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Nasal Drug Delivery

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Dates and venue

11-12 April 2019 **Ref: 10381**

HI London - Kensington Forum
97 Cromwell Road
London
SW7 4DN
Phone: +44 (0) 207 341 3355

Programme schedule

Registration and refreshments: 09.00
Day one: 9.30 – 17.30
Drinks reception: 17.30 – 18.30
Day two: 9.15 – 16.15

Accommodation

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

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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.

PLEASE NOTE: Management Forum Ltd reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, Management Forum will refund the registration fee and disclaim any further liability.

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Media Partner ON drugDELIVERY

MANAGEMENT forum

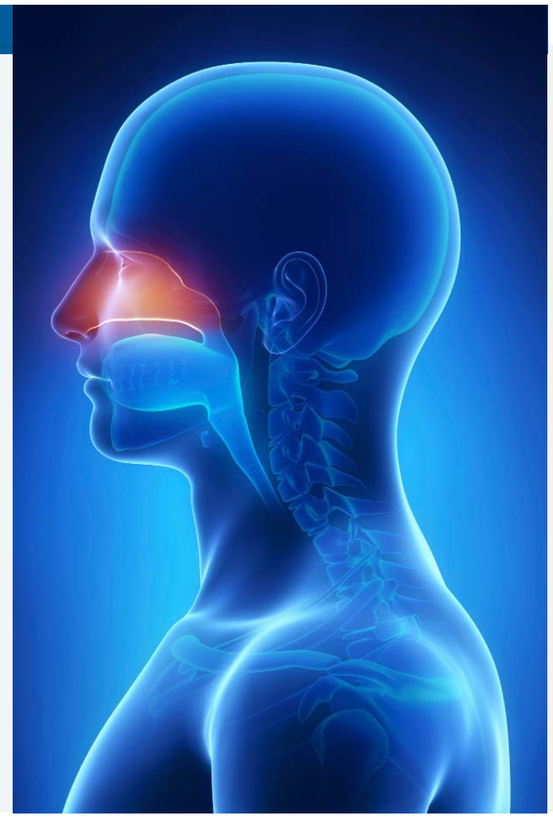
Nasal Drug Delivery

An essential update on the latest scientific developments, technology advances and regulatory guidance

11-12 April 2019 London

Programme to include:

- Nasal drugs to treat nasal disorders: a comprehensive review
- Review of nasal drug delivery devices
- Nasal formulation of drugs
- Rethinking nasal packaging environment
- The unique challenges of nasal drug delivery to treat chronic rhinosinusitis (CRS); considerations before and after sinus surgery
- Key insights for a successful device development to achieve nasal bioequivalence requirements
- Requirements concerning bioequivalence of nasal drug products from an authority's point of view
- Regulatory science associated with BE/TE for nasal products
- Qualification of new nasal drug delivery systems for existing drugs
- Investigations regarding the developability of nasal metered dose inhalers



Co-chaired by:

Dr Julie Suman, President, Next Breath, USA
Dr René Bommer, Director, pharmAccel Consulting, Germany

Keynote speaker:

Professor Valerie Lund, Professor Emeritus of Rhinology at the Ear Institute, University College London

With a panel of expert speakers

Exhibition opportunities available

CPD CERTIFIED The CPD Certification Service

Why you should attend this seminar

What makes nasal delivery systems more challenging than solid dosage forms? How safe is nasal drug delivery? Are there such things as safe excipients? How does all this fit within the regulatory environment in Europe and the USA? How difficult is it to bring all these products to market?

This seminar seeks to explore these and other questions within the field of nasal drug delivery while reviewing interesting new data, innovative technologies and the very latest scientific developments. Leading authorities in nasal drug delivery will cover relevant aspects of nasal physiology, anatomy, absorption of a variety of drugs in various phases of drug development, and new drugs entering the market. In addition, nasal delivery to the sinuses will be discussed and the programme will include interesting case histories.

This seminar will offer an excellent networking opportunity to build business relationships and discuss all these issues with an unrivalled panel of experts in this field of drug delivery.

Who should attend?

- Managing directors
- Medical directors
- Heads of regulatory affairs
- Quality assurance managers
- Senior executives in research and development
- Registration associates
- Marketing managers
- All departments that are involved in nasal drug delivery, or who wish to understand the potential of this alternative therapeutic route

Those already involved in nasal drug delivery will benefit from updating their knowledge and sharing experiences with some of the leading practitioners in this field. If you are involved in nasal drug delivery or are just considering the potential, this seminar is an excellent route to understanding all aspects from the basic physiology through to launching a successful product

Co-chairs

Dr Julie Suman, President, Next Breath, USA
Dr René Bommer, Director, pharmAccel Consulting, Germany

Expert faculty

Professor Valerie Lund, Professor Emeritus of Rhinology at the Ear Institute, University College London
Dr Regina Scherliess, Christian Albrecht University of Kiel, Department of Pharmaceutics and Biopharmaceutics, Germany
Christopher Fuller, Associate Director, Engineering, Impel NeuroPharma
Lee Lucas, Vice President of Applications and Business Development, Aptar CSP Technologies, USA
Pascale Farjas, Global Category Manager, Nemera, France
Céline Petitcolas, Customer Technical Support, Nemera, France
Per Djupesland, CSO, Optinose, Norway
Dr Cornelia Nopitsch-Mai, German Regulatory Authority, BfArM
Anders Fuglsang, Industry Consultant, Fuglsang Pharma, Denmark
Andrew Wood, Associate Director Regulatory Affairs, Aptar Pharma, France
Thomas Grinnan, Senior Commercial Director, Healthcare, Silgan Dispensing Systems, France
Dr Jag Shur, Director, Nanopharm, UK
Dr John Warren, Director, Medicines Assessment, UK

Day one

09.00 **Registration and refreshments**

09.30 **Welcome and introduction**
Dr Julie Suman *and* ***Dr René Bommer***

09.45 **Nasal drugs to treat nasal disorders: a comprehensive review**
- Anatomy and physiology
- Nasal disorders
- Treatment options and future prospects to treat allergic and non-allergic rhinitis
- CRS with and without nasal polyps

Professor Valerie Lund

10.45 **Discussion session**

11.00 **Refreshments**

11.30 **Nasal drug delivery challenges**
- Discuss ideal attributes of a nasal spray formulation
- Present strategies to optimise deposition
- Highlight excipients to facilitate absorption
- Present technology for delivery and formulation characterisation

Dr Julie Suman

12.10 **Nasal formulation of drugs**
- Formulation aspects of liquid systems
- Carrier-based and matrix dry powder formulations for nasal delivery
- (Nano)particulate drug carriers for nasal administration
- Interplay of therapeutic targets and nasal deposition

Dr Regina Scherliess

12.50 **Discussion session**

13.00 **Lunch**

14.00 **Developing next generation powder nasal delivery using POD technology**
- Device development efforts
- Formulation development efforts
- Unique challenges to powder delivery

Christopher Fuller

14.40 **Rethinking nasal packaging environment**
- Using integrated three-phase activ-polymer to control moisture ingress
- Extend shelf life
- Improve performance

Lee Lucas

15.20 **Discussion session**

15.30 **Refreshments**

16.00 **Key insights for a successful device development to achieve nasal bioequivalence requirements**
- Design and testing techniques for nasal spray devices
- In-Vitro BioEquivalence (IVBE) requirements and region-specific regulatory strategies
- Statistical tools and new alternative approach applied to nasal sprays
- Key success factors for nasal spray development projects

Pascale Farjas *and* ***Céline Petitcolas***

16.40 **The unique challenges of nasal drug delivery to treat chronic rhinosinusitis (CRS); considerations before and after sinus surgery**
- Medical therapy in CRS – goals and challenges
- Endoscopic sinus surgery – implications for drug deposition
- Nasal delivery methods – advantages and limitations

Per Djupesland

17.20 **Discussion session**

17.30 **End of day one**

17.30-18.30 **Drinks reception for delegates and speakers**

Day two

09.15 **Review of day one**
Dr Julie Suman *and* ***Dr René Bommer***

09.30 **Review of nasal drug delivery devices**
- Trends in nasal delivery systems
- Advances in device technologies
- Nasal spray characteristics

Dr René Bommer

10.10 **Requirements concerning bioequivalence of nasal drug products from an authority's point of view**
- Bioequivalence of nasal products
- The evaluation of the monograph for nasal products in the European Pharmacopoeia will be outlined

Dr Cornelia Nopitsch-Mai

10.50 **Discussion session**

11.00 **Refreshments**

11.30 **Regulatory science associated with BE/TE for nasal products**
- Average BE versus population BE
- End point right, outcome wrong: why?
- Getting the sample size right
- Lessons learned from inhaled aerosol products

Anders Fuglsang

12.10 **US/FDA regulatory guidance on combination products**
- Origin and objective of the regulations
- The regulation and guidance documents
- Requirements and expectations of FDA

Andrew Wood

12.50 **Discussion session**

13.00 **Lunch**

14.00 **Qualification of new nasal drug delivery systems for existing drugs**
- Formulation analysis
- System and compatibility
- Stability testing
- Performance testing
- Production line and efficiency optimisation

Thomas Grinnan

14.40 **Investigations regarding the developability of nasal metered dose inhalers**
- Findings
- Opportunities

Dr Jag Shur

15.20 **What are chemisimilars and what's the problem?**
- Standardisation
- EU guidance
- FDA guidance
- Assay sensitivity and the best models to test for similarity

Dr John Warren

16.00 **Discussion session**

16.10 **Concluding remarks**

16.15 **Close of conference and refreshments**

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