

# European Continuing Education College

## **Current Requirements for Chemistry and Pharmacy Sections of Regulatory Submissions**

### **Three Day Intensive Course Providing an Overview of Current Requirements Relating to Manufacture and Control of Pharmaceuticals within Submissions for Clinical Trials and Marketing Authorisations**

**Holiday Inn Hotel, Oxford Circus, London, UK**

**12th, 13th and 14th March 2012**

#### **Course Background and Objectives**

This course has been designed to provide an up-to-date and detailed review of the requirements that relate to the chemistry and pharmacy sections of submissions to authorities responsible for the regulation of medicines. Particular features of the course are the hypothetical case histories included in the workshops and the provision of ample opportunities to review and discuss specific problems.

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

Attendees on this course with its incorporated workshop sessions, can expect to gain an enhanced appreciation of:

- The scientific rationale underlying various regulatory requirements and what the authorities expect within submissions.
- The interdependency of the contributory roles of each participatory scientific discipline in the preparation of an acceptable dossier.
- Means of maximising the efficiency of timetabling activities and of deploying resources so as to secure expeditious preparation of the manufacturing and controls sections of regulatory submissions.

#### **Who Should Attend**

Any scientist or manager having responsibility for, or direct involvement in, the generation of data for, and for the incorporation of information in, the chemistry and pharmacy sections of dossiers for submission to medicines regulatory bodies.

The Course should prove of excellent value to pharmacists involved in formulation or in manufacturing, chemists concerned with synthesis and development, analysts, microbiologists, product planners and personnel concerned with standards, stability testing, packaging, product registration and regulatory compliance.

#### **Course Outline**

##### **Introduction and Overview**

Review of the various categories of regulatory submissions and the guidelines published by the major authorities.

Harmonisation of requirements

Formats and contents

##### **The Role of the M.H.R.A.**

The regulatory strategy and what is expected within submissions.

##### **Analytical Aspects**

Including I.C.H. guidelines and method validation.

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## **Course Outline**

### **Stability Considerations**

The requirements pertaining to demonstration that the medicine has acceptable stability.

### **Control of the Drug Substance/Impurities**

Development chemistry and control of starting materials; the different classes of impurities; how requirements differ with the differing types; batch analysis.

### **Development Pharmaceutics**

Formulation aspects, manufacturing process and validation.

### **Microbiological Considerations**

Requirements for different classes of medicines pertaining to microbiological contamination.

### **Packs and Packaging Materials**

What is required of the pack and the generation of the information expected by the authority; labelling requirements; patient information leaflet.

### **Control Tests on the Finished Product**

The design of the Finished Product Specification.

### **Common Technical Dossiers**

The pharmaceutical expert and the preparation of CTD's.  
Preparation of the Expert Report/Quality Overall Summary.

### **The Pharmaceutical Dossier**

A review of the pharmaceutical dossier.

### **Master Files and Certifications**

An account of the various categories and the circumstances of their applicability.  
The requirements of format and content.

## **Workshops/Tutorials**

These are an integral part of the course and involve participation in exercises relating to:

- Rational construction of submissions
- Interpretation and application of requirements
- Identification of shortcomings in some hypothetical submissions
- Common Technical Dossiers

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## Lecturers

### **Michael H. Rubinstein B.Pharm., Ph.D., M.R.Pharm.S., M.I.Chem.E., C.Eng., Q.P. (Course Director)**

Professor Rubinstein is C.E.O of Quay Pharmaceuticals Ltd., a contract pharmaceutical R & D and Clinical Trials Manufacturing company on the Wirral. Previously he was Professor of Pharmaceutical Technology and Director of the School of Pharmacy and Chemistry at Liverpool John Moores University. His research interests include the examination of the granulation process and he has published and lectured widely in the field of tableting technology and the formulation of solid dosage forms. He has provided specialist CMC advice in support of development projects. Professor Rubinstein has worked for AstraZeneca and GlaxoSmithKline in production technical support, pharmaceutical development and research. He has published over 200 research papers and articles in the area of solid dosage form technology and in particular in tablet compression. He lead one of the only academic research teams using a high speed Compaction Simulator to fundamentally characterise powder compression. Professor Rubinstein is both a Chemical Engineer and a Pharmacist with Q.P. Status, is the author of 5 books in pharmaceutical technology and two patents and is the series editor of the book series in Pharmaceutical Technology now published by Taylor & Francis Ltd. Professor Rubinstein is a consultant to a number of pharmaceutical companies and governments and is the Conference Co-Ordinator for the annual Pharmaceutical Technology Conferences.

### **Malcolm Dash B.Pharm**

Mr Dash is a Senior Pharmaceutical Assessor at the Medicines and Healthcare Products Regulatory Agency in the U.K.. He is responsible for the assessment of Applications both national and mutual recognition, EDMF's and Certificates of Suitability. He is the UK nominated expert on EDQM/PhEur Certification Scheme and has specific expertise in EDMF's, Certificates of Suitability, Modified Release, etc. He has a very active working involvement with the UK Medicines Inspectorate. Previously Mr Dash has had 13 years industrial experience at GlaxoSmithKline in both a formulation role and clinical trial supplies preparation. Mr Dash is a Member of the Management Committee of JPAG.

### **Steven Booth B.Pharm., Ph.D., M.R.Pharm.S., C.Eng., F.I.Chem.E., C.Sci.**

Dr Booth is Senior Director of Formulation and Process Design at Merck. Sharp & Dohme. He has responsibilities in formulation and process development and has published widely in the area of powder mechanics and drug delivery.

### **John Glasby Ph.D., B.Pharm., B.A. (Law), M.R.Pharm.S.**

Dr Glasby is a Consultant for Kendle International Ltd., a regulatory affairs consultancy and was previously the Managing Director of Kendle International. Until 1989 he worked for Fisons Pharmaceuticals in Development and Regulatory Affairs and later in Regulatory Affairs for Fisons in the U.S.A. He has very extensive experience of regulatory affairs as it affects clinical trials.

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## Lecturers

### **John M. Midgley O.B.E., BSc., M.Sc., Ph.D., F.R.Pharm.S., F.R.S.C., C.Chem.**

Professor Midgley is Emeritus Professor and Research Professor of Pharmaceutical and Medicinal Chemistry at the University of Strathclyde. Until very recently he was a Member of the Committee on the Safety of Medicines, and of its Chemistry, Pharmacy and Standards Sub-Committee (which he Chaired), for twelve years. Currently he serves on the External Advisory Panel of the MHRA. He was a Member of the Committee on Review of Medicines from 1984 to the end of its remit in 1992 and is currently a Member of the European Panel of Experts on Human Medicines (since 1995), the British Pharmacopoeia Commission (since 1984: including Chairmanship of Committee B, Medicinal Chemicals), the U.K. Delegation to the European Pharmacopoeia Commission (since 1998) and is Chairman of the EPC's Group of Experts 10A (Organic Chemistry, Synthetic Products). He has evaluated over 5,000 Marketing Authorisation Applications and was invested as an Officer of the Most Excellent Order of the British Empire (O.B.E.) for Services to the British Pharmacopoeia and to Regulatory Medicine in 1998. He is a Fellow of the Royal Pharmaceutical Society of Great Britain and of the Royal Society of Chemistry and has published over 150 papers on various aspects of pharmaceutical/analytical chemistry, synthetic organic medicinal chemistry and related subjects. Since 1967 he has acted as a Consultant for a large number of pharmaceutical/chemical companies worldwide, particularly in Europe, the USA and Japan.

### **Peter Taylor MIBiol., Ph.D.**

Dr Taylor is Reader in Pharmaceutical Microbiology at the School of Pharmacy, London University. He has very extensive experience in medical microbiology and has worked for numerous pharmaceutical companies. His research interests include novel approaches to the treatment of infectious diseases and site-selective drug delivery.

### **Kate Arnot B.Sc., M.Sc., C.Chem., M.R.S.C.**

Ms Arnot is Manager, Regulatory CMC at AstraZeneca with responsibilities for providing specialist CMC advice in support of development projects for N.C.E.'s and line extensions with a view to achieving a 'global development' and rapid approval for clinical and marketing submissions. Ms Arnot has over 12 years experience of analytical development in the pharmaceutical industry and has been involved with projects at all stages from early exploratory to development for launch. She has had recent experience of preparing drug substance and drug product contributions and responding to regulatory queries on the CMC section of a marketing submission for an NCE in 3 major markets (U.S., E.U. and Japan).

### **Michael Parker B.Pharm., Ph.D.**

Dr Parker is Associate Director, Product Development, Pharmaceutical and Analytical R & D at AstraZeneca. He is responsible for the development of oral dosage forms of AstraZeneca's new products and their associated manufacturing processes. This includes review and approval of all relevant CMC documentation. Previously Dr Parker has had 15 years experience in the design and development of oral and parenteral dosage forms and in the management of pilot scale GMP manufacturing facilities.

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## **Lecturers**

### **Arnold Stead B.Pharm., Ph.D., C.Chem., F.R.S.C., M.R.Pharm.S.**

Dr Stead is an independent consultant in pharmaceutical research, development and regulatory affairs. He has worked in the pharmaceutical industry for over 25 years including posts as Scientific Advisor to Hoechst Marion Roussel Ltd., and Head of Development at Roussel Laboratories. During 1996 he was an advisor to the World Health Organisation's Task Force on long acting contraceptives. He has been responsible for the development of a wide range of currently marketed products and is the author or co-author of some 30 publications in the pharmaceutical sciences. His first of many pharmaceutical expert reports was in 1985.

### **Stuart Goodall B.Sc., M.Sc. Ph.D., C.Chem., F.R.S.C.**

Dr Goodall is Manager of the Analytical Project Team working in lead-up to final product registration at Pfizer Global Research. He leads a team of 30 analytical staff and UK business lead for LIMs development.

## **Fees and Registration**

The participation fee is £1695.00 (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 12th March and the Course will commence promptly at 9.00am. The Course will finish at about 17.30 on Wednesday 14th March. The Course will end at about 18.00 on each of the first two days.

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## ECEC - Registration Form

### Course - Current Requirements for Chemistry and Pharmacy Sections of Regulatory Submissions

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 asterisk (\*) 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 11th March 2012
- Monday 12th March 2012
- Tuesday 13th March 2012
- Wednesday 14th March 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**