

European Continuing Education College

Preparation, Packaging and Labelling of Clinical Trial Supplies

A 'Team Taught' Three Day Intensive Course for Technical, Scientific, Clinical Managers and Technicians. The Course will be of Special Interest to Newcomers to Clinical Trial Supplies

**Holiday Inn Hotel, Oxford Circus, London, UK
21st, 22nd and 23rd November 2011**

Course Background

The preparation and packing of clinical trial supplies plays a key role in the regulatory process leading to the approval of new drugs and of new indications for existing medicines. Many of the tasks carried out share a common objective with routine production and packaging operations, but there are critical differences, which serve to identify clinical trials preparation as a discipline in its own right with the need for specialist knowledge to cope with its unique problems.

The preparation and packaging of clinical trial supplies is a good starting point for many planning a career in industrial or hospital pharmacy because of the breadth of knowledge gained and the opportunity to interact with a range of related disciplines.

This intensive course will be taught by a team of experts who have 'hands-on' experience of clinical trial supplies. It will provide opportunities for discussion and the exchange of ideas with course tutors and with users and organisers of clinical trials materials. A special feature of this course will be workshop sessions which will allow participants to share their experiences and use knowledge gained on the course to address specific questions of everyday relevance.

Course Objectives

The principal objectives of the course are to provide a comprehensive background and overview of the preparation, packing and labelling of clinical trials materials for people working directly in this area and to provide them with relevant and up-to-date information pertinent to their job function.

Who Should Attend

The Course is designed to be of special interest to anyone (especially newcomers) working in the planning, preparation and compliance aspects of clinical trial supplies, whether in a supervisory or a technical role. It will also benefit anyone who interacts with a Clinical Trials Unit and needs to understand its unique environment.

Course Outline

An Introduction to Clinical Trials

A broad review of the different types of clinical trial and why they are carried out, with comments on the purpose, design and content of protocols.

The Role of the Ethics Committee

Ethical review essentials. NHS Research Ethics Committees. Gaining Approval. Some concerns and developments.

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Course Outline

Statistics and Clinical Trial Design

Statistical testing. Statistical versus Clinical significance. Superiority versus Equivalence trials. Power and sample sizes. Applying statistical principles to trial design. The multiple testing problem.

The Drug Development Process

Drug discovery and design. Pre-clinical testing. Preformulation. Preclinical and clinical formulations. Process development. ICH. Product pack. Postmarketing surveillance.

Regulatory Aspects

A review of licensing requirements affecting both new chemical entities and established drugs with emphasis on Europe and North America (CTX, CTC, IND etc.). The important role of clinical trial data in product registration. Labelling requirements in key countries. Common Technical Document. Clinical Trials Applications. The E.U. Clinical Trials Directive.

Interactive Voice Response Systems

What is an IVR System. IVR Applications. Benefits of Clinical Trial Supply Management with IVR. Inventory control.

Facilities for Packing and Dispensing

Comments on the design of secondary packing and dispensary areas for clinical trials. Issues to be covered will include layout, materials flow, equipment, environmental control, personnel selection and training.

Setting and Maintaining Quality Standards

Aspects of G.M.P., G.C.P., and G.L.P. and the EC Annex on GMP for CT Manufacture. The special problems associated with investigational products. The importance of SOP's and quality audits. Validation in the context of clinical trials - the importance of people.

Cold Chain Distribution

GDP requirements. Design of a transport system. The Science. System and components. Performance. Validation. Other considerations

Labelling Systems

Approaches to multilingual labelling. A clinical trials supplies labelling system. A live demonstration of computer systems designed for the preparation of randomised clinical trial labels.

Outsourcing of Clinical Trial Supplies

Identifying contractors, specifications and controls, building the relationship, advantages and disadvantages of using contractors.

Distribution and Retrieval of Clinical Supplies

Storage. Distribution. Transportation. Receipt. Unused IMP's and returns. Recall of Clinical Supplies.

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Course Outline

The Needs of the Customers

- The Role and Needs of a Clinical Research Associate: Principal responsibilities during a study
- The Primary Care Viewpoint: Carrying out Clinical Trials in a GP Practice. GP Investigators, Research Nurses.
- The Hospital Viewpoint: Clinical trials in hospitals. How they are organized. How hospitals support clinical trials. 'In-House' studies. Setting up a clinical trial. Standards of Practice. Clinical Trial Prescriptions

E.C.E.C. Technical Clinic

An opportunity for an exchange of views on technical issues relevant to clinical trials preparation and packing.

Workshops

Group exercises designed to focus on key issues in clinical trials packaging.

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 & Chemistry at Liverpool John Moores University. His research interests include the design, stability and evaluation of solid dosage forms and he has published and lectured widely in this field. Professor Rubinstein is a pharmacist and a chemical engineer with Q.P. status and has had extensive industrial experience both at AstraZeneca and GlaxoSmithKline and as a worldwide consultant. He has published over 200 papers and six books and is the editor of the book series entitled 'Pharmaceutical Sciences' published by Taylor and Francis Ltd. He has been the Co-Ordinator of the annual Pharmaceutical Technology Conferences.

John Glasby Ph.D., B.Pharm., M.A. (Law), M.R.Pharm.S. Q.P.

Dr Glasby is a Director at 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.

John Aitken BSc., Ph.D.

Dr Aitken is Head of Global QA at Reckitt Benckiser and has responsibilities for all aspects of quality of licensed medicines and personal care products throughout the company worldwide. He has particular expertise in auditing, validation and clinical trial supplies and in his present position, Dr Aitken, risk assesses throughout the end-to-end process from development through manufacture, testing, release, transport distribution and returns.

Joan Perou BSc

Ms Perou is an Independent Clinical Research Consultant and has worked in clinical research for many years. Ms Perou, until recently, worked for 18 years with Novartis Pharmaceuticals and has extensive experience of GCP documentation and practices, quality assurance procedures including audit/inspection and training. She is a recognized expert on Ethics Committees and has worked with the NHS Executive on the training of LRECs and MRECs. Ms Perou is currently Chair of the Ethics Forum and Users Group of the Institute of Clinical Research.

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Lecturers

Susan Scobie B.Pharm., M.Sc., M.R.Pharm.S.

Ms Scobie is Clinical Director of Pharmacy at the University Hospital of North Staffordshire. Ms Scobie has over 20 years of experience in managing the pharmacy aspects of Clinical Trials, in particular the development of "in-house" studies. Ms Scobie also has many years of experience as a member of a Local Research Ethics Committee.

Robyn Wood B.Sc., M.Sc., Ph.D.

Dr Wood is Project Manager at ClinPhone and is responsible for managing IVR (Interactive Voice Response) and IWR (Interactive Web Response) systems as an integral part of client's clinical trials. Dr Wood has managed 35 studies to date, all of which have included medication management, including both open label and double blind studies.

Philip Rowe BSc., M.Sc., Ph.D.

Dr Rowe is Reader in Pharmaceutical Computing at Liverpool John Moores University. He has published over 100 papers and has special relevant expertise in data analysis for a wide range of drug trials, surveys and experiments.

Lynne Abley B.Sc., RGN

Ms Abley is Clinical Research Manager at GlaxoSmithKline UK Ltd. She is responsible for the management of all studies in HIV, oncology, vaccines and anti-infectives, managing a team of clinical study managers. The role involves the co-ordination and delivery of both registration and post-registration studies. In addition, the role involves working across brand teams in the U.K. and ensuring liaison with European colleagues.

Andrew Smithers M.B., B.S.

Dr Smithers is a Principal in General Medical Practice and a network co-ordinator for Profiad Ltd., He is responsible for clinical research within the large G.P. practice and has been an investigator in over 80 clinical studies from Phase II through to Phase IV. He is a visiting lecturer in clinical research at Warwick University.

Debra Choppen B.Pharm., M.R.Pharm.S.

Ms Choppen is a Projects Executive at Almedica Europe, where her responsibilities include local and global strategic business and operational improvement initiatives, training and project management. Previously she was President of DCR Consulting, a company that provides both Management and Pharmaceutical consulting services. Debra has held positions as Manager of Quality Assurance and Head of Development Operations at GlaxoSmithKline in Canada, where her responsibilities included the preparation, packaging and labelling of clinical supplies.

Anthony Waller B.Sc., C.Chem., M.R.S.C., M.R.Q.A.

Mr Waller is Quality Assurance Manager at Almedica Europe and is responsible for all Almedica's quality assurance and quality control functions.

Jason Putt BSc

Mr Putt is the Director of the Lifesciences Division of Prisym Ltd., a U.K. based developer of labelling software for the pharmaceutical and medicinal industries. Mr Putt has had over 8 years experience of direct involvement with major labelling projects for pharmaceutical, medical and clinical trials companies.

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Fees and Registration

The participation fee is £1595.00 (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 21st November and the Course will commence promptly at 9.00am. The Course will finish at about 17.00 on Wednesday 23rd November. The Course will end at about 18.00 on each of the first two days.

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ECEC - Registration Form

Course - Preparation, Packaging and Labelling of Clinical Trial Supplies

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 20th November 2011
- Monday 21st November 2011
- Tuesday 22nd November 2011
- Wednesday 23rd November 2011

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