2019 THRU 2021 STRATEGIC PLAN

Core Objectives

Vision

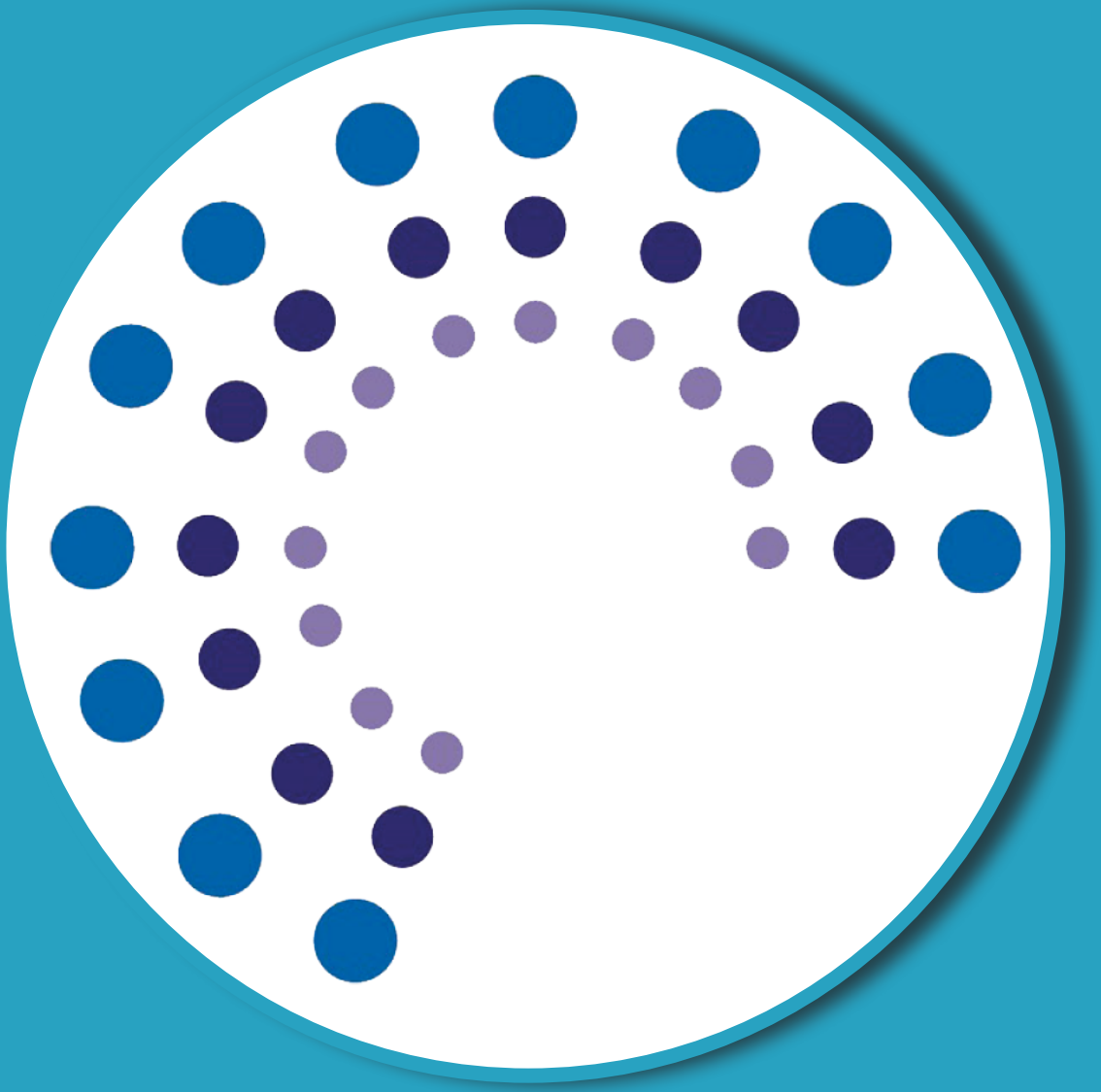
The International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) is and will remain the leading technical resource and advocate of the orally inhaled and nasal drug product (OINDP) industry, with a focus on Chemistry, Manufacturing and Controls aspects.

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.

Purpose

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.



2019-2021

Strategic Goals

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

2. Continue scientific discussions 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. Continuously improve IPAC-RS internal and external communications.

Member 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 regulator contacts. IPAC-RS members benefits extend to a number of areas:

Research

- Members drive impactful IPAC-RS research projects in a cost-effective manner
- Members can learn, develop and implement best industry practices, leverage collective expertise, and shape IPAC-RS public recommendations

Regulation

- Members can develop and present unified positions to strengthen scientific basis of regulatory approaches.
- Through the consortium, members can collect and analyze blinded data from across the industry, which in turn informs IPAC-RS recommendations to regulators and wider community.
- Through regular interactions with industry peers and invited guests, as well as through regular newsletters and flash alerts, members stay up-to-date emerging regulatory developments and can respond to critical issues as appropriate.

Education

- IPAC-RS working groups develop webinars, training courses and detailed technical reports that are accessible to members only. In addition, IPAC-RS regularly invites external experts to present on scientific, technical and regulatory issues of interest. All these resources may be used by member company colleagues as needed.
- In addition, IPAC-RS conducts public conferences and symposia, and publishes research and white papers, thereby contributing to, and shaping, public dialogue on areas critical to the IPAC-RS mission.

IPAC-RS Workstreams

WORKSTREAMS	WORKING GROUPS AND KNOWLEDGE NETWORKS
GENERAL	
▪ Stay abreast of global regulatory developments for OINDPs. ▪ Understand requirements for OINDPs in newer markets ▪ Conduct outreach to regulatory agencies, pharmacopeias & other standard-setting bodies worldwide as appropriate. ▪ Collaborate with other trade groups on relevant issues.	**Global Regulatory Review and Outreach (GRRO)** **China Subgroup** **Brazil Subgroup** **Europe Subgroup** **North America Subgroup** **Public Conferences, e.g.,** **IPAC-RS/RDD 2020 Joint Symposium** **IPAC-RS/ISAM 2019 Joint Workshop**
BA/BE AND IVIVC	
▪ Monitor, evaluate and engage in discussions related to research & regulatory recommendations for bio-availability (BA), bioequivalence (BE), in-vitro/in-vivo correlations (IV/IVC), clinical inputs for Quality-by-Design (QBD) and similar topics. ▪ Stay abreast of clinical research and foster relevant collaborations.	**PK Batch to Batch Variability Discussion Group** **Population Bioequivalence (PBE) WG**
CMC AND PRODUCT DEVELOPMENT TESTS	
▪ Monitor regulatory developments related to chem-istry, manufacturing and controls (CMC) & product development requirements. Assess and respond to regulatory developments as appropriate. ▪ Develop improved approaches, “best industry practices” & other recommendations for CMC and product development tests, such as delivered dose uniformity, aerodynamic particle sizing, material characterization.	**Cascade Impaction (CI)** **Product Quality Demonstration Strategy (PQDS)** **Analytical Methods Knowledge Network**
DELIVERY SYSTEMS	
▪ Study industry practices and regulatory develop-ments related to OINDP devices, device-patient interface, container closure systems. ▪ Develop and promulgate device-related recommen-dations for OINDP industry, device manufacturers, regulators, health-care providers, patients and other potential stakeholders.	**Devices** Instructions for Use Human Factors Relevant ISO standards MDR Implementation **OINDP Materials**

Working Groups develop specific workplans for each year, and present the plans and subsequent updates to the IPAC-RS Board of Directors on a regular basis. The working groups collaborate with each other as needed.

Knowledge Networks comprise 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.


IPAC-RS
www.ipacrs.org