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
Why should you 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, 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 this field, this seminar is an excellent route to understanding all aspects from the basic physiology through to launching a successful product.

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, Insul 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
- Tomas Griffin, Senior Commercial Director, Healthcare, Bilgan Dispensing Systems, France
- Dr Jag Shur, Director, Nanopharm, UK
- Dr John Warren, Director, Medicines Assessment, UK

Co-chairs

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

Programme

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 ➤ Lunch

13.00 ➤ 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 Griffin

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