SMI.LONDON

Pullman London St Pancras 28 June 2023

Venue

Pullman London St Pancras
100-110 Euston Road
London NW1 2AJ
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info@SMI.London

Agenda & Abstracts

The first conference dedicated to **Soft Mist Inhalers**

Session 1 Chair: Prof. Darragh Murnane, University of Hertfordshire

8:30 **Registration, refreshments and networking**

9:30

SMIs: Increasing The Value Of Inhaled Therapies Introducing SMI.London 2023

Dr. Philippe Rogueda,
Merxin

- Welcome to SMI.London
- SMIs are now available, let's play with them, let's learn how
- Availability of SMIs is changing the inhaler market
- Let us help you learn about the building blocks of an SMI product to accelerate the time to launch
- Can SMIs claim 30% market share of the inhaler markets on par with pMDIs and DPIs?

9:45

On The Inexorable Rise Of SMI In Inhaled Drug Delivery

Dr. Jag Shur,
Theela Life Sciences

- Historically, SMIs have been a minority technology
- This is changing and SMIs have making their way to the clinics, let's trace how
- SMIs fill in a gap in the inhaled drug delivery field
- Let's explore their science and how they enable new therapies

MERXIN intertek Total Quality. Assured. ExtLe solutions University of Hertfordshire UH OXFORD LASERS HH Harro Höfliger medHF H&T PRESSPART Inke

10:30

SMIs: Exploring The Device Hardware

Dr. Philippe Rogueda, Merxin

- What qualifies as an SMI? What does not?
- Why are their different from other inhalers?
- How are they built? What are they made of?
- The benefits of SMIs, from high lung deposition to low carbon footprint
- SMI challenges and opportunities, from technology to applications
- Accessing SMIs, the tools required to make it happen

11:00

Coffee break and networking

11:30

Formulation Considerations For SMI Products

Paddy McCarry, Intertek

- What molecules and indications may be a good fit for an SMI? Moving away from generic Respimat
- Excipient choices and how these influence solubility, pH, viscosity and osmolality profiles
- Scaling up to manufacture
- Building a batch release and stability program

12:00

Characterisation And Understanding Of Soft Mist Inhaler Spray Plume

Dr. Seamus Murphy, Oxford Lasers

- Regulatory requirements
- SMI – characterisation – Spray Pattern
- SMI – Emitted Release Profile & Velocity
- SMI vs. pMDI

Session 2 Chair: Chris Vernal, Intertek

12:30

Lunch, exhibition and networking

14:00

Performance Testing Of SMIs For Compliance With Regulatory Requirements

Aurelien Martin, University of Hertfordshire

- Regulatory guidelines of relevance to Soft Mist Inhalers
- Fast screening testing approaches to support development
- Inertial impaction testing and delivered dose requirements
- Issues affecting in vitro-in vivo correlation

14:15

From Single Droplet To Plume: Probing SMI Aerosols

Dr. Dan Hardy,
Microsolscience

- Current tools such as CFD provide very accurate representations of air flow within the respiratory system during inhalation and exhalation
- However, there is a lack of accurate descriptions of the state of formulations in the aerosol
- Phenomena such as hygroscopic growth, crystallisation and particle dissolution may all significantly change the aerodynamic properties of inhaled particles - modifying the deposition profile
- Without accurate representation of the aerosol kinetics, it is not possible to describe the deposition of particles within the lung
- We will present accurate, time-resolved simulations of size distributions relevant to soft mist inhalers in conditions representative of inhalation
- Such simulations reveal the range of time-scales over which hygroscopic response occurs and how these are comparable to the time-scales of deposition
- We will then present a methodology by which the coupled processes of aerosol kinetics and deposition may be represented by integrating a deposition model (ICRP 66) with Microsol's aerosol kinetics model
- With accurate and time-resolved predictions of the properties of the full particle size distribution, it is then possible to suggest modifications to the formulation properties which modulate the dynamics of hygroscopic growth and tune the deposition profile

14:30

Extractables And Leachables: Implications For SMIs

Shane Smith,
Extle Solution

- Regulatory guidance on E&Ls as applied to SMIs
- Extractables studies: what they are and why they are so often an expensive disaster
- Leachables studies: design and execution
- E&L studies within a product development program
- E&L lifecycle management

15:00

Coffee break and networking

15:30

Human Factors Validation For Inhalers

Lee wood,
MedHF

- What is HF Validation and why does it matter?
- When a HF Validation study may not be required
- Current trends in FDA HF Validation protocol reviews
- Evaluating outcomes from HF Validation
- Pitfalls to avoid in HF Validation

16:00

Panel discussion and final remarks

17:00

Close of the Day