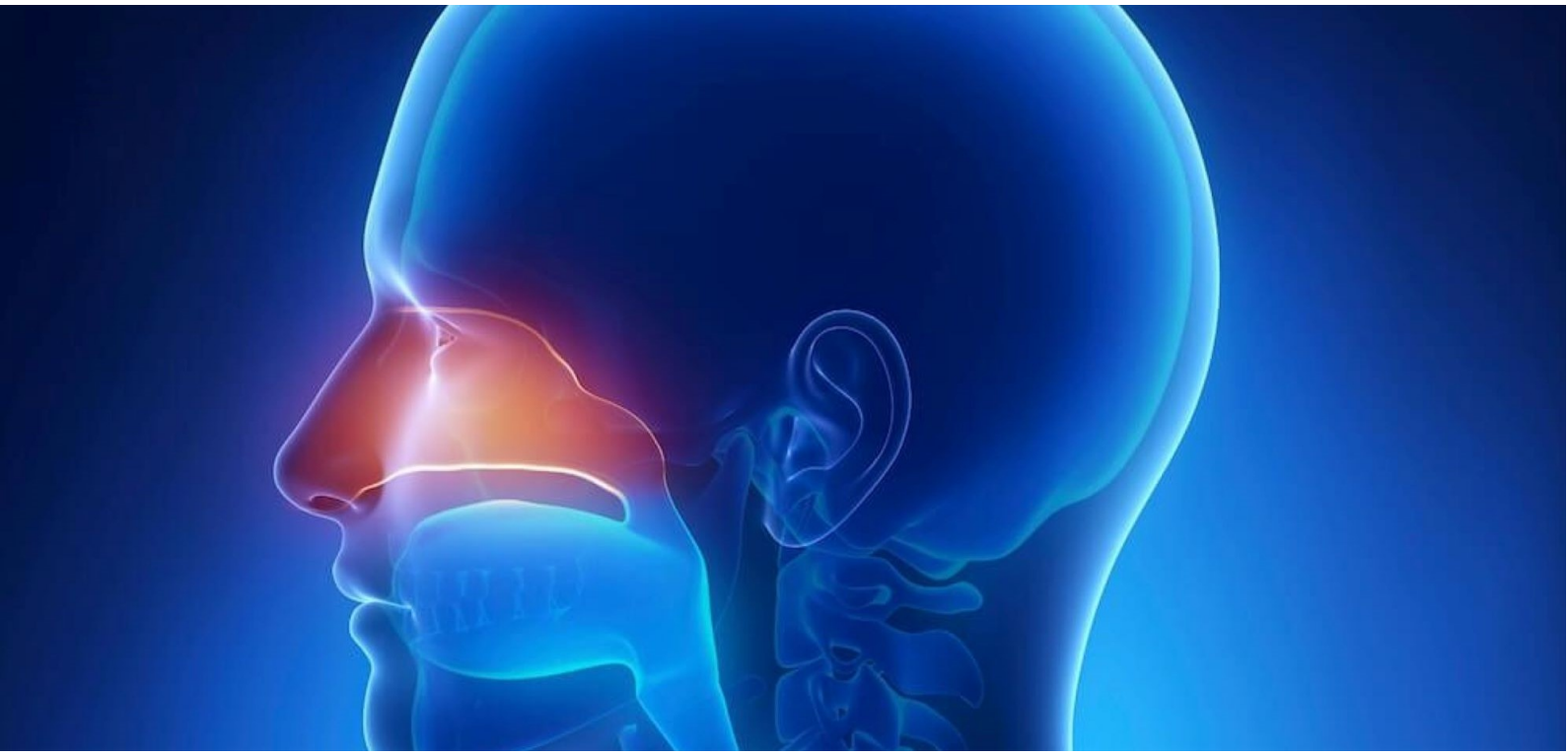
IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Delivery of Biologics to the Nasal Cavity

4 June 2024
+ 8 October 2024

The nasal cavity is an established pathway to treat local diseases as well as systemic conditions using small molecules. As the pharmaceutical industry shifts towards targeted biologics, the nasal cavity is also an attractive target for delivery of peptides, monoclonal antibodies, nucleic acids and stem cells. This is an ideal opportunity to hear from experts in the field of nasal drug delivery who will address topics such as: challenges associated with formulation, barriers to cell penetration and absorption, the pros and cons for liquid versus powder formulations, and strategies for maintaining stability and prolonging retention in the nasal cavity.

Format:
Live online

CPD:
3 hours for your records

Certificate of completion

Overview

The nasal cavity is an established pathway to treat local diseases as well as systemic conditions using small molecules. As the pharmaceutical industry shifts towards targeted biologics, the nasal cavity is also an attractive target for delivery of peptides, monoclonal antibodies, nucleic acids and stem cells. For example, an intranasal mAb formulation is in phase 1 clinical trials for progressive Multiple Sclerosis.

This course will address the challenges associated with formulation and clinical trial manufacture of biologics for delivery to the nasal cavity. The course will also highlight barriers to cell penetration and absorption and identification of an ideal target product profile.

The pros and cons for liquid versus powder formulations will be discussed. In addition, the course will focus on strategies for maintaining stability and prolonging retention in the nasal cavity. Device selection for preclinical and clinical studies using predictive tools such as nasal casts will be presented.

Finally, the session will help prepare the audience with manufacturing strategies for clinical trials with a nasally administered biologic.

Who Should Attend

- Research and Development
- Formulation Development
- Clinical Development
- CMC Managers
- Program Management
- Development Engineers
- Clinical Trial Manufacturing

Programme

Challenges and Opportunities

- Define biologics scope
- Overcoming barriers
- Device selection
- Targeted delivery in the nose
- Liquid vs powder formulations

Julie Suman, Aptar Pharma

Formulation Strategies

- Stabilizing biologics
- Formulation strategies
- Identify CQA and TPP
- Case studies

David Farrow, Aptar Pharma

Analytical Considerations for Nasally Delivery Biologics

- Considerations with compendial analysis for nasal products
- Secondary structure and aggregate analysis
- Modeling of deposition using nasal casts
- Device impact on the formulation

Lucas Silva, Nanopharm

How to Get Ready for a Clinical Trial with a Biologic

- Specification setting
- Drug product manufacturing
- Drug product release testing and stability studies
- Regulatory considerations

Gemma Budd, Nanopharm

Q & A Discussion

Presenters

Julie Suman

Dr. Julie D. Suman is the Vice President of Scientific Affairs for Aptar Pharma. She manages strategic scientific planning and Aptar's Scientific Advisory Board. Dr. Suman is also the co-founder of Next Breath. She holds a B.S. in Pharmacy from Duquesne University (1996) and a Ph.D. in Pharmaceutical Sciences from the University of Maryland, Baltimore (2002). Dr. Suman serves on the External Advisory Committee of the New South Wales RNA Production and Research Network. In addition, she is a co-editor for Respiratory Drug Delivery Proceedings, an international symposium, and an Affiliate Assistant Professor in the Department of Pharmaceutics, School of Pharmacy, Virginia Commonwealth University.

Gemma Budd

Gemma is the General Manager of Nanopharm, an Aptar Pharma company, where she was originally Director of Business Development and now has full responsibility for the Nanopharm business - both operationally and commercially - to continue to drive growth and commercialize innovative services and scientific solutions within the specialist field of OINDP. With a background in molecular genetics and pharmacology, she has spent 15 years working in the pharmaceutical and medical devices industry ranging from clinical pathology, materials science, formulation development and drug delivery device design and manufacturing businesses, mostly in inhaled drug products, nasal sprays, and oral solid dosage forms. She has worked in laboratory, R&D, management and commercial positions at Astrazeneca, Lucideon, Bespak, Nolato and now Nanopharm.

David Farrow

Lucas Silva

Lucas Silva is a Molecular and Cellular Biologist by academic training from the University of Lisbon and currently is working as a Senior Specialist leading the Analytical services at Nanopharm, an Aptar Pharma company.

Prior to his experience in Nanopharm, Lucas did a research internship at University College London focused on the development of particle engineered Dry Powder Inhalers (DPIs) for pulmonary infections.

With over 8 years of immersion in the pharmaceutical industry, Lucas has cultivated expertise spanning analytical services, formulation technology, and drug delivery devices, predominantly within the realm of research and development, particularly in orally inhaled and nasal drug products.

His key research areas are the development of more realistic respiratory and nasal analytical methods, the application of specialized in vitro performance data to de-risk and accelerate drug product development.

Lucas has showcased his research findings at numerous international conferences through both poster presentations and podium talks. Additionally, he has contributed as a co-author to a peer-reviewed paper centred on enhancing impactor testing for assessing the bioequivalence of DPIs.

Currently, Lucas actively engages in discussions within the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS), contributing valuable insights to navigate the evolving landscape of inhaled and nasal drug products.

Course dates

4 June 2024	**Live online** 14:00-17:00 **UK (London)** (UTC+01) *Course code 13759*	GBP **349** EUR **499** USD **579**
8 October 2024	**Live online** 14:00-17:00 **UK (London)** (UTC+01) *Course code 13990*	GBP **299** ~~349~~ EUR **429** ~~499~~ USD **501** ~~579~~ **Until 03 Sep**

How to book

Online:
ipi.academy/2657

Alternatively contact us to book, or if you have any queries:

Email:
info@ipi.academy

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) 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, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★★

Very clear and informative!

Serge PAMPFER
CEO
Maedia
Oct 10 2023

★★★★★

The webinar was an excellent overview and insight into an emerging field - good balance of market intel and technical detail.

Eleanor Catherine Canipa
Senior Business Development Manager
Nanopharm (an Aptar Company)
Jun 6 2023

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:

ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email: inhouse@ipi.academy

YESIM NURKO
Tel: +44 (0)20 7749 4749
Email: inhouse@ipi.academy

IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipi.academy