2025

YEAR IN REVIEW

IPAC-RS

International Pharmaceutical Aerosol Consortium on Regulation & Science

IPAC-RS

2025 YEAR IN REVIEW

Table of Contents

Jennifer Wylie
IPAC-RS Chair

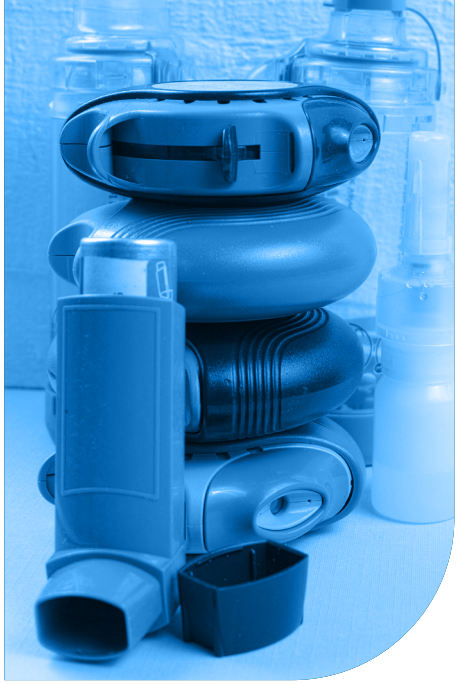
Message from the IPAC-RS Chair

We are pleased to share the 2025 IPAC-RS Year in Review, highlighting another year of collaboration, growth, and impact across the orally inhaled and nasal drugs and biologics (INDB) community. As we reflect on the past year, I am deeply grateful to all IPAC-RS member companies and representatives for their continued commitment to the consortium and for fostering exceptional industry collaboration and thought leadership. Throughout 2025, IPAC-RS continued to advance key initiatives across the industry, with a strong emphasis on scientific dialogue, regulatory engagement, and the development of impactful technical resources. IPAC-RS sustained a robust and active portfolio of projects and work streams, all closely aligned with the consortium's strategic objectives under the newly launched 2025–2027 Strategic Plan. This plan reinforces IPAC-RS's commitment to remaining the leading global technical resource for, and advocate of, the INDB industry. As detailed in this report, 2025 was another highly productive and transformative year for the consortium. Among its many accomplishments, IPAC-RS successfully convened the 2025 Nasal Innovation Forum, Advancing Science, Shaping the Future of Nasal Drug Delivery. In parallel, IPAC-RS continued to expand its scope and impact by addressing scientific and regulatory topics of growing importance to manufacturers of nasal products and biologics. The Inhaled & Nasal Biologics (INB) Steering Committee, established with Board support, remained a critical forum for identifying and addressing emerging challenges in the inhaled and nasal biologics space. We were also pleased to welcome several new companies to IPAC-RS in 2025, further strengthening the consortium's expertise and collaborative reach. I extend my sincere appreciation to all IPAC-RS member companies and participants for their commitment to scientific excellence, dedication to patients, and continued engagement in consortium activities. As we look ahead to 2026, including plans for the September 2026 Nasal Innovation Forum, we remain energized by the progress achieved and committed to advancing scientifically driven approaches that enhance the quality of INDB products for the benefit of patients worldwide.

Lei Mao
IPAC-RS Vice Chair

Message from the IPAC-RS Vice Chair

We are pleased to have witnessed another year of enthusiasm and commitment from IPAC-RS members through joint efforts from each working group that have been continuously advancing inhalation sciences and harmonizing global regulations. For new propellant transitioning, launch of the first HFO1234ze based pMDI marked a new milestone in making our environment greener while maintaining sustainability in supplying life-saving medicines to our patients. The Global Regulatory Review and Outreach (GRRO) Alternative Propellant working group has made a significant contribution to make it happen. The IPAC-RS INB Steering Committee established multiple work streams preparing for immediate and future challenges. Early in the year, a group of IPAC-RS members were invited and presented at the Inhalation Drug Delivery Association (IDDA) conference in China. The positive feedback showcased our global recognition and influence. The GRRO China group's continuous efforts will expand our collaboration with industry and regulatory organizations in emerging market regions, bringing benefits to the inhalation industry worldwide. We look forward to more exciting opportunities in 2026, including supporting continuous streamlining of regulations on complex inhaled combination product development, driving development and manufacture of new propellant inhalers and other inhalation formats to ensure sustainability of the supply satisfying unmet patient needs, being prepared for new challenges, especially related to inhaled biologics and other special inhalation delivery needs, and expediting development of novel compounds for treatment of severe lung diseases. In addition, we are open to new ideas, e.g., on AI enabled discovery and development. To achieve our 2026 goals, working with member organizations, IPAC-RS will ensure that all essential activities are fully supported with a well-aligned budget.



Who We Are

IPAC-RS has been the leading global voice of the inhaled and nasal drugs and biologics (INDB) industry for more than 25 years. Through joint research, benchmarking, collecting and analyzing data, and developing best practices, IPAC-RS advances and supports science-based regulatory approaches for INDBs, to ensure their availability, safety, efficacy and quality. IPAC-RS works collaboratively across the industry and with external experts from regulatory agencies, standard-setting bodies, academia, pharmacopeias, healthcare providers, patient groups, and other stakeholders. IPAC-RS members are based around the world, and its activities are global, with region-specific projects in North and South America, Europe, and Asia. IPAC-RS shares its findings with the larger scientific and regulatory community through publications, online tutorials, in-person training courses, webinars, and conferences.

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.

We value our participation in IPAC-RS because it gives us a trusted space to collaborate across industry, challenge our own thinking, and help shape scientific and regulatory standards that truly matter for patients. Being part of this consortium strengthens our ability to anticipate emerging trends, contribute our expertise, and learn from peers who share the same commitment to high quality, patient-centric innovation.

Monica Ferrari
Head of Global Regulatory Affairs-CMC LCM | Chiesi Farmaceutici
IPAC-RS Board Member

Being part of IPAC-RS gives me an incredible opportunity to collaborate with colleagues across the industry who share the same commitment to advancing inhalation science. This year, our work in the New Modalities Workgroup has been especially exciting as we explore the potential of powder-based nasal and pulmonary vaccines to strengthen global pandemic preparedness. I value Lonza's active involvement in these discussions, as it allows us to contribute our expertise while helping shape the future of respiratory and vaccine delivery.

Beatriz Noriega Fernandes
Principal Investigator, Manager CMC | Lonza
IPAC-RS Board Member

IPAC-RS Successes

New Leadership

In January 2025, IPAC-RS welcomed new IPAC-RS Planning Committee Members. The Planning Committee (PC) is an elected subset of IPAC-RS Board members who advise the Board on the consortium's operations in-between Board meetings. Ann Purrington (Kindeva), Andrew Cooper (Viatris) and Monica Ferrari (Chiesi) were elected to serve two-year terms. Nikki Willis (Phillips Medisize) completed her two-year term on the IPAC-RS PC.

New Members

In 2025, IPAC-RS welcomed several companies to IPAC-RS. Hikma Pharmaceuticals USA Inc, joined as a Full member and Satsuma Pharmaceuticals, Inc., Malvern Panalytical, and MOD3 Pharma joined as Associate Members. IPAC-RS is excited for active engagement and collaboration with these companies.

New Strategic Vision

In January 2025, IPAC-RS released its 2025-2027 Strategic Plan, which is available on the IPAC-RS public website.

New Collaboration Platform

IPAC-RS launched a new Microsoft Teams and SharePoint-based collaborative platform "FOCUS" with enhanced project management tools that facilitate joint drafting and editing, which enabled working groups and committees to improve their inter-connectivity and productivity.

Nasal innovation Forum

The IPAC-RS 2025 Nasal Innovation Forum (NIF): Advancing Science, Shaping the Future of Nasal Drug Delivery was held in September 2025 in New Jersey. Over 140 people from 50+ life sciences companies and other organizations participated in the two-day discussions. The presentations and recordings are available at the link above. Due to the Forum's success, a NIF 2026 event is being planned.

2025 Looking Back

IPAC-RS Board of Directors Meeting Highlights

April 11 | *Virtual*

The IPAC-RS Board of Directors met to review the current IPAC-RS portfolio. The Board and WG chairs were joined by Associate Member representatives and several observers from companies considering membership.

June 26 | *Hybrid*

The IPAC-RS Board met in Washington, DC for a hybrid meeting. The agenda included a debrief from the just-concluded Congress of the International Society for Aerosols in Medicine (ISAM) and the pre-Congress workshop on new-generation propellants, updates from a sister consortium International Pharmaceutical Aerosol Consortium (IPAC), and consideration of a revised membership structure, and other strategic topics.

October 14 | *Virtual*

The IPAC-RS Board, Associate Member contacts, and invited observers met and reviewed the consortium's portfolio, progress, and plans.

October 28 | *Virtual*

The IPAC-RS Board and Planning Committee held a joint meeting to review the 2025 budget and approve the 2026 Statement of Work.

December 9 | *Hybrid*

The IPAC-RS Board met the day before DDL 2026 in Edinburgh, Scotland. The agenda included 1) an overview of the Current Nasal Products Landscape, presented by Carolyn Berg (Catalent), 2) update on the planning for NIF-2026, 3) update on the APSD database platform launch, 4) debrief from meetings of the Inhalation Drug Delivery Association (China), 5) updates from IPAC on environmental issues, 6) a discussion on the importance of commenting on USP Chapter 1664.1 about leachables testing in inhalation and nasal products, and 7) an afternoon Executive Session for Board members only. Several invited EPAG members attended the IPAC-RS breakfast with the Board and Associate Members also attending the meeting and dinner.

Working Group (WG) & Knowledge Network (KN)

Discussion Highlights, Publications, & Comments

Projects & Discussions

- **IPAC-RS and IPAC** conducted a survey of regulatory approaches around the world regarding the propellant transition.
- Several WGs (Global Regulatory Review and Outreach North America WG (**GRRO-NA**), Aerodynamic Particle Size Distribution (**APSD**), and **Nasal WG**) discussed the new Product Specific Guidances (PSGs) issued by the US Food and Drug Administration (FDA) and submitted IPAC-RS responses to FDA throughout 2025.
- The **Inhalation and Nasal Biologics (INB) Steering Committee** discussed reports from the subteams developing their roadmaps in the areas of liquids and powders manufacturing, analytical, novel modalities, and regulatory and created a searchable database containing member's expertise. The Regulatory INB Subteam invited interested regulatory professionals to brainstorm and develop a case-study submission for an inhaled biologic. The INB "liquid formulation and manufacturing" subteam is progressing the creation of an Excel spreadsheet compiling information about excipients used in approved products or described the literature.
- The **Change Management WG** completed a mature draft of its manuscript ***Change Management Considerations for OINDP and other Drug Device Combination Products in the European Union.*** After completing this publication, the WG plans to start addressing change management approaches from the US regulatory perspective.
- **GRRO China** debriefed from the Oct./Nov. IDDA Conference in Nanjing, China, where two presentations were given by IPAC-RS members - Lei Mao (Transpire Bio) presented an overview of IPAC-RS, and Geraldine Venthoye (Phillips Medisize) presented a view from the IPAC-RS GRRO AP WG: ***Key Considerations When Reformulating Pressurized Metered Dose Inhalers with Low Global Warming Potential Propellants (LGWPP).*** The group also discussed and compared pharmacopeial documents from China, EU and US. Finally, the group shared experiences related to the drug registration testing process and overarching legislation in China, and discussed the ChP 0111 Inhalation Preparations chapter.
- **GRRO Alternate Propellants** prepared a brief summary for inclusion in a presentation at IDDA (see above bullet).
- **GRRO China** discussed the final ChP chapter "9017 Guideline for Evaluation of Spray Characteristics of Inhalation and Nasal Preparations" and collaborated with GRRO-North America, GRRO-Europe and Nasal WG to contrast and compare approaches to spray testing across regions.
- **IPAC-RS Dissolution** subteam is considering the possibility of a round robin testing to advance the data-based discussions of method standardization and validation.
- The **Nasal Product Reliability subteam** re-started work on developing consensus recommendations for demonstrating reliability of emergency-use nasal products.
- The **APSD WG** met to discuss ongoing projects, which include:
  - development of the APSD database,
  - plans for the High-Payload NGI DPI experiment,
  - updates on planning for a 2026 workshop at USP, which will address APSD methods and nasal products needs in the pharmacopeia, and updates from EPAG, such as work on mixed inlets

Projects & Discussions *continued*

- **IPAC-RS Materials WG, GRRO NA, and Nasal WG** reviewed the draft USP chapter ⟨1664.1⟩ Assessment of Leachables in Orally Inhaled and Nasal Drug Products published in *PF 51(6).*
- **IPAC-RS Materials WG** launched a Sustainability Subteam that is drafting a publication addressing regulatory, science and technical challenges and approaches to advancing circularity for OINDP container closure system, device, and other key product elements.
- Leaders of **Analytical Lifecycle Management KN and GRRO NA** have discussed Established Conditions concepts from ICH Q12 guideline entitled "Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management" and considered how to implement them to orally inhaled and nasal products. The KN also discussed training materials for that ICH guideline, and reviewed a relevant article co-authored by FDA CDER staff. The paper describes regulatory expectations and case studies, illustrating what regulators might want to see, and in what format, when changes are made.

Comments to Regulatory Agencies

- **Comments to the US Department of Health and Human Services (DHHS)**
  - IPAC-RS submitted comments in response to the "10:1 Deregulation" Request for Information. Among key topics raised by IPAC-RS are the need for better inter-center alignment at FDA, and a more streamlined and clearer regulatory approach for pMDIs with new propellants. A copy of the submitted letter and appendix are available on the corresponding Docket of the Agency for Healthcare Research and Quality (AHRQ).
- **Comments to the US FDA**
  - IPAC-RS responded with comments to several Product Specific Guidances (PSGs) issued by FDA throughout 2025.
  - IPAC-RS reviewed but decided not to prepare comments on the draft FDA guidance Unique Device Identifier Requirements for Combination Products, which includes inhalers and nasal sprays among its examples.
- **Comments to the European Medicines Agency (EMA)**
  - **Leachables and Extractables**: IPAC-RS joint comments (prepared by the Materials WG and GRROs) on the draft ICH Q3E guideline on extractables and leachables were submitted to EMA. The final submission is available on the IPAC-RS website. IPAC-RS will be submitting its comments to the FDA in January 2026 as well.
- **Comments to Health Canada**
  - IPAC and IPAC-RS submitted joint comments on the Health Canada Risk management approach for per- and polyfluoroalkyl substances (PFAS). Copies of the comments are available on the IPAC-RS website.
- **Other**
  - IPAC-RS prepared and submitted a letter of support for the continuation of the Center for Research on Complex Generics. CRCG has provided a valuable forum for regulators, industry, academics and other stakeholders to become educated on each other's perspectives with regard to critical challenges in the development of complex generics, including those for inhaled and nasal delivery.

All IPAC-RS Comments prior to 2025 are posted on our website.

Publications

- (February 2025) Materials Compatibility Considerations for the Transition to Low Global Warming Potential Propellants for Pressurized Metered Dose Inhalers ***AAPS PharmSciTech***.
- (March 2025) PQRI (of which IPAC-RS is a member) published a 4th paper from the Inhaled BCS working group: iBCS: 4. Application of the Inhalation Biopharmaceutics Classification System to the Development of Orally Inhaled Drug Products ***Molecular Pharmaceutics***
- (April 2025) **IPAC-RS: A Review of 2024 Initiatives and Priorities** *Inhalation Magazine*
- The October 2025 issue of the ***Inhalation Magazine*** has several articles from IPAC-RS groups: Inhalation - INH1025
    - ***"Point of View: A better way to set specifications and control quality -General Concepts and examples***" (Product Quality Demonstration Strategy (PQDS) WG)
    - Plus ***Let's Dig Deeper: An interview with the authors*** (PQDS WG)
    - ***Excipients to Consider in Development of Intranasal Pediatric Products*** (Nasal Pediatric Subteam)
- (October 2025) A manuscript summarizing the IPAC-RS/ISAM Biologics workshop held in August 2023 titled "Inhalable and Nasal Biologics: Analytical, Formulation, Development, and Regulatory Considerations" appeared in the ***Journal of Aerosol Medicine and Pulmonary Drug Delivery***
- (December 2025) The IPAC-RS GRRO Alternate Propellants WG published a white paper **Opportunities to Facilitate the Transition of pMDIs to Third-Generation Propellants** summarizing the current landscape and remaining gaps in regulatory approaches to pMDIs using new propellants – based on the
    - December 2024 CRCG/FDA workshop,
    - 2025 FDA GDUFA meeting, and
    - FDA presentation at RDD-2025.
- (December 2025) The 2025 Nasal Innovation Forum (NIF) Organizing Committee published a "Summary of the 2025 NIF and Audience Feedback" available on LinkedIn and on the website.

All IPAC-RS publications prior to 2025 are posted on our website.

Regulatory Agencies, Standards Organizations, and Other Stakeholders

2025 External Engagement

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

IPAC-RS and ISAM coordinated on a Pre-Congress workshop on the transition to New Generation Propellant MDIs, held in conjunction with the ISAM 2025 Congress. Presentations are available on the IPAC-RS website.

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 prepared and submitted comments to the US DHHS "Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation To Make American Healthy Again." Among key topics raised by IPAC-RS are the need for better inter-center alignment at FDA, and a more streamlined and clearer regulatory approach for pMDIs with new propellants.

IPAC-RS supported the continuation of The Center for Research on Complex Generics (CRCG) by submitting a letter of support and will also assist with developing the program and recommending speakers for the a workshop to be held on October 14-15, 2026.

IPAC-RS and the US Pharmacopeia (USP) are re-engaging to prepare a Joint Workshop with participation of US FDA and European Pharmacopoeia, with a working title "Hot Topics in OINDP Performance Testing", to be hosted by USP in Rockville, MD in early 2027.

Representatives of the European Pharmaceutical Aerosol Group (EPAG) attended the IPAC-RS networking breakfast during DDL 2025. IPAC-RS has continued coordinating with EPAG throughout the year, to keep both organizations abreast of relevant developments and to collaborate on topics of mutual interest as appropriate.

Regulatory Agencies, Standards Organizations, and Other Stakeholders

Monitoring, Communications and Networking

IPAC-RS tracked global regulatory developments and standards that are relevant for INDBs, 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 INDBs. IPAC-RS 2025 Comments are summarized on page 8.

Tracking New MDIs: IPAC-RS maintains a public-facing webpage to store relevant information about the scientific and technical aspects of meeting patients' needs with new-generation MDIs.

The IPAC-RS Board, Planning Committee, WGs, and KNs continued to meet regularly, network, and advance IPAC-RS projects throughout 2025.

The IPAC-RS community stays connected and productive using the members-only IPAC-RS Collaboration 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 recordings of IPAC-RS webinars and other resources.

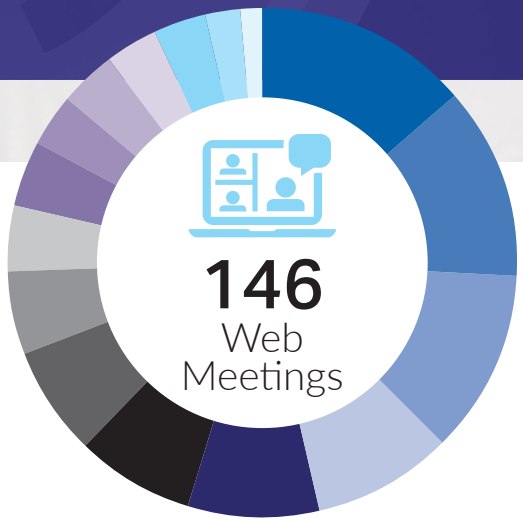
2025 By the Numbers

4 Board Meetings

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

2 Public Forums/Webinars

- Webinar: IPAC-RS 4th Sustainability Roundtable *Designing for a Sustainable Future: Strategies to Address the Device and Delivery System Lifecyle* (April 1, 2025). Agenda, slides, and recording are available here.
- Forum: The IPAC-RS 2025 Nasal Innovation Forum: *Advancing Science, Shaping the Future of Nasal Drug Delivery* (September 18-19, 2025). A Forum summary and the presentations and recordings are available here.



- 20 Aerodynamic Particle Size Distribution *(Full WG and Core)*
- 18 GRRO North America *(plus Dissolution subteam)*
- 17 GRRO Alternate Propellants *(plus drafting team)*
- 13 Nasal Innovation Forum (2025) Organizing Committee
- 12 Materials
- 11 GRRO China
- 10 Change Management
- 8 Planning Committee
- 6 Materials & Propellants
- 6 GRRO Europe
- 5 Inhaled & Nasal Biologics Steering Committee *(Full SC only)*
- 5 Nasal *(Full WG only)*
- 5 Nasal Innovation Forum (2026) Organizing Committee
- 5 Analytical Methods Lifecycle Management
- 3 Board Subcommittee on Budget/Structure
- 2 Membership Committee

What's Next

Looking Ahead to 2026

Guided by the priorities laid out in the 2025-2027 Strategic Plan, IPAC-RS will continue working to remain a leader in the INDB industry in 2026.

- **GRRO Europe** will have a guest speaker at its January 2026 meeting to discuss regulatory trends, Medical Device Regulation (MDR) revision, and other regulatory trends for medical devices and combination products in the UK, EU, and globally.
- **GRRO China** is leading preparation of an IPAC-RS/NIFDC roundtable, along with (co)chairs of IPAC-RS WGs working on Alternative Propellants, Biologics, Materials, and APSD. The roundtable is currently being planned for second quarter 2026.
- Planning for the next **IPAC-RS Nasal Innovation Forum 2026** is ongoing. **SAVE THE DATES: September 16-17, 2026**, in New Jersey. The Organizing Committee is planning a program that will address emerging trends, devices, regulatory issues and innovations in small-molecule and biologics delivered intranasally. A poster session will be a new addition to the event (poster abstracts due by April 15, 2026). Click here for more information.
- IPAC-RS representatives will participate on the Organizing Committee to assist with developing the program and recommending speakers for the CRCG Advancing Bioequivalence Frameworks for Inhalation and Nasal Drug Products: Optimizing In Vitro, In Vivo, and In Silico Methods Workshop to be held on October 14-15, 2026.
- IPAC-RS Board agreed to re-establish a working group focused on Devices. Details of the scope and priorities, as well as leadership and membership of the new working group, will be determined in early 2026.
- The IPAC-RS Board of Directors will meet two times in 2026, at hybrid meetings in April (London, UK) and October (Washington, DC).

What our Members are Saying

Since joining IPAC-RS, I've been truly inspired by this unique organization and its strong sense of community. IPAC-RS stands out for its commitment to open collaboration, cutting-edge innovation, and meaningful partnerships uniting diverse experts in the inhalation and nasal drug delivery industry. Personally, the insightful discussions, workshops, and working groups have greatly expanded my network and deepened my understanding of key regulatory and scientific challenges. I've learned immensely from the shared expertise in this impactful consortium. I'm excited about Malvern Panalytical's contributions and the value it brings to advancing patient solutions.

Tom Ormsbee
Business Development Manager | Malvern Panalytical
Nasal Working Group

IPAC-RS plays a vital role in providing education, influence, and leadership in the ongoing evolution of OINDP science and regulation. As a niche, highly specialised consortium focused on nasal sprays and dry powder inhalers (DPIs) etc. technologies, it brings together a unique depth and breadth of expert knowledge. Being part of this collaborative and authoritative industry voice delivers significant value to our organisation.

As a new member of IPAC-RS in 2025, I greatly value participation in this focused community, where expertise is shared, collaboration advances our collective understanding, and a shared passion for the science underpinning nasal and inhaled drug delivery continues to drive the field forward.

Kalpita Mehta
Principal, Combo Product and Medical Device Expert | Hikma
Change Management Working Group

IPAC-RS provides a vital forum for industry-setting insights, market trends and addressing challenges. Lonza's participation is such a group is vital to the overall success of my organization. I look forward to continuing participating in this fellowship and promoting the advance of orally inhaled drug products.

Rui Alberto Teixeira Cruz
Associate Principal Engineer, Product Development | Lonza
IPAC-RS Inhaled & Nasal Biologics Steering Committee Co-Chair

IPAC-RS is an inspiring platform that brings together OINDP experts to address industry challenges and drive meaningful change. As the field evolves, it fosters knowledge sharing to identify gaps and develop science- and experience-based solutions aimed at improving patient outcomes. Since joining in 2022, and now contributing as part of Aptar Pharma, I view IPAC-RS as a forward-looking consortium where collaboration truly drives impact.

Sana Hosseini
Principal Engineer | Aptar Pharma
IPAC-RS Inhaled & Nasal Biologics Subteam, Nasal Working Group, and 2026 NIF Organizing Committee Co-Chair

What our Members are Saying

IPAC-RS provides its members an opportunity to contribute meaningfully to shaping industry standards and to engage directly and constructively with regulatory bodies. Members also have many opportunities to collaborate and network with other stakeholders, fostering valuable connections. Importantly, Members stay informed about new and evolving global regulations, helping them to stay ahead of the curve. The wide array of IPAC-RS initiatives ensures a rich and diverse experience for everyone involved.

Matthieu Rozanski
Director Regulatory Affairs Global Pharma | Aptar Pharma
IPAC-RS Associate Member

2025 was a special year for Harro (and me personally) as an IPAC-RS Associate Member. We had the privilege of co-organizing the Nasal Innovation Forum 2025, and it was an electrifying experience that we all feel re-energized the nasal drug delivery space both locally and internationally. It is always super interesting and stimulating to take part in the working groups' meetings and discuss scientific challenges and solutions with peers as passionate as we are about respiratory delivery. We're enthusiastically engaging in the 2026 IPAC-RS activities and, especially, looking forward to the Nasal Innovation Forum 2026!

Irene Rossi
Respiratory Science Expert, Pharmaceutical | Harro Höfliger
IPAC-RS Inhaled & Nasal Biologics Steering Committee, Nasal Working Group, and 2026 NIF Organizing Committee Co-Chair

I joined IPAC-RS in 2025 to actively contribute my experience, and that of my company, to a collective industry forum focused on advancing inhaled and nasal drug delivery for patient benefit. Through my participation, including the highlight of the "Designing for a Sustainable Future" roundtable, I have been able to share evidence, learn from peers, and help shape balanced technical, regulatory, and environmental approaches that prioritise patient safety. This engagement through IPAC-RS allows my company to contribute meaningfully to wider industry thinking while strengthening how we develop safe, effective, and sustainable solutions for patients.

Shaun Williams
Product Engineering Manager | Bespak
Materials Working Group

Being part of IPAC-RS as an active member and chair of a Working Group is extremely valuable. It offers incredible opportunities to share knowledge, exchange perspectives, and provide meaningful contribution to alignment and advancement of the OINDP industry. It is a privilege to be involved supporting innovation, dialogue and driving initiatives that can influence industry and regulators. The impactful collaboration within IPAC-RS ensures we stay at the forefront of scientific and regulatory developments while helping shape best practices that will benefit patients.

Marielle Calderini
Senior Manager - Regulatory Affairs | Phillips Medisize
IPAC-RS Change Management Working Group Chair

IPAC-RS 2025

Members & Associate Members

Board Members

Jennifer Wylie
Chair

Lei Mao
Vice Chair

Members

AstraZeneca
François Michelon

Andy Rignall

Bespak
Sarah Bunyan

Ross Errington

Boehringer Ingelheim
Holger Memmesheimer

Morgana Sebenello Wolf

Catalent
Carla Vozone

David Wilcox

Chiesi
Francesca Usberti

Monica Ferrari

GSK
Luis Manso

Amanda Burke
(through Sept. 2025)

Poonam Gulati
(beginning Oct. 2025)

Hikma
Arpita Pal

Nuno Silva

Kindeva Drug Delivery
James Lister

Ann Purrington
(through September 2025)

Nick Smalley
(beginning October 2025)

Lonza
Beatriz Fernandes

Mariam Ibrahim

Lupin Pharmaceuticals, Inc.
Mukul Dalvi

Kalpana Vanam

Merck & Co., Inc.
Robert Berger

Jennifer Wylie, **Chair**

Phillips Medisize
Nicky Ellis

Nikki Willis

Sandoz
Michael Malaun

Thomas Storm

Teva
Brendan Muldoon

Brandon Wood

Lucy Fry
(through March 2025)

Transpire Bio
Lei Mao, **Vice Chair**

Abhishek Gupta

Axel Perlwitz

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
- Malvern Panalytical
- MOD3 Pharma
  (became part of Aptar in July 2025)
- Nemera
- PPD
- Proveris Scientific Corporation
- RxPack
- Satsuma Pharmaceuticals, Inc.

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.

2025 IPAC-RS Workstream Leadership

Working Group Chairs

Aerodynamic Particle Size Distribution

Adrian Goodey, Merck & Co., Inc.

Analytical Lifecycle Management

Andy Rignall, AstraZeneca (through Dec. 2025)

Kerstin Güttler, Sandoz (from Dec. 2025)

Global Regulatory Review and Outreach (GRRO)

- **GRRO Alternate Propellants (AP)**
  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**
  Nilesh Wagh, Honeywell
  Ann Purrington, Kindeva (through Sept. 2025)
  Xiangyin Wei, Phillips Medisize (beginning Dec. 2025)

Change Management

Marielle Calderini, Phillips Medisize

Materials

Jamie Mullis, PPD

Hera Shams Khan, Phillips Medisize

Materials and Propellants Quality Considerations

(sunset as of June 2025)

Dan Dohmeier, Kindeva

Atish Sen, AstraZeneca

Inhaled & Nasal Biologics (INB)

Kai Berkenfeld, Boehringer Ingelheim

Rui Cruz, Lonza

- **Subteams**

  Analytical – Chris Gruenloh, PPD

  Formulation, Manufacturing & Devices (Liquids) – Elena Galfre, Phillips Medisize

  Formulation, Manufacturing & Devices (Powders) – Shyamala Ivatury, AstraZeneca and Rui Cruz, Lonza

  Regulatory – Ruth Cordoba, AstraZeneca

  New Modalities – Mireia Puig, Phillips Medisize and Mark Parry, Intertek

Membership Committee

François Michelon, AstraZeneca

Alan Watts, Catalent

Nasal

Maria Smith, Proveris

- **Subteams**

  Advanced Methods – Bill Doub, IPAC-RS Science Advisor

  Pharmacopeial & Regulatory Standards – Jolyon Mitchell, IPAC-RS Science Advisor & Jamie Clayton, Copley

  Pediatrics – Sana Hosseini, Aptar

  Nasal Casts – Alyssa Rubio, Proveris & Jamie Clayton, Copley

  Reliability of Emergency Use Nasal Products – Annmarie Gambrill, Viatris

Nasal Innovation Forum (NIF) 2026 Organizing Committee

Irene Rossi, Harro Höfliger

Mark Parry, Intertek

Sana Hosseini, Aptar

Picture It *IPAC-RS 2025 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

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

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