



Welcome to the Workshop!



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

September 4-5, 2024



Housekeeping and Rules of Engagement

Presented by Mary Devlin Capizzi
IPAC-RS Secretariat and Legal Counsel

Who We Are

The International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) is an international association that seeks to advance the science, and especially the regulatory science, of orally inhaled and nasal drug products (OINDPs) by collecting and analyzing data, and conducting joint research and development projects.

Representing the OINDP industry since 2000, IPAC-RS aims to build consensus and contribute to effective regulations and standards by sharing the results of its research through conferences, technical journals, and discussions with regulatory bodies.



Our Members

Members - corporations that *develop, manufacture or contract to manufacture OINDPs*

AstraZeneca
Bespak
Boehringer Ingelheim
Catalent
Chiesi
Genentech
GSK
Kindeva Drug Delivery

Lonza
Lupin
Merck & Co., Inc.
Sandoz
Teva
TranspireBio
Vectura
Viatriis

Associate Members – *corporations that (1) develop or manufacture components and/or devices for OINDPs or (2) provide scientific or technical services relating to development and manufacture of OINDPs or (3) are eligible for full membership but have annual revenues of less than seventy-five million US dollars.*

Aptar Pharma
Copley Scientific
Harro Höfliger
H&T Presspart
Honeywell
Intertek

invoX Belgium N.V.
Koura, an Orbia Business
Nemera
PPD
Proveris Scientific Corporation
RxPack

Top 5 Reasons to Join IPAC-RS

1

Stay ahead of emerging international regulatory and scientific challenges facing the OINDP industry.

2

Participate in joint industry discussions with and guidance commenting to regulators in North America, Europe, Asia, and South America.

3

Join industry leaders in providing feedback to standard-setting bodies and international pharmacopoeia.

4

Share knowledge, information and experiences with other industry leaders.

5

Stay abreast of pertinent development and also shape national and international trends and requirements.

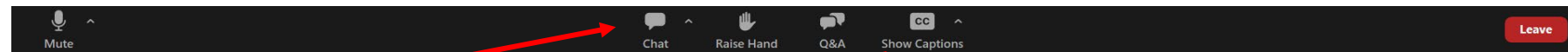
Join IPAC-RS and be part of shaping and participating in the collaborative initiatives which will follow this workshop!
Contact dede.godstrey@faegredrinker.com for any details.

Zoom Webinar Housekeeping I

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



Welcome to the Workshop!



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.

NOTE:

- The Breakouts on Day 1 will be not be recorded, but summaries may be posted with the presentations following the Workshop.
- Day 1 will end at 2:30 PM for virtual attendees.

Thank You – Workshop Organizing Committee

- Co-Chairs, Workshop Organizing Committee
 - Chris Gruenloh, PPD, a part of Thermo Fisher Scientific
 - Chris Vernall, Intertek
 - Alan Watts, Catalent
- Ruth Cordoba-Rodriguez, AstraZeneca
- Diana Fernandes, invoX Belgium N.V.
- Felicia Gioiello, Chiesi
- Tomaso Guidi, Chiesi
- David Lechuga-Ballesteros, AstraZeneca
- John Patton, Kindeva
- Mireia Puig, Vectura
- Atish Sen, AstraZeneca
- Isabel Lopes, invoX Belgium N.V.
- Kim Shepard, Lonza
- Keith Ung, Kindeva
- Ashleigh Wake, Intertek
- IPAC-RS Secretariat (Lana Lyapustina, Mary Devlin Capizzi, Dede Godstrey, Lee Nagao)