transfer upon issuing an invoice. Payment instructions will be provided upon registration.

Registration

Name .....
Surname .....
Position .....
Organization .....
VAT .....
Address. .....
Postal Code .....
City .....
Country .....
Phone/Fax .....
Participant e-mail .....
Billing e-mail .....

PLEASE RETURN BY FAX OR E-MAIL

General information

Cancellations received after August 29, 2016 will be invoiced completely. All cancellations will be subject to euro 250 processing fee. Substitutions may be made at any time. Payment is due once the participant receives an invoice. Certificates will be issued to participants upon completion of the course.

For Information please contact us at:

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