SiTec PharmaBio

CHARACTERIZATION OF PROTEINS FOR DEVELOPMENT AND APPROVAL OF PROTEIN PHARMACEUTICALS AND VACCINES

Learn the "tricks of the trade" to enhance and streamline the efficient and effective use of essential analytical methods

25-26 June, 2013

Parc Científic de Barcelona

Parc Cientific de Barcelona
Baldiri Reixac, 10
08028 Barcelona - Spain

Course Topics Include:
- Fundamentals
- Regulatory Expectations
- Analytical Methods
- Case Studies and Practical Examples
- Interactive Workshop

Who Should Attend

This course will be of interest and value to scientists, supervisors, and managers whose work includes performing, supervising, or managing characterization of protein drugs and drug candidates during preclinical development, clinical development, and for post-marketing changes. Job titles include, but are not limited to:

- R&D • Protein Biochemistry
- Quality Assurance
- Quality Control
- Stability
- Formulation
- Production

The course will also benefit Regulatory Affairs professionals who would like to learn the scientific background of this significant part of regulatory submissions.

Learning Objectives

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

- Explain the basics of how and why protein structure and function can and must be characterized for development and approval of protein drugs.
- Outline the molecular details that are of special interest during pharmaceutical protein characterization.
- Describe what is needed to meet regulatory requirements and expectations for protein characterization throughout the product lifecycle.

Course Description

This course relates primarily to Monoclonal Antibody and rDNA Protein Therapeutics and Vaccines. The basics of protein chemistry/biochemistry will be presented since this knowledge is essential to the remainder of the course learning experience.
The legal/regulatory requirements and expectations for molecular characterization of pharmaceutical proteins are detailed for the entire product lifecycle, from preclinical development through post-marketing changes.
Essential analytical methods will be reviewed along with some "tricks of the trade" to enhance and streamline the efficient and effective use of these methods.
Practical case-study examples and an opportunity for attendees to use their newly acquired knowledge in simulated situations will be included.

Course Director

Thomas J Pritchett, Ph.D., has more than 25 years experience working with the US, European, Canadian pharmaceutical, biopharmaceutical, and biologics industries where he has gained considerable experience in most 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 and for regulators and industry professionals in the Gulf Cooperation Council (GCC).
Dr. Pritchett is also an active industry consultant and the co-founder/publisher of the newsletter BioQuality (www.bioquality.biz).

Course offered by The Center For Professional Advancement

CENTER FOR PROFESSIONAL ADVANCEMENT FOUNDED 1967

COURSE OUTLINE

FIRST DAY

8:30-9:00: **Registration**

9:00-17:00

Review of Learning Objectives

Introduction

Fundamentals of Protein Structure and Function

- The variety of pharmaceutical proteins
- Amino acids, side chains, and the peptide bond
- Levels of structure: primary, secondary, tertiary and quaternary
- Protein translation in the bacterial, insect, plant, and mammalian cell
- Post-translational modifications:
  - Carbohydrates and oligosaccharides of glycoproteins
  - Other important cellular post-translational modifications
  - PEGylation and other production-related modifications
- Dependence of structure on expression systems and bioreactor conditions

Regulatory Considerations

- US FDA and European EMA Characterization Requirements and Expectations for:
  - Clinical Trial Applications/IND
  - Control and Release Assays
  - Stability Testing
  - Marketing Authorization Applications
  - Post-Marketing Changes and Comparability

- Characterization, Good Manufacturing Practice Regulations, and Validation
  - When should characterization work be "GMP"?
  - Is validation required for characterization methods?

SECOND DAY

9:00-17:00

Analytical Methods for Protein Characterization

- Amino acid analysis and sequencing
- UV/Vis and Fluorescence Spectroscopy
- Electrophoresis: gel and capillary
- Isoelectric focusing: gel and capillary
- Chromatographic methods
- Mass Spectrometry
- Nuclear Magnetic Resonance (NMR)
- Hyphenated techniques
- Enzymatic methods
- Immunological methods
- Other important methods

Sequence and Amino Acid "Hot Spots" requiring special attention during characterization

Case Studies, actual and hypothetical

- Example characterization for pre-clinical development
- Example characterization for filing a Phase 1 IND or Clinical Trial Application
- Example characterization as the basis for control and release assays
- Example characterization as the basis for the stability program
- Example characterization for a Comparability Protocol

Interactive Workshop

Attendees will separate into groups and develop a characterization plan assigned by the instructor. One or more group members will then present the plan to the class for discussion.

- Course Wrap-up and Conclusions

Assessment Opportunity

Approximately 15 minutes breaks at 11:00 and at 15:45 and a one and a half -hour lunch at 13:00 planned for each day.

TUITION AND PAYMENT

Early registration:
(received before April 26th, 2013) - Euro 1350+VAT/1215+VAT (group discount*)

Regular registration:
(received after April 26th, 2013) - Euro 1550+VAT/1400+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/C.F. .....
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 June 7, 2013 will be invoiced completely. All cancellations will be subject to Euro 200 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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