

2022

YEAR IN REVIEW



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A Message from the IPAC-RS Chair **Mike Needham**

2022 was another excellent year for IPAC-RS. I am grateful to have been elected in 2022 to serve as Chair of this vibrant consortium. In preparing this IPAC-RS Year in Review, I am struck by the accomplishments of the consortium during another unpredictable and challenging year. Despite the challenges, IPAC-RS has continued to grow and advance key scientific and regulatory initiatives across the global OINDP industry. Consortium members are enthusiastically committed to collaboration and creativity. Regulators have praised the work and integrity of IPAC-RS, and the consortium continues to undertake a robust and active portfolio of projects, including several new initiatives in 2023.



In 2022, IPAC-RS planned and delivered a number of timely and well-received roundtables, which supplemented podium presentations held at the IPAC-RS/RDD Joint session in May 2022, such as patient-centric OINDP development and sustainability of OINDP design and manufacturing. Further, consortium members responded with substantive comments to regulatory agencies (i.e., US FDA) and standard setting bodies (i.e., US Pharmacopeia [USP], and the International

Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use [ICH]). Finally, the interest of a wide-range of industry and regulatory stakeholders in collaboration with IPAC-RS is a testament to the quality of the consortium's deliverables as well as the openness with which IPAC-RS collaborates.

As we enter 2023, IPAC-RS members look forward to another year of optimal collaboration and progress. We have expanded our portfolio of projects and are undertaking important collaborative work in the areas of nasal products, alternative propellants, biologics delivered by inhalation or intranasally.

I encourage all in the IPAC-RS community and beyond to stay in touch in 2023 by following IPAC-RS on LinkedIn and keeping abreast of the consortium's progress via the consortium's website. I congratulate and thank all IPAC-RS participants and member companies for their great engagement and support.

Mike Needham

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

A Message from the IPAC-RS Chair Emeritus **Carla Vozone**

In reflecting on the past few years as Chair of IPAC-RS, I am grateful for and proud of the consortium's growth and accomplishments. We have navigated uncertain times with resilience, generosity, and optimism. I want to sincerely thank all IPAC-RS members for your spirit of collaboration and your unfailing commitment to the advancement of science and regulation of global orally inhaled and nasal drug products.



IPAC-RS is unique—it enables all of us in the OINDP industry to bring our collective commitment to serving patients by sharing best practices, developing thought leadership, and learning from each other. In 2022, the consortium saw the implementation of its strategy to enlarge its membership by recognizing that the OINDP industry has evolved to include a diverse range of stakeholders, from innovative and emerging biopharmaceutical companies to a much broader range of suppliers and service

providers. At the time of this printing, we will have welcomed eight new members and associate members since 2021 (e.g., Members: Genentech, Lonza, Recipharm, and TranspireBio and Associate Members: Nemera, PPD, RxPack, and Impel Pharmaceuticals).

In mid-2022, I completed my tenure as IPAC-RS Chair and now serve as Chair Emeritus. I am confident that IPAC-RS will continue to flourish under the leadership of its new Chair, Mike Needham of Kindeva, and Vice Chair, Jennifer Wylie of Merck. Leadership of IPAC-RS has been a highlight of my professional career and an absolute privilege. I look forward to the organization's continued success in 2023 and for many years to come!

Carla Vozone, PharmD, MBA

Vice President, Strategy, Innovation and Partnerships
Inhalation, Catalent Pharma Solutions

Overview of 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) by collecting and analyzing data. 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 through conferences, webinars, technical journals and discussions with regulatory bodies.



Vision

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



Mission

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

New in 2022



IPAC-RS developed and adopted a new [Strategic Plan for 2022-24](#) to reaffirm the priorities and set goals for the coming years. Strategic priorities include:

2022-2024 Strategic Goals

1

Engage actively with regulatory agencies and standards bodies globally (e.g., in North and South America, Europe, Asia) on current and emerging issues, guidances, compendial chapters, and consensus standards.

2

Advance the science and scientific discourse among IPAC-RS members and with external stakeholders in areas of common interest. Conduct and publicize joint research.

3

Increase public visibility of IPAC-RS advocacy, technical work, and subject matter expertise.

4

Grow and evolve membership to ensure the organization is equipped to address current and future challenges.

In 2022, IPAC-RS hosted a new roundtable series, supplementing podium presentations held at the [IPAC-RS-RDD 2022 joint session](#) that addressed “Regulatory, Science and Technology Innovations Enabling Novel and Improved OINDP Design, Development and Manufacturing.”

- The first webinar in the series, “Patient Centric Product Design,” was held on September 22. [\[Recording\]](#) [\[Slides\]](#)
- The second webinar, “Advancing Sustainability of Device and Container Closure Systems (Part I),” was held on November 30. [\[Recording\]](#) [\[Slides\]](#)

The IPAC-RS Membership Committee conducted a gap analysis survey of members to identify current areas of high interest where IPAC-RS initiatives would be of most value. Some of the high-priority areas are being addressed by IPAC-RS (e.g., alternate propellants, biologics, intranasal products), while others represent emerging topics that may be addressed in the future.

IPAC-RS launched its new “Associate Member Spotlight Series” in the monthly newsletters. The series allows Associate Member companies to share information about their company and connection to OINDP, and what they value most about being part of the IPAC-RS community.

New IPAC-RS Working Groups:

- **Change Management WG:** This group will explore risk-based approaches to deciding if a change is significant, and share examples of changes and regulatory responses requesting Notified Body Opinions. The group will develop recommendations and seek discussions with European health authorities and notified bodies.
- **Materials and Propellants Quality Considerations WG:** This group will develop a framework to guide and inform industry professionals and stakeholders in navigating materials evaluation in conjunction with a switch to alternative propellants.
- **GRRO Alternate Propellants (AP) WG:** The goal of this group is to provide strategic oversight and coordination of IPAC-RS activities and external collaborations and outreach related to alternate propellants.

In 2022, the IPAC-RS consortium welcomed several new Members and an Associate Member. We are excited for active engagement and collaboration with these companies:

New Members:

Lonza
Recipharm

New Associate Member:

RxPack

IPAC-RS Board of Directors Discussions

Highlights

March 31, 2022:

- The Board discussed several emerging topics and ways to address them through IPAC-RS initiatives. In particular, the proposals to address materials aspects of alternate propellants, change management and inter-center regulatory coordination received Board's support. The Board underscored the importance of the ongoing and upcoming external engagements with Respiratory Drug Delivery ([RDD](#)), The Center for Research on Complex Generics ([CRCG](#)), International Society for Aerosols in Medicine ([ISAM](#)) and AAPS Inhalation & Nasal Community ([INC](#)).
- FDA representatives participated in part of the meeting, to which IPAC-RS Members, Associate Members, and interested colleagues were also invited. Participants reviewed opportunities and challenges presented by biological products intended for delivery to the upper or lower respiratory tract. IPAC-RS continued to discuss regulatory and scientific challenges of biological products throughout the year.

June 7, 2022:

- This meeting included an in-depth review of the progress made by current working groups and knowledge networks. Participants also discussed next steps for the change management initiative, alternate propellants, and collaborations with ISAM and AAPS INC, especially in new and emerging areas, such as biologics delivered intranasally or by inhalation.

November 8-9, 2022:

- Participants heard from new working groups, reviewed ongoing collaborations on workshops for inhaled nasal and orally inhaled biologics, discussed updates from CRCG, learned about the [Enabling Technologies Consortium \(ETC\)](#), and received an informational updated from [IPAC](#) about legislative and regulatory developments related to alternate propellants.



The Board met in person in November.

Highlights

IPAC-RS Associate Member Roundtable

- On October 18, IPAC-RS Associate Members came together for an online forum to discuss IPAC-RS priorities for 2023, education and outreach, communications, and potential new activities.

Projects and Discussions

- **IPAC-RS collaborated with RDD** to develop a joint session at RDD 2022 on “Regulatory, Science and Technology Innovations Enabling Novel and Improved OINDP Design, Development and Manufacturing.” Several roundtables were launched as a follow-up to this session.
- **Leaders of GRRO subgroups met in November** to continue planning for IPAC-RS roundtables and to discuss regulatory developments around the world, such as the revision of ICH M4 (eCTD modules) and development of ICH Q3E (leachables and extractables), the USP coordination with the Chinese Pharmacopoeia regarding standards for glass and metal containers, and IPAC-RS outreach to EDQM.
- **IPAC-RS was a co-organizer of the Innovative Drug Delivery Solution (IDDS) summit** established and organized by Aptar. The summit took place in Suzhou, China on November 23-24, 2022, and included sessions on regulatory trends, digital devices, inhalation products, nasal products and sterile products. Adrian Goodey (Merck), Chair of the IPAC-RS Cascade Impaction (CI) Working Group, spoke on the group’s work in a presentation on “APSD Metrics for Quality Control of Orally Inhaled Products.”
- **The GRRO-China WG translated, reviewed and shared** with the Materials WG the Chinese Pharmacopoeia’s draft document “5200 General Rules for Rubber Closures for Pharmaceutical Packaging.” GRRO China also conducted knowledge sharing sessions discussing the suite of new packaging related chapters from the Chinese Pharmacopoeia; and the import drug license process in China, providing an overview of the CDE and NIFDC requirements such as batch testing, and some of the strategies that companies use to meet the requirements.
- **The CI WG is developing a new APSD database.** In 2022, CI WG prepared and submitted for publication a manuscript about CI testing of orally-inhaled aqueous formulations, and continued discussion of the manuscript focused on CMC testing of nasal aqueous formulations.
- **The Analytical Lifecycle Management Knowledge Network monitored** the development of ICH Guidelines Q14 “Analytical Procedure Development” and Q2(R2) “Validation of Analytical Procedures,” considering the application of these guidelines to drug-device combination products such as OINDP.
- **The Materials WG developed manuscripts** on nitrosamines and biocompatibility with a specific focus on relevant considerations and recommendations for OINDP.

Working Group (WG) and Knowledge Network (KN)

Highlights

Publications and Comments

Publications

- ["An update from the International Pharmaceutical Aerosol Consortium on Regulation & Science \(IPAC-RS\)"](#)
Inhalation Magazine (December 2022)
- ["An Overview and Discussion of N-nitrosamine Considerations for Orally Inhaled Drug Products and Relevance to Other Dosage Forms"](#) (December 2022) was accepted for publication in *AAPS PharmSciTech*.
- CI WG's Letter to the Editor Moving Forward from ["Fine Particle Fraction: The Good and the Bad"](#)
(August 2022) *Journal of Aerosol Medicine and Pulmonary Drug Delivery*, 35(4), pp. 225–226
- ["Spray Pattern and Plume Geometry Testing and Methodology: An IPAC-RS Working Group Overview."](#)
(May 2022) *AAPS PharmSciTech* 23, 145.
- ["IPAC-RS Summary of Global Regulatory Developments 2021"](#) (April 2022).

Comments

- [IPAC-RS comments](#) on USP stimulus article ["Testing the In Vitro Product Performance of Inhalation and Nasal Drug Products: Views of the USP Expert Panel"](#) (November 2022)
- [IPAC-RS Comments](#) on USP <601> "Inhalation and Nasal Drug Products: Aerosols, Sprays, and Powders—Performance Quality Tests" PF48(4) (September 2022)
- IPAC-RS comments on [ICH Q2\(R2\) \[IPAC-RS\]](#) and [Q14 \[IPAC-RS\]](#). (July 2022)
- [IPAC-RS Comments](#) on USP <1604> Presentation of Aerodynamic Particle Size Distribution (APSD) Measurement Data for Orally Inhaled Drug Products PF48(1) (March 2022)



Engagement

- **IPAC-RS continued its engagement** with the Product Quality Research Institute ([PQRI](#)) as a member.
- **GRRO- North America**, in collaboration with other IPAC-RS WGs, engaged with USP and submitted comments on several USP draft chapters published in Pharmacopeial Forum. Copies of submitted comments are archived on [IPAC-RS Connect](#) (IPAC-RS membership required for access).
- **GRRO-China conducted knowledge-sharing sessions** on regulatory developments in China related to OINDPs. The group also connected with Dr. Desmond Hunt from USP, who presented on the USP's recent collaborations with the Chinese Pharmacopoeia (ChP) on metal packaging and glass containers.
- **The CI Working Group leaders met** with EDQM representatives to discuss updates in the U.S. and European pharmacopeias and opportunities for collaboration and harmonization.
- **The CI WG and GRRO-North America chairs met** with the USP Aerosol Expert Committee in September, to present the IPAC-RS work on Efficient Data Analysis (EDA) for aerodynamic particle size distributions. Subsequently, USP invited IPAC-RS to continue the discussion and to consider organizing a joint workshop.
- **IPAC-RS sent the FDA examples of areas** in need of enhanced inter-center coordination and requested a meeting with the agency to discuss this topic.
- **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 met in December** with leaders of the European Pharmaceutical Aerosol Group ([EPAG](#)) and outlined a plan for regular informational exchanges and potential collaborations on topics of mutual interest.
- **IPAC-RS and ISAM have co-organized a workshop** on inhaled and nasal biologics, to be held in conjunction with the ISAM 2023 Congress ([details here](#)).



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, with its members and summarized them in the Monthly newsletter, which is distributed to all IPAC-RS members and all interested employees of Member and Associate Member companies.
- “**IPAC-RS Perspectives**,” a special edition of the IPAC-RS Newsletter, was issued in 2022, featuring an interview with Dr. Richard Lostritto. A copy of the interview is [available here](#).
- **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 2021.
- **IPAC-RS maintains a public Pharmaceutical Aerosols Resource Center** ([PARC](#)) webpage, which highlights the latest research, educational materials and regulatory standards relevant for OINDPs.
- **The IPAC-RS Board, Planning Committee, WGs, and KNs continued to meet** regularly, network and advance IPAC-RS projects throughout 2022 using a variety of online tools.
- **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.



By the Numbers

3 Board Meetings
The IPAC-RS Board met in March, June and November 2022, for engaging discussions and updates on current and proposed consortium initiatives.
[More here.](#)

2 Roundtables
Supplementing the podium presentations at the IPAC-RS/RDD Joint session.

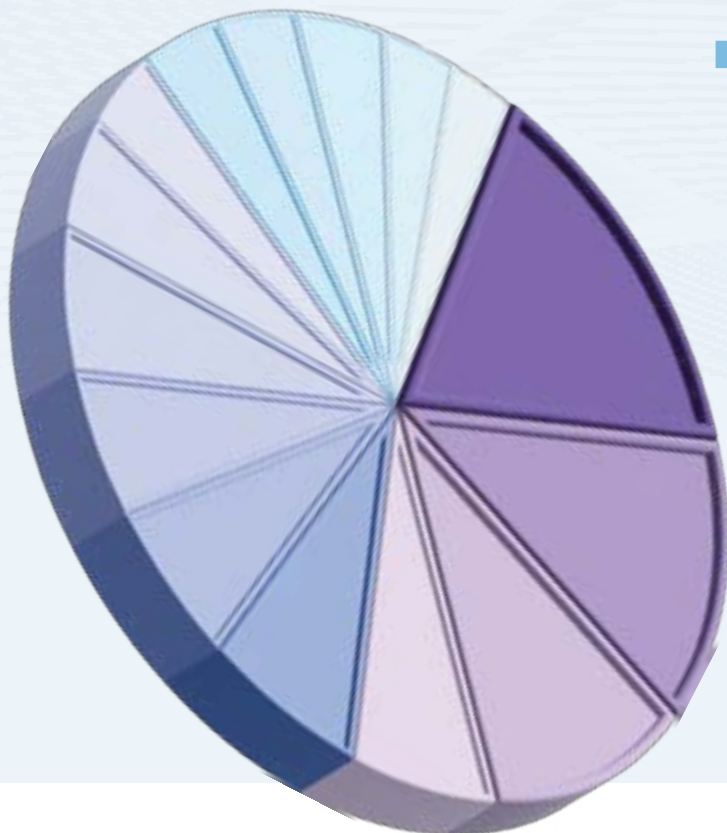
- **Advancing Sustainability of Device and Container Closure Systems (Part I):** November 30, 2022
- **Patient Centric Product Design:** September 22, 2022 [Read more here.](#)



IPAC-RS/RDD Panel (speakers and moderators) on May 5, 2022.

2 Public Conferences
• **Drug Delivery to the Lungs (DDL) 2022:** Several IPAC-RS members and Secretariat attended DDL on December 7-9, 2022.

- **Respiratory Drug Delivery (RDD) 2022:** IPAC-RS prepared a successful joint 2022 session with RDD on May 5, 2022. Presentations and discussions focused on patient-centricity, sustainability, regulatory evolution and advanced analytics.



151 Webmeetings of IPAC-RS Working Groups, Knowledge Networks and subgroups, including:

- 22** OINDP MATERIALS, INCLUDING NITROSAMINES AND BIOCOMPATIBILITY SUBGROUPS
- 21** PRODUCT QUALITY DEMONSTRATION STRATEGY (CORE AND FULL WG)
- 19** CASCADE IMPACTION (CORE AND FULL WG)
- 18** IPAC-RS/RDD JOINT SESSION ORGANIZING COMMITTEE
- 11** GRRO NORTH AMERICA
- 11** PLANNING COMMITTEE
- 10** GRRO CHINA
- 8** IPAC-RS ROUNDTABLE PLANNING CALLS
- 6** GRRO BRAZIL
- 5** GRRO EUROPE
- 5** MEMBERSHIP COMMITTEE
- 5** ANALYTICAL METHODS LIFECYCLE MANAGEMENT
- 5** PLUME CHARACTERIZATION
- 2** CHANGE MANAGEMENT
- 1** MATERIALS AND PROPELLANTS QUALITY CONSIDERATIONS



IPAC-RS 2023

Looking Ahead

Guided by the priorities laid out in the new Strategic Plan, IPAC-RS will continue working to remain a leader in the OINDP industry in 2023:

- **Inhaled biologics, including nebulized biologics. The Membership Committee will continue** to conduct outreach to potential member companies and grow the consortium.
- **The Analytical Lifecycle Management KN will monitor** the progress of ICH guidelines Q2/Q14, will discuss characterization tests and review publications related to analytical methods.
- **The Change Management Working Group will kick off in 2023** to develop a risk-based approach to whether a change is significant and when a Notified Body Opinion is needed.
- **The GRRO AP group will meet on an ad-hoc basis** to provide strategic oversight and coordination of IPAC-RS activities related to alternate propellants.
- **The CI WG will publish their manuscript** “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)” in AAPS PharmSciTech.
- **The “Advancing Sustainability of Device and Container Closure Systems (Part II)” Roundtable** will take place on February 7, 2023. This webinar follows part I which was held in November 2022. Part III will take place in Spring 2023.
- **The IPAC-RS Board of Directors will meet four times in 2023**, twice virtually (March and September) and twice in person (May in Washington, D.C. and December in Edinburgh, Scotland).

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.

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

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 2022

IPAC-RS Members and Associate Members

Members

(including Board members)

Chair: Mike Needham **Vice Chair:** Jennifer Wylie

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
Susan Holmes

Kindeva Drug Delivery

Ann Purrington
Mike Needham, Chair

Lonza

Matthew Ferguson
David Lyon

Lupin Pharmaceuticals, Inc.

Mukul Dalvi
Kalpana Vanam

Merck & Co., Inc.

Robert Berger
Jennifer Wylie, Vice-Chair

Novartis

Jürgen Jauernig
Michael Goller

Recipharm

Peter Hirst
Lei Mao

Sunovion

Andrea Bauer
James Connors

Teva

Julian Blair
Prasad Peri

Vectura

Nicky Ellis
Nikki Willis

Viatrix

Andrew Cooper
David Pole

Associate Members

Amcor Flexibles

Aptar Pharma

Copley Scientific

Nemera

PPD

Presspart Manufacturing Ltd

Proveris Scientific Corporation

RxPack

IPAC-RS Workstream Leadership

Working Group Chairs (2022)

Cascade Impaction

Adrian Goodey, Merck

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**
Mark Hindle, AstraZeneca
- **GRRO Europe**
Franz-Josef Rehmann, AstraZeneca
Sarah Bunyan, Vectura
- **GRRO North America**
Sue Holmes, GSK
Ann Purrington, Kindeva

OINDP Materials

James Connors, Sunovion

Product Quality Demonstration Strategy

David Christopher, Merck
Helen Strickland, GSK

Change Management

Marielle Calderini, Vectura

Materials and Propellants Quality Considerations

Atish Sen, AstraZeneca
Dan Dohmeier, Kindeva

Membership Committee

François Michelin, AstraZeneca
Alan Watts, Catalent

In addition to Working Groups,

IPAC-RS has the following Knowledge Networks, where members can discuss ongoing developments.

- Analytical Lifecycle Management
Andy Rignall, AstraZeneca
- Bioequivalence
Beth Morgan, AstraZeneca
Dave Christopher, Merck
- Devices
- Plume Characterization

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: www.linkedin.com/company/ipacrs
- To view the schedule and register for the upcoming IPAC-RS roundtables, visit <https://www.ipacrs.org/roundtables>
- Visit the IPAC-RS video channel to watch recordings of previous webinars: <https://www.gotostage.com/channel/ipacrswebinars>
- 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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What Our Members Are Saying



“Genentech has enjoyed a vast number of benefits, most especially collaboration with other industry organizations and access to regulatory agencies, through its IPAC-RS membership. My colleagues and I actively participate in IPAC-RS working groups, workshops and panel discussions. The global OINDP regulatory environment is complex and ever-changing. Through IPAC-RS, we have been able to contribute to the broader industry and stay abreast of the challenges and evolving regulatory environment.”

Negar Sadrzadeh, Senior Director, Pharma Technical Regulatory, Genentech, a member of the Roche Group; IPAC-RS Board Member

“I see a great value in what IPAC-RS brings to Recipharm and the OINDP industry. Looking forward, our industry has critical and urgent tasks in front of us, from developing and launching greener inhalers with low global warming potential propellants to broadening application to inhaled and nasal biologics. I am confident that with support from all consortium members, IPAC-RS will continue to provide strong leadership in advancing OINDP regulation and science while navigating these current and forthcoming challenges.”

Lei Mao, Ph.D., Director of Inhalation Science and Product Development, Recipharm Laboratories, Inc.; IPAC-RS Board Member



What Our Members Are Saying



“Being part of IPAC-RS offers Chiesi the possibility of actively interacting with other companies, OINDP experts, and global regulatory agencies, to advance science and regulation in service of patients. Engagement in IPAC-RS is never passive but rather is a great example of the industry collaborating actively to drive change.”

Monica Ferrari, *Manager of GRA-CMC Geographical Expansion & Product Enhancement Unit, Chiesi; IPAC-RS Board Member*

“RxPack is growing its leadership and recognition in the world of pMDIs. Associate membership in IPAC-RS is timely and will facilitate our exposure of key trends and engagement on relevant global development and regulatory matters.”

Massimo Carrara, *Chief Executive Officer, RxPack; IPAC-RS Associate Member*

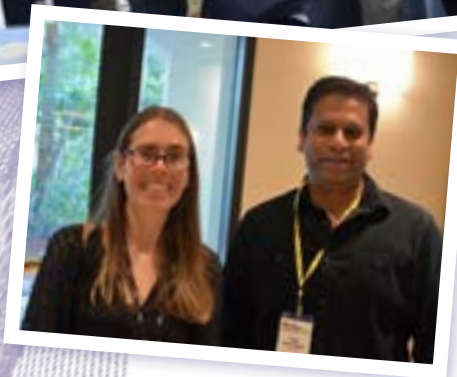
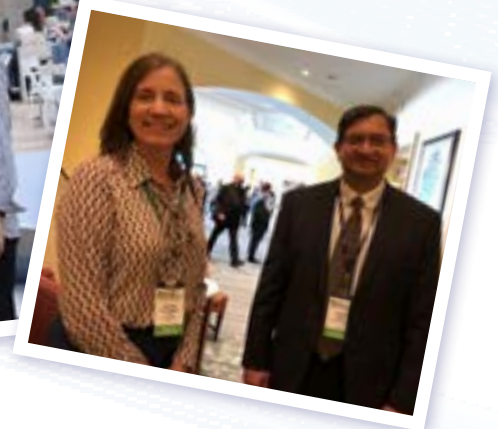


“IPAC-RS plays a critical role in initiating and driving collaboration across the industry. Here at Copley, a key focus is the ongoing evolution of OINDP testing methods. As the world of OINDP testing becomes increasingly complex, our Associate Membership in IPAC-RS enables us to rigorously track regulatory changes and provide consensus feedback on draft proposals. This helps us to continuously ensure the associated methods, equipment and services are relevant, precise, and robustly fit-for-purpose for the customers we serve.”

Mark Copley, *Chief Executive Officer, Copley Scientific; IPAC-RS Associate Member*

IPAC-RS Year in Photos

Picture It





Contact Us



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company/ipacrs/](https://www.linkedin.com/company/ipacrs/)