COBBLESTONE

COURSE ID 2594

Stability Testing for Protein Drug Products & Substances

DIRECTED BY

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12 Hour

ACCREDITED COURSE

- Science and Special Considerations for Protein Pharmaceuticals
- FDA and EU EMA Regulatory Expectations
- Protocols and Reports
- Out of Specification (OOS) and Out of Trend (OOT) Results
- Case Studies/Workshop

about the course

No drug substance or drug product is acceptable without a satisfactory stability profile. Yet, protein drug substances and drug products offer unique challenges when it comes to stability. From storage to handling, to testing, proteins often require thinking creatively to achieve an acceptable stability program.

This accredited 12-hour 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 biotechnology guidelines of the International Council for 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.

Since this training is highly interactive, those attending the live training event must have a webcam on their computer as well as a microphone and speakers/headset in order to fully participate.

who should attend

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

- Stability Departments
- QA/QC
- Production
- Research and Development
- Regulatory Affairs

Professionals who are involved in planning, conducting, reviewing, supervising, or managing protein formulations, manufacturing, and 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 US FDA and EU 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 non-compliance of how others have dealt with these always-present issues

course outline

Review of Learning Objectives

Introduction

- Course outline, flow and format
- Introduction of course director and attendees to learn their background, needs and expectations
- Definitions Terminology and Guidelines: FDA, EMA, WHO and ICH

Science and Fundamentals of Stability of Pharmaceuticals

- Mechanisms and pathways of degradation of drugs
- Theory of degradation kinetics

Stability Issues in Proteins

- Chemical degradation of proteins
- Kinetic degradation of proteins
- Protein specific chemical reactions
- Degradation of proteins in solution
- Degradation of proteins in lyophilized formulations

- Unique issues for monoclonal antibodies

Physical degradation of proteins

- Theory of aggregation and denaturation
- Soluble and insoluble aggregation
- Conformational changes
- Protein adsorption to packaging and other surfaces

Analytical Methods in Protein Stability

- Review of analytical methods and their application in study of chemical and physical changes in proteins

Data Analysis and Practical Aspects of Protein Stability

Stability Testing of Protein Pharmaceuticals

Pre-marketing Study Design

- Accelerated, long-term and stress 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

Post-marketing Stability Studies

Stability programs for marketed products

- Fulfilling the stability commitment
- Stability and process consistency studies
- Annual stability batches
- Data pooling statistical analyses
- OOS and OOT data handling

Case Studies

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

Wrap Up

Question and Answer Session

Assessment Opportunity

course instructor

Dr. Pardeep Gupta is a Professor of Pharmaceutics in Philadelphia College of Pharmacy at Saint Joseph's University in Philadelphia. He received his B. Pharm. and M. Pharm. (pharmaceutical chemistry) degrees from India. He also received a M.S. degree in medicinal chemistry from USciences and his Ph.D. in pharmaceutics from University of Wisconsin. His research interests include delivery of proteins and peptides and study of the interaction of drugs with biomembranes. He has published several articles and has authored several book chapters. His teaching responsibilities include courses in solubility, controlled drug delivery and drug stability at the graduate level. He has served on the editorial board of Remington: The Science and Practice of Pharmacy and has served as the editor of Pharmaceutical Chemistry and Pharmaceutical Testing, Analysis and Control sections of the book.

Accreditations

International Accreditors for Continuing Education and Training (IACET)

Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 12 contact hours, or 1.2 CEUs. For further information, visit www.iacet.org