

European Continuing Education College

Design and Development of Conventional and Modified Release Oral Drug Delivery Systems

Three Day Intensive Course for Managers, Scientists and Technicians with the Emphasis on the Principles of Oral Drug Development from Preformulation through to Regulatory Requirements

**Holiday Inn Hotel, Oxford Circus, London, UK
23rd, 24th and 25th April 2012**

Course Background

Solid oral dosage forms, whether produced as conventional or extended release systems, are the major dosage form of the Pharmaceutical Industry. Although conventional and extended release systems are frequently discussed separately, there are many elements common to the two types of dosage form. The purpose of this course is to provide the common links between the systems. The starting point for any decision as to the type of dosage form to be produced is a thorough understanding of the physico-chemical and biological properties of the drug. If some of these properties are unfavourable, for example, solubility, there may be a need to alter the properties of the drug at an early stage. All dosage forms will require the use of excipients in their production and an understanding of the behaviour of these materials during processing is essential for successful formulation. Although some of the course will be directed solely to an understanding of extended release systems, the majority of the lectures will emphasise the common ground in the realisation that formulators will be required to work on both types of system.

Course Objectives

The principle objectives of the course are to provide an up-to-date understanding of the principles of the formulation of solid dosage forms from the preformulation stage through to marketing acceptance. The common links between the different types of dosage forms will be emphasised. The course will be taught in such a way as to provide both theoretical and practical aspects of the subject.

Who Should Attend

There are no prerequisites of knowledge or expertise for participants attending the course. Individuals who require a knowledge of the many facets of the formulation of solid oral dosage forms will benefit from attendance. The course will be most suited to those working in pharmaceutical formulation, research and development, manufacturing, quality control and assurance, validation of pharmaceutical processes, technology transfer and marketing. The course will also benefit other individuals working in regulatory affairs, licensing and project planning.

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Course Outline

Biopharmaceutics in Pre-Development

Understanding absorption; biopharmaceutical classification system; models for studying drug absorption from the G.I. tract, particularly cell based models; physico-chemical properties of drugs affecting bioavailability; formulation approaches to overcoming poor bioavailability.

Poorly Soluble Drugs

Methods for increasing dissolution rates; particle size, wettability; pH effects; salt formation; metastable polymorphic forms; glassy state. Advantages and disadvantages of the following techniques; solid dispersions; solvent deposition; cyclodextrins; co-mixing; liquid fill capsules

Excipients

Review of available excipients for conventional and extended release, their properties and the rationale for selection; current trends in excipients and formulation; direct compression materials; improvements in compaction characteristics.

Basic Principles of Extended Release

Suitability of drug candidates for formulation as extended release delivery systems with emphasis on the importance of drug physico-chemical properties; technical and dosage form design considerations in the formulation of extended release systems; fabrication options for single and multiple unit oral systems.

Mechanisms of Drug Release

Particular emphasis on extended release products; diffusion control across membranes (reservoir), through inert matrices (monolithic), by matrix erosion, across hydrophilic gels; swellable systems (hydrogels), swelling controlled and relaxation dependent diffusion.

Assessment and Evaluation of Solid Dosage Forms

In vitro dissolution testing and its relevance in quality assurance and bioavailability; in vivo release - non invasive methodologies; in vitro/in vivo correlations.

Polymer Film Formulation

Advances in techniques and formulations; polymer properties; enteric formulations; systems for extended / controlled release and targeting; new functional and non-functional systems.

Case Studies/Data Analysis

Participation in Group workshops.

Lecturers

John Collett PhD DSc FRPharmS (Course Director)

Professor Collett is Professor of Drug Delivery in The School of Pharmacy and Pharmaceutical Sciences at the University of Manchester. He has extensive research experience in the UK and USA and is a leading authority on polymeric drug delivery. He collaborates extensively with pharmaceutical companies in this field.

John Fell B.Sc., Ph.D., M.R.Pharm.S

Dr Fell is a Reader in Pharmacy at the University of Manchester and is well known for his work in tableting. He also has published widely in the areas of the wetting and surface energetics of solids and the imaging and in vivo behaviour of solid dosage forms.

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Lecturers

James Ford B.Sc., Ph.D., M.R.Pharm.S

Professor Ford is Professor of Pharmaceutics at Liverpool John Moores University. His research interests include controlled oral drug delivery via matrices and pellets, the interactions between hydrophilic polymers and water, modifications of the solid state to improve compaction properties of drugs and excipients and pharmaceutical aspects of thermal analysis. Professor Ford has published widely in these areas including, with Dr Timmins, a standard text on thermal analysis. He collaborates widely with pharmaceutical companies.

Hiep Huatan Ph.D., B.Pharm.

Dr Huatan is a Senior Principal Scientist at Pfizer and is Team Leader of the Controlled Release Group based in Sandwich, U.K. He is responsible for the development of Pfizer's controlled release dosage forms for both NCE's and product enhancement candidates. He has published widely in the area of controlled release and published more than 30 papers and abstracts over the last 5 years. Dr Huatan has had considerable experience at Pfizer in pre-formulation and biopharmaceutical areas for both human and veterinary health.

Chris Moreton B.Pharm., M.Sc., M.R.Pharm.S., Inst. Pkg (Dip.), Ph.D.

Dr Moreton is Vice President, Pharmaceutical Sciences at Idenix Pharmaceuticals, Cambridge, U.S.A. and is responsible for all formulation activities from preclinical safety studies through preformulation, formulation design and development, scale-up, clinical supply manufacture and technology transfer to the commercial manufacturing sites. Dr Moreton has over 25 years industrial experience at Pfizer Central Research, Sterling Winthrop R & D, ACO in Sweden and more recently at Penwest both in the U.K. and the U.S.A. At Penwest Pharmaceuticals he worked with excipients covering technical service and support, R & D and QA/QC for the drug delivery business. Dr Moreton is a member of the USP Expert Working Group on Excipient Test Methods. He is currently Chairman of the IPEC-Americas (International Pharmaceutical Excipients Council of the Americas) and a member of the Drug Product Technical Committee (DPTC) of the Product Quality Research Institute (PQRI). Dr Moreton has special expertise in the formulation of solid dosage forms.

Kevin Sooben Ph.D., B.Pharm., M.R.Pharm.S.

Dr Sooben is a Senior Pharmaceutical Scientist in the Preformulation and Biopharmaceutics Group within the Pharmaceutical and Analytical Research and Development Department at AstraZeneca. The Group is responsible for the characterisation and prediction of the biopharmaceutical properties of candidate drugs and formulations with particular reference to the per oral route and complex parenteral formulations.

Marcel Cimpan B.Eng.

Mr Cimpan is Technical Manager, Europe, Middle East and Africa for Colorcon Ltd. He is responsible for technical aspects of the range of Colorcon excipients.

Marina Levina MSc., Ph.D.

Dr Levina is Global Technical Manager, Excipients at Colorcon Ltd. and is responsible for all technical aspects of the range of Colorcon excipients. She has experience in the production of tablets by conventional and by ultrasound assisted compaction and with the development of solid oral dose formulations for both immediate release and sustained release applications

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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 23rd April and the Course will commence promptly at 9.00am. The Course will finish at about 17.00 on Wednesday 25th April. The Course will end at about 18.00 on each of the first two days.

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ECEC - Registration Form

Course - Design and Development of Conventional and Modified Release Oral Drug Delivery Systems

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 22nd April 2012
- Monday 23rd April 2012
- Tuesday 24th April 2012
- Wednesday 25th April 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