

European Continuing Education College

Pharmaceutical Aerosols and Dry Powder Inhalation Systems

Three Day 'Team Taught' Intensive Course for Scientists, Managers and Technicians

**Holiday Inn Hotel, Oxford Circus, London, UK
11th, 12th and 13th June 2012**

Course Background

Pharmaceutical aerosols, (particularly as metered dose inhalers (M.D.I.'s) and dry powder inhalation systems, have over recent years, shown a steady growth in conjunction with nebulisers and nebulisation systems. More recently nasal delivery devices are increasingly being used as novel drug delivery systems. The advantages and disadvantages of all these devices will be compared, with M.D.I.'s and dry powder inhalation systems being covered in detail from development through marketing, launch and patient use. The increasing demands of the world's regulatory authorities in terms of product performance, safety and quality and how this has led to more sophisticated testing procedures together with a rational approach to product evaluation and supporting documentation will be reviewed.

Course Objectives

The purpose of the Course is to provide a sound background in aerosols generally and metered inhalers and dry powder devices, specifically. Since none of these product administration systems can be developed in isolation, a high level of integration is required between product, pack/device so that an adequate performance and shelf life can be achieved by effective testing procedures. This involves a thorough knowledge of formulations and the materials (metal, plastics, rubbers, etc.) from which the pack/device component may be produced. The aim of the Course is to provide information across these diverse areas.

Who Should Attend

The Course is designed to provide a broad knowledge base on aerosols and dry powder devices with limited reference to nebulisers. It is therefore intended for those who require an overview of the technologies involved as well as those who require specialised knowledge of more specific areas, ie. R & D, Development, Production, QA, QC and Regulatory Affairs.

Course Outline

Aerosol Introduction

Aerosols and aerosol technology

Formulation Of Aerosols

General formulations and formulations for MDI's. Challenges for formulating proteins and peptides

Aerosols, Valves and Containers

Understanding valve systems, drawings, properties of materials and functional features.

Propellant Systems and their Properties

Established and new propellant systems, their properties and safety concerns, particularly 134a/227. The latest propellant systems.

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Aerosol Filling, Facilities and Equipment

A review of methods, equipment, facilities and environmental needs.

The Challenge Between M.D.I.'S, Dry Powder Devices and Nebuliser Systems

A review of each system. Common areas between aerosols, dry powder devices etc.

Inhalation Technology, the Role of Particle Size Analysis and Powder Characterisation

A review of methods and equipment, and interpretation of particle size analysis. The properties of powders and the production of powders of the required particle size.

Testing and Stability Aspects

Standard tests. Non standard tests and stability profiling. Influence of compendial standards and ICH guidelines.

Quality Assurance, Quality Control, Specifications, Validation and Regulatory Requirements

A review of documentation and procedures.

Microbiological and Sterile Aspects

Evaluating and minimising bioburden. Production and evaluation of sterile products.

Dry Powder Inhalation Systems

The testing and evaluation of dry powder inhalation systems: stages and methods of evaluation, clinical and laboratory.

Dry Powder Inhalation Devices

A review of current and development devices, including practical case histories. Powder technology and powder characterisation.

Materials Science Aspects of Dry Powder Inhaler Development

Characterisation and control of the active pharmaceutical ingredient physical properties. Function, characterization and control of lactose for inhalation. Some particle and formulation strategies for D.P.I.'s

Inhalation Product Development

Including case studies on DPI and CFC to HFC transition programmes.
Future Trends and Technology in Inhalation Aerosol Devices

In-Vivo Testing of Inhaler Devices

An Overview of Nasal Delivery Device Technology

Physiology, formulation approaches, hardware, testing and evaluation.

Workshops

The above will be supported by workshop projects related to aerosol and dry powder devices.

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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. 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. 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.

David J. Alexander B.Sc., C.Biol., M.I.Biol., Dip.R.C.Path., D.M.S.

Mr Alexander has over 25 years experience in toxicology, specialising in inhalation toxicology, covering the regulatory safety testing of a wide range of compounds both in contract and in-house research laboratories. The past 15 years he has spent working with pharmaceuticals and is currently a Group Toxicologist at GlaxoSmithKline R & D.

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 GlaxoSmithKline.

Kevan Chippendale Ph.D. C.Chem, M.R.S.C

After graduating from the University of Salford, Dr Chippendale spent several years working for The Metal Box Company and Reckitt and Colman where he was involved with the development of novel printing and packaging systems for a wide range of materials and products. He later joined Fison's (now Sanofi-Aventis Pharma) where he became responsible for the development of drug administration devices and packaging systems for the Company's range of products. Subsequently he held a number of other positions in both Product Development and Manufacturing Operations. He has been actively involved in the development and manufacture of a wide range of inhalation products, including dry powder inhalers and pMDIs for over 20 years. Since leaving Sanofi-Aventis in 2003 Kevan has been providing consultancy services through Indtechsol Ltd.

Colin Dickens BSc

Mr Dickens is a Senior Scientist at Bepak Europe Ltd. and leads the scientific research and device development team for nasal drug delivery devices. This involves evaluating current requirements, predicting future trends and driving the research and device development to meet both short term and long term business objectives. Mr Dickens has published very extensively in the area of nasal delivery devices and is a recognized expert in this developing field of expertise.

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Lecturers

Joseph Lim B.Pharm. Ph.D.

Dr Lim is a Pharmaceutical Assessor at the Medicines and Healthcare Products Regulatory Agency (MHRA) in London. He is responsible for assessing the chemical and pharmaceutical data in relation to abridged applications (national and incoming MR) and has been involved in the assessment of applications for new inhaled products, including dry powder inhalers and MDI's (CFC free). Previously Dr Lim was Section Manager for over 10 years at Sanofi-Aventis and has specialist expertise in the pharmaceutical and process development of inhalation products, regulatory advice and has been involved in formulating and developing the Guidelines for inhalation products.

Martyn Ticehurst BSc., Ph.D.

Dr Ticehurst is a Section Manager in a research group at Pfizer Central Research which focuses on the materials science aspects of dry powder inhaler development.

David Morton BSc. Ph.D.

Dr Morton is Head of Technology and Intellectual Property at Vectura Group PLC; a company that is developing a range of inhaled drugs for the treatment of lung diseases and conditions where delivery via the lungs can provide significant benefits. Previously Dr Morton joined the Centre for Drug Formulation Studies at the University of Bath to manage their dry powder inhaler product development programme. In 1999, this group spun out into the drug delivery company, Vectura and David was appointed Head of Pulmonary Research, where he co-developed the emerging PowderHale™ technology.

Steven Nichols B.Sc., Ph.D.

Dr Nichols is Section Manager at Aventis Pharma responsible for Respiratory Physics and M.D.I. Analytical Development. Respiratory Physics is a research group investigating the in-vitro and in-vivo dynamics of delivery to the lung. The Analytical Development group is responsible for the Analytical Chemistry activities associated with Metered Dose Inhaler development through from method development to transfer to industrialisation.

Gary R. Pitcairn Ph.D., B.Sc., C.Chem., M.R.S.C.

Dr Pitcairn is Head of Inhalation Sciences at Pharmaceutical Profiles Ltd. He is responsible for the technical aspects of scintigraphic studies assessing aerosol deposition.

Tol S. Purewal Ph.D., M.R.Pharm.S.

Dr Purewal is Head of Pulmonary R & D at Bepak Europe Ltd. He was until recently Manager of Inhalation Development at 3M Health Care in Loughborough. Dr Purewal began his industrial career with Merck, Sharpe and Dohme and later became leader in aerosol development at GlaxoSmithKline Research.

Paul Sullivan B.Sc.

Mr Sullivan is Managing Director of D & H Industries, who supply a variety of aerosol filling equipment to both the pharmaceutical and cosmetic industries.

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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 11th June and the Course will commence promptly at 9.00am. The Course will finish at about 17.00 on Wednesday 13th June. The Course will end at about 18.00 on each of the first two days.

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ECEC - Registration Form

Course - Pharmaceutical Aerosols and Dry Powder Inhalation 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 10th June 2012
- Monday 11th June 2012
- Tuesday 12th June 2012
- Wednesday 13th June 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