Cross-industry organizations

An update on the activities of IPAC-RS

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On behalf of IPAC-RS

The International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS) continues its efforts to advance regulatory science impacting inhalation and intranasal drug products by working in a collaborative and constructive way, involving as many stakeholders as possible.

Several working groups are currently researching a range of technical issues, including cascade impaction testing, delivered dose uniformity testing and population bioequivalence strategies.

Examples of IPAC-RS activities

Recently, IPAC-RS formed a new feasibility group that has conducted a benchmarking survey on plume geometry methods and the application and value of the test. The consortium is now evaluating the merits of establishing a formal Plume Geometry Working Group for orally inhaled and nasal drug products (OINDPs). Such a working group, if established, would provide a forum for sharing experiences related to this test and develop a paper assessing and discussing the survey results.

Other IPAC-RS working groups, especially those covering patient-focused activities—such as Devices, Human Factors, and Instructions for Use (IFU)—are engaged in both technical and regulatory discussions. In the past year, these groups have tracked the ISO development of standards for aerosol delivery systems, prepared best-practice IFU content for metered dose inhalers, and submitted detailed comments on the Draft Guidances for Human Factors issued by the US FDA and the UK's MHRA.

Publishing consensus recommendations

In those areas where IPAC-RS members see a gap or a need for a common standard, consensus recommendations are developed and publicized. For example, the IPAC-RS Materials Working Group recently finished updating its *Baseline Requirements for Materials used in Orally Inhaled and Nasal Drug Products*, which is publicly available on the IPAC-RS website. The document provides information for developers and suppliers regarding the types of testing and certifications that may be needed for packaging components and container closure systems for OINDPs. The document also discusses expectations and rationales for security of material supply, controlled extraction studies, routine extractables testing and quality agreements. The Materials Working Group is planning a public workshop to discuss *Baseline Requirements* with suppliers and other interested stakeholders, which will take place on March 15, 2018 in Washington, DC.

Interacting with regulatory agencies

The IPAC-RS Global Regulatory Review and Outreach (GRRO) focuses primarily on direct and constructive interactions with regulatory bodies. GRRO consists of four different groups that conduct regulatory assessments and outreach to the regions identified by IPAC-RS members as priorities: Brazil, China, Europe and North America.

The GRRO Brazil group meets regularly to share information and updates, with a focus on Brazil's medicines agency, the Agência Nacional de Vigilância Sanitária (ANVISA), as well as on activities pursued by local pharmaceutical associations. The GRRO Brazil group has met several times with ANVISA representatives to discuss OINDP regulations, specifically ANVISA's development of a guideline addressing therapeutic equivalence for inhalation products. The group has also collaborated with the IPAC-RS Population Bioequivalence (PBE) Working Group to discuss the PBE statistical approach with ANVISA representatives, in relation to this developing guideline.

The GRRO China group shares information and coordinates joint IPAC-RS comments on OINDP regulation from China, specifically with respect to the Chinese Food and Drug Administration (CFDA) and its affiliated agencies, such as the National Institute of Food and Drug Control (which comprises the main CFDA testing labs), the Center for Drug Evaluation (which develops industry guidance) and the Chinese Pharmacopoeia. The GRRO China group has held knowledge-sharing meetings with representatives from these agencies in collaboration with subject-matter experts from other IPAC-RS working groups (e.g., Materials and Cascade Impaction) and has presented regularly at public scientific

meetings in that world region, such as Inhalation Asia.

The GRRO Europe group monitors emerging regulations and legislation relevant to OINDPs issued by the European Medicines Agency (EMA) as well individual national agencies in Europe. For example, the group held a discussion with EMA representatives to discuss experiences with the current EMA OINDP quality guideline and the OIP therapeutic equivalence and clinical documentation guideline. The group also coordinated submission of IPAC-RS comments to the recent concept papers proposing revisions to these guidelines. The GRRO Europe group has supported the IPAC-RS Device Working Group in its meetings with MHRA (during which device design and development, human factors, and instructions for use were discussed); and conducted outreach to other national agencies.

The North America group is the newest GRRO effort, established at the end of 2016. It proactively monitors, reports and discusses current and emerging US FDA and Health Canada regulations and initiatives. The North America GRRO will be spearheading preparation of the IPAC-RS comments on the anticipated FDA revised draft guidance for chemistry, manufacturing and controls of metered dose inhalers and dry powder inhalers from the FDA's Center for Evaluation and Drug Research (CDER).

For more information

For additional resources from IPAC-RS, please visit our website: http://ipacrs.org.

Reference

1. United States Food and Drug Administration, Center for Evaluation and Drug Research (CDER), Guidance Agenda: New & Revised Draft Guidances https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm417290.pdf

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