Dry Powder Inhalers
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Date and venue
19-20 June 2019  Ref: 10474
The Rembrandt Hotel
11 Thurloe Place, London, SW7 2RS
Tel: +44 (0)20 7589 8100

Programme schedule
Day one
Registration and refreshments: 09.00
Start: 09.30, close: 17.45
Drinks reception: 17.45 - 18.45
Day two
Start: 09.15, close: 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.
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1. Invoice which can be paid by bank transfer or credit/ debit card
2. Online through our secure website when registering

Programme to include:
- Current and future challenges for DPI formulations
- Novel DPI delivery platforms
- Design and characterisation of breath actuation mechanisms
- Method for the determination of delivered-dose uniformity and aerodynamic particle size distributions of DPIs
- Sampling and analysis of inhalation devised in accordance with ISO 18562
- Development of a new moisture-resistant DPI which performs well irrespective of orientation
- How can the physicochemical properties of DPIs and their stability impact product performance?
- Spray drying of nanopharmaceuticals into microsphere formulations
- INFORM 2020: new analytical insights into dry powder formulations for inhalation
- Dry powder formulations: from low dosage API delivery to biopharmaceuticals
- Inhalation products, transitioning from less regulated markets
- Challenges with generics
- Overcoming the need for comparative clinical endpoint bioequivalence studies in a 505(j)
- ANDA weight of evidence approach for orally inhaled products
- The 1nhaler and its two jobs
- Opportunities and challenges in the design of a high-performance unit-dose DPI

Co-chairs
Mike Holroyd
Senior Director, Mylan, UK

Helen Muirhead
Senior Vice President, Respiratory Medicines, GMPharma Ltd, UK

With a panel of expert speakers from:
- Aston Particle Technologies
- Ballington Hall Associates
- Cambridge Design Partnership
- Coalesce Product Development
- Copley Scientific
- H&T Presspart
- Hovions
- 1nhaler
- Intertek Melbourne
- Kings College London
- Markes International
- Paul Johnson Consulting
- PharmaDelivery Solutions
- RCPE
- University of Bath
- University of Hertfordshire

Exhibition opportunities available

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Programme

Day one

09.00  ▶ Registration and refreshments

09.30  ▶ Chair's welcome and introduction

Mike Holroyd

09.40  ▶ Current and future challenges for DPI formulations

Today's DPI marketplace
- The challenge of formulating new chemical entities (NCEs)
- The challenge of developing generic DPIs
- Quality by design in DPI formulation
- Advanced manufacturing technology

Dr David Wyatt

10.20  ▶ Novel DPI delivery platforms

- Marketed DPI platforms
- Novel DPI platforms
- Capability gaps
- Value in the eyes of the consumer

Paul Johnson

11.00  ▶ Discussion session

11.10  ▶ Refreshments

11.30  ▶ Design and characterisation of breath actuation mechanisms (RAMs)

- Rationale and user requirements for the use of RAMs in inhaled drug delivery products
- Design considerations for RAMs
- Experimental characterisation of RAMs
- Comparison of the trigger characteristics in different marketed breath actuated inhaler products

James Tibbatts

12.10  ▶ Methods for the determination of delivered-dose uniformity and aerodynamic particle size distributions of DPIs

- Introduction to inhaled device types and their nuances
- Current regulatory requirements for in-vitro testing of DPIs
- Delivered dose uniformity testing and APSD measurements by cascade impaction
- Advances in measurement techniques for bioequivalence testing and improving MIVCs

Mark Copley

12.50  ▶ Sampling and analysis of inhalation devices in accordance with ISO 18562

- ISO 18562 overview - requirements for respiratory medical devices
- Introduction to thermal desorption
- Biocompatibility testing using thermal desorption gas chromatography

13.00  ▶ Lunch

14.10  ▶ Development of a new moisture-resistant DPI which performs well irrespective of orientation

- Moving from concept to a working prototype - challenges and opportunities
- Integration of moisture-scavenging technology
- Creating a sealed device
- Testing challenges
- Next steps to a marketed device

Paul Ballington

14.50  ▶ Discussion session

15.30  ▶ Refreshments

15.40  ▶ How can the physicochemical properties of DPIs and their stability impact product performance? A process and delivery perspective

- An overview on formulation physicochemical attributes affecting DPI processability and delivery performance
- Screening of the distinct overtime solid-state, micromeritics and surface properties of inhalable particles and de-convolution of their impact on product performance
- Evaluation of distinct formulation approaches and their potential impact on product performance

Joana Pinto

16.10  ▶ Discussion session

16.50  ▶ Spray drying of nanoparticle formulations into microsphere formulations

- Nanoparticles as drug carriers
- Safety and efficacy, in vitro and in vivo
- Respirable dry powder formulations

Professor Ben Forbes

17.30  ▶ Discussion session

17.45  ▶ End of day one

17.45-18.45  Drinks reception for delegates and speakers

Day two

09.15  ▶ Review of day one

Helen Muirhead

09.30  ▶ INFORM 2020: new analytical insights into dry powder formulations for inhalation

- Structural equivalence for inhalation formulations
- Microstructural analytical techniques
- Microscopy and quantification approaches to look inside formulations
- Identifying metrics of relevance to inhalant product performance

Professor Darragh Murnane

10.10  ▶ Dry powder formulations: from low dosage API delivery to bio-pharmaceutical evaluation

- Drivers for choosing amongst different DPI formulation approaches
- Case study on carrier-based DPI formulation development
- Case study on spray dried composite DPI formulation development
- Capsule filling of challenging DPI powders

Eunice Costa

11.00  ▶ Discussion session

11.30  ▶ Inhalation products, transitioning from less to more regulated markets, can it be that difficult?

- What is ‘less regulated’?
- Combination product regulation and how it impacts inhalation products
- Regulatory trends, where are things headed?
- The typical GAPS and how to try to close them
- Is there an easy route?
- Is the transition worth it?

David Howlett

12.10  ▶ Formal product characterization studies required for DPI’s

- Why and when these tests are performed
- What to include - how to design an appropriate product characterization study
- Differences between US and EU requirements
- In-depth look at the specific tests required (Stability studies, Temperature Cycling, Effect of Patient Use, Effect of Orientation, Drug Deposition on Mouthpiece, Effect of Varying Flow Rate, Device Robustness

Christopher Vernall

12.50  ▶ Lunch

13.00  ▶ Overcoming the need for comparative clinical endpoint bioequivalence studies in a 505(j) ANDA weight of evidence approach for orally inhaled products

Dr Rob Price

14.10  ▶ The Inhaler and its two jobs

- The functional, emotional and social reasons that there is a large market for single-dose DPIs

Don Smith

14.50  ▶ Discussion session

15.30  ▶ Opportunities and challenges in the design of a high-performance unit-dose DPI

- Design opportunities and challenges for a ‘fit for purpose’ capsule-based DPI
- Prototyping challenges
- Preliminary performance data

Anselm Ebert and George Bostock

16.10  ▶ Discussion session

16.20  ▶ Closing remarks

16.30  ▶ Close of conference and refreshments

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