Cross-industry organizations

IPAC-RS: An update on recent activities

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Since its formation in 2001, the International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) has been serving the orally inhaled and nasal drug products (OINDPs) community by driving scientific and regulatory advancements in the field.

What's new

The year 2019 has been very busy for IPAC-RS. In the past 12 months, IPAC-RS has been actively working on the goals set forth in its strategic plan. The Consortium engaged with regulatory and standard-setting authorities, provided up-to-date information to the members on relevant developments, identified and publicized the OINDP industry's positions on key issues of regulatory science, provided a forum for member discussions, and actively participated in conversations in the wider stakeholder community.

In North America

The Consortium and its Global Regulatory Review and Outreach (GRRO)-North America working group continued to focus on engagement with the United States Food and Drug Administration (FDA), including follow-up related to the 2018 Draft Guidance for Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) products-quality considerations. IPAC-RS also submitted comments to the FDA on draft guidances titled "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," and "Instructions for Use—Patient Labeling for Human Prescription Drug and Biological Products and Drug-Device and Biologic-Device Combination Products—Content and Format."

In addition to the FDA, IPAC-RS continued its commitment to working closely with the US Pharmacopeia (USP), providing feedback on revised chapters <601>, <1603> and <1604>, as well as responding 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."

In China, Brazil and Europe

The GRRO-China working group led the IPAC-RS collection and submission of comments to China's National Medical Products Administration (NMPA) Center for Drug Evaluation (CDE) "Oral Inhalation Formulations of Generic Pharmaceuticals and Human Bioequivalence; Guiding Principles for Research." The group submitted comments on the inhalation and nasal-related chapters 0111 (Inhalation Preparations), 0112 (Sprays) and 0113 (Aerosols) developed by the Chinese Pharmacopeia, and also commented on the China Pharmaceutical Packaging Association (CNPPA) draft guideline on extractables studies for inhalation products. The group also hopes to develop a China-based workshop for 2020, focusing on regulatory topics related to review and approval of OINDPs in China.

The GRRO-Europe has been actively engaging with European regulators. In addition to commenting on the European Medicines Agency (EMA) "Guideline on the Quality Requirements for Drug-Device Combinations," IPAC-RS submitted a joint letter to the European Commission with the IPAC-RS Devices Working Group Medical Device Regulations (MDR) subteam on "Rule 20 of Annex VIII of MDR" and provided feedback on the Medicines and Healthcare Products Regulatory Agency (MHRA)'s "Consultation on the Application of Analytical Quality by Design concepts to pharmacopeial standards for medicines."

The GRRO-Brazil working group met with the Brazilian Health Regulatory Agency (ANVISA) in August to discuss the newly-issued Resolution (RDC 278) and Normative Instruction (IN 33) on OINDP therapeutic equivalence, and co-authored and published an "Overview of Brazilian Requirements for Therapeutic Equivalence of Orally Inhaled and Nasal Drug Products" in the June issue of AAPS PharmSciTech. The group also held three discussions with ANVISA regarding recent OINDP regulations and plans for the upcoming IPAC-RS/ANVISA Population Bioequivalence (PBE) webinar, currently scheduled for early 2020.

In the broader stakeholder community

Following the November 2018 Materials Summit, where IPAC-RS actively engaged with materials, device and packaging component suppliers and regulators, the Consortium held joint workshops with Drug Delivery to the Lungs (DDL) in Scotland (December 2018) and the International Society for Aerosols in Medicine (ISAM) on Digital Health in Respiratory Products in Switzerland (May 2019).

Seven publications on topics ranging from plume geometry to international OINDP requirements and harmonization, PBE, aerodynamic particle size distribution and cascade impactor equivalence testing served to highlight IPAC-RS' key learnings.

Future focus

IPAC-RS is anticipating a productive 2020 and is planning for the joint IPAC-RS/RDD symposium in Palm Desert, California. The symposium is titled "The Global Regulatory Landscape and Advances in Digital Technology: Transforming the Patient Experience with OINDPs." A series of podium presentations and a panel discussion will be held on the morning of Thursday, April 30, as part of the RDD 2020 conference program. The IPAC-RS Symposium will continue on the afternoon of Thursday, April 30 through Friday, May 1.

In 2020, IPAC-RS will continue developing a "Matrix of Common Use Errors," finalizing a manuscript on "Aerodynamic Particle Size Assessment of Orally Inhaled Products," conducting a biocompatibility survey, developing a manuscript on plume geometry and spray pattern, and discussing statistical approaches around product quality demonstration strategy for quality assessments and PK batch-to-batch variability in bioequivalence assessments.

For more information on IPAC-RS, or to join, please visit www.ipacrs.org.

About IPAC-RS

The International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) is an international association that seeks to advance the science, and especially the regulatory science, of orally inhaled and nasal drug products (OINDPs) by collecting and analyzing data, and conducting joint research. IPAC-RS aims to build consensus and contribute to effective regulations and standards by sharing the results of research through conferences, technical journals and discussions with regulatory bodies.