

European Continuing Education College

Managed by PharmaCourses Ltd

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

26 & 27 September 2018, London UK

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

Course Background and Objectives

To provide attendees with -

- a solid understanding of the most common mechanisms of protein degradation; an overview of where pharmaceutical proteins 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, especially for aggregate quantitation and characterisation;
- an overview of the latest advances in protein formulation development
- an appreciation of the importance of packaging in product performance
- 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

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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.

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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 26th September and the Course will commence promptly at 9.00am. The Course will finish at about 16.00 on Tuesday 27th 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

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Course Outline

Overview of Formulation Strategies and Principles

Physical Stability of Polypeptides

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

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

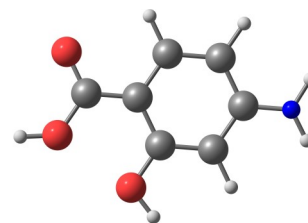
- High Concentration Formulations and Alternative Delivery Systems
- Packaging of Biopharmaceuticals
- Peptide Formulation Challenges
- Stability Issues during Processing (purification, filtration, etc.)

Lecturer

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.



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REGISTRATION DETAILS:

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

26 & 27 September 2018, London UK

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

For registering and paying before **30 July 2018**

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 24 & 25 September 2018
and **Latest Advances in the Stabilisation and Formulation of Protein and Peptide Drugs**
26 & 27 September 2018

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

For registering and paying before **30 July 2018**

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

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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
26 & 27 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
24 & 25 May 2018 **London**
