

Annual International Conference

NASAL DRUG DELIVERY

Explore this Rapidly Developing Area of Drug Delivery

EXHIBITORS INCLUDE:

Valois
Pharmaceutical Division

Pfeiffer

REXAM

Increase your
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reception

Programme to include:

- Anatomy and Physiology of the Nose and Sinuses
- The Future of Nasal Fentanyl: Pro and Cons of the Products Entering the Market
- Nasal Drugs to Treat Nasal Disorders
- Nasal Vaccines
- Nose to Brain Transport of Drugs - Does Deposition Matter?
- Effective and Safe Excipients in Nasal Drug Delivery
- Alternatives to Animal Testing for the Safety Evaluation of Nasal Drug Delivery Systems
- Recent Findings in the Pharmacokinetics of Nasal Drugs
- Testing of Nasal Sprays from a Regulatory Perspective
- Enhancing the In-Vitro Assessment of Nasal Sprays
- Intranasal Delivery of Dry Powder Vaccines
- New Nasal Sinus Drug Delivery Device
- Nasal Drug Delivery Systems

Co-chairmen:

Phil Seeney Member of the Drug Delivery Group, PA Consulting Group, UK

Professor Frans W H M Merkus Emeritus Professor of Biopharmaceutics, Leiden University, The Netherlands & Chairman of Innoscience Technology, Belgium

With a panel of key opinion leaders including:

Professor Valerie Lund Royal Free University College Hospital, London, UK

Professor Michael Benninger Henry Ford Medical Systems, USA

Professor Anthony Hickey University of North Carolina School of Pharmacy, USA

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1 & 2 April 2009
The RAC Club, St James, London

MANAGEMENT FORUM



INTRODUCTION

Nasal drug delivery has always been a key development area for both pharmaceutical and device development companies, presenting many opportunities and challenges. The physiology of the nose presents obstacles, but offers a promising route for systemic delivery of numerous therapies and debatably a drug delivery route to the brain. Vaccine delivery via the nose has yet to meet the promised potential but is this changing? Just how difficult is it to bring a product to market and how is In-Vitro testing of nasal products changing? Can drugs be delivered via the nose to the brain and if so, does deposition matter? Are there such things as safe excipients and are there alternatives to animal testing for safety evaluation? How does all this fit within the regulatory environment? This conference seeks to explore these and other questions within the field of nasal drug delivery reviewing interesting new data. Leading authorities in nasal drug delivery and associated technologies will cover aspects of physiology, nasal anatomy, nasal delivery to the brain, vaccination via the nose, nasal delivery to the sinuses, the regulation of nasal products and much more. In addition, case histories of existing/in development products/delivery systems will be explored.

WHO SHOULD ATTEND THIS EVENT

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.

Reserve your place on-line at www.management-forum.co.uk
or telephone +44 (0) 1483 730071. If you require further information contact
andrea.james@management-forum.co.uk

Day One

PROGRAMME

1 April 2009

- 09.30 ► **Chairman's Welcome and Introduction**
Professor Frans W H M Merkus, Leiden University and Innoscience Technology, Belgium
- 09.40 ► **Anatomy and Physiology of the Nose and Sinuses**
Professor Valerie Lund, University College Hospital, UK
- 10.20 ► **The Future of Nasal Fentanyl: Pro and Cons of the Products Entering the Market**
 - What is breakthrough pain
 - Shortfall in current management
 - Role of transmucosal fentanyl
 - Pros and cons of current nasal preparationsDr. John Zeppetella, St Clare Hospice, UK



11.00 ► **Discussion**

11.10 ► **Coffee**

11.30 ► **Nasal Drugs to Treat Nasal Disorders**

- Allergies
- Non-allergic Rhinitis
- Acute and chronic Sinusitis
- Polyps

Professor Michael Benninger, The Cleveland Clinic, USA

12.10 ► **Perspectives on Nasal Vaccine Delivery**

- Product composition
- Characterization
- Immunogenicity
- Protection

Professor Anthony Hickey, University of North Carolina School of Pharmacy, USA

12.50 ► **Discussion**

13.00 ► **Lunch**

14.10 ► **Nose to Brain Transport of Drugs – Does Deposition Matter?**

Dr Per Djupesland, OptiNose, Norway

14.40 ► **Recent Findings in the Pharmacokinetics of Nasal Drugs**

Professor Ola Dale, Trondheim University, Norway

15.30 ► **Discussion**

15.40 ► **Tea**

16.00 ► **Effective and Safe Excipients in Nasal Drug Delivery**

Prof Jean Paul Remon, University of Ghent, Belgium

16.40 ► **Alternatives to Animal Testing for the Safety Evaluation of Nasal Drug Delivery Systems**

- Brief introduction to the concept of alternatives to animal testing (3Rs)
- Overview of alternative methods to assess irritation and mucosal damage of nasal drug formulations
- Alternative method to predict clinical discomfort (e.g. stinging, itching and burning sensations)

Dr Els Adriaens, University of Ghent and Adriaens Consulting, Belgium

17.20 ► **Discussion**

17.30 ► **End of Day One**

17.30 – 18.30 Drinks Reception for all Delegates and Speakers



- 09.15 ► **Chairman's Welcome**
Phil Seeney, PA Consulting, UK
- 09.30 ► **Nasal Drug Delivery Systems**
 - The review will discuss the various options of nasal dispensing systems in terms of their applicability for an efficient nasal drug delivery
 - Nasal dispensing systems represent more than functional primary packaging
 - The presentation will cover the latest options in terms of the delivery devices and its relevant corresponding technical, analytical, regulatory and marketing issuesDr René Bommer, pharmAccel Consulting, Germany
- 10.10 ► **If You Want to Get There I Wouldn't Start From Here. 'From Device Concept to Market – How Difficult Can it Be?'**
David Howlett, Pharma Delivery Solutions, UK
- 10.50 ► **Discussion**
- 11.00 ► **Coffee**
- 11.30 ► **Defining and Testing of Nasal Sprays from a Regulatory Perspective**
Dr Julie Suman, Next Breath LLC, USA
- 12.10 ► **CPS Nasal**
New generation of nasal spray systems
Degenhard Marx, Ing. Erich Pfeiffer, Germany (invited)
- 12.50 ► **Discussion**
- 13.00 ► **Lunch**
- 14.10 ► **Enhancing the In-Vitro Assessment of Nasal Sprays**
 - Analytical approaches to in-vitro characterisation
 - Expectations of the different markets
 - Correlating in-vivo assessment to real patient useGérald Williams, Valois Pharmaceutical Division, France
- 14.50 ► **Intranasal Delivery of Dry Powder Vaccines**
Intranasal vaccination has gained increased interest in recent years as a delivery route for new vaccines as it can provide superior protection at mucosal surfaces. This, in combination with the minimally invasive nature of the nasal vaccination route, makes intranasal delivery an attractive alternative to immunization via injection. Our data indicates that administration of certain vaccines to the nasal mucosa provides a means to achieve strong immune responses.
Vincent J. Sullivan, BD Technologies, USA.
- 15.30 ► **New Nasal Sinus Drug Delivery Device**
 - Anatomic challenges of nasal aerosol delivery
 - Theory of "vibrating" or "sonic" aerosols
 - Requirements for efficient sinus drug delivery and their implementation in a new device
 - Results from a deposition and clearance study in volunteers and the clinical effect in CF patientsUwe Schuschnig, PARI Pharma GmbH, Germany
- 16.10 ► **Chairman's Concluding Remarks**
- 16.15 ► **Close of Conference and Tea**



CO-CHAIRMEN

Phil Seeney, Member of the Drug Delivery Group, PA Consulting Group, UK

Professor Frans WHM Merkus, Emeritus Professor of Biopharmaceutics, Leiden University, The Netherlands & Chairman of Innoscience Technology, Belgium

SPEAKERS

Dr Els Adriaens, Post Doctorate Research, University of Ghent and Consultant, Adriaens Consulting, BVBA, Belgium

Professor Michael Benninger, Chairman, Head and Neck Institute, The Cleveland Clinic, USA

Dr René Bommer, Director, pharmAccel Consulting, Germany

Professor Ola Dale, Trondheim University, Norway

Dr Per Djupesland, Chief Scientific Officer, OptiNose, Norway

Professor Anthony Hickey, University of North Carolina School of Pharmacy, USA

David Howlett, Director, Pharma Delivery Solutions, UK

Professor Valerie Lund, Professor in Rhinology, Honorary Consultant ENT Surgeon, Royal Free University College Hospital, London, UK

Denghard Marx, Business Development Manager, Ing. Erich Pfeiffer, Germany (invited)

Professor Jean Paul Remon, University of Ghent, Belgium

Uwe Schuschnig, Senior Manager Aerosol Characterisation, PARI Pharma GmbH, Germany

Gerallt Williams, R & D Laboratory Manager, Valois Pharmaceutical Division, France

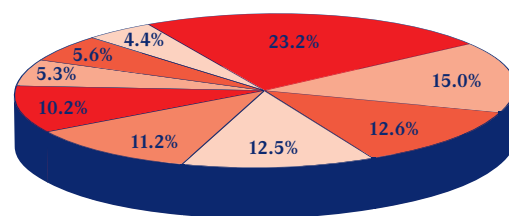
Vincent Sullivan, Group Leader, Chemistry & Pharmaceutics, BD Technologies, USA

Dr Julie Suman, President, Next Breath LLC, USA

Dr. John Zeppetella, Medical Director, St Clare Hospice, UK

A Selection of Companies that Attended in 2008

ALCHEMY HEALTHCARE
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BRITANNIA PHARMACEUTICALS LTD
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SANOFI AVENTIS GROUPE
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TECHNOLOGY PARTNERSHIP
VALOIS UK LIMITED
VALOIS SA



Position	Count	Of Position
Senior Management	23	23.2%
Scientist	15	15.0%
Business Development	13	12.6%
Head Pharmaceutical Development	13	12.5%
Project Management	11	11.2%
R&D	10	10.2%
Product Manager	5	5.3%
Quality	6	5.6%
Sales & Marketing	4	4.4%
	100	100.00%

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Innovations in Pharmaceutical Technology (IPT) is a quarterly magazine dedicated to following advances in drug discovery and development, biotechnology, drug delivery and formulation, and manufacturing. <http://www.iptonline.com/>

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NASAL DRUG DELIVERY



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1 & 2 April 2008, Conf. No. N4-8009

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If you do not want to receive future mailings from Management Forum please contact nick@management-forum.co.uk
If you do not wish to receive selected third party mailings please contact nick@management-forum.co.uk

REGISTRATION INFORMATION

Dates 1 & 2 April 2009

Registration & Coffee 1 April 09.00

Times 1 April 2009 Start 09.30 – Finish 17.30

Drinks Reception 17.30 – 18.30

2 April 2009 Start 09.15 – Finish 16.15

Dress Code

Please note a jacket and tie is required for all gentleman.

Venue

The RAC Club, The Royal Automobile Club,
89 Pall Mall, London SW1Y 5HS
Telephone 0207 747 3387

Directions

Nearest Underground station: Piccadilly Circus or Charing
Cross. Map available on Website under Hotels and Venues.

Accommodation

A limited number of bedrooms have been reserved at the
The Cavendish London Hotel, 81 Jermyn Street (main
entrance in Duke Street), St James's, London SW1, at a special
rate of £178.00 +15% VAT – inc. full English breakfast, subject
to availability.

Hotel Tel: +44(0)20 7930 2111.

Hotel Fax: +44(0)20 7839 4369.

Email: reservations@thecavendishlondon.com

Alternatively, The Flemings Mayfair Hotel, Half Moon Street,
Mayfair, London W1J 7BH

Hotel Tel: +44(0)20 7499 2964.

Email: reservations@flemings-mayfair.co.uk

All bookings should be made directly with the hotel
quoting Management Forum and your credit card
number.

Conference Fee

£1,280 +15% VAT. The fee includes course documentation as
well as mid-session refreshments, lunch and drinks
reception on Day One. Invoice and confirmation will be
forwarded to you.

Conference No. N4-8009

Discounted Rates

Available on application for personnel from non-profit
making organisations and registered charities.

Group discount available on request.

Cancellation Policy:

Over 14 days prior to the Seminar: Cancellation fee of £75.
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days or if no notification received: Registrant liable to pay
FULL seminar fee.

NB: Cancellations must be received in writing by
lesley@management-forum.co.uk.

In the event of circumstances beyond its control,
Management Forum reserves the right to alter the
programme, the speakers, the date or the venue.

Exhibition spaces and promotional opportunities will be available at this meeting.
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