Strategic Plan
2025–2027

IPAC-RS

International Pharmaceutical Aerosol Consortium on Regulation & Science

Vision

The International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) is and will remain the leading technical resource for and advocate of the orally inhaled and nasal drug product (OINDP) industry, with a focus on Chemistry, Manufacturing and Controls (CMC).

Mission

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

Purpose

1. **Advance the science and regulation of orally inhaled and nasal drug products (OINDPs) through discussion, research, and publication.** Identify and address key questions for OINDPs through key initiatives and develop and publish best practices for OINDPs.
2. **Drive scientific knowledge and sound assessment of global regulatory requirements for OINDPs.** Engage in initiatives to facilitate current and future OINDP development, which benefit the entire industry in the service of patients.
3. **Collaborate with the broader OINDP industry, OINDP suppliers, regulatory authorities, and other stakeholders.** Expand relationships with decision-makers at global regulatory agencies and standard-setting bodies. 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, actively comment on OINDP regulations and guidances, and promote clear and harmonized international regulatory expectations in the field.** Engage regulatory authorities in constructive discussion and sharing of ideas on OINDP best practices.

2025–2027

Strategic Goals

01 Engage actively with global regulatory agencies and standard-setting bodies by monitoring and responding to current and emerging issues, commenting on guidances and compendial chapters, developing and discussing consensus standards, and other appropriate means.

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

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

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

05 Educate industry and regulatory bodies on current and future challenges through workshops, seminars, white papers, etc.

Priority Topics for 2025-2027

Under the guidance of IPAC-RS Board of Directors, the priorities listed below will be addressed by the Consortium in 2025-2027. Specific implementation will be determined according to each topic's specifics, such as its regulatory import, external timeframes, availability of experts, project's maturity, and other factors. The work will be conducted through Working Groups, Subteams, and Knowledge Networks (see Appendices). Limited-duration committees (e.g., to organize a conference or a roundtable, develop comments on a guidance or compendial chapter, plan a meeting with an agency, etc.) will be established and dissolved, as needed.

Regulatory Priorities

- Monitor and respond to regulatory guidelines and standards around the world.
- Continue development of working relationships and constructive collaboration with global regulatory agencies and standard-setting bodies of interest to IPAC-RS members.
- Develop and share educational materials through publications, workshops, webinars.
- Facilitate dialogue and harmonization of requirements across regions and agencies, e.g., by identifying areas in need of alignment and discussing them through meetings and publications.
- Clarify regulatory expectations on advanced and emerging issues, such as inhaled and nasal biologics, low-global-warming-potential (LGWP) propellants, sustainability, and others.
- Engage EMA and Heads of Medicines Agencies to develop a mechanism for provision of scientific advice from Notified Bodies on complex or novel approaches or devices.
- Understand how the F-gas & P-FAS regulation is being implemented through different country regulations.

Scientific Priorities

- Understand the current state of the art, as well as develop and publish best practices for:
  - Environmentally-sustainable OINDPs throughout their entire lifecycle (from research and development, through manufacturing and commercialization, to recovery and recycling)
  - CMC characterization of biological products for inhaled or nasal delivery
  - LGWP propellant transition
  - Formulation development and product manufacturing for current and new product types, for example, biologics products

Priority Topics for 2025-2027 *continued*

External Engagement, Education, Communication Priorities

- Establish contacts and collaborate with other organizations, such as:
  - Aerosol Society (UK)
  - Center for Research on Complex Generics (CRCG)
  - Circularity in Primary Pharmaceutical Packaging Accelerator (CiPPPA)
  - European Pharmaceutical Aerosol Group (EPAG)
  - International Pharmaceutical Aerosol Consortium (IPAC)
  - International Society for Aerosols in Medicine (ISAM)
  - Product Quality Research Institute (PQRI)
- Engage with patients, caregivers, and healthcare providers to better understand their needs and experiences.
- Further strengthen the IPAC-RS and broader OINDP community through:
  - Research and position papers
  - Regular meetings of all groups, committees, and Board of Directors
  - Internal and public webinars and roundtables on key topics of interest
  - Members only IPAC-RS Connect portal and the public website (https://www.ipacrs.org)
  - Monthly members only newsletters
  - Public conferences and symposia organized by IPAC-RS and in collaboration with other organizations
  - Presentations at meetings organized by other stakeholders (e.g., regulatory agencies, trade associations)

Future-Growth Priorities

- The following areas will be actively monitored and periodically discussed, with a potential for initiating IPAC-RS activities in the future:
  - Nebulizers and soft-mist inhalers
  - Impact of environmental regulations (e.g., PFAS, F-Gas, AIM, plastics) on OINDP componentry and excipients
  - Nose-to-brain delivery
  - Reformulating injectable and IV formulations for inhaled or nasal delivery
  - Utility and application of artificial intelligence in product development, e.g., data capture and analysis as well as modelling and product use

Membership Growth

- Continue to grow the consortium. Actively integrate Associate Members in IPAC-RS projects.

Benefits

IPAC-RS provides long-term benefits to the full OINDP community by advancing regulatory science of OINDPs, facilitating sound research to support scientifically-driven policy, and developing relationships with key industry, supplier, and regulatory contacts. IPAC-RS Members and Associate Members enjoy a number of benefits from participation, including the following areas:

► Research and Best Practices

- Members drive impactful IPAC-RS research projects in a cost-effective manner.
- Through engagement in IPAC-RS activities, members learn, develop, and implement best industry practices, leverage collective expertise, and shape IPAC-RS public recommendations.
- Through the consortium, Members can collect and analyze blinded data from across the industry, which in turn informs IPAC-RS recommendations to regulators, pharmacopeias, global regulatory agencies and standard-setting bodies , and other stakeholders.

► Global Regulations

- Members can develop and present unified positions to strengthen the scientific basis of regulatory approaches around the world.
- Through regular interactions with industry peers and invited guests, as well as through regular newsletters and flash alerts, Members stay up-to-date on emerging regulatory developments and can respond to critical issues, as appropriate.

► Education and Support of Community

- IPAC-RS develops roundtables, webinars, training courses, and detailed technical reports, some of which are accessible only to Members and others are public, as appropriate.
- All IPAC-RS resources are freely available to all colleagues in IPAC-RS member companies, enriching their internal training and educational offerings.
- IPAC-RS regularly invites external experts to discuss scientific, technical, and regulatory issues of mutual interest.
- IPAC-RS conducts public conferences and symposia, publishes research and white papers, maintains a public website, and offers other resources to support IPAC-RS Members as well as those interested in OINDPs.
- IPAC-RS contributes to, and shapes, the public discourse on areas critical to the IPAC-RS mission.

► Networking

- IPAC-RS Members enjoy sustained interactions with their peers on meaningful topics, as they jointly develop and implement workplans, discuss emerging trends, and enable adoption of best practices throughout the IPAC-RS community and beyond.

IPAC-RS Workstreams

As of December 2024

WORKSTREAMS	WORKING GROUPS & KNOWLEDGE NETWORKS[1]
GLOBAL REGULATORY REVIEW AND OUTREACH (GRRO)	
• Stay abreast of global regulatory developments for OINDPs. • Understand requirements for OINDPs in emerging markets. • Engage in outreach to regulatory agencies, pharmacopeias and other global regulatory agencies and standard-setting bodies, as appropriate. • Monitor and address, as appropriate, environmental and sustainability priorities.	• **China Subgroup** • **Brazil Subgroup** • **Europe Subgroup** • **North America Subgroup** • **Alternate Propellants Subgroup**
EXTERNAL OUTREACH	
• Grow and evolve membership to ensure IPAC-RS is equipped to address current and future challenges. • Develop and implement visibility and outreach strategies to achieve growth goals. • Advance the science and scientific discourse between IPAC-RS and external stakeholders in areas of common interest. • Collaborate with other trade groups on relevant issues. • Increase public visibility of IPAC-RS advocacy, technical work, and subject matter expertise.	• **Membership Committee** • **Roundtables, webinars, and conferences with key stakeholders and thought leaders** • **Collaborations with other organizations, as appropriate (e.g., ISAM, RDD, DDL, EPAG, AAPS, CRCG, IPAC, PQRI)**
PRODUCT DEVELOPMENT	
• Monitor, assess, and respond to regulatory developments related to chemistry, manufacturing, and controls (CMC) and product development for small/synthetic molecules as well as large molecules and biologics. • Develop improved approaches, "best practices" and other recommendations for CMC and product development analytical testing, formulation, manufacturing, stability, material selection, product characterization, and other topics.	• **Aerodynamic Particle Size Distribution (APSD) Testing/Cascade Impaction (CI)** • **Inhaled and Nasal Biologics** • **Product Quality Demonstration Strategy (PQDS) KN** • **Analytical Methods Lifecycle Management KN**
DELIVERY SYSTEMS	
• Develop and share industry practices and monitor regulatory developments related to OINDP devices, device-patient interface, and container closure systems. • Develop and promulgate device-related recommendations for OINDP industry, device manufacturers, regulators, health-care providers, patients, and other potential stakeholders. • Explore and collaboratively address challenges related to nasal delivery systems. • Discuss and publish considerations for materials selection and quality with new propellants. • Examine regulatory requirements related to change management, starting with Europe and thereafter in the US and later in other world regions. Promote streamlining and harmonization of requirements.	• **OINDP Materials** • **Materials and Propellants Quality Considerations** • **Change Management** • **Nasal Working Group and Subteams**

[1] Knowledge Networks (KN) are comprised of IPAC-RS experts in a given subject matter (typically from sunset working groups), who may monitor developments and share relevant updates, and may be called upon to address specific topics, if a new need arises.

Details of WG Plans

As of November 2021.
The Board may establish new working groups to meet the 2022-2024 objectives.

GROUP NAME	SPECIFIC GOALS	GROUP TYPE
GENERAL GUIDANCE		
GRRO - China	Work with the Chinese agencies to develop webinars and roundtables on key and emerging topics.	WG
GRRO - Brazil	Work with Anvisa, track and respond to developments and guidelines. Organize knowledge sharing sessions	WG
GRRO - Europe	Monitor and respond to the guidelines from European (including UK) agencies and pharmacopeias. Engage with EMA and HMA regarding Notified Bodies. Contrast and compare 2024 draft EMA guidelines with their previous versions.	WG
GRRO – North America	Track and respond to guidelines from FDA, USP, Health Canada. Collaborate with CRCG, discuss regulatory science with FDA (CDER, CDRH, Office of Combination Products), USP and others	WG
GRRO - Alternate Propellants	Monitor global regulatory and scientific developments related to the LGWP propellant transition, develop educational materials, participate in public meetings, organize webinars, present at conferences in order to facilitate a timely transition to environmentally friendly propellants. Coordinate activities of other IPAC-RS WGs that impact the LGWP propellant transition.	WG
EXTERNAL OUTREACH		
Roundtables, Webinars, Conferences	Complete the digital-device roundtable series and consider developing further roundtables on emerging topics (e.g., nebulized biologics, environmental sustainability, etc.). Organize conferences and summits, e.g., on technological innovations, in collaboration with RDD, ISAM, and others as appropriate.	Org. Cmte. (short duration)
Membership Committee	Identify potential new members, introduce them to IPAC-RS portfolio and benefits, and facilitate growth of the consortium.	
PRODUCT DEVELOPMENT		
APSD Testing/ Cascade Impaction (CI)	Update the APSD database. Plan and conduct experiments on high-payload particles. Advance AIM and EDA topics and promote harmonization of USP and European Pharmacopeia requirements. Research and publicize findings related to compendial methods and current practices.	WG
Inhaled & Nasal Biologics	Discuss areas of common interest to developers of inhaled and nasal biologics (for example, bioassay variabilities, plaque assays, immunogenicity, stability, excipients, formulation, manufacturing, microbial testing, etc.) and develop specific projects to address these challenges through collaboration.	WG
Product Quality Demonstration Strategy (PQDS)	Discuss PQDS approaches and promote them through publications, presentations, and comments to guidelines and pharmacopeial chapters.	KN
Analytical Methods Lifecycle Management	Track and discuss ICH guidelines related to analytical methods lifecycle management, seek to provide input from the OINDP perspective. Coordinate with other IPAC-RS groups (e.g., PQDS, APSD,) to discuss Established Conditions as applied to OINDP methods, prepare comments, and publicize IPAC-RS positions in this area, as appropriate.	KN

Details of WG Plans *Continued...*

GROUP NAME	SPECIFIC GOALS	GROUP TYPE
DELIVERY SYSTEMS		
OINDP Materials	Respond to guidelines and standards for testing of materials, components, final product (e.g., biocompatibility, leachables and extractables, compatibility). Lead on outreach to supply chain entities; develop output from packaging sustainability roundtables	WG
Materials & Propellants Quality Considerations	Create a framework to guide and inform industry and regulatory agencies in navigating the propellant change, focusing on drug product and manufacturing process, materials selection and evaluation.	WG
Change Management	Develop risk-based approaches to assess whether a change that affects the performance and safety characteristics of a device needs a Notified Body Opinion, or if the variation process can be submitted to the Competent Authority with the Risk Assessment report in support of the "non substantial" classification of the change. Seek ways to engage EMA (or competent authority) on developing a mechanism for their consultation with Notified Bodies during a pre-submission process with the goal of developing a more consistent process for advice on major/minor device related changes.	WG
Nasal	Address regulatory-science issues for intranasal products. In the first phase, the following specific topics are being addressed through subteams: Pediatrics, Pharmacopeial Standards and Regulatory Guidance Review and Gap Analysis, Reliability Expectations, Advanced Methodologies, Statistics, and Bioequivalence Approaches.	WG

IPAC-RS

International Pharmaceutical Aerosol Consortium on Regulation & Science

www.ipacrs.org

info@ipacrs.org