Nasal Drug Delivery

To book online go to: management-forum.co.uk/936

Date and venue
12-13 April 2018  Ref: 10046
The Rembrandt Hotel
11 Thurloe Place
London
SW7 2RS
Tel: +44 (0)20 7589 8100

Programme schedule
Registration and refreshments: 09.00
Day one        Day two
Start 09.30          09.15
Close 17.30          16.15
Drinks reception day one: 17.30-18.30

Accommodation
We have arranged a preferential rate for accommodation at the venue. To take advantage of this please contact reservations_rembrandt@sarova.co.uk
state you are a Management Forum delegate and quote promo code Manforum. 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

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

12-13 April 2018 London

Programme to include:

- Nasal drugs to treat nasal disorders: a comprehensive review
- Review of nasal drug delivery devices
- Nasal formulation of drugs
- Nose to brain drug delivery of Oxytocin
- XHANCE™ - a new approach to reach the target sites of inflammation in chronic rhinosinusitis
- Retronose concept: Aerosol delivery by oral route for nasal drug targeting
- Advanced water technology: a unique platform for innovative OTC products
- What are Chemisimilars and what is the problem?

To be co-chaired by:

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

Keynote address:
Professor Michael S Benninger, Chairman, The Head and Neck Institute, Professor of Surgery, Lerner College of Medicine, The Cleveland Clinic, USA

The small print
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.

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 341323109. Any questions please contact Customer Services on +44 (0)20 7749 4730.

Payment options
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2. Online through our secure website when registering

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CANCELLATIONS AND TRANSFER: Once we have received your booking the places are confirmed.

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Exhibition opportunities available

Nasal Drug Delivery

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### Introduction

How difficult is it to bring all these products to market? What makes nasal drug delivery systems more challenging than solid dosage forms? How safe is nasal drug delivery? Are there such things as safe excipients? How do we “fit within the regulatory environment in Europe and the USA?” This conference seeks to explore these and other questions within the field of nasal drug delivery while reviewing interesting new data and innovative technologies. 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, the conference will discuss nasal delivery to the sinuses and interesting case histories.

### Who should attend?

Managing directors, medical directors, head of regulatory affairs and quality assurance, senior executives in research and development, registration, marketing, and all departments that may be 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 conference is an excellent route to understanding all aspects from the basic physiology through to launching a successful product.

### Three reasons to attend this event

1. **Gain an update on the very latest scientific developments and technology advances in this field**
2. **Hear from an unrivalled panel of expert speakers**
3. **An excellent networking opportunity to build business relationships**

### To be co-chaired by:

**Dr Julie Suman**, President, Next Breath, USA  
**Dr René Bommer**, General Manager, pharmAccel Consulting, Germany

### Expert faculty

**Professor Michael S. Benninger**, Chairman, The Head and Neck Institute, Professor of Surgery, Lerner College of Medicine, The Cleveland Clinic, USA  
**Dr Regina Scherliess**, Christian Albrecht University of Kiel, Department of Pharmaceutics and Biopharmaceutics, Germany  
**Dr Per Gisle Djupesland**, CSO, OptiNose, Norway  
**Pascale Farjas**, Global Category Manager – Ear, Nose and Throat, Nemerla  
**Laurent Vecellio**, Researcher, INSERM, France  
**George Bourille**, CEO, ADWATIS SA, Switzerland  
**Jean-Michel Verjus**, Pharmacist, ADWATIS SA, Switzerland  
**Sai Shankar**, Director, Business Development - Connected Devices, Aptar Pharma, USA  
**David Exline**, President, Gateway Analytical, USA  
**Thomas Grinnan**, Senior Commercial Director, Healthcare, Silgan Dispensing Systems, France  
**Dr John Warren**, Director, Medicines Assessment, UK  
**Professor Yannis Paloyelis**, Lecturer in Neuroscience and Psychology, Neuromaging Department, Kings College, UK  
**Cecilie Vo**, Quality Advisor and Business Development Representative, Curida, Norway

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### Day one

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<td>09.00</td>
<td>Registration and refreshments</td>
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| 09.30 | Welcome and introduction  
**Dr Julie Suman**, President, Next Breath, USA  
**Dr René Bommer**, General Manager, pharmAccel Consulting, Germany |
| 10.45 | Discussion |
| 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, President, Next Breath, USA** |
| 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, Christian Albrecht University of Kiel, Department of Pharmaceutics and Biopharmaceutics, Germany** |
| 12.50 | Lunch |
| 14.00 | Nose to brain drug delivery of Oxytocin  
**Professor Yannis Paloyelis**, Lecturer in Neuroscience and Psychology, Neuromaging Department, Kings College, UK |
| 14.40 | Methodology for comparing particle size of nasal spray formulations  
**Introduction to analytical methods used to characterize particulate**  
**Agglomerate characterization of particulate**  
**Statistical considerations**  
**Case studies**  
**David Exline, President, Gateway Analytical, USA** |
| 15.30 | Refreshments |
| 16.00 | XHANCE™ – A new approach to reach the target sites of inflammation in chronic rhinosinusitis  
**The Exhalation Delivery System (EDS)**  
**Reaching the sites of sinus ventilation**  
**Accessing the sinuses in the post-surgical patient**  
**Clinical outcomes in chronic rhinosinusitis with and without polyps**  
**Dr Per Gisle Djupesland, CSO, OptiNose, Norway** |
| 16.40 | Retronose concept: Aerosol delivery by oral route for nasal drug targeting  
**Proof of concept with nebulization system**  
**Differences between oral and nasal routes in terms of nasal deposition and clearance**  
**Key points for a PMDI development using Retronose concept**  
**Pro and cons for Retronose concept**  
**Paascale Farjas, Global Category Manager – Ear, Nose and Throat, Nemerla and Laurent Vecellio, Researcher, INSERM, France** |
| 17.00 | Discussion |
| 17.30 | End of day one |
| 17.30-18.30 | Drinks reception for delegates and speakers |

### Day two

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<th>Time</th>
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| 09.15 | Review of day one  
**Dr Julie Suman, President, Next Breath, USA**  
**Dr René Bommer, General Manager, pharmAccel Consulting, Germany** |
| 09.30 | Review of nasal drug delivery devices  
**Trends in nasal delivery systems**  
**Advances in device technologies**  
**Nasal spray characteristics**  
**Dr René Bommer, General Manager, pharmAccel Consulting, Germany** |
| 10.10 | Advanced water technology: A unique platform for innovative OTC products  
**Is water a simple, innocent molecule?**  
**High pH water – a change of paradigm**  
**The electrical double layer (EDL) and negative ions**  
**Water: from a noble solvent to an innovative active ingredient**  
**Promised Water’s unique mechanisms of action**  
**How can water make your OTC products smarter?**  
**Great opportunities for nasal applications** |
| 10.50 | Discussion |
| 11.00 | Refreshments |
| 11.30 | FRI as a tool to optimize regional delivery of nasal aerosols  
**What is FRI**  
**Challenges of nasal drug delivery**  
**Advantages of in-silico clinical trials**  
**Evaluating nasal drug efficacy with FRI**  
**Dr Wim Vos, Chief Operating Officer, FLUIDDA, Belgium** |
| 12.10 | Digital healthcare: Improving patient health outcomes through connected devices  
**Challenges with drug adherence and patient health outcomes**  
**How connected devices and digital healthcare can make a difference**  
**Clinical and commercial**  
**Sai Shankar, Director, Business Development - Connected Devices, Aptar Pharma, France** |
| 12.50 | Discussion |
| 13.00 | Lunch |
| 14.00 | Qualification of new nasal drug delivery systems for existing drugs  
**Formulation analysis**  
**System fit and compatibility**  
**Stability testing**  
**Performance testing**  
**Production line and efficiency optimization**  
**Thomas Grinnan, Senior Commercial Director, Healthcare, Silgan Dispensing Systems, France** |
| 14.40 | Aseptic vs non-aseptic filling strategies for nasal spray trends and the evidence behind  
**Different product – different filling strategy**  
**Technical and procedural alternatives**  
**The role of a Contract Development and Manufacturing Organization**  
**Cecilie Vo, Quality Advisor and Business Development Representative, Curida, Norway** |
| 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, Director, Medicines Assessment, UK** |
| 16.00 | Discussion |
| 16.10 | Concluding remarks |
| 16.15 | Close of conference and refreshments |

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