Parenteral Products

12, 13 & 14 November 2018, London UK

A Three Day Intensive Course Covering Formulation, Product Development, Sterile Manufacture and Quality Assurance with Special Emphasis on Formulation, Biotechnology Products, Operational and GMP Issues and Sterilisation Processes

Course Background

Compared to other dosage forms, Parenteral Products present unique challenges in both their development and manufacture as their method of administration requires sterile and pyrogen free products. During formulation and development studies, products need to be formulated to meet solubility and stability requirements, as well as ensuring compatibility with manufacturing operations and the intended administration route. Biological products present additional formulation and analytical challenges often including the need for freeze drying to facilitate long term storage.

Primary packaging is particularly critical for parenteral products as sterility and efficacy needs to be maintained throughout the product's shelf life. In recent years there has been increasing emphasis on devices to facilitate the administration of parenteral products and enable products suitable for self-administration to be developed.

From a manufacturing perspective, the need to achieve sterile, pyrogen free products that also have extremely low particulate levels is paramount. Facilities, equipment and utilities must all be appropriately designed and validated to ensure that microbial, chemical and physical contamination is prevented. Sterile product operations are considered the highest risk category amongst the main pharmaceutical dosage forms by the regulatory authorities and subsequently, are the focus of detailed licence application review and frequent inspections.

Course Objectives

This Course will provide an overview of the design and manufacture of a range of parenteral products, with a mixture of lectures, case studies and workshops. The workshops are designed to encourage interaction between delegates and presenters and to enhance participants understanding of specific key aspects of parenteral products. The course will cover routes of parenteral administration, types of parenteral product, common formulation strategies and relevant regulatory guidelines.
The formulation of biological and freeze dried products will also be discussed as well as primary packaging and delivery devices.

The discussion of parenteral product manufacture will include problems encountered in the production environment, sterilisation, depyrogenation, media simulations and the quality assurance of parenteral products. The Course will also outline the use of isolators and access barriers for aseptic processing and discuss the quality criteria for water for injection GMP requirements and regulatory expectations specific to parenteral products and sterile processing will be discussed throughout the course.
A feature of the Course is the Workshops designed to enhance participant's understanding of specific aspects of Parenteral Products

Summary of Key Benefits of Attending

After attending the course participants should be familiar with:

- Routes of parenteral administration and the different types of parenteral product
- Critical Quality Attributes for parenteral products
- Common formulation strategies for parenteral products, including approaches to overcome solubility and stability challenges and to meet sustained release criteria
- Formulation and analytical approaches in the development of biological products
- Formulation and manufacture of freeze dried products
- Parenteral product primary packaging and administration devices
- Sterilisation and depyrogenation processes
- Cleanroom standards and environmental monitoring
- The control of Water For Injection and clean steam systems
- Principles of quality control, quality assurance and documentation in relation to parenteral products
- Process validation

PharmaCourses Ltd, Suite 1327 Kemp House, 152 City Road, London EC1V 2NX UK
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Email: info@pharma-training-courses.com
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Course Outline

Product Development and Formulation

- Routes of Administration
- Types of parenteral product
- Sterility considerations in parenteral product development
- Target product profiles and quality attributes
- Simple solution formulations
- Formulating poorly soluble drugs
- Formulating poorly stable drugs
- Slow release parenteral products

Biotechnology Products

- Special considerations when formulating and developing macromolecules

Primary Packaging and Devices for Parenteral Products

- Types of devices for administration
- Compatibility issues

Freeze Drying

- Theory and practice of freeze drying
- Formulation and development of freeze dried products
- Freeze drying in a production environment

Sterilisation, Depyrogenation and Sanitation Techniques

- Moist and dry heat sterilisation processes
- Chemical sterilisation and disinfection
- Irradiation
- Depyrogenation technologies

Filters and Parenteral Products

- Filtration mechanisms and filter types
- Product compatibility and process development
- Integrity testing

Cleanrooms, Isolators and Barriers

- Cleanroom standards and design
- Aseptic processing considerations
- Environmental monitoring and control
- Isolators and Restricted Access Barriers

Critical Utilities

- Production and control of water for injection
- Clean steam attributes

Validation

- Process validation
- Process simulations
- Production and control of water for injection
- Clean steam attributes

Regulatory

- Regulatory expectations
- GMP issues
- Quality Assurance

The course will include workshops on specific aspects of Parenteral Products

Who Should Attend

Graduates, Managers, Scientists and Technical staff in industry or hospitals who wish to develop an overall understanding of the formulation and manufacture of parenteral products. This includes scientists in QA/QC and Regulatory Affairs. The course will be particularly useful for staff that are transferring or changing responsibilities to a role involving the development and manufacture of parenteral products.

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 12 November and the Course will commence promptly at 9.00am. The Course will finish at about 17.00 on Wednesday 14 November. The Course will end at about 18.00 on each of the first two days

The Course language will be English. An approved Certificate of Attendance will be given to each participant at the end of the Course

Lecturers

Peter Cameron (Course Director) Mr Cameron has worked for the last 20 years as a Pharmaceutical and Healthcare Consultant, originally within the Pharmaceutical Division of Bovis Lend Lease and more recently with his own company, 3CP. He specialises in parenteral production operations, regulatory issues and validation. He has been associated with the production of sterile products for over 40 years, during which time he worked for Parke Davis as a Technologist with special responsibility for parenteral validation and process development and CAMR, managing the production of clinical trial material. Mr Cameron is a member of the Pharmaceutical and Healthcare Sciences Society of Great Britain, freeze drying special interest group and been closely involved in the production of many of the society's monographs. He has edited and contributed to a book on Good Pharmaceutical Freeze Drying Practice.

Joanne Broadhead B.Pharm., Ph.D. Dr Joanne Broadhead is an Independent Consultant specialising in parenteral product development and manufacture. Prior to forming her own consultancy company in 2011, she worked for many years in the Product Development group at AstraZeneca. Within AstraZeneca she led both formulation and manufacturing teams and from 2006-2011 managed the pilot scale parenteral manufacturing facility at the company's Charnwood site. Joanne is a registered Pharmacist and co-chair of the Parenteral's Focus Group of the Academy of Pharmaceutical Sciences. In her current role, Joanne works with client companies on various parenteral product development projects. She also works part time with the DeMontfort University Quality by Design team in a business development capacity and as a Lecturer on their postgraduate MSc programme.

Keith Wickert B.Sc (Hons) Mr Wickert is Technical Manager for Amazon Filters Limited. He is responsible for managing new product development and technical support, including supporting internal and customer validation projects. He has served on various Pharmaceutical Industry committees including the PDA, IMechE Pharmaceutical Group and Parenteral Society and presented at numerous international conferences. Keith has worked with the Pharmaceutical industry for over 40 years and before he joined Amazon Filters held a variety of Management positions in Production of Pharmaceutical Products, supply of critical equipment and Compliance Consultancy.

Andy Donnelly Ph.D. Andy Donnelly has 20 years of experience working within the field of parenteral science and joined Bespak's Innovation Group in September 2013 as an Innovation Manager, helping to develop next generation delivery devices to meet the ever increasing requirements of the pharmaceutical and biotech industry. Previously Andy was based in the USA where he established and subsequently led MedImmune's drug delivery and device development group, responsible for evaluation and development of innovative device and formulation drug delivery technologies. Prior to this, Andy spent over 12 years working in AstraZeneca's formulation development groups in both Sweden and the UK, work that included both small and large molecules. Andy has a degree in Pharmacy and a Ph.D. in drug delivery from the Welsh School of Pharmacy UK

Eddie J French Ph.D. Eddie French of TEKH Consulting Ltd, is an independent pharmaceutical consultant who specializes in therapeutic product design and development. Eddie has 25 years experience in the pharmaceutical industry. The majority of this time was spent with Pfizer as a director within Pharmaceutical Sciences, focusing on drug delivery and drug product development. This included 9 years leading a global team formulating proteins, peptides and nucleic acids. Eddie has a PhD in drug delivery from the University of Bath where he was also a lecturer in pharmaceutics, prior to his industrial career. Eddie is a previous chair and is currently on the advisory board of the Academy of Pharmaceutical Sciences of Great Britain. He is an honorary professor in biopharmaceutical development at the University of Bath and the special professor of formulation at the university of Nottingham

European Continuing Education College

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REGISTRATION DETAILS:

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Early-bird fee: 3 day course £1526.00 (+ VAT £305.20 if applicable, see notes on VAT)

For registering and paying before **17 September 2018**

Full Fee: 3 day course £1695.00 (+ VAT £339.00 if applicable, see VAT NOTES)

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

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.

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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 of commencement of the course. Upon receipt of payment, a proof of payment will be sent to you.

Cancellation Policy - Full refunds less a handling fee of £100 will be made for cancellations received in writing within 28 days of the commencement of the course. Refunds of 50% will be made for cancellations received in writing between 28 and 7 days prior to the commencement of the course. Regrettably no refunds will be made after 7 days prior to commencement of the course. Substitutions can be made at any time.

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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**

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

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Stability Testing in Pharmaceutical Development and Manufacture
24 & 25 May 2018 **London**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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