

2020

Year in Review



IPAC-RS

International Pharmaceutical Aerosol
Consortium on Regulation & Science

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A MESSAGE FROM THE IPAC-RS CHAIR

CARLA VOZONE



Welcome to the IPAC-RS 2020 Year in Review. In looking back on this unprecedented time, I am grateful for and proud of all that the IPAC-RS community accomplished in 2020. In the face of the COVID-19 pandemic, the pharmaceutical industry and global regulatory agencies rallied around and dedicated themselves to a shared goal: combating the worst healthcare crisis of our lifetime. Breakthrough science resiliently pursued for decades is now bringing COVID-19 vaccinations to humanity at a pace faster than ever imagined. During the past year, IPAC-RS members mobilized to deliver lifesaving orally inhaled and nasal drug products (OINDPs) to treat the pulmonary morbidities associated with the SARS-CoV-2 infection, while managing multiple disruptions in supply chains and operations.

Despite the intense challenges of the pandemic, IPAC-RS remained focused and productive in continuing to serve as a leading technical resource and advocate of the global OINDP industry. IPAC-RS pivoted seamlessly to a virtual platform, progressed many important industry initiatives, engaged actively with global regulatory authorities, and brought OINDP thought leadership to a much broader audience. For example, IPAC-RS' round-table discussion with FDA addressing the challenges of COVID in the fall of 2020 was accessed by a record number of attendees. Further, IPAC-RS' strong and collaborative nature fostered OINDP industry community-building and information sharing during the difficult months of quarantine. Many members noted that they felt even more connected to IPAC-RS and one another by the end of 2020 as a result of regular and helpful interactions with similarly situated industry colleagues.

IPAC-RS's mission of advancing the regulatory science of OINDPs remains critically important as we move in 2021. Orally inhaled and nasal drug delivery is experiencing breakthrough innovation with nearly 500 clinical trials on-going for new therapeutic approaches such as non-respiratory diseases, delivery of macromolecules, nucleic acids and high dose small molecules, converging with substantial innovation in devices. In 2020, the Board committed to restructuring its membership model to facilitate greater access to IPAC-RS by the evolving OINDP ecosystem, including small and innovative companies developing OINDPs. The new membership model is effective in 2021 and expands the IPAC-RS Associate Membership category to small and emerging OINDP companies.

I congratulate all members of IPAC-RS for their committed dedication and service to patients and for their active and generous engagement in IPAC-RS in 2020. I look forward to continuing to expand the reach of IPAC-RS in furtherance of our mission.

With wishes for good health and safety in the coming year and continued OINDP collaboration, outreach and thought leadership in 2021!



WHO WE ARE

IPAC-RS is an international association that seeks to advance the science of OINDPs 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 OINDP industry, with a focus on Chemistry, Manufacturing and Controls aspects.



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 STRATEGIC GOALS

1. Advance the science and regulation of inhalation products through discussion, research, and publication.

IPAC-RS identifies and addresses key questions for OINDP through key initiatives and develops and publishes best practices for OINDP.

2. Provide information and services to enable member companies to achieve their current and future product development and regulatory goals.

IPAC-RS serves as a resource for sound assessment of OINDP regulatory requirements and engages in initiatives to facilitate current & future OINDP product development processes.

3. Effectively collaborate with the broader OINDP industry, OINDP suppliers, regulatory authorities, and other stakeholders.

IPAC-RS seeks to expand relationships with decision-makers at worldwide regulatory agencies and standard-setting bodies. We provide educational opportunities and collaboration with the OINDP industry, suppliers, and regulators on current and emerging scientific and regulatory topics relevant to OINDP.

4. Be a well-respected and effective advocate for the OINDP industry.

IPAC-RS actively comments on OINDP regulations and guidances, and promotes clear and harmonized international regulatory expectations in the field. IPAC-RS engages regulatory authorities in constructive discussion and sharing of ideas on OINDP best practices.

IPAC-RS SUCCESS IN 2020

ONGOING COLLABORATIONS
with international partners and academic institutions

5

MEETINGS / ENGAGEMENTS
with international regulators

6

RESPONSES
to international regulatory guidances or standards

9

PUBLICATIONS
[view list of publications](#) →

12



5



IPAC-RS

RESPONSE TO THE PANDEMIC

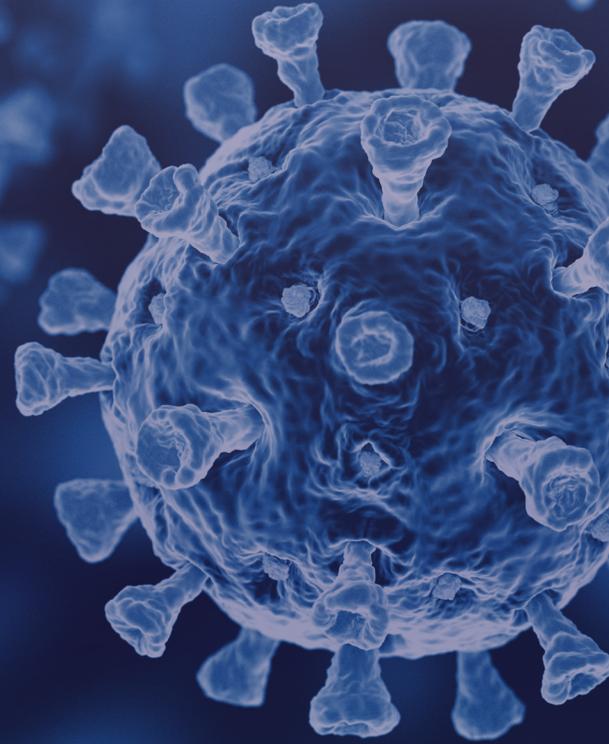
In line with the IPAC-RS overall mission, during the pandemic IPAC-RS not only served its members but also shared its knowledge and strove to support all developers of respiratory products. For example, IPAC-RS launched a public [Pharmaceutical Aerosols Resource Center \(PARC\)](#), which highlights the latest research, educational materials, and regulatory standards relevant for OINDPs.

Furthermore, in response to the pandemic-related stay-at-home orders and travel restrictions that affected all businesses and all parts of the world, IPAC-RS pivoted to all-virtual meetings in 2020.

I sincerely appreciated the ways in 2020 that IPAC-RS brought the industry together in a meaningful way around a lot of important topics and in the middle of a very trying time.

François Michelon

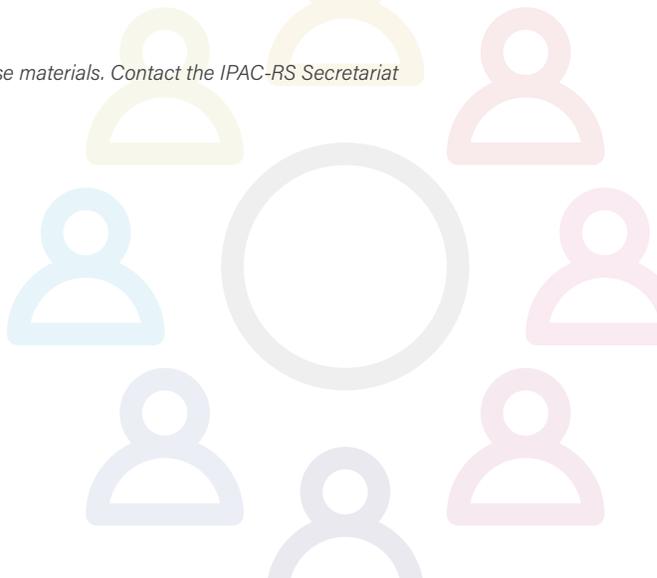
ASTRAZENECA
IPAC-RS BOARD MEMBER



5 INTERACTIVE REGULATORY-SCIENCE ROUNDTABLES

- 1. "A Conversation with the FDA: Perspectives in the Time of COVID-19"**
November 2, 2020
A summary is available on the IPAC-RS website. Further discussions are planned for 2021. →
- 2. "Implications of European Medical Device Regulations (MDR) Article 17 for Drug-Device Combination Products: A conversation with Notified Bodies (TÜV SÜD and BSI)"**
November 6, 2020
A summary is available to members on IPAC-RS Connect.* Further interactions with stakeholders interested in MDR implementation are planned for 2021. →
- 3. The Materials Working Group** held a roundtable discussion with MedPharmPlast Europe (MPPE) on November 16, 2020. Topics ranged from MDR implementation, REACH requirements, perfluoro-alkane discussions, and titanium dioxide legislation. IPAC-RS and MPPE will discuss potential areas for collaboration in 2021. →
- 4. The GRRO China** held a roundtable with the Chinese National Institutes of Food and Drug Control, the Chinese Pharmacopoeia and the Chinese Pharmaceutical Industry Association on December 17, 2020. The discussions included an overview of OINDP-relevant activities in China and other regions, as well as Q&As. A summary is available to members on IPAC-RS Connect.* →
- 5. GRRO Brazil and Population Bioequivalence (PBE) Knowledge Network** held a webinar with Anvisa staff and Brazilian CROs/Testing labs. About 90 attendees participated. The presentation is available on IPAC-RS Connect. A recording of the webinar is available here.* →

** Become an IPAC-RS member for full access to these materials. Contact the IPAC-RS Secretariat (info@ipacrs.org) for information.*



2 PUBLIC CONFERENCES

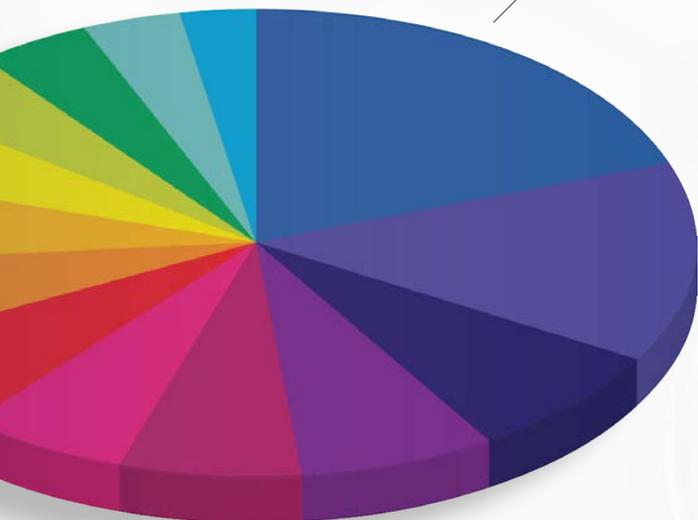
1. **Virtual-podium and podium presentations at the Joint IPAC-RS/RDD Symposium “The Global Regulatory Landscape and Advances in Digital Technology: Transforming the OINDP-Patient Experience.”**
April - May 2020
[This public IPAC-RS webpage](#) connected to the [virtual RDD 2020](#) and includes: the IPAC-RS 2019 Year in Review, video testimonials, and IPAC-RS posters associated with the Symposium from various IPAC-RS WGs. →
2. **The GRRO-China** presented at the Innovative Drug Delivery Solutions symposium on October 29, 2020, providing a comparison of FDA and EMA regulatory guidance for OINDP and provided an overview of IPAC-RS.

6 BOARD OF DIRECTORS MEETINGS

- The IPAC-RS Board met virtually in April, June, July, September, October, and December 2020, with both plenary and breakout sessions to brainstorm and work out specific issues, topics and proposals.

194 WEBMEETINGS

of IPAC-RS working groups, knowledge networks and subgroups, including:



- 38 - PK BATCH-TO-BATCH VARIABILITY
- 27 - PRODUCT QUALITY DEMONSTRATION STRATEGY
- 15 - MDR ANALYSIS
- 14 - CASCADE IMPACTION
- 13 - DEVICES AND RELATED SUBGROUPS
- 12 - OINDP MATERIALS, INCLUDING NITROSAMINES SUBGROUP
- 12 - GRRO- CHINA
- 12 - GRRO- BRAZIL
- 12 - PLUME CHARACTERIZATION
- 10 - PLANNING COMMITTEE
- 9 - IPAC-RS/RDD-2020 SYMPOSIUM ORGANIZING COMMITTEE
- 8 - GRRO - EUROPE
- 7 - GRRO - NORTH AMERICA
- 5 - ANALYTICAL METHODS LIFECYCLE MANAGEMENT

IPAC-RS

2020 GLOBAL ENGAGEMENT

with Regulatory Agencies and Standard Setting Organizations

US FDA

- On February 25, 2020, IPAC-RS met (in person) with FDA CDER and CDRH representatives to discuss regulatory-science approaches for the 2018 draft CMC MDI DPI guidance. Meeting materials, including an IPAC-RS summary and the post-meeting submission to FDA clarifying the IPAC-RS position on risk-management based approaches, statistical PTIT approaches, quality-by-design, and considerations for a longer implementation period, are available to members on IPAC-RS Connect.* →
- IPAC-RS Comments on FDA EUA Draft Guidance 2020 (June 2020) →
- IPAC-RS Comments on FDA Draft Guidance, Select Updates for Biocompatibility of Certain Devices in Contact with Intact Skin (Dec 2020)
- An FDA CDER representatives joined the June 2020 IPAC-RS Board of Directors virtual meeting to discuss developments related to OINDPs and the pandemic.
- A Regulatory-Science Roundtable with FDA scientists on November 2, 2020 (see page 7).

** Become an IPAC-RS member for full access to these materials. Contact the IPAC-RS Secretariat (info@ipacrs.org) for information.*

US PHARMACOPEIA

- IPAC-RS comments on USP Stimuli Article Elastomeric Components for Inhalation Packaging/Delivery Systems (Jan 2020) →
- IPAC-RS submitted comments on USP Revised Chapter [601] Inhalation and Nasal Drug Products: Aerosols, Sprays, and Powders — Performance Quality Tests (Jan 2020) →
- IPAC-RS Comments on USP White Paper “The Role of Public Standards in Assuring Quality of Digital Therapeutics” (Aug 2020) →
- IPAC-RS Comments on USP’s Approach for Future Revision of Biological Reactivity Chapters (87), (88), and (1031) (Sept 2020) →
- IPAC-RS Comments on USP <1220> Analytical Procedure Life Cycle (Oct 2020) →
- IPAC-RS Response to the USP General Announcement “USP New Inhalation Product Monographs: Proposed Approach for Performance Tests Employing on-Standard Apparatus” (Nov 2020) →
- IPAC-RS was invited and will participate in the planning of the next USP Prescription/Nonprescription Stakeholder Forum.



HEALTH CANADA

IPAC-RS Comments on Draft Guidance Document for Consultation: Comparative Pharmacokinetic Studies for Orally Inhaled Products. (June 2020) →

BRITAIN

IPAC-RS comments on the MHRA Guidelines for the "Post Transition" Regulations in the UK. (October 2020) →

EUROPE — EMA

IPAC-RS submitted to EMA, OINDP industry case studies and other materials for the EMA-organized "Multi-stakeholder workshop to support the implementation of Article 117 of Regulation (EU) 2017/745 (the Medical Device Regulation) affecting drug-device combinations (DDC)". The workshop, originally planned to be held in person in Amsterdam in March 2020, was postponed due to COVID-19. In this effort, IPAC-RS is working jointly with EFPIA and EuropaBio. →

A copy of the IPAC-RS materials are available to members on IPAC-RS Connect.* →

EUROPE — NOTIFIED BODIES

An IPAC-RS Regulatory-Science Roundtable with representatives of the Notified Bodies (see page 7).

CHINA

The IPAC-RS GRRO-China coordinated with Chinese counterparts in preparation for the December 2020 Regulatory Roundtable. The Roundtable was held on 17 December 2020, with NIFDC, ChP, CPIA participating.

BRAZIL

GRRO Brazil and Population Bioequivalence (PBE) Knowledge Network held a webinar with Anvisa staff and Brazilian CROs/Testing labs (see page 7).

* Become an IPAC-RS member for full access to these materials. Contact the IPAC-RS Secretariat (info@ipacrs.org) for information.

Our company is very supportive of the work IPAC-RS is doing with OINDP stakeholders and regulators in China. This work reflects the fruits of many years of communicating, collaborating and building strong relationships in China. We look forward to the continuation of this important work.

Xian-Ming Zeng

LUPIN
IPAC-RS GRRO CHINA WG MEMBER & BOARD MEMBER



IPAC-RS

MONITORING, COMMUNICATIONS AND NETWORKING



- IPAC-RS summaries of the May-4th FDA GDUFA Regulatory Science Workshop were discussed in-depth by the CI WG and GRRO – North America.* →
- IPAC-RS prepared and posted a summary of OINDP-relevant highlights from the September 29-30, 2020 FDA workshop “Advancing Innovative Science in Generic Drug Development Workshop”. Available to members on IPAC-RS Connect.* →
- IPAC-RS monitored relevant regulatory and scientific developments around the world, provided timely updates to pertinent working groups and the Board of Directors, and summarized them in the Monthly Newsletter, which is distributed to all IPAC-RS experts and all interested employees of Member and Associate Member companies.
- The IPAC-RS Board, Planning Committee, and all Working Groups and Knowledge Networks continued to meet regularly, network and advance IPAC-RS projects throughout 2020 using a variety of online tools.
- The IPAC-RS community stays connected and productive using the members-only [IPAC-RS Connect](#) portal*, maintains high visibility through the [IPAC-RS website](#) and [LinkedIn](#).
- In 2020, IPAC-RS developed and launched a new IPAC-RS public website. The site has an attractive clean look, is intuitive for navigation and offers improved search capabilities. →

** Become an IPAC-RS member for full access to these materials. Contact the IPAC-RS Secretariat (info@ipacrs.org) for information.*

RESEARCH AND CONSENSUS POSITION PUBLICATIONS

1. IPAC-RS Position Paper on pMDI as Non-Active Medical Device, Nov-Dec 2020. →
2. Internal IPAC-RS technical report "Performance of Multiple-Batch Approaches to Pharmacokinetic Bioequivalence Testing for Orally-Inhaled Drug Products with Batch-to-Batch Variability", Sept-Oct 2020 (available to members on IPAC-RS Connect).* →
3. Cascade Impactor Stage Groupings: Poor Decisions from Degraded Data. Inhalation, August 2020. →
4. Addressing the Need for Controls on Particle Bounce and Re-entrainment in the Cascade Impactor and for the Mitigation of Electrostatic Charge for Aerodynamic Particle Size Assessment of Orally Inhaled Products: An Assessment by the International Consortium on Regulation and Science (IPAC-RS). AAPS PharmSciTech 21, Article number: 239, August 2020. →
5. Evaluation of the Sensitivity and Robustness of Modified Chi-Square Ratio Statistic for Cascade Impactor Equivalence Testing Through Monte Carlo Simulations. AAPS PharmSciTech; vol. 21, Article number: 147, May 2020. →
6. The Liability of Fine Particle Dose (FPD) Can We Rely on Fine Particle Dose Metric Alone for Quality Control? Inhalation magazine, April 2020. →
7. Patient-Centric Considerations for PTIT: Addressing Unintended Consequences in the Draft 2018 Guidance by IPAC-RS Product Quality Demonstration Strategy Working Group, poster, 2020. →
8. Designs for a Robust Outcome in Pharmacokinetic Bioequivalence Testing of Orally-Inhaled Drug Products with Batch-to-Batch Variability by IPAC-RS PK Batch-to-Batch Variability Working Group, poster, 2020. →
9. Update from the Cascade Impactor Working Group by IPAC-RS Cascade Impactor Working Group, poster, 2020. →
10. Sharing Information Across the Globe: IPAC-RS Global Regulatory Review and Outreach (GRRO) by GRRO Brazil, GRRO China, GRRO Europe and GRRO North America Working Groups, poster, 2020. →
11. Common Use Error Matrix for pMDIs. Poster and Excel spreadsheet by IPAC-RS Devices WG, 2020. →
12. Reflections on Digital Health Tools for Respiratory Applications. Journal of Aerosol Medicine and Pulmonary Drug Delivery, March 2020. →

* Become an IPAC-RS member for full access to these materials. Contact the IPAC-RS Secretariat (info@ipacrs.org) for information.



As a Scientific Advisor to the Cascade Impaction WG, I have found great value in the bi-weekly stimulating conversations related to the work of the group. In addition to the professional aspects of our collaboration, we have developed friendships that have endured through this past year when face-to-face contact has been impossible due to COVID-19 restrictions. In retirement from my full-time position, I find the thought processes both stimulating and helpful in maintaining my knowledge base relating to inhaler quality testing and the cascade impaction method, in particular.

Jolyon Mitchell

IPAC-RS SCIENCE ADVISOR



LOOKING FORWARD TO 2021

IPAC-RS will continue work towards its strategic objectives set by the [2019-2021 Strategic Plan](#). In addition, the consortium will monitor and may consider more active engagement in such areas as:

- Digital-health tools for respiratory drug delivery
- Environmental sustainability of OINDP products
- International harmonization

IPAC-RS will also continue to enhance ways for members to interact and collaborate using virtual platforms. Several Regulatory and Scientific Roundtables are planned for 2021, as well as IPAC-RS Webinars for members and larger audiences, presenting and discussing results of the IPAC-RS research and emerging hot topics.

IPAC-RS activities include:

- **Materials WG**
Developing papers on industry practices and regulatory challenges related to biocompatibility, and on nitrosamines evaluation.
- **GRRO China**
Reviewing the CDE bioequivalence guideline for OIPs and developing second regulatory and science roundtable with Chinese agencies and industry organizations. →
- **PK Batch-to-Batch Variability WG**
Developing publication "Performance of Multiple-Batch Approaches to Pharmacokinetic Bioequivalence Testing for Orally-Inhaled Drug Products with Batch-to-Batch Variability"
- **Plume Characterization WG**
Completing manuscript "Spray Pattern and Plume Geometry Testing and Methodology: An IPAC-RS Working Group Overview,"
- **Analytical Method Lifecycle Management Knowledge Network**
Will continue discussion of the ICH revision of guidelines Q12/Q2/Q14. →

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WHAT OUR MEMBERS ARE SAYING



IPAC-RS continues to provide valuable education on OINDP regulations and science to Vectura colleagues, including timely webinars and papers.

Martin Oliver

VECTURA
IPAC-RS VICE CHAIR

One thing that speaks to the heart of people in our company is science. IPAC-RS produces materials, including white papers and recommendations, which are extremely important from a regulatory perspective. Our membership in IPAC-RS allows us to access helpful and timely information and to incorporate it in our decision making as well as educational processes. IPAC-RS is the most important network in the OINDP industry, especially with respect to science, technical and regulatory matters.

Eunice Costa

HOVIONE
IPAC-RS BOARD MEMBER



2020 was an extremely busy year for IPAC-RS! The consortium prepared numerous responses to regulatory guidances and interacted and engaged with FDA and other global health authorities. The scientific and regulatory discussions with FDA are always excellent.

Prasad Peri

TEVA
IPAC-RS BOARD MEMBER



WHAT OUR MEMBERS ARE SAYING

IPAC-RS provides an invaluable forum for OINDP industry colleagues to interact and share scientific and regulatory insights with one another. Because of its deep experience in the science and regulation of OINDPs, IPAC-RS is well positioned to share its learning and insights to a broader universe of manufacturers and service providers. An example of this is the IPAC-RS Materials Working Group's white paper on the assessment of nitrosamines, which will be helpful beyond the OINDP industry.

Jim Connors

SUNOVION
IPAC-RS BOARD MEMBER & MATERIALS WG CHAIR



In 2020, everything was disruptive, but everything in IPAC-RS continued. I appreciate how the consortium leveraged virtual tools to ensure that the work of IPAC-RS continued. It was also incredibly helpful during COVID to interact with and hear insights and perspectives from the U.S. FDA.

Jürgen Jauernig

NOVARTIS
IPAC-RS BOARD MEMBER

We see tremendous value in our IPAC-RS membership. We appreciate that our team members receive important professional opportunities by engaging actively in important and timely scientific and regulatory work streams. In 2020, IPAC-RS webinars and discussions were extremely well done and offered a lot of value to members.

Jen Wylie

MERCK & CO., INC.
IPAC-RS BOARD MEMBER



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.



MEMBERS

(Including Board Members)

AstraZeneca

- François Michelon
- Andy Rignall

Boehringer Ingelheim

- Holger Memmesheimer
- Morgana Sebenello Wolf

Catalent

- Craig Davies-Cutting
- David Wilcox

Chiesi

- Francesca Usberti
- Monica Ferrari

GlaxoSmithKline

- Jeremy Clarke
- Susan Holmes

Hovione

- Eunice Costa
- Carla Vozona, IPAC-RS Chair

Kindeva Drug Delivery

Formerly 3M

- Kathy Ledoux
- Mike Needham

Lupin Pharmaceuticals, Inc.

- Axel Perlwitz
- Xian-Ming Zeng

Merck & Co., Inc.

- Robert Berger
- Jennifer Wylie

Novartis

- Jürgen Jauernig
- Hans Keegstra

Sunovion

- Andrea Bauer
- James Connors

Teva

- Julian Blair
- Prasad Peri

Vectura

- Nicky Ellis
- Martin Oliver,
IPAC-RS Vice-Chair

Viatrix

Formerly Mylan

- Andrew Cooper
- David Pole



ASSOCIATE MEMBERS

- Amcor Flexibles →
- Aptar Pharma →
- Copley Scientific →
- H&T Presspart →
- Oxford Lasers →
- PPD →
- Proveris Scientific Corporation →
- Team Consulting Ltd →

WORKING GROUP & CHAIRS

Cascade Impaction

- Adrian Goodey, Merck

Product Quality Demonstration Strategy

- David Christopher, Merck
- Helen Strickland, GlaxoSmithKline

Plume Characterization

- Sherryl Baxter, AstraZeneca
- Frank Chambers, IPAC-RS Science Advisor

Devices

- Alessandro Agosti, Vectura
- Tim Chesworth, AstraZeneca
- Roisin Wallace, Viatrix

OINDP Materials

- James Conners, Sunovion

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

- Susan Holmes, GlaxoSmithKline

Population Bioequivalence

- David Christopher, Merck

Analytical Lifecycle Management

- Andy Rignall, AstraZeneca

PK Batch-to-Batch Variability

- Elise Burmeister Getz, Sandoz Inc.



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 global companies address complex regulatory, compliance and other topics of mutual interest. For more than 25 years, the team's work has focused on issues impacting the pharmaceutical and medical device industries.



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

SECRETARIAT SERVICES INCLUDE:

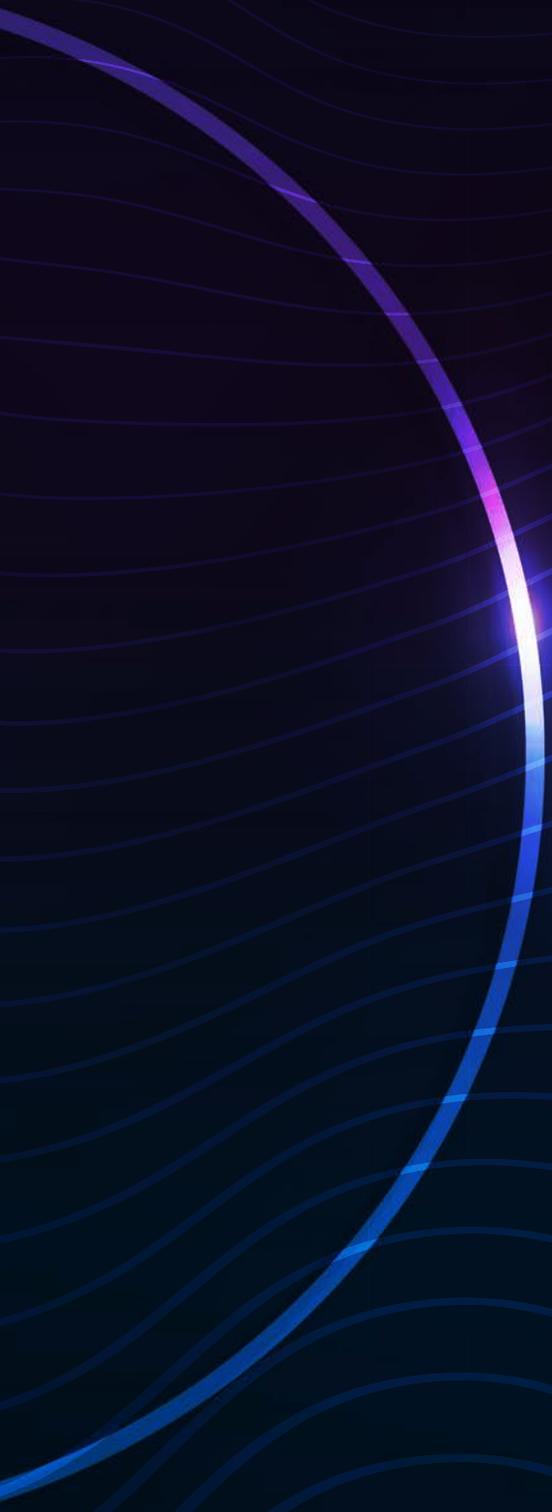
- Facilitating decision-making processes to develop consensus positions on strategic initiatives and projects
- Ensuring antitrust compliance by providing training, oversight, and legal counsel
- Providing broad scientific, project management, legal, and administrative support
- Providing the Board of Directors with robust strategic, operational, and planning support
- Supporting the exploration and scoping of data-sharing initiatives
- Implementing and executing data-sharing projects through custom-designed databases and surveys
- Reviewing manuscripts under development to ensure antitrust compliance
- Facilitating external engagements with global regulatory agencies and key stakeholders
- Managing internal and external communications
- Managing the public website and internal collaboration portal
- Providing venue and logistical support for virtual and in-person meetings

The IPAC-RS Secretariat is absolutely critical in managing, coordinating, and keeping important IPAC-RS initiatives moving ahead.

Monica Ferrari

CHIESI
IPAC-RS BOARD MEMBER





IPAC-RS

International Pharmaceutical Aerosol
Consortium on Regulation & Science

ipacrs.org