2024

YEAR IN REVIEW

IPAC-RS

International Pharmaceutical Aerosol Consortium on Regulation & Science

IPAC-RS

2024 YEAR IN REVIEW

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Jennifer Wylie
IPAC-RS Chair

Message from the IPAC-RS Chair

We are proud to share with you the 2024 IPAC-RS Year in Review! In reflecting on the past year, I am grateful to all IPAC-RS member companies and representatives for supporting the consortium and facilitating outstanding industry collaboration and thought leadership. IPAC-RS continues to advance key initiatives across the orally inhaled and nasal drugs and biologics (INDB) industry while focusing on delivering timely discussions and thoughtful resources. IPAC-RS maintains a robust and active portfolio of projects and work streams – all aligned with the consortium's strategic objectives. The consortium launched a new three-year strategic plan at the end of 2024 and is committed to ensuring that that IPAC-RS remains the leading technical resource for and advocate of the global INDB industry.

As this report details more fully, 2024 was another productive year for IPAC-RS. Among its many initiatives, the consortium organized and executed a successful IPAC-RS Biologics Workshop and was a key thought leader at the December 2024 CRCG/FDA Workshop. IPAC-RS continues to actualize its vision to serve a broader group of INDB stakeholders by addressing scientific and regulatory topics of interest to manufacturers of nasal products and biologics. This is an exciting expansion of IPAC-RS' scope. Last year, the IPAC-RS Board supported the creation of a new Inhalation and Nasal Biologics (INB) Steering Committee to address key industry issues emerging in the inhaled and nasal biologics space.

I congratulate and thank all IPAC-RS member companies and participants for their dedication to science, unwavering service to patients, and active and generous collaboration and engagement in IPAC-RS. As we enter 2025, we look forward to another year of optimal collaboration and progress. Together we are advancing scientifically driven approaches to enhance product quality of INDBs for the benefit of patients!

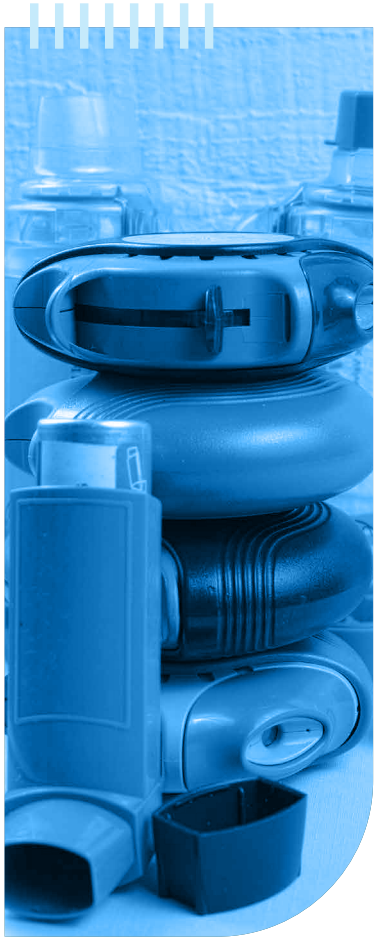
Lei Mao
IPAC-RS Vice Chair

Message from the IPAC-RS Vice Chair

2024 was another productive and evolving year for the inhalation industry where the teams have made great efforts in the new wave of development to satisfy unmet patient needs while making our earth greener. With active involvement and contributions from all member organizations and collaboration with regulatory agencies, IPAC-RS has effectively formulated proposals and solutions to those urgent needs, including transitioning to low global warning propellants, addressing regulatory updates, and outreach to wider global regions, Importantly, the consortium continues to advance scientific development such as expanding to non-invasive delivery of biologics, standardizing aerosol characterization, addressing regulatory considerations for nasal delivery platforms, and initiating collaborative discussions on application of AI technologies in the inhalation/nasal product area.

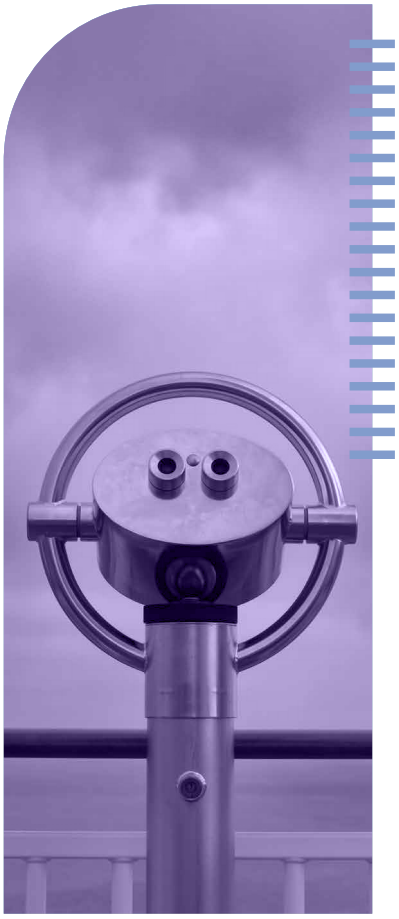
With the 2025-2027 strategic plan in place, the consortium has clearly defined goals for the next 3 years that not only focus on the current needs but also lay a stronger foundation for future development. The visibility, networks, talent, experience and collective knowledge of the consortium continues to attract interest from the industry. We look forward to welcoming new members.

Personally, it is my great honor and pleasure to serve such a wonderful organization and I look forward to continued collaboration with all colleagues in the coming years while we navigate through important transitions in the industry.



Who We Are

IPAC-RS is an international association that seeks to advance the science, and especially the regulatory science, of orally inhaled and nasal drugs and biologics (INDB). Representing the INDB industry for more than two decades, IPAC-RS aims to build consensus and contribute to effective regulations and standards by sharing the results of its research and collective knowledge through conferences, webinars, technical journals, and discussions with regulatory bodies.



Vision

IPAC-RS is and will remain the leading technical resource for and advocate of the global INDB industry, with a focus on Chemistry, Manufacturing and Controls (CMC).

Mission

The mission of IPAC-RS is to advance scientifically driven approaches to enhance product quality of INDBs for the benefit of patients.

IPAC-RS Successes *New in 2024*

New Leadership

In July 2024, the IPAC-RS Board members elected Lei Mao (Bespak) as the next Vice Chair of IPAC-RS. Jennifer Wylie (Merck) assumed the Chair position, succeeding the outgoing Chair, Mike Needham (Kindeva).

In January 2024, IPAC-RS welcomed new IPAC-RS Planning Committee Members! The IPAC-RS Planning Committee (PC) is an elected subset of IPAC-RS Board members who take on the responsibility to prepare for Board meetings and advise the Board on the consortium's operations in-between Board meetings. Amanda Burke (GSK), Beatriz Fernandes (Lonza), and Francois Michelon (AstraZeneca) were elected to serve two-year terms and Monica Ferrari (Chiesi) was elected to serve a one-year term. Robert Berger (Merck) and Negar Sadrzadeh (Genentech) completed their two-year terms on IPAC-RS PC.

New Members

In 2024, IPAC-RS welcomed several Associate Members. IPAC-RS is excited for active engagement and collaboration with these companies:

- Koura, Orbia's Fluor & Energy Materials Business Group
- Honeywell
- Harro Höfliger

Addressing Emerging Regulation & Advancing Innovation in 2024

Biologics: OINDP is now INDB

Since IPAC-RS has evolved significantly in the past few years and has broadened its membership criteria to recognize the expanding and diverse ecosystem that its work serves, we are retiring the old acronym OINDP (orally inhaled and nasal drug products) and in 2025 will start using INDB (inhaled and nasal drugs and biologics).

IPAC-RS Biologics Workshop

The IPAC-RS Biologics Workshop Organizing Committee lead by Co-Chairs Chris Gruenloh (PPD), Chris Vernall (Intertek), and Alan Watts (Catalent) worked diligently throughout 2024 to pull off a very successful workshop held in September 2024. The presentations and recordings are here.

As a follow-up from the Workshop, IPAC-RS created a new Inhalation and Nasal Biologics (INB) Steering Committee to oversee targeted areas identified during the Workshop.

LGWP Propellants

In early 2024, IPAC-RS began preparations for a follow-up workshop on low global warming potential (LGWP) propellants, as a sequel to addressing issues that were not addressed at the IPAC-RS Workshop held in October 2023. In order to avoid duplicating efforts, IPAC-RS coordinated with CRCG to lead a session at the CRCG/FDA workshop Navigating the Transition to Low Global Warming Potential Propellants held in December 2024.

In preparation for the above workshop, IPAC-RS prepared and released the IPAC-RS scenarios document entitled *"Transition to Low Global Warming Potential Propellants in Metered Dose Inhalers: Proposed Pathways to US FDA Approval"*. The document outlines suggested regulatory pathways for the approved and in-development (A)NDAs switching propellants. The IPAC-RS Scenarios document was used to assist in developing the IPAC-RS session and small group discussion session at the workshop

Strategic Plan

IPAC-RS conducted a survey to collect Member and Associate Member input for the 2025-2027 IPAC-RS Strategic Plan. The IPAC-RS Board and Working Group (WG) Chairs reviewed and approved the draft IPAC-RS Strategic Plan 2025-2027. The Plan was released in January 2025 (see page 13). IPAC-RS thanks the IPAC-RS Board for its leadership in developing this exciting strategic plan. We also thank all member companies for their support of and engagement in IPAC-RS.

2024
Looking Back

April 30 | *Virtual*

The IPAC-RS Board of Directors met to review the IPAC-RS portfolio, including plans and progress for all Working Groups, and planning for the LGWP Propellants and Biologics Workshops. The IPAC-RS Board was joined by Associate Member representatives and representatives from several prospective companies interested in joining IPAC-RS.

July 1-2 | *Hybrid*

The IPAC-RS Board of Directors met in Parma, Italy for a 2-day hybrid meeting, hosted by Chiesi Farmaceutici. The agenda included a review of IPAC-RS comments on EMA guidelines, a debrief from meetings in China, updates on progress of the CRCG Workshop and Biologics Workshop, brainstorming for the 2025-2027 Strategic Plan, legislative updates from IPAC, and several presentations from invited guests.

October 28 | *Virtual*

The IPAC-RS Board held a joint virtual meeting with the Planning Committee to review the IPAC-RS 2024 Budget and review and approve the IPAC-RS Statement of Work for 2025.

December 2-3 | *Hybrid*

The IPAC-RS Board of Directors met in Washington, DC for a 2-day hybrid meeting. The agenda included review of the IPAC-RS Working Group portfolio, update from IPAC, preparation for the CRCG workshop, IPAC-RS guidance commenting opportunities, a report from the meeting with FDA OCPR, a report and next steps for the INB WG, and finalizing the 2025-2027 Strategic Plan. IPAC-RS Associate Members also attended the meeting as observers.

Working Group (WG) & Knowledge Network (KN)

Discussion Highlights, Publications, & Comments

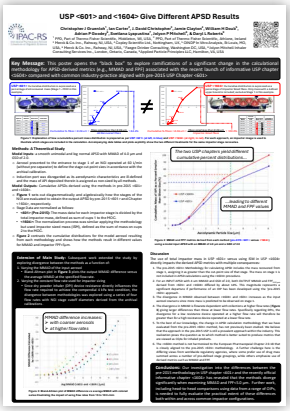
Projects & Discussions

- Several WGs discussed and planned for the CRCG/FDA workshop on alternate propellants (GRRO AP, GRRO NA).
- Several WGs (GRRO NA, APSD, and Nasal) discussed the new Product Specific Guidances (PSGs) issued by FDA and submitted IPAC-RS responses to FDA throughout 2024.
- Several WGs reviewed and discussed IPAC-RS Comments on the recently issued Pharmeuropa chapters. (GRRO Europe, Nasal, and PQDS)
- **GRRO-Alternate Propellants** (GRRO AP) discussed developments related to PFAS and F-gas regulations and heard and discussed a guest presentation from Chair of CiPPPA (Circularity in Primary Pharmaceutical Packaging Accelerator), which works to establish a pre-competitive collaborative platform for reducing environmental impacts from plastics used in pharmaceutical packaging.
- **GRRO-North America** (GRRO NA) discussed the ICH Q12 Established Conditions examples for OINDPs and coordinated the IPAC-RS response to FDA's PSGs for inhaled and nasal products.
- **GRRO NA and the IPAC-RS Board** discussed key messages from the April 2024 Global Bioequivalence Harmonisation Initiative (GBHI) 6th Conference and implications for OINDPs. Session 4 at the Conference was focused on BE Study Considerations for orally inhaled drug products (OIDPs). One presentations highlighted the changes in the EMA guidelines for OIDPs.
- The **Analytical Lifecycle Management Knowledge Network** (KN) continued discussion of current practices applying ICH Q2 and Q14 concepts and tools, both internally and/or for regulatory filings.
- **Materials WG** prepared for and held a sustainability roundtable (Part III) in March 2024 (see page 12), revised and released an update to the Baseline Requirements for materials quality (see page 9), and discussed platform devices that can be used with a variety of API/formulations -- approaches for materials quality evaluation.
- **The Aerodynamic Particle Size Distribution** (APSD) [formerly the Cascade Impaction WG] 1) reviewed and prepared comments of the draft Japanese Pharmacopeal Chapter for APSD of liquid inhalations; 2) made a presentation to the USP Inhalation Subteam about the divergent interpretations of MMAD calculations in USP <601> vs <1604> (a poster on the same topic was presented at DDL 2024); 3) discussed High-Payload particles DPI Experiment; 4) planned for an IPAC-RS APSD Database Refresh, 5) a subteam is preparing for a USP IPAC-RS Workshop: Hot Topics in OINDP Performance Testing, to be hosted by USP in Rockville, MD; and 6) held regular coordination with an EDQM representative.
- **GRRO China** debriefed from the May meetings in China (the complex drugs section of DIA China and the regulatory roundtable). Due to internal issues, the CDE and NIFDC were unable to attend the roundtable session in person. However, the Chinese Pharmacopoeia did attend, and the discussions focused on current understanding in China related to the topics (i) use of alternative propellants in MDIs; (ii) "hybrid" pathway for OINDP; (iii) alternative BE approaches; and (iv) change management/lifecycle approaches.
- **Materials WG and GRRO China** prepared comments on the draft "Guideline for Packaging System of Preparations for Inhalation," recently issued by the Chinese Pharmacopoeia."

Projects & Discussions *continued*

- **Materials & Propellants Quality Considerations** prepared and submitted a manuscript "Materials Compatibility Considerations for the Transition to Low Global Warming Potential Propellants for Pressurized Metered Dose Inhalers" published in AAPS PharmSciTech in 2025.
- **Nasal WG**: 1) Nasal WG's Subteam on Regulatory and Compendial Standards prepared a stimulus article for the USP Pharm Forum, about the need for a "Nasalia" type chapter in the USP; 2) Nasal WG's Product Reliability Subteam prepared a poster for DDL 2024; and 3) Nasal WG's Pediatric Subteam prepared a poster for RDD 2024.
- **The Product Quality Demonstration Strategy** (PQDS) Core Group prepared a paper for Inhalation Magazine and converted to a Knowledge Network at the end of 2024.

External Publications/Posters



- At RDD 2024, two IPAC-RS posters were presented from the Nasal WG Pediatric Subteam and the APSD WG. Copies available on the IPAC-RS website.
  - Laser Diffraction Size Analysis of Products for Nasal Inhalation: A Survey of Expert Users
  - Regulatory Topics in Nasal Product Development: Pediatrics and Reliability Expectations
- At DDL 2024, two IPAC-RS posters were presented from the APSD WG and the Nasal WG Nasal Product Reliability Subteam. Copies available on the IPAC-RS website.
  - USP <601> and <1604> Give Different APSD Results
  - Reliability Expectations for Emergency-Use Nasal Products: IPAC-RS Nasal Subteam Considerations

Publications

- IPAC-RS Scenarios – Transition to LGWP Propellants in MDSs: Proposed Pathway to US FDA Approval IPAC-RS website (Nov 2024)
- UPDATED: Recommended Baseline Requirements for Materials Used in Orally Inhaled and Nasal Drug Products (OINDP) IPAC-RS Website (Nov 2024)
- Point of view: A better way to set specifications and control quality—General concepts and examples Inhalation Magazine (Oct 2024)
- IPAC-RS Summary of Global Regulatory Developments 2023 IPAC-RS Website (March 2024)
- IPAC-RS: An update and review of 2023. Inhalation Magazine (February 2024)
- A final paper based on the 2023 IPAC-RS LGWP Propellants Transition workshop was approved to be published in 2025 in AAPS PharmSciTech.
- A manuscript based on the 2023 ISAM/IPAC-RS CMC-Biologics workshop has been submitted to the Journal of Aerosol Medicine and Pulmonary Drug Delivery.
- A subteam of the Nasal WG submitted to USP a stimulus article entitled "Current needs for support for Nasally Inhaled Products (NPs) in the United States Pharmacopeia (USP): recommendation from the Nasal Working Group of the International Pharmaceutical Consortium on Regulation & Science (IPAC-RS)". A copy is available to IPAC-RS Members upon request.

All IPAC-RS publications prior to 2024 are posted on our website.
ipacrs.org/publications

Comments

Comments to FDA

- IPAC-RS responded with comments to several New Product Specific Guidances (PSGs) issued by FDA throughout 2024 (GRRO-NA, APSD, and Nasal).
- In particular, GRRO NA noted that for the New PSGs, this is the first time that FDA has included details for alternative BE approaches and incorporated recommendations for in vitro BE studies, comparative characterization studies, an in vivo PK BE study, formulation sameness and device similarity, along with recommendations for an optional supportive computational modeling study. Copies of final comments are available on the regulations.gov website and available to Members upon request.
- IPAC-RS Comments on FDA Draft Guidance Purpose and Content of Use-Related Risk Analyses for Drugs, Biological Products, and Combination Products (September 6, 2024)
- IPAC-RS Comments on FDA Draft Guidance Essential Drug Delivery Outputs for Devices Intended to Deliver Drugs and Biological Products (September 20, 2024)

Comments to EMA

- IPAC-RS comments on "Guideline on the requirements for demonstrating therapeutic equivalence between orally inhaled products (OIP) for asthma and chronic obstructive pulmonary disease (COPD)" (October 2015, 2024)
- IPAC-RS and EFPIA comments on "Guideline on the pharmaceutical quality of inhalation and nasal medicinal products" (October 15, 2024)

Comments to EDQM on Pharmaeuropa 36.2

- IPAC-RS Comments on PhEur "PREPARATIONS FOR INHALATION" (June 2024)
- IPAC-RS Comments on "NASAL PREPARATIONS, Nasalia" (June 2024)

Other Comments

- IPAC-RS Comments on draft Japanese Pharmacopeia Chapter *"Uniformity of delivered dose of nasal preparations"*, published by PMDA. (March 2024)
- IPAC-RS and ELSIE Comments to Chinese Pharmacopoeia draft Guideline for Packaging System of Preparations for Inhalation (July 2024)
- GRRO Europe and Nasal WG are preparing IPAC-RS comments on the EMA "Concept paper for the development of a guideline on the demonstration of therapeutic equivalence for nasal products"
- IPAC-RS Commenting Group reviewed the newly issued Draft Guidance on Predetermined Change Control Plans for Medical Devices which focuses on device-led combination products.

All IPAC-RS Comments prior to 2024 are posted on our website.
ipacrs.org/ipacrs-comments

Regulatory Agencies, Standards Organizations, and Other Stakeholders

2024 External Engagement

IPAC-RS continued its engagement with the Product Quality Research Institute (PQRI) as a member.

IPAC-RS compiled and submitted examples of CDER/CBER/CDRH misalignment to the FDA Office of Combination Products (OCPR) leaders and then held a successful virtual meeting with FDA OCPR in October 2024. IPAC-RS and FDA OCPR discussed ways to improve inter-center coordination and alignment of reviewers requests and regulatory requirements for drug-device combination products. FDA colleagues indicated openness to further dialogue.

IPAC-RS and the US Pharmacopeia (USP) are preparing for a Joint USP IPAC-RS Workshop: Hot Topics in OINDP Performance Testing, to be hosted by USP in Rockville, MD.

IPAC-RS and ISAM are coordinating on sessions at the ISAM 2025 Congress.

APSD WG leaders continued to meet with Dr. Erika Stippler (EDQM) to continue the dialogue about updating and harmonizing pharmacopeial chapters for aerosol-based products.

IPAC-RS coordinated with EFPIA to submit comments on the EMA "Guideline on the pharmaceutical quality of inhalation and nasal medicinal products."

IPAC-RS regularly coordinates with the International Pharmaceutical Aerosol Consortium (IPAC) to share information and updates on propellant transition legislation and regulatory developments.

IPAC-RS representatives participated on the CRCG LGWP Propellants Organizing Committee to assist in organizing the December 2024 CRCG workshop Navigating the Transition to Low Global Warming Potential Propellants. IPAC-RS developed the agenda for Session 2: Current Industry Experience with New Drug LGWP Propellant MDI Development and served as moderators for Session 3, the small group working sessions. Slides and recordings from the Workshop are available here.

IPAC-RS representatives attended a networking luncheon during DDL 2024, hosted by EPAG, and shared updates on the consortium's activities. Further interactions with EPAG are planned for 2025.

Regulatory Agencies, Standards Organizations, and Other Stakeholders

Monitoring, Communications and Networking

IPAC-RS tracked global regulatory developments and standards that are relevant for OINDPs, discussed key publications, and shared insights from webinars and conferences, in the Monthly newsletter, which is distributed to all IPAC-RS members and all interested employees of Member and Associate Member companies.

IPAC-RS March 2024 NEWSLETTER

IPAC-RS Activities

- The IPAC-RS Roundtable on ***Regulatory and Technical Considerations in Sustainable Lifecyle Approaches for OINDP Device and Container Closure Systems Part III*** will be held on Thursday, 14 March, from 10:00 AM – 11:30 AM US ET. For more details and to register for this free virtual event, please click here.
- The date of the IPAC-RS Biologics Workshop has been finalized to Sept 4-5 (Wednesday-Thursday) in Washington, DC. The program is under development. A Save-the-Date will be circulated shortly.
- The planning of a joint workshop with USP is progressing. USP will host it in Rockville, Maryland at the end of March 2025. The program will focus on APSD, AIM and Nasal topics. Leaders of CI WG, Nasal WG and other IPAC-RS representatives are joining USP's planning calls.
- GRRO-North America discussed the new and revised product-specific bioequivalence guidances (see the list of inhalation PSGs in the next section). In particular, GRRO NA noted that for the New PSGs, this is the first time that FDA has included details for alternative BE approaches and incorporated recommendations for in vitro BE studies, comparative characterization studies, an in vivo PK BE study, formulation sameness and device similarity, along with recommendations for an optional supportive computational modeling study.

IPAC-RS actively engages in reviewing and commenting on regulatory developments around the world and works collaboratively with all stakeholders to improve science-based regulations affecting OINDPs. IPAC-RS prepared a summary of relevant global regulatory developments in 2023. CLICK HERE

Alternative Propellants Information Repository: IPAC-RS maintains a public-facing webpage to store relevant information about the scientific and technical aspects of LGWP propellants. CLICK HERE

The IPAC-RS Board, Planning Committee, WGs, and KNs continued to meet regularly, network and advance IPAC-RS projects throughout 2024.

The IPAC-RS community stays connected and productive using the members-only IPAC-RS Connect portal, and maintains high visibility through the IPAC-RS website and its LinkedIn page. IPAC-RS also has its own video channel where you can watch recording of IPAC-RS webinars and other resources.

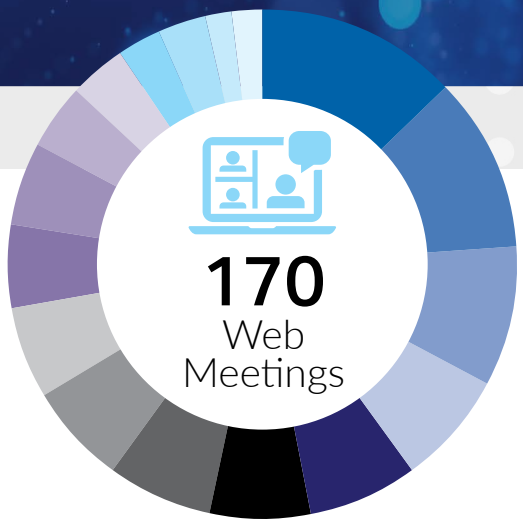
2024 By the Numbers

4 Board Meetings

The IPAC-RS Board met virtually in April and October and held hybrid meetings in July and December for engaging discussions and updates on current and proposed consortium initiatives.

3 Public Workshops/Webinars

- Roundtable: ***Regulatory and Technical Considerations in Sustainable Lifecyle Approaches for OINDP Device and Container Closure Systems Part III***. (March 14, 2024) Agenda, slides, and a recording are available here.
- IPAC-RS Workshop: ***Inhaled Biologics: Preparing for a Future Being Small Molecules*** (September 2-5, 2024). The presentations and recordings are available here.
- IPAC-RS representatives contributed to the planning of and presented at the CRCG Workshop: Navigating the Transition to Low Global Warming Potential Propellants. (December 4-5, 2024). Workshop presentations and recordings available here.



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- 11 OINDP Materials
- 11 GRRO China
- 10 LGWP Propellants Committee
- 9 Product Quality Demonstration Strategy *(Full WG and Core)*
- 9 Planning Committee
- 7 Guidance Commenting Team
- 6 Analytical Methods Lifecycle Management
- 5 GRRO Europe
- 5 Nasal *(Full WG only)*
- 3 Membership Committee
- 3 Inhaled & Nasal Biologics Steering Committee

What's Next

Looking Ahead to 2025

Guided by the priorities laid out in the newly released 2025-2027 Strategic Plan, IPAC-RS will continue working to remain a leader in the INDB industry in 2025.

- In January 2025, IPAC-RS released its 2025-2027 Strategic Plan.

- IPAC-RS Roundtable Series: IPAC-RS is continuing its Roundtable series in 2025. Designing for a Sustainable Future: Strategies to Address the Device and Delivery System Lifecycle will take place on April 1, 2025. Visit the Roundtable webpage for more information.

- In 2025, the Analytical Lifecycle Management KN plans to conduct an IPAC-RS survey to determine the broader state of industry implementation, with a goal of identifying gaps and needs, and subsequently potentially developing training materials with a focus on OINDP drug-device combination products.

- In 2025, the newly formed Inhalation and Nasal Biologics (INB) Steering Committee will oversee five Subteams, who will focus on the following areas:

    1. Analytical (Powders + Liquids)
    2. Formulation, Manufacturing & Devices - Liquids
    3. Formulation, Manufacturing & Devices - Powders
    4. Regulatory Outreach
    5. Emerging Modalities (LNPs, exosomes, phages, viral vectors, oligos, RNA vaccines, nanocarriers, transporters, GLP-1 agonists etc.)

- The IPAC-RS Board of Directors will meet four times in 2025, twice virtually (April and October) and twice in person (June in Washington, DC and December in Edinburgh, Scotland).

What our Members are Saying

I have represented AstraZeneca in IPAC-RS for about six years. In that time I have learned a lot from discussions with industry experts, workshops and publications. IPAC-RS is a valuable asset as an industry forum for discussions on all aspects of aerosol products.

Atish Sen, Ph.D.
Principal Scientist, Analytical Sciences-Inhalation Product Development | AstraZeneca
IPAC-RS Materials & Propellants Quality Considerations WG Co-Chair

I joined IPAC-RS midway through 2024 and was amazed by the instant level of engagement and value in the discussion forums being provided. Highlights for Bespak included Lei Mao taking the position of Vice Chair and having the opportunity to chair in-person events. The end of year review with the FDA was excellent. Although I could only join on line, the engagement and value of the discussions was clear to see. These conversations continued in earnest at DDL the following week. Looking forward to continuing to contribute to IPAC-RS in 2025!

Ross Errington
Head of Drug Product Development | Bespak
IPAC-RS Board Member

IPAC-RS is a fantastic consortium, made up of many companies with significant experience and expertise in all things relating to pharmaceutical aerosol science. I have personally had the pleasure of being involved in the Inhaled and Nasal Biologics initiative, which was able to bring in world leading experts in this area for a workshop held last September. It was a privilege to have access to the vast amount of knowledge that was being shared and a testament to the reputation of IPAC-RS that it was able to bring in these speakers – as well as a participant from the FDA who joined the panel discussions.

As is normal for IPAC-RS, the event and the subsequent working groups that have formed in this area have been done so extremely collaboratively and with a sense of joint ownership across the many individuals and companies represented.

Chris Vernall
Commercial Director | Intertek Pharmaceutical Services
Co-Chair, IPAC-RS Inhaled & Nasal Biologics Steering Committee

Lonza's membership in IPAC-RS is invaluable. Through active participation, we gain access to critical information, foster valuable collaborations, and contribute to the advancement of the OINDP field. The timely access to regulatory updates, scientific insights, and the opportunity to engage with industry leaders are essential for addressing the evolving challenges in inhaled drug delivery and ensuring the successful development of innovative therapies for our clients.

Beatriz Fernandes
Principal Investigator, Manager CMC | Lonza
IPAC-RS Planning Committee and Board Member

What our Members are Saying

There really is no organization quite like IPAC-RS! The consortium allows you to come together with experts in your field for the sole purpose of creating a written collective perspective on emerging and complicated new scientific efforts to make better therapies. In the process, one gets an elevated perspective on the new fields that is hard to come by otherwise. Plus, you make new friends and connections and know who to call when you need certain kinds of information.

John Patton

Senior Strategic Advisor | Kindeva Drug Delivery

IPAC-RS Inhaled & Nasal Biologics Steering Committee Member

I have really enjoyed engaging with IPAC-RS over the last couple of years. It has been a collaborative and informative experience. Being fairly new to the world of inhalation, IPAC-RS has been a remarkable source of information and education. I have learned a lot! It is a generous community and a wonderful forum for interacting with industry thought leaders. IPAC-RS gets things done -- and in a manner that helps the industry advance scientifically driven approaches and, ultimately, to better serve patients. I look forward to continued collaboration in IPAC-RS for years to come.

Rina Joshi, Ph.D.

Director Regulatory Affairs | Teva Pharmaceuticals

IPAC-RS GRRO Alternate Propellants and GRRO Europe Member

Having joined IPAC-RS as a new company member in 2024, we at Honeywell are deeply impressed by the Consortium's dedication to scientific research, regulatory advocacy and international collaboration. IPAC-RS truly represents a professional platform enabling industry peers across the supply chain to work together to solve common challenges.

The highlight for Honeywell in 2024 was the pivotal involvement of IPAC-RS in the December US FDA-CRCG workshop on "Navigating the Transition to Low Global Warming Potential Propellants" It clearly underscores IPAC-RS's commitment to advancing the understanding and development of propellant technologies within the pharmaceutical aerosol industry.

Mark Boelens

Global Senior Director - Product Stewardship & Toxicology | Honeywell

IPAC-RS Change Management WG member

Harro Höfliger greatly values its membership in IPAC-RS, as it offers us invaluable insights into the latest advancements and regulatory trends in orally inhaled and nasal drug products. Through IPAC-RS, we collaborate with industry leaders to enhance regulatory standards & clarity, identify regulatory gaps and work towards addressing them. This collaboration empowers us to design and build state-of-the-art machinery that meets the ever-evolving needs of the industry, ensuring optimal performance and compliance for our customers.

Kris Brosig

Director Sales, Aerosols | Harro Höfliger

GRRO Alternate Propellants WG member

What our Members are Saying

IPAC-RS continues to provide education and influence and evolve OINDP science and regulations and being part of this collaborative industry voice is of huge value to our organisation.

As a member of IPAC-RS we value the opportunity to be part of a community in which we can learn from others, collaborating to evolve our collective understanding, passion for the science, and expertise.

Nikki Willis
Vectura
IPAC-RS Board Member

IPAC-RS provides the perfect platform to work with other experts in the OINDP field to identify challenges associated with product development as well as opportunities for improvement. Working Groups encourage open communication from diverse contributors across the OINDP community which drives productive discussions on potential solutions and novel approaches, as well as providing an established route for liaison with regulatory bodies in order to influence future practices and standards.

Jamie Clayton
CEO | Copley Scientific Ltd.
Nasal Working Group Sub-Committee Co-Chair

General Information

IPAC-RS Organization

IPAC-RS is governed by a Board of Directors composed of Member-company representatives.

The IPAC-RS Board of Directors establishes the consortium's mission and objectives, forms working groups to achieve specific goals, oversees budget, and provides strategic guidance.

Members and Associate Members participate in and drive working groups, which address current and emerging INDB scientific and regulatory topics.

Membership Information

Full Membership in IPAC-RS is open to corporations that develop, manufacture or contract to manufacture INDBs.

Associate Membership is open to corporations that (1) develop or manufacture components and/or devices for INDBs; (2) provide scientific or technical services relating to development and manufacture of INDBs; or (3) are eligible for full membership but have revenues of less than $75 million U.S. dollars.

Benefits of Membership

IPAC-RS enables members to advance regulatory science of INDBs, facilitating sound research to support scientifically driven policy, and developing relationships with key industry, supplier and regulator contacts. Member benefits extend to several areas including research, regulation, education and networking.

IPAC-RS membership is at the company rather than individual participant level. Accordingly, Members and Associate Members can leverage IPAC-RS with unlimited participation from interested colleagues.

IPAC-RS 2024

Members & Associate Members

Board Members

Jennifer Wylie
Chair

Lei Mao
Vice Chair

Members

AstraZeneca
François Michelon

Andy Rignall

Bespak
Lei Mao, Vice Chair
(as of July 2024)

Louise Righton
(through June 2024)

Ross Errington
(beginning July 2024)

Boehringer Ingelheim
Holger Memmesheimer

Morgana Sebenello Wolf

Catalent
Carla Vozone

David Wilcox

Chiesi
Francesca Usberti

Monica Ferrari

Genentech
Negar Sadrzadeh
(through mid-July 2024)

Stephanie Goebel
(beginning mid-July 2024)

Yoen-Ju Son

GSK
Amanda Burke

Luis Manso

Kindeva Drug Delivery
Ann Purrington

Mike Needham, Chair
(through June 2024)

James Liste
(beginning July 2024)

Lonza
Beatriz Fernandes

Kimberly Shepard
(through November 2024)

Mariam Ibrahim
(beginning December 2024)

Lupin Pharmaceuticals, Inc.
Mukul Dalvi

Kalpana Vanam

Merck & Co., Inc.
Robert Berger

Jennifer Wylie, Vice Chair
through June 2024, then Chair

Sandoz
Mariska Kraaij

Thomas Storm

Teva
Julian Blair

Lucy Fry

Transpire Bio
Abhishek Gupta

Axel Perlwitz

Vectura
Nicky Ellis

Nikki Willis

Viatris
Andrew Cooper

David Pole

Associate Members

- Aptar Pharma
- Copley Scientific
- Harro Höfliger
- Honeywell
- H&T Presspart
- Intertek
- invoX Belgium N.V.
- Koura, Orbia's Fluor & Energy Materials Business Group
- Nemera
- PPD
- Proveris Scientific Corporation
- RxPack

2024 IPAC-RS Workstream Leadership

Working Group Chairs

Aerodynamic Particle Size Distribution

Adrian Goodey, Merck & Co., Inc.

Global Regulatory Review and Outreach (GRRO)

- **GRRO Alternate Propellants (AP)**
  Sue Holmes, GSK
  Christy Gilbert, AstraZeneca
- **GRRO Brazil**
  Leticia Grecchi, Chiesi
- **GRRO China**
  Ken Shen, AstraZeneca
  Beatrice Grand-Demars, Nemera
- **GRRO Europe**
  Franz-Josef Rehmann, AstraZeneca
  Hema Khan, Vectura
- **GRRO North America**
  Ann Purrington, Kindeva
  Xiangyin Wei, Vectura (through Dec. 2024)
  Nilesh Wagh, Honeywell (from Dec. 2024

Change Management

Marielle Calderini, Vectura

Inhaled & Nasal Biologics

Kai Berkenfeld, Boehringer Ingelheim

Chris Vernall, Intertek

IPAC-RS Biologics Workshop Organizing Committee

Chris Gruenloh, PPD

Chris Vernall, Intertek

Alan Watts, Catalent

Materials and Propellants Quality Considerations

Dan Dohmeier, Kindeva

Atish Sen, AstraZeneca

Membership Committee

François Michelon, AstraZeneca

Alan Watts, Catalent

Nasal

Maria Smith, Proveris

Adam Gibbons, Bespak (through Nov. 2024)

OINDP Materials

Hera Shams Khan, Vectura

James Mullis, PPD

Product Quality Demonstration Strategy (through Dec. 2024, then converted to KN)

David Christopher, Merck & Co., Inc.

Helen Strickland, GSK

In addition to WGs, IPAC-RS has the following Knowledge Networks (KN), where members can discuss ongoing developments.

Analytical Lifecycle Management

Andy Rignall, AstraZeneca

Picture It *IPAC-RS 2024 in Photos*

Secretariat Support

The law firm of Faegre Drinker Biddle & Reath LLP serves as Legal Counsel and Secretariat to IPAC-RS. Composed of attorneys, scientists, policy analysts, and project managers, the Consortia Management Team forms and supports life sciences industry collaborations that help companies through the world address complex regulatory, compliance and other topics of mutual interest. For three decades, the team has been dedicated to helping clients in the pharmaceutical, medical device, and supporting industries.

The Secretariat provides a wide range of services, as requested by each consortium. For example, in support of IPAC-RS, the Secretariat:

- Organizes teleconferences, meetings, & workshops
- Prepares meeting agendas, summaries, & presentations
- Facilitates dialogue, consensus-building, & governance
- Prepares and issues monthly newsletters
- Manages outreach to stakeholders & prospective members
- Serves as antitrust counsel

Stay Connected

Public Website: ipacrs.org

Follow the consortium on LinkedIn: CLICK HERE

To view the schedule and register for the upcoming IPAC-RS roundtables, CLICK HERE

Visit the IPAC-RS video channel to watch recordings of previous webinars: CLICK HERE

For questions about IPAC-RS' priorities, progress, or membership, please email info@ipacrs.org or contact a member of the Secretariat.

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