CROSS-INDUSTRY Organizations

An update from the International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS)

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

The International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) has been driving scientific and regulatory progress for orally inhaled and nasal drug products (OINDPs) since 1999. The consortium facilitates collaborative research and knowledge-sharing with the goal of building consensus and contributing to regulations and standards. In this article, we provide an update on 2021-2022 initiatives and accomplishments of IPAC-RS. Further information is available in the IPAC-RS 2021 Year in Review at https://www.ipacrs.org.

An overview

IPAC-RS has continued active engagement in a number of key areas over the past year. In late 2021, the IPAC-RS Board of Directors developed and adopted a new Strategic Plan for the years 2022-2024. The Board reaffirmed several long-standing priorities of the consortium—including regulatory outreach, research and publication of best practices—and also recognized environmental sustainability, nasal drug development, patient centric design, and biologics delivered by inhalation or intranasally, as specific new priorities. The tactical goals and specific topics that IPAC-RS plans to address will ensure that IPAC-RS remains a leading technical resource and advocate for the OINDP industry. Furthermore, interactions with global regulatory agencies and re-engaging in the Product Quality Research Institute (PQRI) as a member, has broadened the reach of the consortium. IPAC-RS activities and collaborations continue to play an important role in the US, EU, Asia and South America, and have resulted in several publications, presentations and a roundtable series.

Regulatory activities

The Global Regulatory Review and Outreach (GRRO)-North America Working Group (WG) has made great strides with various initiatives. Notably, members connected with the leaders of the Center for Research in Complex Generics (CRCG) established by the United States Food and Drug Administration (FDA) in 2020. IPAC-RS and the CRCG are discussing areas of mutual interest and considering potential future collaborations related to OINDP regulatory science approaches. IPAC-RS also engaged with the US Pharmacopeia (USP) and submitted comments on several USP draft chapters published in *Pharmacopeial Forum.*

The GRRO-China WG has been working to hold another scientific roundtable with regulatory agencies and organizations in China, which could cover topics including combination products, digital components, new formulation types delivered by OINDPs and international harmonization. Other recent work by this group included submitting comments to the Center for Drug Evaluation's (CDE's) draft guideline "Technical Requirements for Pharmaceutical Research on Chemical Inhalation Liquid Preparations." In addition, regular knowledge-sharing sessions on current regulatory developments in China relevant to OINDPs were conducted.

The GRRO-Brazil WG hosted a special presentation titled "Biosafe Cabin for Spirometry in Response to COVID-19 Restrictions," discussing research done by an IPAC-RS member company and use of the cabin in healthcare situations in Brazil. Another notable project by this group was a survey to gauge companies' experiences with the therapeutic equivalence resolution (RDC 278) and normative instruction (IN 33), with respect to post-approval changes. The group collaborated with Interfarma to circulate the survey within Brazil. The group continues to monitor and report on Anvisa activities and issues.

The GRRO-Europe WG held a "summer chat" roundtable in 2021 on Medical Device Regulation (MDR) implementation. Representatives from BSI and TUV SUD shared their experience with the recent Q&A guideline and other MDR updates.

Technical activities

The Cascade Impaction (CI) WG met with representatives of USP, as well as the European Directorate for the Quality of Medicines & HealthCare (EDQM), to discuss harmonization of pharmacopeial approaches, Abbreviated Impactor Measurements (AIM) and Efficient Data Analysis (EDA). The CI WG is continuing development of best practices for aqueous formulations and considering a refresh of the IPAC-RS Aerodynamic Particle Size Distribution (APSD) database.

The Analytical Lifecycle Management Knowledge Network monitored the development of ICH Guidelines Q14 "Analytical Procedure Development" and Q2(R2) "Validation of Analytical Procedures." They also discussed application of these guidelines to drug-device combination products such as OINDPs, and spearheaded the preparation of IPAC-RS comments on those guidelines.

Some of the publications developed by IPAC-RS during the last two years include:

- "Performance of Multiple-Batch Approaches to Pharmacokinetic Bioequivalence Testing for Orally-Inhaled Drug Products with Batch-to-Batch Variability." AAPS PharmSciTech. https://doi.org/10.1208/s12249-021-02063-1
- "Spray Pattern and Plume Geometry Testing and Methodology: An IPAC-RS Working Group Overview." PharmSciTech. https://doi.org/10.1208/s12249-022-02278-w
- "Efficient Data Analysis (EDA), a Science-based Alternative to Fine Particle Dose and Stage Groupings: A Win-Win for Patients and Industry." Inhalation. Inhalation: August 2021 (mydigitalpublication.com)
- The CI Working Group's Letter to the Editor of the Journal of Aerosol Medicine and Pulmonary Drug Delivery: "Moving Forward from "Fine Particle Fraction: The Good and the Bad." JAMPDD. https://doi.org/10.1089/jamp.2022.0017

In the broader stakeholder community

IPAC-RS has maintained a strong presence in the broader stakeholder community by co-organizing and partcipating in conferences and broadly sharing its work. IPAC-RS collaborated with Respiratory Drug Delivery to develop a joint session at RDD 2022 on Regulatory, Science and Technology Innovations Enabling Novel and Improved OINDP Design, Development and Manufacturing. As a follow-up to this session, several roundtables are being scheduled for late 2022 and into 2023.

IPAC-RS has organized a number of roundtables with thought leaders to discuss key regulatory and scientific topics regarding respiratory products. The 2021 Roundtable Series focused on drug/device combination products with digital components and, more broadly, digital health opportunities and challenges. Presented by subject matter experts in the pharmaceutical sciences, this series was a unique opportunity to learn about the latest research and regulatory trends in digital devices. Dynamic discussions and Q&A sessions made for an interactive and educational experience for the audience.

In the Fall of 2022, a new series of Roundtables launched on patient centric design, sustainability, supply chain, advanced analytics, the regulatory evolution of OINDP, and other topics building on the joint IPAC-RS/RDD session.

Stay connected

For more information on IPAC-RS initiatives and upcoming events, please visit http://www.ipacrs.org and follow the consortium on LinkedIn at https://www.linkedin.com/company/ipacrs.

IPAC-RS now has its own video channel. To watch recordings of previous webinars, visit https://www.gotostage.com/channel/ipacrswebinars.

To view the schedule and register for the upcoming Roundtables, visit https://www.ipacrs.org/roundtables.

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