

European Continuing Education College

Managed by PharmaCourses Ltd

Introduction to the Formulation & Stabilisation of Protein and Peptide Drugs

16 & 17 September 2019, London UK

A Two-Day Short Course with the Emphasis on Formulation and Dosage Form Design Strategies, Mechanisms of Degradation and Excipient Choices

Course Background and Objectives

The aim of this course is to provide attendees with:

- A perspective on the importance of formulation development in the biopharmaceutical industry
- An understanding of the most common mechanisms of protein degradation
- An overview of where pharmaceutical macromolecules are most likely to be damaged during handling and storage
- The physical basis for the aggregation and solubility behaviour of polypeptides
- Descriptions of the most important analytical tools needed in formulation development
- Detailed strategies for stabilization of peptide proteins and chemically modified proteins.

In addition to lectures, the course will include 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 course is intended for those new to the field and those who simply wish to obtain an overview of this important discipline. 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.

Overview of Formulation Development and Principles of Proteins Stabilisation

Introduction to Protein Structure and Physical Properties Overview of Instability Issues with Proteins

- Chemical Instability
- Conformational Instability (unfolding)
- Colloidal Instability
- Interfacial Instability

PharmaCourses Ltd, Suite 1327 Kemp House, 152 City Road, London EC1V 2NX UK

Phone: ++44 208133 2605

Email: info@pharma-training-courses.com

www.pharma-training-courses.com

Introduction to the Formulation & Stabilisation of Protein and Peptide Drugs

16 & 17 September 2019, London UK

Course Outline

Introduction to Protein Structure and Physical Properties Protein Aggregation

- Basic Aggregation Mechanisms
- Controlling Aggregation
- Quantifying Aggregation

Rational Development of Liquid Dosage Forms

- Formulation Strategy
- Excipient Selection
- Selection of Analytical Methods

Rational Development of Dried Dosage Forms

- Formulation Strategy
- Excipient Selection
- Selection of Analytical Methods

Special Topics

- High Concentration Formulations
- Chemically Modified Proteins (PEGylated proteins, antibody-drug conjugates, fusion proteins etc.)

Lecturers

Mark Cornell Manning, Ph.D.

Dr. Manning is Chief Scientific Officer for Legacy BioDesign LLC in the USA. 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 US 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.

Venue

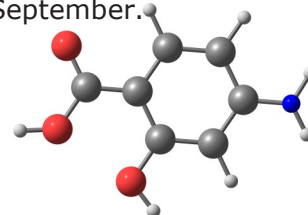
Holiday Inn Oxford Circus, 57-59 Welbeck St, Marylebone, London W1G 9BL, United Kingdom

Website: <https://www.ihg.com>

Timing of the course

Registration will be at 8.45am on Monday 16th September and the Course will commence promptly at 9.00am. The Course will finish at about 16.00 on Tuesday 17th September.

The Course will end at about 17.00 on the first day.



PharmaCourses Ltd, Suite 1327 Kemp House, 152 City Road, London EC1V 2NX UK

Phone: ++44 208133 2605

Email: info@pharma-training-courses.com

www.pharma-training-courses.com

European Continuing Education College

Managed by PharmaCourses Ltd

REGISTRATION DETAILS:

Introduction to the Formulation & Stabilisation of Protein and Peptide Drugs

16 & 17 September 2019, London UK

Early-bird fee: 2 day course £1436.00 (+ VAT £287.20 if applicable, see notes on VAT)

For registering and paying before **31 July 2019**

Full Fee: 2 day course £1595.00 (+ VAT £319.00 if applicable, see VAT NOTES)

Academic rates are available, please enquire: info@pharma-training-courses.com

BOOK both courses for a reduced rate -

Introduction to the Formulation & Stabilisation of Protein and Peptide Drugs 16 & 17 September 2019
and **Latest Advances in the Stabilisation and Formulation of Protein and Peptide Drugs**
18 & 19 September 2019

Early-bird fee: 2x2 day courses £2711.50 (+ VAT £542.30 if applicable, see notes on VAT)

For registering and paying before **31 July 2019**

Full Fee: 2x2 day courses £2871.00 (+ VAT £574.20 if applicable, see VAT NOTES)

VAT NOTES:

UK: Under UK law all UK-based applications are subject to VAT at the prevailing rate however most UK VAT registered companies/organisations can reclaim this tax.

EU: With effect from 1 January 2011 applications from delegates whose companies are based in EU countries will not be subject to VAT **PROVIDED THAT** valid VAT ID details are provided at the time of booking, otherwise VAT will be charged.

OTHER: With effect from 1 January 2011 applications from delegates whose companies are based outside of the UK/EU will be outside the scope of VAT, ie no VAT is charged or payable.

Methods of Payment available:

Cheque (**Please make payable to "PharmaCourses Ltd"**)

Bank transfer

Credit/Debit Card (Paying by Credit Card please register online)

Registration is available online:

www.pharma-training-courses.com

Data Protection

PharmaCourses Ltd gathers personal data in accordance with the UK Data Protection Act 1998 and we may use this to contact you by telephone, fax, post or email to tell you about other products and services. If you have any queries or want to update any of the data that we hold then please contact us.

Terms and Conditions:

Liability - PharmaCourses Ltd reserves the right to change the programme, speakers, date or venue without notice or cancel the event. If cancellation occurs delegates will be notified as soon as possible and will receive full refund of fees paid. PharmaCourses will not be responsible for any airfare, accommodation or other travel costs incurred.

Delegate fees - Fees for this programme are shown overleaf. Delegate fees are inclusive of course documentation, refreshments and lunch. Payment of the registration fee must be paid within 14 days

PharmaCourses Ltd, Suite 1327 Kemp House, 152 City Road, London EC1V 2NX UK

Phone: ++44 208133 2605

Email: info@pharma-training-courses.com

www.pharma-training-courses.com

Course Programme 2018

Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
13, 14 & 15 March 2018, **Croydon Greater London**

HPLC Analytical Method Development and Validation
10 & 11 May 2018 **Istanbul Turkey**

Pharmaceutical Dissolution Testing – a 2 day course
21 & 22 May 2018 **London**

Pharmacokinetics in Drug Development - an integrated approach
18 & 19 June 2018 **London**

Pharmaceutical Packaging – an introductory course
25 June 2018 **London**

Powder Technology for Pharmaceutical Development and Manufacturing
26, 27 & 28 September 2018 **London**

Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
13, 14 & 15 June, **Croydon Greater London**

Introduction to the Formulation and Stabilisation of Protein and Peptide Drugs
24 & 25 September 2018 **London**

Latest Advances in the Formulation & Stabilisation of Protein and Peptide Drugs
25 & 26 September 2018 **London**

Pharmaceutical Dissolution Testing – a Hands-on Course
23, 24, 25 & 26 October 2018 **London**

Pharmaceutical Granulation and Compression
29, 30 & 31 October 2018 **London**

GMP Auditor Training for Quality Systems
7, 8 & 9 November 2018 **London**

Parenteral Products
12, 13 & 14 November 2018 **London**

Pharmaceutical Aerosols, Dry Powder Inhalation Systems and Nasal Delivery Devices
19, 20 & 21 November 2018 **London**

Development of Stability-Indicating HPLC Methods
21 November 2018 **London**

HPLC Analytical Method Development and Validation
22 & 23 November 2018 **London**

Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
5, 6 & 7 December 2018, **Croydon Greater London**

Stability Testing in Pharmaceutical Development and Manufacture
2 & 3 October 2018 **London**
