

# European Continuing Education College

## Parenteral Products

### **Three Day Intensive Course Covering Formulation, Manufacture and Quality Assurance Aspects with Special Emphasis on Formulation, Stability, Biotechnology Products, Freeze Drying and Sterilisation Processes**

**Holiday Inn Hotel, Oxford Circus, London, UK  
27th, 28th and 29th February 2012**

#### **Course Background**

Formulation and manufacture of sterile products requires a clear knowledge of all criteria including production techniques, which affect their bioavailability and toxicity. Parenteral products are designed to be sterile, pyrogen and particulate free and isotonic wherever possible. Production processes and the selected primary packaging materials and delivery systems also affect the physical and chemical stability of the products. Routes of administration and the intended shelf life of the product may also dictate variations in formulation. Formulations vary from simple, small volume aqueous solutions in vials and ampoules, through oily suspensions and emulsions, to implants and large volume infusions in glass bottles and plastic bags.

Successful formulation and manufacture requires a detailed knowledge of all aspects of the drug and the physical chemistry of solutions and disperse systems, plus a comprehensive understanding of manufacturing and primary packaging constraints and regulations specific to sterile processing.

#### **Course Objectives**

The Course will provide an overview of the design and manufacture of a range of parenteral products and will introduce some recent developments in formulation and production processes. The Course will cover the selection of excipients in relation to physiological and toxicological problems and cover practical issues related to formulation design and stability.

Problems encountered in the production environment, sterilisation, depyrogenation and quality control of parenteral products will be discussed. The Course will outline the use of isolators for aseptic processing, look at product stabilisation using freeze drying (lyophilisation) and discuss the quality criteria for water for injection.

***A Feature of the Course is the Three Workshops on 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 bioavailability of drugs from various sites
- Major criteria of quality and special precautions required for parenteral products
- Preformulation studies of parenteral products
- Formulation of aqueous and oily products
- Formulation of suspensions, emulsions and sustained release products
- Stability testing of parenteral products
- Biotechnology Products and Devices
- Formulation and production of freeze dried products
- Sterilisation and depyrogenation processes

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## **Summary of Key Benefits of Attending**

After attending the course participants should be familiar with:

- The control of Water For Injection Systems
- Principles of quality control, quality assurance and documentation in relation to parenteral products
- Regulatory Issues

## **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 presently working in pharmaceutical development or production.

## **Course Outline**

### **Routes of Parenteral Administration**

- Intravenous, intramuscular, subcutaneous and localised administration
- Bioavailability and pharmacokinetic considerations
- Effect of physical chemistry of drugs on bioavailability

### **Major Criteria of Quality**

- Selection of method of sterilisation and definition of sterility
- Pyrogens - avoidance and removal
- Particulate contamination
- Control of manufacturing

### **Preformulation Studies**

- Drug solubility
- Assay development and techniques

### **Formulation of Solutions**

- Electrolytes and buffer systems
- Cosolvent systems
- Isotonicity
- Compatibility of product and primary packaging components
- Formulating with proteins
- Novel devices for administration of parenterals

### **Formulation of 'Complex' Parenterals Suspensions**

- Wetting, sedimentation and caking
- Ostwald ripening and particle size
- Syringeability
- Effect of salt formation and biopharmaceutical considerations

### **Emulsions**

- Stability of emulsions and methods of sterilisation
- Parenteral nutrition - special considerations
- Liquid phases, partitioning and bioavailability

### **Controlled Release Depots**

- Formulation Types
- Manufacturing considerations
- Sterilisation

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## **Course Outline**

### **Biotechnology Products**

- Special considerations when formulating macromolecules

### **Devices for Parenteral Products**

### **Sterilisation, Depyrogenation and Sanitisation Technologies**

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

### **Filters and Parenteral Products**

- Filtration processes
- Process validation
- Integrity testing

### **Use of Isolators**

- Aseptic processing considerations
- Control and testing

### **Production and Control of Water for Injection**

### **Freeze Dried Products**

- Formulation, process and equipment considerations

### **Quality Control Tests**

### **Regulatory Aspects**

## **Workshop**

Three Workshops on specific aspects of Parenteral Products.

## **Lecturers**

### **Peter Cameron (Course Director)**

Mr Cameron is a Senior Pharmaceutical Consultant with the Pharmaceutical Division of Bovis Lend Lease, specialising in parenteral production, regulatory issues and validation. He has been associated with the production of sterile products for over 25 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 Parenteral Society of Great Britain, freeze drying technical group and was the main author of the Parenteral Society monograph number 8 on freeze dryer inlet filter testing and has contributed to many others. He has edited and contributed to a book on Good Pharmaceutical Freeze Drying Practice.

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## **Lecturers**

### **Colin Booth B.Sc. (Hons)**

Mr Booth is VP Science and Technology for Oxoid Ltd, a leading supplier of microbiological culture media and innovative rapid diagnostic tests. Colin and his team based in Basingstoke in the UK are responsible for the research and development of new products, the Quality control and Quality assurance associated with product manufacture and the continuous drive to develop and improve existing products and processes. He is currently Chairman of the UK chapter of the PDA and is a member of the EP working party on Pyrogen testing. Colin has over 25 years experience in the Pharmaceutical industry and was formally responsible for Pharmaceutical microbiology in GSK.

### **Ed Cahill PhD., MSc., B.Sc.**

Dr Cahill is Manager, Product Development at AstraZeneca. He is responsible for managing a formulation team within AstraZeneca developing parenteral dosage forms. Previously he worked at Medeva developing vaccines and biotech products and has worked within the pharmaceutical industry for over 10 years, primarily working on parenteral dosage forms.

### **Keith Wickert BSc.**

Mr Wickert is European Marketing Manager for the Pharmaceutical Division of Cuno Europe. He is responsible for managing new product development and technical support. He is active in many of the key industry associations and has helped organise many of the PDAs meetings in Europe. Before joining Cuno, Mr Wickert spent 10 years at the Bio Products Laboratory and managed the department responsible for the production of Albumin and Immunoglobulin parenteral products.

### **Mike Hannay BSc(Hons.), MSc, MRPharms**

Mike Hannay is a pharmacist with seventeen years experience in the pharmaceutical industry. He joined Rhône-Poulenc in 1988 as a Formulation Scientist in the Pharmaceutical Sciences Department. During the next four years he moved through the pre-formulation group and headed a Clinical Supplies team. In 1992 he joined Fisons Pharmaceuticals as Section Manager developing line extensions and transferring new products into production. During his time at Fisons he led teams responsible for developing and validating manufacturing processes for the production of HFA MDI's. Following the acquisition of Fisons by Rhône-Poulenc and the subsequent merger to form Aventis, Mr Hanah moved sites becoming Industrial Technology Manager responsible for sterile products and solid dosage forms. In October 2000 he joined Schwarz as Head of Formulation and Technology where he is responsible for New Product Development and Clinical Trial Supplies. Since February 2004, Mr Hannay has been R & D Director with Ivax Pharmaceuticals.

### **Larry Staines B.Pharm**

Mr Staines is Site Operations and Sterile Products Manager at Wyeth and his responsibilities include freeze drying and process characterisation to improve technology transfer. He was employed at Pfizer Central Research in Formulation Research and later at Cyanamid, where he was responsible for a group engaged in clinical supplies and process development.

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## **Fees and Registration**

The participation fee is £1495.00 (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 Monday 27th February and the Course will commence promptly at 9.00am. The Course will finish at about 17.00 on Wednesday 29th February. The Course will end at about 18.00 on each of the first two days.

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## ECEC - Registration Form

### Course - Parenteral Products

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:

- Sunday 26th February 2012
- Monday 27th February 2012
- Tuesday 28th February 2012
- Wednesday 29th February 2012

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**