2023 YEAR IN REVIEW

IPAC-RS

International Pharmaceutical Aerosol Consortium on Regulation & Science

TABLE OF

CONTENTS

A MESSAGE FROM THE

IPAC-RS Chair

How time flies! Another year is behind us and I'm already three quarters of the way through my term as Chair of IPAC-RS. 2023 may have gone quickly but I think it will, when we look back in years to come, prove to be quite a pivotal time for the IPAC-RS consortium.

In 2022 we started to lay the foundations of what the future should look like for IPAC-RS. We focused in on 3 areas which we believed would be key to the industry, and more importantly, to patients. These were (i) the alternative propellant transition facing the pMDI industry, (ii) the increasing pipeline of biological and macromolecule therapies, and (iii) nasal as a route of administration. The latter is certainly not a new topic, but it is definitely one with renewed interest given the growing pipeline of biological and macromolecule treatments.

The great test of any new initiative are the real actions that follow once the talking is finished and everyone returns to their 'day job'. Each of these 'initiatives' passed this test with flying colors. IPAC-RS held the Inhaled / Nasal Biologics Roundtable in May and the Transition to Low GWP propellants workshop in October. Both of these, and other events, have been very well attended and have triggered much further discussion and debate within the consortium and beyond. There are several other events in the planning stages for 2024, but one thing is for sure, these critical topics are now embedded in our DNA as an organization, and the wider industry.

If the high popularity and attendance of such events is not enough to demonstrate the relevance of the organization, the membership of IPAC-RS remains strong. There will always be a degree of 'churn' in any group with such diverse membership as strategies develop and priorities change in each member organization. But here again we have also seen encouraging signs of the value of IPAC-RS, with multiple new Members and Associate Members (Transpire Bio, invoX Belgium, N.V., Impel, and Intertek) joining during 2023.

And what of 2024 and beyond? I believe that IPAC-RS is as relevant today as it has ever been. Not only are the new initiatives already mentioned rapidly gaining momentum, and membership is healthy, but our core 'heartland' activities around the GRRO and technical working groups are still making great contributions to our members, the wider industry, and ultimately the patients that rely on the treatments which we develop and manufacture. And ultimately that is what really matters; making people's lives healthy, longer and happier. What a wonderful thing for us all to be part of …

Thank you all for your continued collaboration and engagement. I look forward to a great year!

Mike Needham
Global R&D Director; Product, Process and Device Development
Kindeva Drug Delivery

ABOUT IPAC-RS

WHO WE ARE

IPAC-RS is an international association that seeks to advance the science of orally inhaled and nasal drug products (OINDP). Representing the OINDP industry for 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 OINDP industry, with a focus on Chemistry, Manufacturing and Controls (CMC).

Mission

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

IPAC-RS SUCCESSES

NEW IN 2023

Addressing Emerging Regulation and Advancing Innovation in 2023

Sustainability, Alternative Propellants, PFAS

In 2023, IPAC-RS continued its roundtable series, and hosted a webinar on February 7, 2023, ***Advancing Sustainability of Device and Container Closure Systems (Part II)***. Presenters and panelists discussed renewable feedstocks, currently available technologies, as well as business and regulatory considerations for sustainable or recyclable materials and devices. Visit the Roundtable webpage for presentation PDFs and a link to the recording.

IPAC-RS and IPAC conducted a joint industry-wide survey ***IPAC/IPAC-RS Survey: Impact of PFAS Restrictions on OINDPs***, in order to gather relevant for preparing the IPAC-RS/IPAC joint comments to ECHA REACH proposal for PFAS restrictions.

- IPAC-RS IPAC Preliminary Joint Comments to ECHA REACH on Proposal to Restrict PFAS (May 2023) CLICK HERE
- IPAC-RS IPAC ECHA REACH Feedback Final Submission (Sept 20, 2023) CLICK HERE

IPAC-RS also prepared and submitted comments to Health Canada Risk Management Report Regarding PFAS (July 2023) CLICK HERE

IPAC-RS organized and conducted a free, public workshop entitled "IPAC-RS Workshop on the Transition to Low Global Warming Potential (LGWP) Propellants for Metered Dose Inhalers", and posted a summary and other related materials at IPAC-RS Workshop: Transition to LGWP Propellants for MDIs (ipacrs.org)

IPAC-RS conducted a survey on Stakeholder Perspectives On Switching Current Pressurized Metered Dose Inhalers To New Propellants. (AltProp Survey Summary Oct 2023.pdf (ipacrs.org))

Large Molecules and Biologics

IPAC-RS conducted a benchmarking survey ***"Large Molecules and Biologics Delivered by Inhalation or Intranasally"*** as a way to identify gaps in regulatory science, pinpoint areas that might benefit from a collaborative approach, and to gauge members' interests in specific initiatives. Addressing biologics was identified by the IPAC-RS Board of Directors as a strategic priority back in 2021, and IPAC-RS held several roundtables and workshops since then, involving industry, academia, and regulators (see page 7). IPAC-RS used results of this latest survey to prioritize CMC and preclinical topics for further discussion.

In 2023, IPAC-RS also co-organized with the International Society for Aerosols in Medicine (ISAM) a public workshop "Addressing CMC Questions for Development of Inhaled/Intranasal Biologic Products" in conjunction with the ISAM Congress 2023. The program included speakers from industry, US FDA, and the German regulatory authority BfArM. A conference report is now in preparation.

Nasal Products

In 2023, IPAC-RS made progress on another strategic priority – Nasal products. The Nasal Working Group was formed to address regulatory-science issues for intranasal products. In its first phase, the group is addressing specific through Subteams: Pediatrics; Pharmacopeial Standards and Regulatory Guidance Review and Gap Analysis; Reliability Expectations; Advanced Methodologies; Statistics and Bioequivalence Approaches.

New Members

In 2023, IPAC-RS welcomed a new Member and several Associate Members. IPAC-RS is excited for active engagement and collaboration with these companies:

New Members:

- Transpire Bio (January)

New Associate Members:

- Impel (January)
- invoX Belgium, N.V. (FKA Softhale) (July)
- Intertek (November)

LOOKING BACK

IPAC-RS BOARD OF DIRECTORS MEETING HIGHLIGHTS

MAR 28 | VIRTUAL

The IPAC-RS Board of Directors met to review the IPAC-RS portfolio, including plans and progress for all working groups, and to discuss external developments, such as the PFAS ECHA proposal. The IPAC-RS Board was joined by Associate Member representatives and representatives from several prospective companies interested in joining IPAC-RS.

MAY 23-24 | HYBRID

The IPAC-RS Board of Directors held a meeting to discuss biologics delivered by inhalation or intranasally, as well as ongoing key topics, such as transition to LGWP propellants, PFAS restrictions, updates from IPAC and PQRI, and a debrief from recent conferences (CRCG/FDA, RDD). A recording of the first day, focused on biologics delivered by inhalation or intranasally, is available to IPAC-RS members.

SEP 20 | VIRTUAL

The IPAC-RS Board of Directors met to review and discuss the consortium's working group portfolio. The IPAC-RS Board was joined by Associate Member representatives and representatives from several prospective companies interested in joining IPAC-RS

OCT 23 | VIRTUAL

The IPAC-RS Board of Directors met and approved the consortium's budget and statement of work for 2024, and refined plans for the in-person meeting in December.

DEC 4-5 | HYBRID

The IPAC-RS Board of Directors met before the DDL conference in Edinburgh, UK. The Board discussed developments related to LGWP propellants, inhaled and nasal biologics, and nitrosamines. The IPAC-RS Nasal Working Group as well as invited guests - Professor Regina Scherließ (Kiel University) and Professor Ben Forbes (King's College London) presented their work to the Board. The meeting wrapped up with an update from Inhalanda (EDQM), by Jan Olof Svensson (AstraZeneca), and a networking lunch with representatives from EPAG.

WHAT OUR MEMBERS

ARE SAYING

"The Cascade Impaction Working Group of IPAC-RS has been exceptionally busy in 2023. In addition to ongoing projects focusing on design of a database, publications and conference presentations, our members brought new ideas to the table for general awareness and collaboration, such as particle sizing of high-payload DPIs, the use of the pressure-drop to qualify impactors, and others. IPAC-RS CI WG has also continued to strengthen communications with the US and European Pharmacopieas to promote harmonization whenever possible. In particular, the CI WG is partnering with the USP to develop a workshop on the science and regulation of OINDPs for 2025."

Adrian Goodey
Senior Principal Scientist, Analytical R&D | Merck & Co., Inc.
IPAC-RS Cascade Impaction Working Group Chair

"Lonza's membership in IPAC-RS is valued for enabling us to better serve our clients and address new challenges as our industry evolves. In 2023, Lonza specifically benefited from engaging with IPAC-RS around high respirable mass aerosol characterization. IPAC-RS not only provides an effective platform for collecting comments and alerting regulatory agencies to some of the limitations of incumbent aerosol characterization approaches, but also provides access to world-class experts who can offer insights into proposed solutions and collaborate to demonstrate a path forward."

Cameron Kadleck
Sr. Scientist, Product Development | Lonza

"As a relatively recent addition to IPAC-RS, we at Intertek have appreciated the energy and enthusiasm that members bring to the organization to address common problems jointly. World leading scientists collaborating to tackle pressing technical and regulatory issues is not common in the industry. The work IPAC-RS does, and the active and collaborative participation of members, is helpful and inspiring! We look forward to contributing more as our involvement in key working groups increases, and solving the biggest challenges the respiratory community has."

Chris Vernall
Commercial Director | Intertek Pharmaceutical Services
IPAC-RS Biologics Workshop Organizing Committee Co-Chair

"IPAC-RS is a great forum to discuss and collaborate on pressing issues associated with OINDP development. Members can learn about the ongoing challenges in the technical and regulatory areas, provide constructive solutions, and influence science and regulatory development through collaborations with and outreach to global regulatory agencies, pharmacopeial groups, academic experts, and other interested parties."

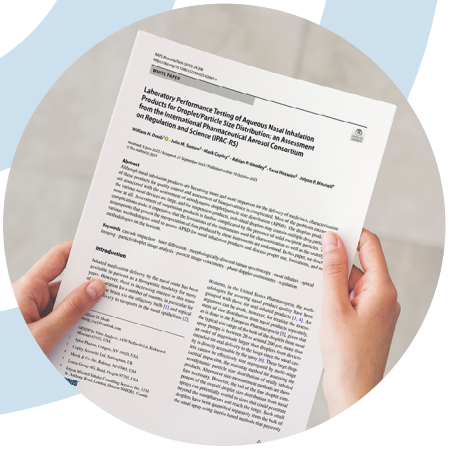
Xiangyin Wei
Manager - Regulatory Affairs (Combination Products & Medical Devices) | Vectura Limited, a member of the Vectura Group of companies
IPAC-RS GRRO North America Co-Chair

WORKING GROUP AND KNOWLEDGE NETWORK

DISCUSSION HIGHLIGHTS

PROJECTS AND DISCUSSIONS

- The CI WG conducted a survey - ***IPAC-RS Laser Diffraction - Characterization of Nasal Products Survey***.
- GRRO NA and CIWG discussed scheduling a joint workshop with USP focused on topics that affect the OINDP industry.
- GRRO NA discussed (1) IPAC-RS recent and planned interactions with FDA and CRCG, (2) reports from recent public FDA meetings, with a focus on sessions relevant for OINDPs, (3) reviewed recent FDA and USP publications and their impact on OINDPs, (4) recently issued relevant guidances, such as FDA's policy on testing for methanol in any alcohol containing product, including inhalation products.
- GRRO NA discussed outcomes of the FDA CRCG conference ("Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products") and an industry workshop for inhaled biologics ("Inhaled Biologics: Challenges, Opportunities, and Future Directions"), hosted by Lyohub.org and AstraZeneca.
- Materials WG discussed the role of CDRH in the review of OINDPs, reported on the WG's updates on the progress of encouraging better CDER-CDRH alignment, ongoing modernization of the 510(k) process, and other developments.
- IPAC-RS GRRO-China discussed (1) the draft Chinese Pharmacopeia's draft document on metal canisters for inhalation products, (2) a document issued by the NMPA Center for Food and Drug Inspection (CFDI) entitled "Guidelines for On-Site Inspection of Inhalation Preparations." (An English translation was made available to IPAC-RS members.) and (3) new guidelines addressing plastic packaging and components issued from the Chinese Pharmacopoeia. GRRO-China also updated and discussed its tracker of Chinese Guidelines and Standards.
- The GRRO-Alternate Propellants (AP) WG discussed recent feedback from FDA that pMDIs with new propellants will require clinical studies and therefore a new NDA. GRRO AP also discussed the IPAC joint Open Letter regarding the European F-gases regulations.
- GRRO AP, GRRO NA, Materials WG and Materials & Propellants assisted with the preparation for the October 11th LGWP propellants October 11th workshop (see page 13).
- Leaders of IPAC-RS GRRO North America, Europe, Brazil, and China met to discuss regulatory developments in various world regions and to coordinate activities, as appropriate.



PUBLICATIONS

External Presentations:

- At this year's AAPS Annual Meeting, Cascade Impaction (CI) WG Chair Adrian Goodey (Merck & Co., Inc.) presented on fine particle dose and stage groupings (his presentation is available to IPAC-RS members). Sue Holmes, GSK (GRRO-NA, GRRO-AP) presented results of the IPAC-RS Survey on alternative propellants for pMDIs. Both presentations were well received.
- IPAC-RS Chair and Vice Chair, Mike Needham (Kindeva) and Jen Wylie (Merck & Co., Inc.), presented an overview of IPAC-RS at the Plenary Meeting of the European Pharmaceutical Aerosol Group (EPAG), and learned about the current EPAG portfolio. IPAC-RS and EPAG agreed to continue and strengthen collaboration on topics of mutual interest, such as cascade impaction.

Publications

- Biocompatibility Considerations for Orally Inhaled and Nasal Drug Products and other Drug Device Combination Products *PDA Journal of Pharmaceutical Science and Technology* (November 2023) CLICK HERE
- Laboratory Performance Testing of Aqueous Nasal Inhalation Products for Droplet/Particle Size Distribution: an Assessment from the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS) *AAPS PharmSciTech* (October 2023) CLICK HERE
- Limitations of metrics used in the regulation of aerodynamic particle size distributions (APSDs) of orally inhaled products (OIPs) - An interview with Adrian Goodey of the IPAC-RS Cascade Impaction Working Group on reactions in the inhaler community to a series of published articles *Inhalation Magazine* (October 2023) CLICK HERE
- Good Practices for the Laboratory Performance Testing of Aqueous Oral Inhaled Products (OIPs): an Assessment from the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS) *AAPS PharmSciTech* (March 2023) CLICK HERE
- IPAC-RS Summary of Global Regulatory Developments 2022 (August 2023) CLICK HERE
- An Overview and Discussion of N-nitrosamine Considerations for Orally Inhaled Drug Products and Relevance to Other Dosage Forms *AAPS PharmSciTech* (January 2023) CLICK HERE

All IPAC-RS publications prior to 2023 are posted on our website.

CLICK HERE

COMMENTS

- IPAC-RS Comments on USP <429> “Particle Size Analysis by Laser Light Diffraction” [PF 49(5)] (November 1, 2023) CLICK HERE
- IPAC-RS IPAC ECHA REACH Feedback Final Submission (Sept 20, 2023) CLICK HERE
  - PQRI position paper submitted to ECHA on September 23, 2023. CLICK HERE
- IPAC-RS and IPAC Joint Comments to Environment and Climate Change Canada and Health Canada on Draft State of PFAS Report and Risk Management Scope for PFAS (July 17, 2023) CLICK HERE
- IPAC-RS Comments on Pharmacopoeial Forum 49(2) Chapter <1031> “The Biocompatibility of Materials Used in Drug Containers, Medical Devices, and Implants” (May 2023) CLICK HERE
- Joint IPAC-RS IPAC EFPIA Submission of comments on “Questions and answers on data requirements when transitioning to low global warming potential (LGWP) propellants in oral pressurized metered dose inhalers” (May 2023) CLICK HERE
- IPAC-RS IPAC Preliminary Joint Comments to ECHA REACH on Proposal to Restrict PFAS (May 2023) CLICK HERE
- IPAC-RS Comments on Pharmacopoeial Forum 49(2) Chapter <87> “Biological Reactivity Tests, In Vitro” and Chapter <88> “Biological Reactivity Tests, In Vivo” (May 2023) CLICK HERE
- IPAC-RS Comments on Draft FDA Guidance for Industry “Statistical Approaches to Establishing Bioequivalence” (February 2, 2023) CLICK HERE
- IPAC-RS Comments on USP Revised Chapter <604> “Leak Rate (of aerosol containers)” (January 2023) CLICK HERE

All IPAC-RS comments prior to 2023 are posted on our website.

CLICK HERE

EXTERNAL ENGAGEMENT

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

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

- IPAC-RS briefly discussed with leaders of the FDA Office of Combination Products a way to mitigate divergent requirements coming from CDER and CDRH with respect to drug-device combination products. The Materials WG and GRRO-NA discussed potential ways to continue this conversation with the Agency.

- Several IPAC-RS representatives met with co-directors of the FDA-funded Center for Research on Complex Generic(CRCG) in March 2023, and discussed a number of topics such as the upcoming CRCG workshop on bioequivalence considerations for OINDP, CRCG educational offerings, and “green propellants”.

- 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 presented an update on IPAC-RS initiatives to EPAG on March 28, 2923 and also met EPAG leaders in person in December 2023 to continue plans for regular informational exchanges and potential collaborations on topics of mutual interest.

- IPAC-RS and ISAM co-organized a workshop on inhaled and nasal biologics held in conjunction with the ISAM 2023 Congress (see page 12).

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 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 2022. CLICK HERE
- IPAC-RS maintains a public Pharmaceutical Aerosols Resource Center (PARC) webpage, which highlights the latest research, educational materials and regulatory standards relevant for OINDPs.
- **Alternative Propellants Information Repository:** IPAC-RS has created a public-facing webpage to store relevant information about the scientific and technical aspects of LGWP propellants. CLICK HERE

  Materials include IPAC-RS survey results, IPAC-RS comments and output from the October 11th IPAC-RS LGWP workshop (see page 12).
- The IPAC-RS Board, Planning Committee, WGs, and KNs continued to meet regularly, network and advance IPAC-RS projects throughout 2023.
- 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.

"Discussing European regulatory affairs within IPAC-RS' Europe Global Regulatory Review and Outreach team has allowed me to stay abreast of relevant developments in my field, and to spot emerging trends. Sharing insights with colleagues from other companies prepares us all to better respond to the ongoing challenges, such as those related to PFAS and F-gas regulations."

Franz Josef Rehmann
Regulatory CMC Associate Director | AstraZeneca
IPAC-RS GRRO Europe Co-Chair

IPAC-RS YEAR IN REVIEW

BY THE NUMBERS

5 BOARD MEETINGS

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

1 ROUNDTABLE

Roundtable Advancing Sustainability of Device and Container Closure Systems (Part II) (February 7, 2023)
CLICK HERE

3 PUBLIC WORKSHOPS

IPAC-RS Biologics Workshop (May 23, 2023)

A discussion on Inhaled and Nasal Biologics was held in May as part of the IPAC-RS Board of Directors meeting. Invited speakers included **Nitesh Kunda**, St. John's University, **Gregg Duncan**, University of Maryland, **Julie Suman**, Aptar and **Irene Rossi**, Nanopharm, **David Cipolla** (Insmed), **Eric Munson** and **Tony Zhou**, Purdue University, and **Karen Jaffee**, Mannkind. Presentations and a recording are available to IPAC-RS members.

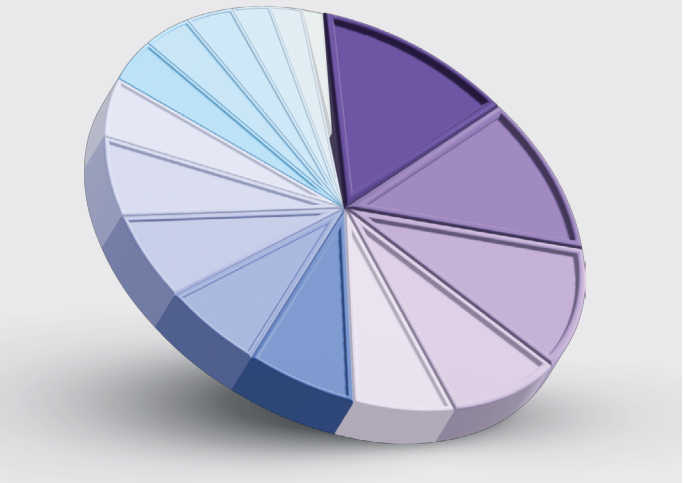
IPAC-RS/ISAM Workshop: Discussing Scientific Challenges for Development of Inhaled/Intranasal Biologic Products (August 26, 2023)

IPAC-RS co-hosted this workshop with ISAM at the ISAM Congress, which attached over 50 attendees and generated an active discussion. Speakers and panelists are preparing a publication. Presentations are available to IPAC-RS members.

IPAC-RS Workshop on the Transition to Low Global Warming Potential Propellants for Metered Dose Inhalers (October 11, 2023)

The October Workshop attracted over 200 attendees from approximately 68 organizations. A recording, materials from the workshop, and a summary of the questions addressed during the Workshop are posted on the public website. A white paper summarizing the discussions, overseen by GRRO-AP, is also available on the website.

In addition, a summary of the IPAC-RS Survey - Stakeholder Perspectives on Switching Current pMDIs to New Propellants is available here.



168 WEBMEETINGS

of IPAC-RS Working Groups, Knowledge Networks and Subgroups

- 22 Product Quality Demonstration Strategy (Full WG and Core)
- 20 Cascade Impaction (Full WG and Core)
- 19 GRRO Alternate Propellant
- 15 LGWP Workshop Organizing Committee
- 12 Materials & Propellants Quality Considerations
- 12 Change Management
- 11 Planning Committee
- 11 OINDP Materials
- 11 GRRO China
- 9 GRRO North America
- 6 Membership Committee
- 6 GRRO Europe
- 4 Analytical Methods
- 3 Lifecycle Management
- 2 GRRO Brazil
- 1 GRRO Leadership

WHAT'S NEXT

LOOKING AHEAD TO 2024

Guided by the priorities laid out in the 2022-2024 Strategic Plan, IPAC-RS will continue working to remain a leader in the OINDP industry in 2024.

IPAC-RS Roundtable Series: IPAC-RS is continuing its Roundtable series in 2024. Regulatory and Technical Considerations in Sustainable Lifecyle Approaches for OINDP Device and Container Closure Systems (Part III) will be held on Thursday, March 14, 2024. Visit the Roundtable webpage for details.

Inhaled, Nasal and Nebulized Biologics Workshop. Planning has started for an IPAC-RS Biologics Workshop 2024 to be held on September 4-5, 2024 in Washington, DC. The Organizing Committee is chaired by Chris Gruenloh (PPD), Alan Watts (Catalent), and Chris Vernall (Intertek).

LGWP Propellants Workshop II. Planning for a second LGWP Propellants workshop is in progress. IPAC-RS plans to hold the workshop prior to the CRCG Workshop - Navigating the Transition to Low Global Warming Potential Propellants to be held on December 4-5, 2024. Several IPAC-RS members are representing IPAC-RS on the organizing committee for the December workshop.

2024 DIA China. GRRO-China secured an inclusion of IPAC-RS in the 2024 DIA China meeting's program (May 18-19, 2024), with expected participation from NIFDC, CHP, CDE and relevant colleagues from regulatory, industry and scientific institutions.

IPAC-RS/USP Workshop (1Q 2025). IPAC-RS members are working with members of the USP aerosols committee to organize a 1 – 1.5 day workshop to provoke discussion of several topics that affect OINDPs.

The IPAC-RS Board of Directors will meet four times in 2024, twice virtually (April and October) and twice in person (July in Parma, Italy and November in Washington, D.C.).

"Biologics delivered by inhalation is a relatively new field with incredible potential. IPAC-RS has stepped up to lead in this exciting space by facilitating discussions across industry and with academicians and regulators to help educate and uncover challenges faced during development. I am excited that we are now making progress towards defining specific initiatives where we aim to clarify development and regulatory pathways for these new modalities. Ultimately, we hope our contributions will improve the safety and efficacy of these promising therapies."

Alan Watts
Director, Innovation & Partnerships, Orally Inhaled Products | Catalent
IPAC-RS Biologics Workshop Organizing 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 OINDP scientific and regulatory topics.

Membership Information

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

Associate Membership is open to corporations that (1) develop or manufacture components and/or devices for OINDPs; (2) provide scientific or technical services relating to development and manufacture of OINDPs; 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 OINDPs, 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 2023

MEMBERS AND ASSOCIATE MEMBERS

Members (including Board members)

Mike Needham
Chair

Jennifer Wylie
Vice Chair

AstraZeneca
François Michelon
Andy Rignall

Boehringer Ingelheim
Holger Memmesheimer
Morgana Sebenello Wolf

Catalent
Carla Vozone
David Wilcox

Chiesi
Francesca Usberti
Monica Ferrari

Genentech
Negar Sadrzadeh
Yoen-Ju Son

GSK
Jeremy Clarke (through Oct 2023)
Susan Holmes (through Oct 2023)
Amanda Burke (beginning Nov 2023)
Luis Manso (beginning Nov 2023)

Kindeva Drug Delivery
Ann Purrington
Mike Needham, Chair

Lonza
Matthew Ferguson (through Nov 2023)
David Lyon (through March 2023)
Kimberly Shepard (beginning April 2023)
Beatriz Fernandes (beginning in Nov 2023)

Lupin Pharmaceuticals, Inc.
Mukul Dalvi
Kalpana Vanam

Merck & Co., Inc.
Robert Berger
Jennifer Wylie, Vice-Chair

Novartis/Sandoz
Jürgen Jauernig
Mariska Kraaij

Recipharm
Peter Hirst (through Jan 2023)
Louise Righton (beginning Feb 2023)
Lei Mao

Teva
Julian Blair
Lucy Fry (beginning in April 2023)
Prasad Peri (through March 2023)

Transpire Bio
Abhishek Gupta
Axel Perlwitz

Vectura
Nicky Ellis
Nikki Willis

Viatris
Andrew Cooper
David Pole

Associate Members

- Aptar Pharma
- Copley Scientific
- H&T Presspart
- Impel Pharmaceutical
- Intertek
- invoX Belgium N.V.
- Nemera
- PPD
- Proveris Scientific Corporation
- RxPack

IPAC-RS WORKSTREAM LEADERSHIP

WORKING GROUP CHAIRS (2023)

Cascade Impaction

Adrian Goodey, Merck & Co., Inc.

Change Management

Marielle Calderini, Vectura

Global Regulatory Review and Outreach (GRRO)

- **GRRO Alternate Propellants (AP)**
  Sue Holmes, GSK
  Christy Gilbert, AstraZeneca
- **GRRO Brazil**
  Leticia Grecchi, Chiesi
  Marcia Cavallin Silva, Boehringer Ingelheim
- **GRRO China**
  Ken Shen, AstraZeneca
  Beatrice Grand-Demars, Nemera
- **GRRO Europe**
  Franz-Josef Rehmann, AstraZeneca
  Hema Khan, Vectura
- **GRRO North America**
  Sue Holmes, GSK (through Sept 2023)
  Ann Purrington, Kindeva
  Xiangyin Wei, Vectura

Materials and Propellants Quality Considerations

Atish Sen, AstraZeneca
Dan Dohmeier, Kindeva

Nasal

Adam Gibbons, Recipharm
Maria Smith, Proveris

Membership Committee

François Michelon, AstraZeneca
Alan Watts, Catalent

OINDP Materials

James Mullis, PPD
Hera Shams Khan, Vectura

Product Quality Demonstration Strategy

David Christopher, Merck & Co., Inc.
Helen Strickland, GSK

In addition to Working Groups, IPAC-RS has the following Knowledge Networks, where members can discuss ongoing developments.

- **Analytical Lifecycle Management**
  Andy Rignall, AstraZeneca

SECRETARIAT

SUPPORT

Faegre Drinker's Pharmaceutical Consortia Management Team 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 global companies 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, the Secretariat:

- Facilitates decision-making processes to develop consensus positions on strategic initiatives and projects
- Ensures antitrust compliance by providing training, oversight and legal counsel
- Provides broad scientific, project management, legal and administrative support
- Provides the Board of Directors with robust strategic, operational and planning support
- Supports the exploration and scoping of data-sharing initiatives
- Helps design, develop, implement, execute, and curate custom-designed databases and surveys and other data-sharing projects
- Assists with writing technical reports and papers, and contributes to and reviews manuscripts under development to ensure antitrust compliance
- Facilitates external engagements with global regulatory agencies, standard setting organizations, industry associations, advocacy groups and other stakeholders
- Manages internal and external communications, including public websites and internal collaboration portals
- Provides venues and logistical support for virtual and in-person meetings

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.

Mary Devlin Capizzi, JD
mary.devlincapizzi@faegredrinker.com
+1 202 230 5101

Svetlana Lyapustina, PhD
svetlana.lyapustina@faegredrinker.com
+1 202 230 5179

Lee Nagao, PhD
lee.nagao@faegredrinker.com
+1 202 230 5165

Dede Godstrey, Project Coordinator
dede.godstrey@faegredrinker.com
+1 202 230 5607

Mary Kate Bielinski, Project Coordinator
marykate.bielinski@faegredrinker.com
+1 202 230 5280

PICTURE IT

IPAC-RS YEAR IN PHOTOS

PICTURE IT

IPAC-RS YEAR IN PHOTOS

IPAC-RS

International Pharmaceutical Aerosol Consortium on Regulation & Science

CONTACT US

ipacrs.com

info@ipacrs.org

www.linkedin.com
company/ipacrs/