

# CROSS-INDUSTRY Organizations

## The International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS): An update and review of 2023

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On behalf of the International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS)

### An overview

The International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) is an international association that seeks to advance the regulatory science of orally inhaled and nasal drug products (OINDPs) by collecting and analyzing data, and conducting joint research and development projects. 2023 was another productive and highly prolific year for IPAC-RS through the collaboration of 16 members and 10 associate members.

### Regulatory activities

IPAC-RS remains highly active in the global regulatory space. One substantial effort was the development of joint comments by IPAC-RS and IPAC (the International Pharmaceutical Aerosol Consortium) to the European Chemicals Agency (ECHA) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regarding proposed per- and polyfluoroalkyl substances (PFAS) restrictions. IPAC-RS and IPAC also submitted comments to Health Canada on the Draft State of PFAS Report and Risk Management Scope for PFAS. Copies of the joint comments are available on the IPAC-RS website (<https://www.ipacrs.org/lgwppropellants>).

IPAC-RS Working Groups regularly engage with the United States Food and Drug Administration (FDA). IPAC-RS provided comments on the FDA draft guidance on Statistical Approaches to Estab-

lishing Bioequivalence. IPAC-RS met with the Center for Complex Generics (CRCG) to discuss mutual areas of interest. IPAC-RS also met with the FDA Office of Combination Products to discuss a way to mitigate divergent requirements coming from the Center for Drug Evaluation and Research (CDER) and the Center for Devices and Radiological Health (CDRH) with respect to drug/device combination products.

IPAC-RS reviews United States Pharmacopeia (USP) updates regularly and has provided comments on chapters including revised chapter <604> Leak Rate (of aerosol containers), <429> Light Diffraction Measurement of Particle Size, and the following chapters published in Pharm.Forum 49(2): USP 87, 88, 1031, 660 and 661.2. Additionally, in May, joint IPAC-RS/IPAC/EFPIA (European Federation of Pharmaceutical Industries and Associations) comments were developed on the document titled, "Questions and Answers on Data Requirements When Replacing Hydrofluorocarbons as Propellants in Oral Pressurized Metered Dose Inhalers" (European Medicines Agency Committee for Medicinal Products for Human Use (EMA/CHMP) 83033/2023).

IPAC-RS reviewed draft guidances from the Chinese and Japanese regulatory authorities. The IPAC-RS Global Regulatory Review and Outreach China group secured an inclusion of IPAC-RS in the

2024 Drug Information Association (DIA) China meeting's program, with expected participation from the China Center for Food and Drug International Exchange (CCFDIE), National Institutes for Food and Drug Control (NIFDC), Chinese Pharmacopoeia (CHP), Centre for Drug Evaluation (CDE) and relevant colleagues from regulatory, industry and scientific institutions.

### Technical activities

IPAC-RS published three high-impact papers in AAPS PharmSciTech:

- An Overview and Discussion of N-nitrosamine Considerations for Orally Inhaled Drug Products and Relevance to Other Dosage Forms,
- 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) and
- Laboratory Performance Testing of Aqueous Nasal Inhalation Products for Droplet/Particle Size Distribution: An Assessment from the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS).

The Materials Working Group prepared a paper on biocompatibility considerations for OINDPs, currently under review.

IPAC-RS workshops and webinars in 2023 included: “

- Advancing Sustainability of Device and Container Closure Systems Part II, which expanded on sustainability concepts presented during the 2022 IPAC-RS/RDD Joint Session
- Transition to Low Global Warming Potential Propellants for Metered Dose Inhalers, which included a US FDA and an EMA speaker and covered regulatory and technical aspects of the ongoing transition
- Joint IPAC-RS/ISAM workshop on inhaled and nasal biologics, which included representatives from the Federal Institute for Drugs and Medical Devices [of Germany] (BfArM) and the US FDA, and covered CMC aspects of inhaled and nasal biologics.

### **In the broader stakeholder community**

IPAC-RS remains engaged with the broader stakeholder community through participation in OINDP conferences including PharmSci 360. An overview of IPAC-RS was presented at the Plenary Meeting of the European Pharmaceutical Aerosol Group (EPAG) and the two organizations agreed to continue discussions on topics of mutual interest, such as cascade impaction.

In 2023, IPAC-RS conducted a survey on Stakeholder Perspectives on Switching Current pMDIs to New Propellants. Another survey focused on Laser Diffraction—Characterization of Nasal Products to gather industry perspectives on laboratory use including issues encountered, suggestions for improved use and recognized complementary technology.

IPAC-RS also has started collecting information about the scientific and technical aspects of LGWP propellants, which is stored in an Alternative Propellants Information Repository on

the public website (<https://www.ipacrs.org/lgwppropellants>).

IPAC-RS works closely with IPAC on efforts related to sustainability and inhalers. IPAC strives to ensure global environmental policies relevant to inhaled therapies are patient-centric and appropriately balance patient care and sustainability. Information about IPAC can be found at [www.ipacinhale.org](http://www.ipacinhale.org).

### **Learn more**

Visit the IPAC-RS public website, <http://www.ipacrs.org>, to learn about ongoing activities and follow the consortium on LinkedIn. IPAC-RS also has a video channel featuring past webinars: <https://www.gotostage.com/channel/ipacrswebinars>. To view the schedule and register for upcoming Roundtables, visit <https://www.ipacrs.org/roundtables>.

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