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

Thomas J Pritchett, has worked with the US, European, and Canadian pharmaceutical, biopharmaceutical, and biologics industries for more than 25 years, during which he has gained considerable experience in regulatory and technical aspects of Quality Assurance, Quality Control and CGMP Compliance for both investigational and marketed products. He is also an experienced teacher, and has been directing courses for the Center for Professional Advancement since 1995. In addition, Dr. Pritchett has provided training sessions for the US FDA, for regulators and industry professionals in the Gulf Cooperation Council (GCC) and at the National Institutes of Health. Dr. Pritchett is also an active industry consultant and the co-founder/publisher of the newsletter BioQuality (www.bioquality.biz). He sits on the editorial advisory board of BioProcess International.

Course offered by
COURSE OUTLINE

Billing e-mail
Phone/Fax
Country
City
Postal Code
Address
VAT
Organization
Position
Surname
Registration
Payable by bank transfer upon issuing an invoice. Payment instructions will be provided upon registration.

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

Participants are responsible for their own hotel reservations.

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.

General information
Cancellations received after August 23, 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:
Office: +34 93 4487156
Cell: +34 691676055
Fax: +34 93 4037109
e-mail: info@sitec-pharmabio.com

PLEASE RETURN BY FAX OR E-MAIL