

European Continuing Education College

Latest Advances in the Stabilisation and Formulation of Protein and Peptide Drugs

Two-Day Intensive Course with the Emphasis on Formulation and Dosage Form Design Strategies, Analytical Methods and Excipient Choices

Holiday Inn Hotel, Oxford Circus, London, UK

5th and 6th October 2011

Course Background and Objectives

To provide attendees with

- a solid understanding of the most common mechanisms of protein degradation;
- an overview of where pharmaceutical macromolecules are most likely to be damaged during bioprocessing and storage
- the physical basis for the aggregation and solubility behaviour of polypeptides;
- descriptions of the most important analytical tools needed in formulation development
- an overview of the latest advances in protein formulation development
- detailed strategies for stabilization of peptides as well as proteins. In addition to lectures, the course will include individual and group exercises for evaluating the suitability of various formulations of pharmaceutical proteins

Key Benefits of Attending

Pharmaceutical macromolecules, whether proteins or peptides, are highly susceptible to degradation throughout the development process. From the time the active pharmaceutical ingredient is synthesized, it is subjected to stresses that can induce damage. For example, the processes of isolation, purification, formulation, packaging, and storage each provide opportunities for chemical and physical changes to occur with potentially disastrous consequences to the final product. This course will provide a detailed overview of the common methods of degradation for proteins, as well as the most current strategies for stabilisation and formulation of pharmaceutical macromolecules. Emphasis will be placed on a mechanistic, rather than a phenomenological approach, towards stabilisation of peptides and proteins. Special emphasis will be given to the differences between peptides and proteins.

Who Should Attend

Anyone involved in the development of pharmaceutical macromolecules as commercial therapeutic agents, whether for human or veterinary use. This would include those involved in research & development, production, purification, formulation, manufacturing, and delivery of peptides and proteins. Those involved in overseeing these operations would benefit as well as those working at the bench. This course is intended for those currently working in the field and presumes a basic working knowledge of protein structure.

Course Outline

Overview of Formulation Strategies

Physical Stability of Polypeptides

- Conformational Instability
- Colloidal Instability and Solubility Issues (including phase separation and opalescence)
- Interfacial Instability

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Course Outline

Recent Advances on the Chemical Instability of Peptides and Proteins

Protein Aggregation

- Aggregation Kinetics
- Mechanisms of Aggregation
- Controlling Aggregation
- Detailed Overview of Methods for Characterization and Quantitation of Aggregates

Rational Design of Protein Formulations

- Frozen Formulations
- Liquid Dosage Forms
- Lyophilised Dosage Forms
- Other Dried Dosage Forms

Strategies for Excipient Selection

- Liquid Dosage Forms
- Lyophilised Dosage Forms

Analytical Methods

- Spectroscopic Methods (e.g., IR, CD, fluorescence, NMR, etc.)
- Methods for Characterization of Lyophilised Powders
- Methods for Monitoring Denaturation
- Methods for Detecting and Quantifying Aggregation

Special Topics

- High Concentration Formulations and Alternative Delivery Systems
- Packaging of Biopharmaceuticals
- Peptide Formulation Challenges
- Stability Issues during Processing (purification, filtration, etc.)

Lecturers

Mark Cornell Manning, Ph.D.

Dr. Manning is Chief Scientific Officer for Legacy BioDesign LLC in the U.S.A. Previously, he was Chief Technical Officer at HTD BioSystems. Before that he held a position as Associate Professor of Pharmaceutics at the University of Colorado School of Pharmacy. He received his B.A. in Chemistry from Hope College and his Ph.D. in Inorganic Chemistry from Northwestern University. After postdoctoral work at Colorado State University, he joined the Department of Pharmaceutical Chemistry at the University of Kansas as Assistant Professor. In 1990, he joined the faculty at the School of Pharmacy at the University of Colorado Health Sciences Center, where he was co-founder and co-director of the University of Colorado Center for Pharmaceutical Biotechnology (a joint enterprise between the schools of pharmacy and engineering). Dr. Manning is an affiliate faculty member in chemistry at Colorado State University and an adjunct faculty member at the University of Colorado. He has published over 100 scientific articles, received four U.S. patents, and has co-edited three books in the series, Pharmaceutical Biotechnology. He has worked on a wide variety of formulation projects and drug delivery systems. His research interests include protein stabilization, drug delivery, and spectroscopy.

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Fees and Registration

The participation fee is £1195.00 (exclusive of VAT). Places are strictly limited and therefore applications will be accepted on a first come basis. Under UK law all applications are subject to Value Added Tax (VAT) irrespective of the country of origin of participants. Most VAT registered companies/organisations can reclaim this tax. The fee includes full personal participation, extensive bound course notes, luncheons and light refreshments, on all days of the Course. Dinner at night is not included. Cancellations cannot be accepted less than 14 days prior to the start of the Course, but substitutions may be made at any time. The Course language will be English. An approved Certificate of Attendance will be given to each participant at the end of the Course.

Timing of The Course

Registration will be at 8.45am on Wednesday 5th October and the Course will commence promptly at 9.00am. The Course will finish at about 16.00 on Thursday 6th October. The Course will end at about 17.00 on the first day.

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ECEC - Registration Form

Course - Latest Advances in the Stabilisation and Formulation of Protein and Peptide Drugs

Please fill in the following details to apply for a place. No payment is necessary now. When filling in the form, fields marked with an asterix (*) are compulsory. Your form will not be submitted if they are left blank.

Personal Details

First name: *	<input type="text"/>
Surname: *	<input type="text"/>
Organisation:	<input type="text"/>
Job title:	<input type="text"/>
Address: *	<input type="text"/>
Post/zip code: *	<input type="text"/>
Telephone no:	<input type="text"/>
Extension:	<input type="text"/>
Fax no:	<input type="text"/>
Email address: *	<input type="text"/>

I wish/do not wish to receive future mailings from ECEC about forthcoming courses. (Please note, we do not disclose your email address to any third party)

Accommodation

Accommodation will be at the: Holiday Inn Hotel, Oxford Circus, London, UK
Room Rates: Single Room - Bed & Breakfast per person, per night £159.00
Twin Room - Bed & Breakfast per person, per night £189.00
Double Room - Bed & Breakfast per person, per night £189.00

Choose accommodation Type:

- I don't want accommodation
- I would like a Single Room - Bed & Breakfast
- I would like a Twin Room - Bed & Breakfast
- I would like a Double Room - Bed & Breakfast

Choose which days:

- Tuesday 4th October 2011
- Wednesday 5th October 2011
- Thursday 6th October 2011

Other nights (please specify): _____

* Please note: Under UK law all applications are subject to Value Added Tax (VAT), irrespective of the country of origin of the Participant

PLEASE FAX THIS COMPLETED FORM TO +44 (0)151 724 6343