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Inhaled Drug Delivery

To book online go to: management-forum.co.uk/1714

Date and venue

1-2 November 2018

Ref: 10218

The Rembrandt Hotel
11 Thurlow Place
London SW7 2RS
Tel: +44 (0)20 7589 8100

Programme schedule

Registration and refreshments: 09.00

Drinks reception day one: 17.45 - 18.45

	Day one	Day two
Start	09.30	09.15
Close	17.45	16.30

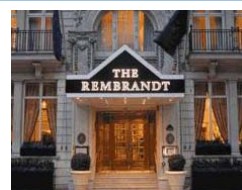
Accommodation

We have arranged a preferential rate for accommodation at the venue. To take advantage of this please contact the hotel on the email below and state you are a Management Forum delegate. There are limited rooms available at this rate so please book early to avoid disappointment.

Email: reservations_rembrandt@sarova.co.uk

Web: www.sarova-rembrandthotel.com

For information on alternative accommodation please visit our website: management-forum.co.uk/accommodation



Three ways to book

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Fees and payment

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Exhibition opportunities available

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FEE: The fee includes all meals and refreshments for the duration of the course and a complete set of course materials. If you have any particular requirements please advise customer services when booking.

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Annual Conference for Inhalation Professionals



Inhaled Drug Delivery

Industry case studies, regulatory updates, latest therapies and technology innovations

1-2 November 2018 London



Programme to include:

- Modern respiratory medicines
- Innovation in nebulised therapy
- Current and future trends for DPI formulation
- Opportunities of nanoformulations in the lung
- The role of lung protease in delivery of inhaled biopharmaceuticals
- Lung deposition software: Mimetikos prelude: a new pharma friendly aerosol drug deposition calculator
- Could smart inhalers dramatically change the way that Asthma and COPD patients are treated?
- Decoding FDA's recent combination drug product guidance: Applications to DPIs, pMDIs, and nasal sprays
- The UK regulatory future – the way forward after Brexit
- Navigating human factors in device development
- The 1nhaler and its two jobs
- Opportunities and challenges in the design of high-performance unit-dose dry powder inhalers
- Design characterization of breath actuation mechanisms
- Digitally enabled inhalers

Co-chairmen



Day one:

Mike Holroyd

Senior Director, Mylan, UK

“Excellent content, valuable and knowledgeable speakers. Liked it. Good”

[Aravind Rambhau Sonawane, Sunpharma Global](#)



Day two:

Stephen Eason

Independent Consultant, UK

“Very good conference with plenty of time for networking and high level talks. I will recommend it to my colleagues”

[Segolene Sarrailh, Aptar France](#)

Exhibition opportunities available

Attend the drinks reception to maximise your networking



Introduction

Inhaled drug delivery is achieved using four principle technologies, dry powder inhalers, metered dose inhalers, nebulisers and liquid inhalers. Although there are many differences between these technologies there are many fundamental principles that are followed to achieve an effective delivered dose, as such there is much shared learning across the technologies.

This meeting includes presentations on each of these delivery technologies with the intent to share knowledge and learning across the inhaled drug development business. The future European and UK regulatory processes following Brexit will be critical when developing product approval strategies, we shall be considering regulatory issues on this and other important hot topics.

There are a number of key areas that are currently evolving and the latest thinking and progress on these will be presented, including Human factor design and sensing/connecting technologies. These key evolving areas are subject to much debate and require careful consideration whilst developing an inhaled drug product.

Reasons to attend

- A valuable update on the advances in inhalation technology and inhaled drug delivery
- An opportunity to keep abreast of trends in the market
- The chance to develop business relationships

Co-chairmen:

Mike Holroyd, Senior Director, Mylan, UK
Stephen Eason, Independent Consultant, UK

Expert faculty:

George Bostock, Consultant Mechanical Engineer, Cambridge Design Partnership, UK
Mark Copley, Chief Executive Officer, Copley Scientific Ltd, UK
Richard Costello, Consultant Physician, Royal College of Surgeons, Ireland
Anselm Ebert, Director Business Development, H&T Presspart, UK
Nicky Ellis, Associate Director, Regulatory Affairs, Vectura, UK
Badre Hammond, Associate Director, Market Development Aptar Pharma, USA
Dr David Jefferys, Senior Vice President Global Regulatory, Eisai Europe, UK
Sarika Joshi, Engineer (Human Factors & Design Assurance) - Medical Devices, Vectura UK
Alison Moore, Clinical Development Manager, GSK, UK
Helen Muirhead, SVP Respiratory Medicines, GMPharma, UK
Dr Bo Olsson, Senior Inhalation Consultant, Emmace Consulting, Sweden
Prof.Dr Regina Scherliess, Department of Pharmaceutics and Biopharmaceutics, Christian-Albrechts-University Kiel, Germany
James Tibbatts, Head of Business Development at Coalesce Product Development, UK
Dr John Pritchard, Director PMO and Technology, Respiratory Drug Delivery, Sleep & Respiratory Care, Philips Healthcare, UK
Don Smith, Founder, and Inventor, 1nhaler, UK
Dr Arcadia Woods, Kings College London
Dr David Wyatt, Chief Operating Officer, Aston Particle Technologies Ltd, UK

A certificate of attendance for professional development will be available to each participant who completes the seminar

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Day one

09.30	▶	Chairman’s welcome and Introduction Mike Holroyd , Senior Director, Mylan, UK
09.40	▶	You can breathe easily now; modern respiratory medicines... • Burden of respiratory diseases • The patient and the Quality Target Product Profile • Guidelines for lung disease treatment • Enhancements of older devices • Digital advancements for patients Helen Muirhead , SVP Respiratory Medicines, GMPharma, UK
10.20	▶	Innovation in nebulised therapy • Nebulised therapy is growing faster than other inhaled dosage forms, albeit from a smaller base • There are significant unmet medical needs for patients that would benefit from nebulised therapy, which will be reviewed • There are potential commercial advantages to develop nebulised therapies ahead of the corresponding inhaler • The use of electronics facilitates the introduction of patient management solutions Dr John Pritchard , Director PMO and Technology, Respiratory Drug Delivery, Sleep & Respiratory Care, Philips Healthcare
11.00	▶	Discussion followed by refreshments
11.30	▶	Current and future challenges for DPI formulation • odays DPI marketplace • The challenge of formulating New Chemical Entities • The challenge of developing generic DPIs • Quality by Design in DPI formulation • Advanced Manufacturing Technology Dr David Wyatt , Chief Operating Officer, Aston Particle Technologies Ltd, UK
12.10	▶	Opportunities of nanoformulations in the lung • What is nano? What are characteristics of nanoformulations and what could be beneficial? • Possible formulation options • Challenges and opportunities Prof.Dr Regina Scherliess , Department of Pharmaceutics and Biopharmaceutics, Christian-Albrechts-University Kiel, Germany
12.50	▶	Discussion followed by lunch
14.10	▶	The role of lung protease in delivery of inhaled biopharmaceuticals • Proteases are known to play an important role in lung function in health and disease. They can also have a significant effect on the bioavailability and duration of action for inhaled biopharmaceuticals due to their ability to degrade protein-based therapeutics. • However, as of yet little work has been reported which attempts to model the effects of lung protease activity in an in vitro system. • This talk will report the development of a biorelevant lung protease activity model, and the key findings from a study using this model to investigate the protease-mediated degradation of albumin nanoparticles, a promising protein-based nanocarrier for inhaled use. Arcadia Woods , Kings College, London, UK
14.50	▶	Mimetikos preludeum: a new pharma friendly aerosol drug deposition and disposition simulator • Regional lung deposition from - aerosol properties, lung geometry and breath parameters • PK simulation - Mechanistic absorptive and non-absorptive lung clearance - Compartmental systemic disposition and elimination Dr Bo Olsson , Emmace Consulting, Sweden
15.30	▶	Discussion followed by refreshments
16.10	▶	Could smart inhalers dramatically change the way that asthma and COPD patients are treated? • The burden of asthma and COPD remains high despite many new medicines • A major factor is poor adherence • Smart inhalers are being developed to monitor the way that patients use their inhalers • Can the data from smart inhalers improve patient-clinician communication? • Can smart inhalers improve adherence and ultimately lead to better health outcomes? Alison Moore , Clinical Development Manager, GSK, UK
16.50	▶	Decoding FDA’s recent combination drug product guidance: Applications to DPIs, pMDIs, and nasal sprays • The basics – medical device, combination product, and packaging components • NDA/ANDA submissions: regulatory pathway review for combination products • Human Factor studies in the context of combination product • Clarify expectations: Sponsor, device supplier, and regulators Badre Hammond , Associate Director, Market Development Aptar Pharma, USA
17.30	▶	Discussion
17.45	▶	Networking drinks reception
18.45	▶	End of day one

Day two

09.15	▶	Review of day one Stephen Eason , Independent Consultant, UK
09.30	▶	The UK regulatory future – the way forward after Brexit • What are the key issues for the pharmaceutical industry for UK and EU 27 • What have we learnt so far and what are the next stages of the negotiations • Preparations for March 2019 • What should we expect from March 2019 Dr David Jefferys , Senior Vice President Global Regulatory, Eisai Europe, UK
10.10	▶	Methods for the determination of delivered-dose uniformity and aerodynamic particle size distributions of OINDPs • Introduction to inhaled device types and their nuances • Current regulatory requirements for in-vitro testing of OINDPs • Delivered dose uniformity testing and APSD measurements by cascade impaction • Advances in measurement techniques for bioequivalence testing and improving IVIVCs Mark Copley , Chief Exectutive Officer, Copley Scientific Ltd. UK
10.50	▶	Discussion followed by refreshments
11.30	▶	Navigating human factors in device development • Integration of human factors and device development • Varying perspectives in application of the regulations and guidance • Application beyond the procedures Sarika Joshi , Engineer (Human Factors & Design Assurance) - Medical Devices and Nicky Ellis , Associate Director - Regulatory Affairs, Vectura, UK
12.10	▶	The 1nhaler and its two jobs • The functional, emotional and social reasons that there is a growth market for single-dose DPI's Don Smith , Founder, and Inventor, 1nhaler, UK
12.50	▶	Discussion followed by lunch
14.10	▶	Opportunities and challenges in the design of a high-performance unit-dose dry powder inhaler • Design opportunities and challenges for a “fit for purpose” capsule based DPI • Prototyping challenges • Preliminary performance data Anselm Ebert , Director Business Development, H&T Presspart, UK and George Bostock , Consultant Mechanical Engineer, Cambridge Design Partnership, UK
14.50	▶	Design and characterisation of breath actuation mechanisms • Rationale and user requirements for the use of breath actuation mechanisms (BAMs) in inhaled drug delivery products • Design considerations for BAMs • Experimental characterisation of BAMs • Comparison of the trigger characteristics in different marketed breath actuated inhaler products James Tibbatts , Head of Business Development at Coalesce Product Development, UK
15.30	▶	Digitally enabled inhalers • Types of technology that could be included in inhalers • The value of digital inhaler monitoring Richard Costello , Consultant Physician, Royal College of Surgeons, Ireland
16.10	▶	Discussion
16.20	▶	Chairman’s closing remarks
16.30	▶	Close of conference and refreshments

Companies participating include:

GSK, Mylan, Philips Healthcare, Aptar Pharma, Coalesce Products, Vectura, H & T Presspart, Eisai Europe, Royal College of Surgeons, Cambridge Design Partnership, Emmace Consulting, Kings College London, Christian-Albrechts University Kiel, 1nhaler

"Very worthwhile. Some good and valuable information"

Annmarie Gambrell, Mylan Pharma UK Ltd

"Very impressed with all speakers"

Peter Davies, Bespak Europe Ltd

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