Pharmaceutical Aerosols, Dry Powder Inhalation Systems and Nasal Delivery Devices

19, 20 & 21 November 2018

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

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

The course will cover -

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.

pMDI Performance, Testing and Issues

Aerosol Filling, Facilities and Equipment
A review of methods, equipment, facilities and environmental needs.

Venue

Holiday Inn Oxford Circus, 57-59 Welbeck St, Marylebone, London W1G 9BL, United Kingdom

Website: https://www.ihg.com

Timing of the course

Registration will be at 8.45am on Monday 19 November and the Course will commence promptly at 9.00am. The Course will finish at about 17.00 on Wednesday 21 November. The Course will end at about 18.00 on each of the first two days
The Course language will be English. An approved Certificate of Attendance will be given to each participant at the end of the Course

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Course Outline

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.

Development and Manufacturing Issues of Inhaled Products

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.

Regulatory Considerations for Inhaled Delivery Systems

Workshops: The above will be supported by workshop projects related to aerosol and dry powder

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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 in North Wales. 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.

Julia Mottishaw BSc QP Ms Mottishaw is Qualified Person at Teva in the UK. Previously she was Head of Microbiology at Sanofi-Aventis with responsibilities for quality of the company's inhalation systems.

Martyn Ticehurst PhD., B.Sc Dr Ticehurst is an Associate Research Fellow, Materials Sciences at Pfizer Global R & D. He has many years experience of material science and powder technology aspects of dry powder inhalation systems and has pioneered the development of these devices at Pfizer.

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.

Robert Clayborough Ph.D., B.Sc., MBA, Cchem, MRSC, CPhys, MInstP Dr Clayborough is an OINDP independent Consultant and CEO of Alchemy PharmaTech. Previously he was Principal Consultant with Sagenta UK, VP of Product Development at Akela Pharma based in Austin, Texas and CEO of LAB Pharma in Finland. Prior to joining LAB Pharma, Dr Clayborough spent 4 years at 3M Health Care heading up the pMDI Inhalation Formulation & Device Development Group. Before joining 3M Health Care he worked in a variety of increasingly senior positions within the Respiratory Technology Group at Aventis Pharma.

Gary R. Pitcairn Ph.D., B.Sc., C.Chem., M.R.S.C. Dr Gary Pitcairn is Head of Portfolio Management for Respiratory, Inflammatory and Autoimmune Diseases at AstraZeneca. Previously he was Senior Director of Respiratory Drug Delivery in the Global Respiratory Group at Mylan Pharmaceuticals UK Ltd. Dr Pitcairn spent a number of years working at Pharmaceutical Profiles, evaluating drug delivery from a wide range of pulmonary and nasal drug delivery devices in both in vitro studies and Phase I and II studies. Whilst at Pfizer R&D, he was responsible for helping to select and progress new inhaled drug candidates from discovery through to First in Human studies, and on to Proof of Concept studies in patients. During this time, he was also responsible for developing patient focused testing and incorporating this approach into the development process for new inhaled products. Dr Pitcairn has published over 40 peer reviewed papers and is a frequent speaker at international meetings. He is the chair of the organizing committee for Drug Delivery to the Lungs (DDL), which delivers a successful international conference each year. He is also part of the organizing committee for the 'Drugs to the Lung Network', which runs small annual meetings (via the Academy of Pharmaceutical Scientists), focusing on particular topics of interest to the inhaled aerosol community.

Tol S. Purewal Ph.D., M.R.Pharm.S. Dr Purewal is an independent consultant and was formerly Head of Pulmonary R & D at Bespak Europe Ltd. Previously he was 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.

Geralllt Williams PhD., B.Sc. Dr Williams is Director of Scientific Affairs at Aptar in France.
He is responsible for all new development initiatives in Nasal Delivery and has published very widely in the area of nasal drug delivery.

REGISTRATION DETAILS:

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Early-bird fee: 3 day course £1526.00 (+ VAT £305.20 if applicable, see notes on VAT)

For registering and paying before **24 September 2018**

Full Fee: 3 day course £1695.00 (+ VAT £339.00 if applicable, see VAT NOTES)

Academic rates are available, please enquire: info@pharma-training-courses.com

VAT NOTES:

UK: Under UK law all UK-based applications are subject to VAT at the prevailing rate however most UK VAT registered companies/organisations can reclaim this tax.

EU: With effect from 1 January 2011 applications from delegates whose companies are based in EU countries will not be subject to VAT **PROVIDED THAT** valid VAT ID details are provided at the time of booking, otherwise VAT will be charged.

OTHER: With effect from 1 January 2011 applications from delegates whose companies are based outside of the UK/EU will be outside the scope of VAT, ie no VAT is charged or payable.

Methods of Payment available:

Cheque (**Please make payable to "PharmaCourses Ltd")**
Bank transfer
Credit/Debit Card (Paying by Credit Card please register online)

Registration is available online:

www.pharma-training-courses.com

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Delegate fees - Fees for this programme are shown overleaf. Delegate fees are inclusive of course documentation, refreshments and lunch. Payment of the registration fee must be paid within 14 days of commencement of the course. Upon receipt of payment, a proof of payment will be sent to you.

Cancellation Policy - Full refunds less a handling fee of £100 will be made for cancellations received in writing within 28 days of the commencement of the course. Refunds of 50% will be made for cancellations received in writing between 28 and 7 days prior to the commencement of the course. Regrettably no refunds will be made after 7 days prior to commencement of the course. Substitutions can be made at any time.

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Course Programme 2018

Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
13, 14 & 15 March 2018, **Croydon Greater London**

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HPLC Analytical Method Development and Validation
10 & 11 May 2018 **Istanbul Turkey**

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Stability Testing in Pharmaceutical Development and Manufacture
24 & 25 May 2018 **London**

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Pharmaceutical Dissolution Testing – a 2 day course
21 & 22 May 2018 **London**

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Pharmacokinetics in Drug Development - an integrated approach
18 & 19 June 2018 **London**

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Pharmaceutical Packaging – an introductory course
25 June 2018 **London**

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Powder Technology for Pharmaceutical Development and Manufacturing
26, 27 & 28 September 2018 **London**

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Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
13, 14 & 15 June, **Croydon Greater London**

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Introduction to the Formulation and Stabilisation of Protein and Peptide Drugs
24 & 25 September 2018 **London**

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Latest Advances in the Formulation & Stabilisation of Protein and Peptide Drugs
24 & 25 September 2018 **London**

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Pharmaceutical Dissolution Testing – a Hands-on Course
23, 24, 25 & 26 October 2018 **London**

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Pharmaceutical Granulation and Compression
29, 30 & 31 October 2018 **London**

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GMP Auditor Training for Quality Systems
7, 8 & 9 November 2018 **London**

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Parenteral Products
12, 13 & 14 November 2018 **London**

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Development of Stability-Indicating HPLC Methods
21 November 2018 **London**

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HPLC Analytical Method Development and Validation
22 & 23 November 2018 **London**

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Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
5, 6 & 7 December 2018, **Croydon Greater London**

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