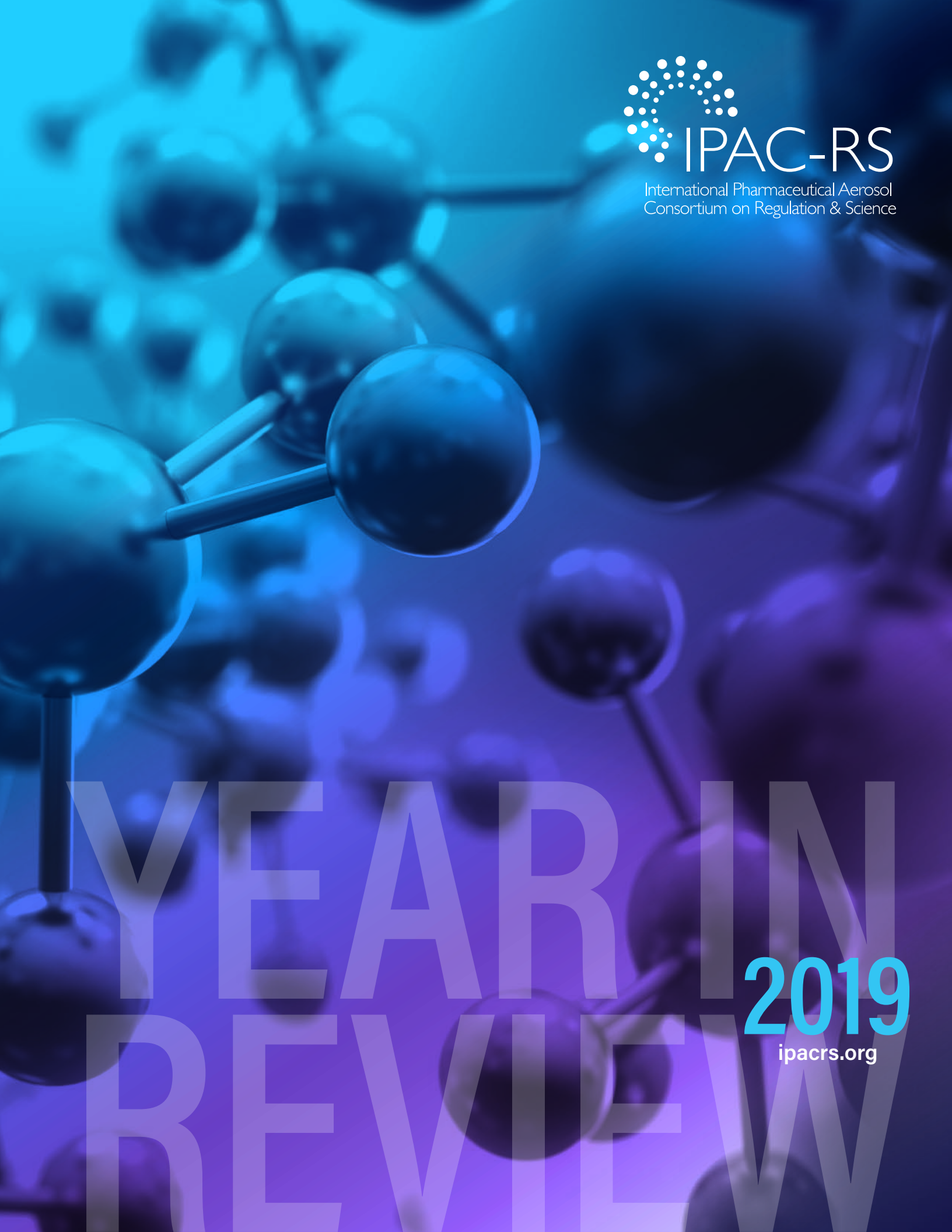

IPAC-RS
International Pharmaceutical Aerosol
Consortium on Regulation & Science
YEAR IN
REVIEW
2019
ipacrs.org

CONTENTS

PAUL ATKINS
ORIEL THERAPEUTICS/NOVARTIS

A NOTE FROM **PAUL ATKINS**, IPAC-RS CHAIR

Since its inception over 20 years ago IPAC-RS has become recognized globally as a key stakeholder in consensus building around regulation of OINDPs based on sound science. In 2019 this commitment to help shape the global regulations has been furthered by making comments and proposals on draft regulations from FDA, USP, EMA and MHRA. In addition, we have continued to strengthen our collaboration with the key decision-making regulatory bodies in both China and Brazil.

IPAC-RS

Serving the orally inhaled and nasal drug products (OINDP) community by driving scientific and regulatory advancements in the field.

WHO WE ARE

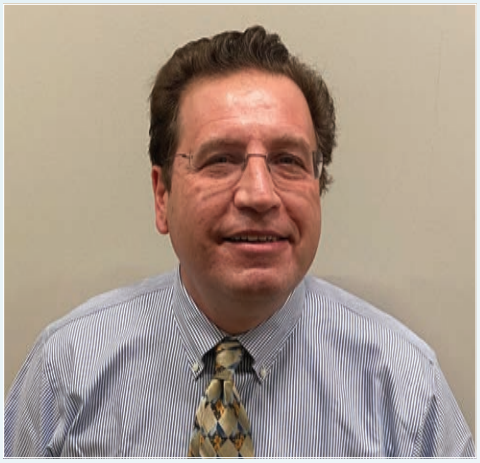
IPAC-RS is an international association that seeks to advance the science of OINDPs by collecting and analyzing data. Representing the OINDP industry for two decades, IPAC-RS aims to build consensus and contribute to effective regulations and standards by sharing the results of its research through conferences, 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 inhaled and intranasal drug products for the benefit of patients.



ROBERT BERGER, MERCK
PAST-CHAIR, IPAC-RS BOARD OF DIRECTORS

MEMBER PERSPECTIVE

"IPAC-RS has proven itself to be an effective vehicle for its members to amass and communicate consensus thinking on scientific best practice for areas of emerging OINDP science. In many cases science can effectively suggest a path forward to resolve ambiguous or regionally divergent regulation.

This consensus thinking not only benefits IPAC-RS member companies, but can enrich the broader scientific/regulatory communities and ultimately the quality of the medicines that go to patients."

OVER 20 YEARS
OF OINDP LEADERSHIP

Four Workstreams:
CMC tests, BE/IVIVC tests, Devices, General regulatory

20 Working Groups and subgroups,
including Board and Planning Committee

Publications:
More than 125 articles in peer reviewed journals, including an AAPS Outstanding Manuscript award

Comments on 32 international guidances
from China's agencies, EMA, European Commission, Health Canada, ISO and ICH, MHRA, US FDA, and USP

Dozens of meetings
with international regulators and standard setting bodies in the US, EU, China, and Brazil.

Webinars and Conferences:
more than 70 presentations

IPAC-RS STRATEGIC PRIORITIES

ENGAGE

Engage actively with regulatory agencies and standard setting bodies globally on current and emerging issues, guidances, compendial chapters and consensus standards.

CONTINUE SCIENTIFIC DISCUSSIONS

Continue scientific discussions among IPAC-RS members and with external stakeholders in areas of common interest. Conduct and publicize joint research.

IMPROVE COMMUNICATIONS

Continuously improve IPAC-RS internal and external communications and provide up-to-date information to IPAC-RS members on relevant developments.

INCREASE VISIBILITY

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

IPAC-RS SUCCESSES IN 2019

15 Responses to international regulatory guidances or standards

9 Meetings/Engagements with international regulators

8 Publications

3 Ongoing collaborations with international partners and academic institutions.

2019 REGULATORY ENGAGEMENT

COMMENTS TO FDA

- Contents of a Complete Submission for Threshold Analyses and Human Factors Submissions to Drug and Biologic Applications Guidance for Industry and FDA Staff →
- Principles of Premarket Pathways for Combination Products Guidance for Industry and FDA Staff →
- Instructions for Use — Patient Labeling for Human Prescription Drug and Biological Products and Drug-Device and Biologic-Device Combination Products →

COMMENTS INCLUDING USP

- On revised chapter <601> →
- On chapters <1603> and <1604> →
- Responses to FDA comments on the Stimuli Article The Application of Abbreviated Impactor Measurement and Efficient Data Analysis in the Lifecycle of an Orally-Inhaled Product: A Roadmap [Pharmacopeial Forum (PF), Vol. 44, No. 4] →

COMMENTS TO EUROPEAN MEDICINES AGENCY (EMA)

- Guideline on the quality requirements for drug-device combinations →

LETTER TO EUROPEAN COMMISSION

- On Rule 20 of Annex VIII of Medical Device Regulation (MDR) →

COMMENTS TO MHRA

- Consultation on the application of Analytical Quality by Design concepts to pharmacopoeial standards for medicines. →

ENGAGING WITH CHINA AGENCIES AND ORGANIZATIONS

- Submitted comments to the Center for Drug Evaluation's guideline on bioequivalence for orally inhaled drug products
- Engaged with National Institutes for Food and Drug Control representatives to develop scientific exchanges
- Submitted comments on the inhalation and nasal related chapters 0111 Inhalation Preparations; 0112 Sprays; 0113 Aerosols; to the Chinese Pharmacopeia
- Submitted comments on the China National Pharmaceutical Packaging Association (CNPPA) draft guideline on extractables studies for inhalation products

2019 PUBLICATIONS

Plume Geometry Testing Relevance and Methodology: An IPAC-RS Survey. →
Frank Chambers, Samiran De, Sherryl Baxter, Adrian Parkinson, Bill Doub, Iain Breakwell, Manfred Fischer, and Lee M. Nagao. RDD 2018, Volume 2, 2018: 437-442.

Performance of the Population Bioequivalence (PBE) Statistical Test with Impactor Sized Mass Data →
AAPS PharmSciTech (2019) 20:296. DOI: 10.1208/s12249-019-1507-8 Stephanie Chen, Beth Morgan, Hayden Beresford, Elise Burmeister Getz, David Christopher, Göran Långström, Helen Strickland, Christopher Wiggenhorn, and Svetlana Lyapustina.

Aerodynamic Particle Size Assessment of Orally Inhaled Products: An Assessment of the Need for Controls on Particle Bounce and Re-entrainment in the Cascade Impactor and for the Mitigation of Electrostatic Charge by the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS), William Doub, Steven Stein, Jolyon Mitchell. Manuscript in preparation.

Overview of Brazilian Requirements for Therapeutic Equivalence of Orally Inhaled and Nasal Drug Products →
Marcia Silva, Helena Costa, Bruna Nardy, Lee Nagao, Gustavo Mendes Lima Santos. AAPS PharmSciTech August 2019, 20:235.

Determination of Passive Dry Powder Inhaler Aerodynamic Particle Size Distribution by Multi-Stage Cascade Impactor: International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) Recommendations to Support Both Product Quality Control and Clinical Programs. →
Jolyon P. Mitchell, Stephen W. Stein, William Doub, Adrian P. Goodey, J. David Christopher, Rajni B. Patel, Terrence P. Tougas, Svetlana Lyapustina. AAPS PharmSciTech. July 2019, 20:206 10.1208/s12249-019-1416-x.

Cascade Impactor Equivalence Testing: Comparison of the Performance of the modified Chi-Square Ratio Statistic (mCSRS) with the original CSRS and EMA's Average Bioequivalence Approach. →
Abhinav Kurumaddali, David Christopher, Dennis Sandell, Helen Strickland, Beth Morgan, Juergen Bulitta, Christopher Wiggenhorn, Stephen Stein, Svetlana Lyapustina, Günther Hochhaus. doi:10.1208/s12249-019-1443-7 AAPS PharmSciTech; 2019;20:249; 1–17.

C**omments on FDA Combination Product Guidance submitted to FDA (2019).** →

An IPAC-RS Overview. → Inhalation, Feb 2019.

WHAT PEOPLE ARE SAYING...
INDIVIDUAL PERSPECTIVES ON IPAC-RS.

"The benefit of being part of the IPAC-RS Consortium is that it allows us to keep up with emerging trends in regulatory considerations regarding OINDP and to help gain industry consensus, scientific based positions regarding any proposed new regulations."

PAUL ATKINS, CHAIR, IPAC-RS BOARD OF DIRECTORS
ORIEL THERAPEUTICS/NOVARTIS

"By bringing together the top experts in the world in Inhalation development and manufacturing, IPAC-RS enables a cohesive, credible and strong voice of the industry towards guidance commenting to health agencies, standard-setting bodies and international pharmacopeias across several regions."

CARLA VOZONE, VICE CHAIR, IPAC-RS BOARD OF DIRECTORS
HOVIONE

"GSK participates in IPAC-RS to help advance the science of OINDP. Our membership enables us to work collaboratively as an industry group and to engage with many regulatory agencies, gaining a better understanding of requirements but also working to ensure that requirements are sound and will lead to safe and effective medicines for patients."

SUE HOLMES, PAST-CHAIR, IPAC-RS BOARD OF DIRECTORS
CURRENT CHAIR, GRRO NORTH AMERICA
GLAXOSMITHKLINE

"IPAC-RS is well established inside the regulatory dialogue, with industry leaders involved in key meetings, workshops and communication with global regulatory agencies, sharing their knowledge and experience for the benefit of members, healthcare professionals and patients. Both from when I was an assessor at MHRA and currently as part of the IPQ editorial team, I have been impressed with the collaborative approach at IPAC-RS – supporting research and developing unified industry positions to drive science- and risk-based regulation of OINDP."

JANINE JAMIESON, EUROPEAN EDITOR
INTERNATIONAL PHARMACEUTICAL QUALITY

WHAT'S NEW FOR 2020

IPAC-RS IS:

- Participating in, and submitting case studies to inform OINDP knowledge sharing.
- Developing joint symposia in collaboration with the Respiratory Drug Delivery (RDD) conference highlighting 'The Global Regulatory Landscape and Advances in Digital Technology: Transforming the Patient Experience with OINDPs.'
- Collaborating with Aptar and the CPIA to develop a drug delivery workshop to be held in Beijing, China.
- Developing a 'Matrix of Common Use Errors.'
- Finalizing a manuscript on Aerodynamic Particle Size Assessment of Orally Inhaled Products.
- Assessing results from an industry bencharking survey on biocompatibility.
- Developing a manuscript on plume geometry and spray pattern.
- Discussing statistical approaches around product quality demonstration strategy for quality assessments and PK batch-to-batch variability in bioequivalence assessments.
- Responding to the changing needs of the OINDP community, it is actively reviewing its membership levels and associated benefits.
- Faciliting "Review of the Population Bioequivalence Criterion (PBE)" webinar with Anvisa to be held on March 12, 2020.

IPAC-RS MEMBERSHIP

3M
AstraZeneca
Boehringer Ingelheim
Catalent
Chiesi
GlaxoSmithKline
Hovione
Lupin Pharmaceuticals, Inc.
Merck & Co., Inc.
Mylan
Novartis
Sunovion
Teva
Vectura

ASSOCIATE MEMBERS

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

2019 IPAC-RS BOARD OF DIRECTORS

Chair, Paul Atkins, Oriel Therapeutics/Novartis
Vice Chair: Carla Vozone, Hovione
Kathy Ledoux, 3M
Richard Moody, 3M
Mike Needham, 3M
Francois Michelon, AstraZeneca
Andy Rignall, AstraZeneca
Jochen Faul, Boehringer Ingelheim
Holger Memmesheimer, Boehringer Ingelheim
Morgana Sebenello Wolf, Boehringer Ingelheim
Craig Davies-Cutting, Catalent
Carol Evans, Catalent
David Wilcox, Catalent
Gaetano Brambillia, Chiesi
William Nadler, Chiesi
Francesca Usberti, Chiesi
Jeremy Clarke, GlaxoSmithKline
Sue Holmes, GlaxoSmithKline
Eunice Costa, Hovione
Axel Perlwitz, Lupin
Robert Berger, Merck
Jennifer Wylie, Merck
Andrew Cooper, Mylan
Michelle Lee-Bourner, Mylan
David Pole, Mylan
Valerie, Diart, Novartis
Juergen Jauernig, Novartis
J.R. Keegstra, Novartis
Andrea Bauer, Sunovion
James Conners, Sunovion
Julian Blair, Teva
Prasad Peri, Teva
Samir Shah, Teva
Martin Oliver, Vectura
Helen Spain, Vectura

WORKING GROUP LEADERSHIP

CASCADE IMPACTION
Adrian Goodey, Merck

PRODUCT QUALITY DEMONSTRATION STRATEGY
Helen Strickland, GlaxoSmithKline

PLUME CHARACTERIZATION
Sherryl Baxter, AstraZeneca
Samiran De, Catalent

DEVICES
Tim Chesworth, AstraZeneca
Julian Dixon, Team Consulting, Ltd.
Bjorg Hunter, GlaxoSmithKline
Nia Stevens, Team Consulting, Ltd.
Roisin Wallace, Mylan

OINDP MATERIALS
James Conners, Sunovion

GLOBAL REGULATORY REVIEW AND OUTREACH

GRRO BRAZIL
Leticia Grecchi, Chiesi
Marcia Silva, Boehringer Ingelheim

GRRO CHINA
Mark Hindle, AstraZeneca

GRRO EUROPE
Franz-Josef Rehmann, AstraZeneca
Sarah Polley, Vectura

GRRO NORTH AMERICA
Sue Holmes, GlaxoSmithKline

POPULATION BIOEQUIVALENCE
Dave Christopher, Merck
Beth Morgan, AstraZeneca

PK BATCH TO BATCH
Beth Morgan, AstraZeneca

ANALYTICAL METHODS KNOWLEDGE NETWORK
Andy Rignall, AstraZeneca

IPAC-RS/RDD ORGANIZING COMMITTEE
Jeremy Clarke, GlaxoSmithKline
Andy Rignall, AstraZeneca

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.

TEAM SUPPORT FOR IPAC-RS INCLUDES:

- Facilitating member company 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 in-person meetings

JOIN TODAY!

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

Associate Membership is open to corporations that develop or manufacture components and/or devices for OINDPs or provide scientific or technical services relating to development and manufacture of OINDPs.

Because membership is at the company level, members enjoy unlimited participation on IPAC-RS working groups and IPAC-RS educational webinars.

For questions about IPAC-RS' priorities, progress, or membership, please email **info@ipacrs.org** or contact:

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