Inhaled Drug Delivery

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

6-7 November 2019 London

Date and venue
Ref: 10513
6-7 November 2019
The Rembrandt Hotel
11 Thurloe Place
London SW7 2RS
Tel: +44 (0)20 7589 8100

Programme schedule
Registration and refreshments: 09.00
Day one 09.30 - 17.45
Drinks reception 17.45 - 18.45
Day two 09.15 - 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

Inhaled Drug Delivery

To book online go to: management-forum.co.uk/1714
Book before 23 August 2019 and SAVE £200/€280

Fees and payment

EARLY BOOKING DISCOUNT
Book BEFORE 23 August 2019
£1299.00 + VAT = €1558.80 • €1819.00 + VAT = €2182.80

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Book AFTER 23 August 2019
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Multiple booking discount for 2nd or subsequent delegates - 15%
£1274.15 + VAT = €1528.98 • €1784.15 + VAT = €2140.98

Payment options
1. Invoice which can be paid by bank transfer or credit/debit card
2. Online through our secure website when registering

Benefits of attending:
- Hear from an unrivalled faculty of speakers
- Discover what is new in nebulised therapy
- Explore new concepts in inhaled corticosteroid therapeutic equivalence
- Gain new analytical insights into dry powder formulations for inhalation
- Understand the challenges with triple combination inhalers
- Consider the environment with inhaler devices
- Discuss success criteria in technology transfer
- Review new inhalation technologies
- Hear about innovation in production technologies
- Understand the regulatory requirements for respiratory products
- Gain an insight into the regulatory position post Brexit
- Learn about human factors and its relevance in product development
- Explore opportunities with smart and digital inhalers

Co-chairs:
Day one
Mike Holroyd
Senior Director, Mylan, UK

Day two
Helen Muirhead
Senior Vice President, Respiratory Medicines, GMPharma, UK

With a panel of experts from Aptar Pharma, Bruce Davis Consulting, Chiesi, DLRC, Eisai, Emergo by UL, FLUIDDA, GMPharma, GSK, Inspiring Strategies, Mylan, Royal College of Surgeons, University of Hertfordshire

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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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For event cancellation policy and T&Cs see our website
Inhaled Drug Delivery 6-7 November 2019, London

Why you should attend
This seminar includes presentations and knowledge-sharing from world-recognised experts from industry, academia and regulation in the area of respiratory medicines and is an essential event for all those new to or experienced in inhaled drug delivery.

Inhaled drug delivery is achieved using four principal technologies: dry powder inhalers, metered-dose inhalers, nebulisers and liquid inhalers. Although there are many differences between these technologies, there are a number of fundamental principles that are followed to achieve a successful delivered dose. This event will provide an excellent forum to share knowledge and explore the opportunities across the dose forms with key industry leaders.

The most recent and innovative developments in inhaled drug delivery will be addressed including the use of triple therapies in lung disease, the development of long-awaited generic inhalers, the use of quality by design (QbD) principles in continuous manufacture, innovation in nebuliser treatment, reviews of connected devices, and the use of human factors in the design process. Regulations are key to respiratory medicines and future European and UK regulatory processes following Brexit will be critical when developing product approval strategies. Regulatory issues on this and other important hot topics will be considered.

This programme will provide valuable insights into inhaled drug delivery from experts in the field and will give you:
- A comprehensive update on the advances in inhalation technology and inhaled drug delivery
- An opportunity to keep abreast of global trends
- An excellent forum to discuss challenges and how to overcome them
- A chance to develop business relationships

Co-chairs
Mike Holroyd, Senior Director, Mylan, UK
Helen Muirhead, Senior Vice President, Respiratory Medicines, GMPharma, UK

Expert Faculty
Ian Ashurst, Principal Regulatory Consultant, DLRC Ltd, UK
Chris Baron, Associate Director, Business Development, Aptar Pharma, France
Richard Costello, Consultant Physician, Royal College of Surgeons, Ireland
Peter Daly-Yates, Director, Clinical Pharmacology, GSK, UK
Bruce Davis, Senior Consultant, Bruce Davis Consulting, UK
Jan de Backer, CEO, FLUIDUSA, UK
Richard Featherstone, Research Director, Human Factors Research & Design, Estergon by UL, UK
Dr David Jefferys, Senior Vice President Global Regulatory, Eisai, UK
Allison Moore, Clinical Development Manager, GSK, UK
Professor Darragh Murnane, Professor of Pharmacaceutics, Associate Dean (Business and Enterprise), Department of Clinical and Pharmaceutical Sciences, School of Life and Medical Sciences, University of Hertfordshire, UK
Francesca Ubersit, Head of Respiratory Technical Leadership, CMC, R&D, Chiesi, Italy
Dr John Pritchard, Owner of Inspiring Strategies, providing consultancy on respiratory drugs, devices and digital health, UK

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

Exhibition opportunities available. Please contact customer services on +44 (0)20 7749 4730 or email info@management-forum.co.uk

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Programme

Day one
09.00 ➤ Registration and refreshments

09.30 ➤ Chair’s welcome and introduction
Mike Holroyd

09.40 ➤ You can breathe easily now: modern respiratory medicines
- Burden of respiratory diseases
- The patient and the Quality Target Product Profile (for respiratory medicines)
- Guidelines for lung disease treatment
- Enhancements of older devices
- Digital advancements for patients
Helen Muirhead

10.20 ➤ Innovation in nebulised therapy
- How nebulised therapy is growing faster than other inhalation dosage forms, albeit from a smaller base
- A review of the significant unmet medical needs for patients that would benefit from nebulised therapy
- The use of digital technologies to develop nebulised therapies ahead of the corresponding inhaler
- The use of electronics to facilitate the introduction of patient management solutions
Dr John Pritchard

11.00 ➤ Discussion session

11.10 ➤ Refreshments

11.30 ➤ New concepts for inhaled corticosteroid therapeutic equivalence
- Potency and clinical efficacy
- Dose response
- Duration of action
- Therapeutic index
Peter Daly-Yates

12.10 ➤ INFORM 2020: new analytical insights into dry powder formulations for inhalation
- Structural equivalence for inhaled formulations
- Microstructural analytical techniques
- Multi-scale computed tomography approaches to look inside formulations
- Identifying metrics of relevance to inhaled product performance
Professor Darragh Murnane

12.50 ➤ Discussion session

13.00 ➤ Lunch

14.10 ➤ Developing triple combination inhalers
- The challenges and opportunities
Francesca Ubersit

14.50 ➤ Bringing better inhaled drugs faster to market through functional respiratory imaging (FRI) and artificial intelligence (AI)
- Conventional lung function tests fail to provide regional information on lung structure and function and regional information matters
- FRI and AI yield clinically relevant regional information
- FRI received FDA support as part of the Biomarker Qualification Program
- FRI and AI can:
  - Facilitate the development of novel treatments in COPD
  - Help in tackling environmental challenges such as wildfire exposure
Jan de Backer

15.30 ➤ Discussion session

15.40 ➤ Refreshments

16.10 ➤ Digitally enabled inhalers – a clinician’s perspective
- Types of technology that could be included in inhalers
- The value of digital inhaler monitoring
Richard Costello

16.50 ➤ Technology transfer (TT) for inhaled drugs
- TT requirements per ICH Q10
- Regulatory (FDA, EU, WHO, Japan) and industry guidance for TT
- Where TT fits in the product lifecycle
- Importance of critical quality attributes and control strategy
- Implications for transfer of manufacture to or between third parties
- Success criteria
- Analytical method transfers
Bruce Davis

17.30 ➤ Discussion session

17.30 ➤ End of day 1

17.45-18.45 Networking drinks reception

Day two
09.15 ➤ Review of day one
Helen Muirhead

09.30 ➤ Review of new inhalation technologies
- What is there to get excited about?
- New innovations
- Challenges in delivering inhalation dosage forms
- Novel delivery platforms

10.10 ➤ How to navigate a smooth regulatory pathway for inhaled products
- Leveraging pre-submission advice to build a robust development plan
- A major factor is poor adherence
- Smart inhalers are being developed to monitor the way that patients use their inhalers
- The burden of asthma and COPD remains high despite many new medicines
- Questions and challenges
Dr David Jefferys

10.50 ➤ Discussion session

11.00 ➤ Refreshments

11.30 ➤ Regulatory alignment between the UK and Europe post Brexit
- Latest position on Brexit
- Implications for EU 27 and for UK inhalated products
- Future role for the MHRA
- Introduction of Regulation 3027/746 and Article 117 on combination products
Dr David Jefferys

12.10 ➤ Human factors (HF) studies – a hype or a must-do?
- Legal and regulatory guidelines covering human factors for pharmaceutical products
- HF and risk management
- Human factors in clinical trials
- Generic combination products – ANDAs and HF Questions and challenges
Richard Featherstone

12.50 ➤ Discussion session

13.00 ➤ Lunch

14.10 ➤ Inhaled devices and the environment
- Carbon footprints, an overview of the situation
- Where now for the MDIs and HFAs?
Chris Baron

14.50 ➤ 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
- Questions and challenges
Dr Aravind Rambhau Sonawane, Sunpharma Global

15.30 ➤ Panel discussion: As we move into the digital age, what do patients want from their disease treatment and medicines?
Led by Helen Muirhead with Alison Moore and Ian Ashurst

16.10 ➤ Discussion session

16.20 ➤ Chair’s closing remarks

16.30 ➤ Close of seminar and refreshments

Previous attendees have said:
‘Excellent content, valuable and knowledgeable speakers.’
Aravind Rambhau Sonawane, Sunpharma Global
‘Very good conference with plenty of time for networking and high level talks. I will recommend it to my colleagues.’
Sepronee Sarnath, Apta France
‘Very worthwhile. Some good and valuable information.’
Anna Marie Gambrell, Mylan Pharma UK Ltd
‘Very impressed with all speakers.’
Peter Davies, Bespin Europe Ltd