



Welcome to the Workshop!



IPAC-RS Workshop:
Inhaled Biologics: Preparing for
a Future Beyond Small
Molecules

September 4-5, 2024



Welcome, Workshop Objectives & Introductions

Presented by Chris Vernall, Intertek, Co-Chair

Background to Workshop

- There are over 200 large molecules in development for either inhaled or nasal delivery, spanning many different modalities.
- Additionally, a huge number of biologics are currently being administered by injection or IV. Inhaled or nasal delivery may represent an attractive alternative, given the potential for targeted delivery to the respiratory system, avoidance of first pass metabolism, rapid onset of action and a better (and less expensive) patient experience.
- In May 2023, an IPAC-RS survey of its Members and Associate Members revealed a strong desire to add an initiative that focused on inhaled and nasal biologics.
- To help define what this new initiative and what its core areas of focus will be, the IPAC-RS Board of Directors recommended an organization of a workshop, open to the general public and the IPAC-RS membership, with expert speakers covering a wide range of topics.
- Following the expert presentations and discussions, the Workshop Organizing Committee will meet after the Workshop to consider options and recommendations to the IPAC-RS Board for the new biologics focused workstream.

Workshop Objectives

- This IPAC-RS Workshop serves as a meeting place for industry and regulatory thought leaders to consider the burgeoning field of pulmonary and nasal delivery of biologics. In developing these types of products, the general principles of pharmaceutical aerosol generation for safe and effective delivery to the respiratory tract need to be combined with the approaches and techniques suitable for large, complex, and generally fragile entities that fall under the umbrella of biologics.
- Day 1 will focus on The Inhaled Biologics Landscape, their Critical Quality Attributes, and Aggregation Considerations.
- Day 2 will focus on Chemistry, Manufacturing, and Controls for Inhaled Biologic Drug-Device Combinations.
- Through podium presentations from expert speakers and roundtable discussions, attendees will identify current gaps in regulatory science of inhaled and nasal biologics and consider ways to address those gaps through targeted initiatives to be pursued after the Workshop.
- In-person breakout sessions will focus on three major areas: (A) Definitions, Delivery and Manufacturing of Biologic Products; (B) Analytical Testing & Control Strategies; (C) Safety & Toxicological Testing.

Day 1 Agenda

9:00 – 2:30 PM ET Presentations

Classes of Inhaled and Nasal Biologics: Current Trends in the Industry

Tomaso Guidi, Chiesi

Overview of Regulatory Landscape

Ruth Cordoba-Rodriguez, AstraZeneca

Testing Requirements for Protein Biologics Therapies

Wai Lam Ling, Catalent

Preclinical Toxicology: Navigating the Respiratory Tract Barrier

Emily Resseguie, Labcorp Early Development Laboratories

Testing for Inhaled and Nasal Oligonucleotide and mRNA Products

Ashleigh Wake, Intertek

Relevance of Protein Aggregates in the Lung

Markus Fridén, AstraZeneca

2:30 PM ET Wrap Up and End of Day 1 for Virtual Attendees

3:00 – 5:00 PM ET Breakouts and Readouts

5:00 PM ET End of Day 1 for In-Person Attendees

5:00 – 6:30 PM ET Networking Reception for In-Person Attendees

Day 2 Agenda

9:00 – 2:30 PM ET Presentations

Excipients for Respiratory Delivery of Large Molecules

Diana Fernandes, invoX

Michael Shultz and Kim Shepard, Lonza

Spray Drying of Biologics

Sune Klint Andersen, Janssen

A Platform Approach to Spray Dried, Thermostable, Mucosal Vaccines

Reinhard Vehring, Access to Advanced Health Institute

Influence of Device on Aqueous Stability

Ronan MacLoughlin, Aerogen

Particle Precision: The Importance of Sample Preparation in Insoluble Particle Analysis in Inhaled Biologic Powders

Scott Sides, AstraZeneca

Collection and Detection (Compendial) Strategies for Inhaled Biologics

Philip J. Kuehl, Lovelace Biomedical

Christopher J. Gruenloh, PPD, a part of Thermo Fisher Scientific

2:30 – 3:30 PM ET Panel Discussion

3:30 – 3:45 PM ET Closing Remarks

3:45 PM ET End of Workshop

Key Points

This Workshop is **your** opportunity to:

- share experiences,
- raise questions,
- learn from each other,
- shape future collaborative initiatives

Therefore, **GET INVOLVED** in the discussions!