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Dry Powder Inhalers

To book online go to: **management-forum.co.uk/1318** W

Date and venue

27-28 June 2017 **Ref: 9886**

The Rembrandt Hotel
11 Thurloe 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: **reservations_rembrandt@sarova.co.uk** and state you are a Management Forum delegate. There are limited rooms available at this rate so please book early to avoid disappointment. 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

EARLY BOOKING DISCOUNT **Book BEFORE 5 May 2017**
£1199.00 + VAT = £1438.80 • €1679.00 + VAT = €2014.80

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£1399.00 + VAT = £1678.80 • €1959.00 + VAT = €2350.80

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The small print

FEE: The fee includes lunch 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.

HOW TO REGISTER AND PAY: A VAT invoice and booking confirmation will be sent within 7 days, please contact us if you have not heard anything after that time. Payment can be made by credit/debit card, by bank transfer (for bank account details please see payment details section on our website). VAT no GB 41232109. Any questions please contact Customer Services on +44 (0)20 7749 4730. **ALL PAYMENTS MUST BE RECEIVED IN ADVANCE OF THE EVENT.**

MULTIPLE BOOKING DISCOUNTS: This discount may not be used in conjunction with any other offer

CANCELLATIONS AND TRANSFER: Once we have received your booking the place(s) are confirmed.

Delegate	Up to 28 days before course	27 to 14 days before course	13 to 0 days before course
Cancellation	10% admin fee	100% admin fee	100% admin fee
Transfers	Free	10% admin fee	100% admin fee
Substitution	Free	Free	Free

A maximum of one transfer is allowed. After the transfer no cancellation can be accepted and the full invoiced fee will be charged. Transfers are subject to payment of the difference on higher value courses. All cancellations must be received in written form.

For event cancellation policy and T&Cs see website

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Media Partner: ON drugDELIVERY **Exhibitor:** 3P innovation

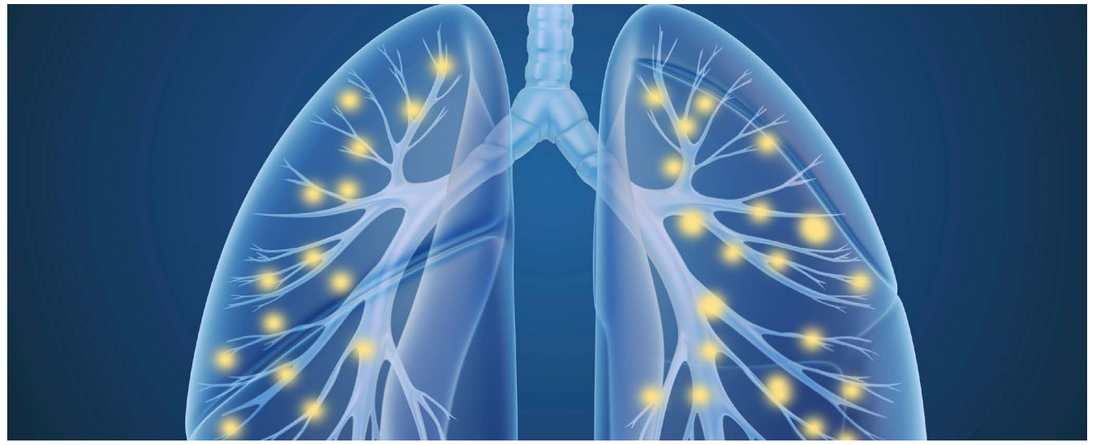
MANAGEMENT forum

25th Annual Conference

Dry Powder Inhalers

A valuable update on dry powder inhaler technology and inhaled drug delivery

27-28 June 2017 London



Programme to include:

- How to develop a generic DPI: from scratch to market
- Designing drugs for inhalation – achieving solutions
- How much does it cost to develop a generic DPI inhaler?
- Easyhaler device and performance under simulated real-life conditions
- Clinical Bioequivalence of OT329 Solis and ADVAIR DISKUS
- Asthma UK's 2016 Annual Report
- The AOS add-on device as a novel tool to improve powder dispersion
- Parameters influencing the performance of interactive blends for inhalation
- Challenges of industrialisation of a novel user friendly DPI
- Case study: comparing usability of two inhalers with the same drug but different user steps

Co-chairmen

Dr Steve Nichols
Director, OINDP Consultancy, UK

Mike Holroyd
Senior Director, Mylan, UK

With a panel of international speakers from:

- OINDP Consultancy • Mylan • PA Consulting Group • RespiVert, Ltd
- ICONOVO • Merxin Ltd • Orion Corporation • University of Parma
- King's College London • Aston Particle Technologies • Christian-Albrecht University
- Medical Device Usability • H&T Presspart • Intertek Melbourn
- Oriel Therapeutics, a Novartis Company • Asthma UK

Exhibition opportunities available

CPD CERTIFIED The CPD Certification Service

Introduction

The second generation of DPIs have become either established on the market or are a significant way along the approval process, these have been a great success story in improving inhaled drug delivery. However, we now have to tackle the technical and regulatory issues with 'generic' inhalers and their approval. The development of triple therapies is well underway, these bring about their own challenges of formulation and bioequivalence. Amazingly, new DPIs are still being created, with some moving in to development programs. Further, one of the areas where much study and recent guidance has been applied is in considering the patient use, compliance and human factors associated with DPIs. These linked topics are creating a whole new area that requires better understanding during product development and associated studies.

This conference aims to: address many of the issues around generic inhalers, provide case studies of bioequivalence testing, focus on the difficult formulation challenges and the strategies used so that they may be overcome and to discuss in-depth patient and human factor issues when developing a DPI to gain regulatory approval.

Why you should attend

1. **A valuable update on the advances in DPI technology and inhaled drug delivery**
2. **An opportunity to keep abreast of business opportunities in the market**
3. **The chance to develop business relationships**

Co-chairman:

Dr Steve Nichols, Director, OINDP Consultancy, UK
Mike Holroyd, Senior Director, Mylan, UK

Expert faculty:

David Harris, Leading Respiratory Drug Delivery, PA Consulting Group, UK
Steve Collingwood, Head of Chemistry, RespiVert, Ltd, The London Bioscience Innovation Centre
Dr Orest Lastow, CEO, ICONOVO, Sweden
Phillipe Rogueda, Director and co-Founder, Merxin Ltd
Jussi Haikarainen, Senior Development Manager, Orion Corporation, Finland
Francesca Buttini, Assistant Professor, University of Parma, Italy, and Visiting Professor-King's College London, UK
Professor Afzal R Mohammed, Director, Aston Particle Technologies, UK
Dr Regina Scherliess, Department of Pharmaceutical and Biopharmaceutics, Christian-Albrecht University, Kiel, Germany
Richard Featherstone, Managing Director, Medical Device Usability, UK
Dr Anselm Ebert, Global Business Development Manager, H&T Presspart, Germany
Mark Parry, Technical Director, Intertek Melbourn, UK
Malinda Longphre, Director, Clinical Research, Oriel Therapeutics, a Novartis Company, USA
Cat Broadbent, Senior Insight Analyst, Asthma UK
Professor Ben Forbes, Professor of Pharmaceutics, King's College London
Lars Asking, Vice President MVIC, Sweden

Day one

09.00 ▶ **Registration and refreshments**

09.30 ▶ **Chairman's welcome and introduction**
Dr Steve Nichols, Director, *OINDP Consultancy, UK*

09.40 ▶ **Dry Powder Inhalers - the wrong hammer**
- Deagglomeration in passive DPIs is like taking a sledgehammer to a walnut - but finding it doesn't work
- So what is the "right" energy?
- What can we learn from this for future inhaler development...?

David Harris, *Leading Respiratory Drug Delivery, PA Consulting Group, UK*

10.20 ▶ **How to develop a generic DPI: from scratch to market**
- ICOres DPI platform case study
- Setting up the requirement specification for a generic DPI platform
- Quality by design development of key features
- Customer specific adaptations
- Integration and optimisation with the formulation

Dr Orest Lastow, *CEO, ICONOVO, Sweden*

10.50 ▶ **Discussion followed by *refreshments***

11.30 ▶ **Designing drugs for inhalation - achieving solutions**
- This presentation will attempt to overview the over lapping and sometimes competing molecular design parameters for novel inhaled candidates
- Examples will be described of how projects can seek to include physical form and formulation requirements in the flowchart for new candidate discovery

Steve Collingwood, *Head of Chemistry, RespiVert, Ltd, The London Bioscience Innovation Centre, UK*

12.10 ▶ **Formulation of biologics for inhaled delivery**
- Introduction and discussion of the current market
- Manufacturing process review and discussion of key manufacturing and formulation challenges
- Review of formulation strategies for biologics including discussion of current examples
- Overview of the testing approaches and differences for biologics compared to small molecules, and how these interact with the development strategy

Mark Parry, *Technical Director, Intertek Melbourn, UK*

12.50 ▶ **Discussion followed by *Lunch***

14.10 ▶ **MRX001 and MRX003: how to get generic inhalers right**
- Understanding the reference product and matching the target
- Perfect match vs. bio-equivalence
- IP hurdles and smokescreens: what routes for a 505j substitutable DPI device?
- The economics of a generic DP devices: reduce costs, reducing risks
- Avoid the route to disaster: don't invest $MM on a filling line and skimp on the device

Phillipe Rogueda, *Director and co-Founder, Merxin Ltd, France*

14.50 ▶ **Strategies for an efficient development of a generic DPI carrier based formulation**
Lars Asking, *Vice President MVIC, Sweden*

15.30 ▶ **Discussion followed by *refreshments***

16.10 ▶ **Easyhaler device and performance under simulated real-life conditions**
- Design, operating principles and user ergonomics
- Device and formulation integration
- Product performance under simulated real life conditions

Jussi Haikarainen, *Senior Development Manager, Pharmaceutical Sciences Platform, Orion Corporation - Orion Pharma, Finland*

16.50 ▶ **Clinical bioequivalence of OT329 SOLIS and ADVAIR DISKUS**
- Hurdles in bringing a AB-rated generic ICS/LABA combination product to market in the US are both technical and regulatory in nature
- Product-specific FDA guidance now require large clinical endpoint studies to support in vitro and PK equivalence findings for orally-inhaled products
- Oriel has completed a clinical endpoint study demonstrating clinical lung function equivalence of OT329 SOLIS and ADVAIR DISKUS at Day 1 and week 4 of treatment

Malinda Longphre, *Director, Clinical Research, Oriel Therapeutics, a Novartis Company, USA*

17.30 ▶ **Discussion followed by *close of day one***

17.45-18.45 **Drinks reception for delegates and speakers**

Day two

09.15 ▶ **Review of day one**
Mike Holroyd, *Senior Director, Mylan, UK*

09.30 ▶ **Asthma UK's 2016 Annual Survey**
- What proportion of people with asthma are not receiving basic care?
- How does asthma affect people's work, education and free time?
- How do prescription payments influence the lives of people with asthma?

Cat Broadbent, *Senior Insight Analyst, Asthma UK*

10.10 ▶ **The AOS (Axial Oscillating Sphere) add-on device as a novel tool to improve powder dispersion**
- Two version of RS01 device were tested with or without AOS
- Two laboratories at different altitudes performed the study
- Formoterol fumarate lactose blend was used
- Aerosol quality (dispersion) and effect of altitude/atmospheric pressure were evaluated

Francesca Buttini, *Assistant Professor, University of Parma, Italy and Visiting Professor-King's College London, UK*

10.50 ▶ **Discussion followed by *refreshments***

11.30 ▶ **Parameters influencing the performance of interactive blends for inhalation**
- Different types of interactive blends
- Micronised and particle engineered API
- Different carrier materials (lactose, mannitol and particle engineered materials)
- Influence of fines in interactive blends
- Influence of blending parameters

Dr Regina Scherliess, *Department of Pharmaceutical and Biopharmaceutics, Christian-Albrecht University, Kiel, Germany*

12.10 ▶ **Particle engineering using a novel dry coating technology - opportunities for DPI formulations**
- Principle of dry coating for particle surface modification
- Particle engineering using dry coating for dry powder inhalers
- Flowability, content uniformity and in vitro evaluation of DPI dry coated particles
- Reverse engineering of particles to optimise dosage form performance

Professor Afzal R Mohammed, *Director, Aston Particle Technologies, UK*

12.50 ▶ **Discussion followed by *Lunch***

14.10 ▶ **Is dissolution a critical attribute for inhaled products?**
- Dissolution methodologies for inhaled products
- Biorelevant techniques for studying dissolution
- The impact of dissolution on inhaled drug PK

Professor Ben Forbes, *Professor of Pharmaceutics, King's College London*

14.50 ▶ **Challenges of industrialisation of a novel user friendly DPI - a DPI case study on Presspart's new PowdAir Plus**
- Introduction on DPIs
- Understanding market and user needs
- Regulatory and quality requirements
- From design to product
- Production of a medical device

Dr. Anselm Ebert, *Global Business Development Manager, H&T Presspart, Germany*

15.30 ▶ **Case study: comparing usability of two inhalers with the same drug but different user steps**
- Defining the outcomes
- Identifying and comparing the use steps
- Deciding which use errors are important
- Comparing usability outcomes
- Usability and substitutability

Richard Featherstone, *Managing Director, Medical Device Usability, UK*

16.10 ▶ **Discussion and *Chairman's closing remarks***

16.30 ▶ **Close of forum and refreshments**

Some of the organisations who have sent representatives to this conference include:

3M Healthcare Ltd
3P Innovation Ltd
Alfred E Tiefenbacher GmbH & Co KG
Aptar Pharma
AstraZeneca
Bayer Pharma AS
Chiesi Ltd
Coalesce Product Development Ltd
Forteq Healthcare
Glenmark Pharmaceutical Europe R&F Ltd
Harro Höfliger Verpackungsmaschinen GmbH
Hovione Capital
MIAT SpA
Mylan
Nypro Healthcare
Orion Pharma
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