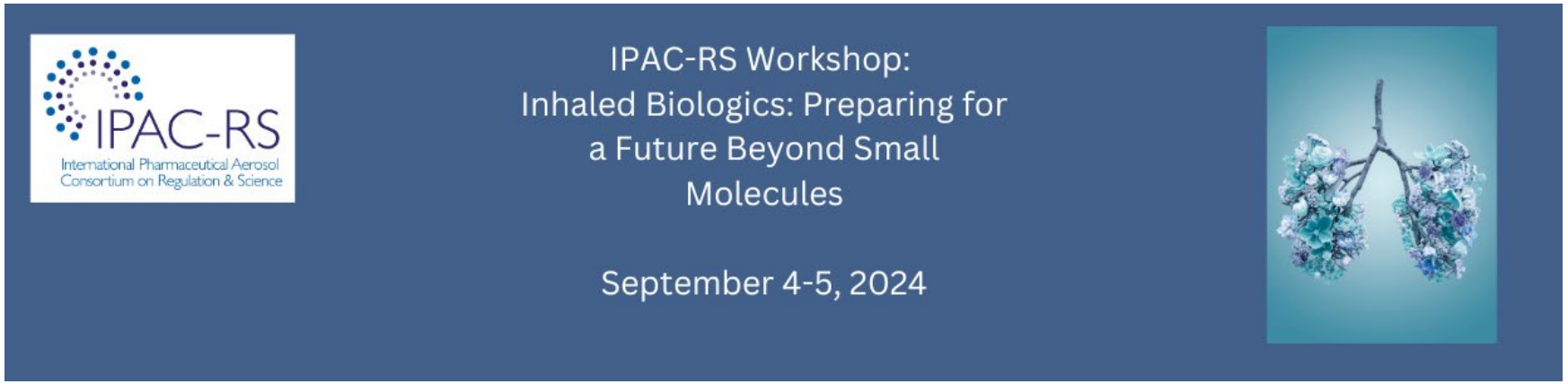
IPAC-RS
International Pharmaceutical Aerosol Consortium on Regulation & Science

Welcome to Day 2of the Workshop!



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Welcome and Review of Day 2

Presented by Alan Watts, Catalent

Workshop Co-Chair

Zoom Webinar Housekeeping I

- All Attendees are muted.
- The recordings will be shared after the Workshop.

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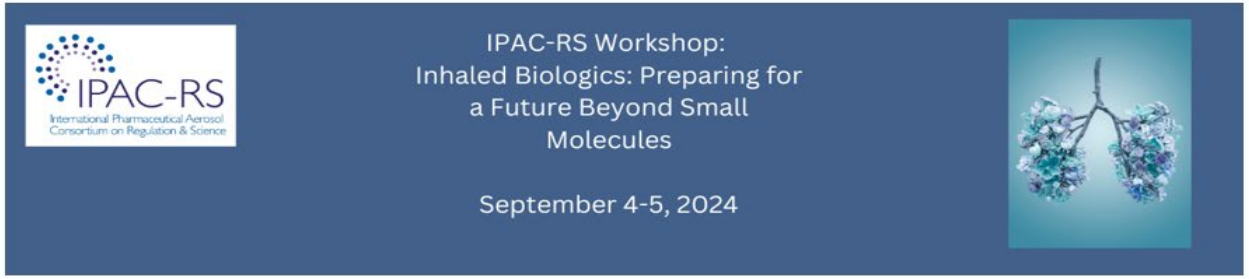

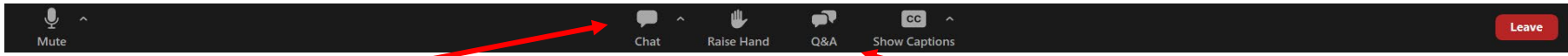

The Chat function has been disabled for Attendees. Type your question(s) in the Q&A box.

Housekeeping II

Bios

All Speaker bios are posted on the Workshop webpage, under Workshop Materials
https://www.ipacrs.org/biologics-workshop

Presentations

Post-workshop PDFS of available presentations will be posted on a password protected page.

Recordings

The recordings will be posted after the Workshop has concluded.

We will send out a notice to attendees with the link to view the recordings and presentations.

Recap of Day 1 Presentations

Day 1 takeaways:

- Tomaso – 217 biologic products in pipeline, the vast majority nebulized with VM, protein/peptide are most mature with nucleic acids in early dev
- Ruth – biologics are <40 amino acids, Essential Drug Delivery Outputs 2024 guidance, non-Arrhenius stability, aggregates, non-sterile powder
- Wai Lam – Glycosylation is a CQA, DS is manufacture is complex, DS/DP release for mAb, Developability assessment (Mech & Thermal Stress)
- Emily – 1 species for biologic, 4w Mouse study can get you to Ph2 (oligos), delivered dose determination, different classes have different effects on histopath
- Ashleigh – ASO stabilization, ASO impurities are really tough (UV+MS), UPLC-CAD for LNP components, potency for mRNA, not ASOs
- Markus – Immunogenicity: pulmonary>subQ>IV, Crosslink B cell receptor and dendritic uptake, Agg is conc dependent, bio-relevant testing and modeling needed

Recap of Day 1 Breakouts

Day 1 Breakout takeaways:

- Manufacture and Device – Microbial controls, post-nebulization potency, moisture control
- Analytical – APSD and DDU (detection), post-neb characterization, potency testing (cell based and otherwise)
- Toxicity – adjuvants and novels excipients, FDA reformulation guidance, FDA AI data share, immunogenicity in preclinical not helpful, dose frequency drives study design, understand neutralizing antibodies

Day 2 Workshop Objectives

- Day 2 will focus on Chemistry, Manufacturing, and Controls (CMC) for Inhaled Biologic Drug-Device Combinations.

- Day 2 will conclude with a Panel Discussion, which will address Key CMC/Analytical Issues/Gaps to Address.

- Panelists:
  - Ruth Cordoba-Rodriguez, AstraZeneca
  - Philip Kuehl, Lovelace Biomedical
  - John Patton, Kindeva
  - Michael Shultz, Lonza
  - Hailin (Sheena) Wang, OPQAIII/CDER/US Food and Drug Administration

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 to remember

This Workshop is **your** opportunity to:

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

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