

CROSS-INDUSTRY Organizations

An IPAC-RS update: Events and GRRO, Cascade Impaction and Device working groups



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

The International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS) is an association committed to advancing consensus-based, scientifically driven standards and regulations for orally inhaled and nasal drug products. In this article, the IPAC-RS GRRO, Cascade Impaction, and Device Working Groups are discussed. Recent and upcoming IPAC-RS events, as well as the new IPAC-RS website, are also featured.

IPAC-RS activity updates

GRRO China

An excellent article was prepared by the Global Regulatory Review and Outreach (GRRO) China Subgroup and a presentation given by Dr. Ying Li (China Subgroup Chair) at RDD 2014 on Addressing China's Growing Need for Inhaled Drugs: Development Strategies for Marketing, Distribution and Regulation. Following these, RDD organizers invited the subgroup to prepare a supplementary paper for the initial article and give a podium presentation at RDD Asia in November 2014.

Representatives of the Secretariat and IPAC-RS members participated in the Chinese National Pharmaceutical Packaging Association's (CNPPA) 2014 Forum for Infusion Packaging Development in Qingdao, China. At this meeting, the Chinese version of the IPAC-RS Leachables and Extractables (L&E) Handbook was launched. IPAC-RS representatives also participated in an associated knowledge exchange regarding materials and L&E with members of the Chinese Food and Drug

Administration (CFDA) Center for Drug Evaluation, National Institutes for Food and Drug Control (NIFDC), Chinese Pharmacopoeia and China National Pharmaceutical Packaging Association (CNPPA) representatives. This was a follow-up to many of the discussions at the IPAC-RS/CFDA/CNPPA meetings held in March. IPAC-RS representatives also made similar presentations on materials quality and L&E matters to the Taiwan Center for Drug Evaluation in Taipei.

GRRO Brazil

The Global Regulatory Review and Outreach (GRRO) Brazil Group will be sharing information and insights on current issues related to aerodynamic particle size distribution (APSD) comparisons, with representatives from the National Health Surveillance Agency (ANVISA). ANVISA has indicated to the group that this topic, as well as dissolution tests with respect to inhalation products and population bioequivalence, are of interest to the agency.

Cascade Impaction Working Group

A subgroup of Cascade Impaction (CI) working group members is developing an online tutorial to be eventually posted on the IPAC-RS website. The purpose is to create a set of easily-accessible educational materials about good cascade impactor practices, APSD testing, AIM and EDA. The need for this education is increasing as more companies and regulatory agencies use CI testing or evaluate CI data. The tutorial will consist of short video clips and slides with links to more detailed tech-

nical articles, books, standards and other resources. The overarching goal of this effort is to provide a consensus understanding of CI testing and data analysis that can be used in companies, educational institutions, regulatory agencies, testing labs and other contexts.

Device Working Group

At the International Organization for Standardization ISO/TC 84 committee meeting in Como, Italy in June 2014, the committee agreed to create an ad hoc group that will outline the structure for a guidance document related to device change management, a topic initially proposed to ISO by the IPAC-RS Device Working Group.

Events

IPAC-RS/UF Orlando Inhalation Conference

In March 2014, more than 200 experts from around the globe representing industry, academia and regulators came together for a three-day conference at the University of Florida Research and Academic Center in Medical City near Orlando, Florida. The program and venue proved conducive to numerous plenary and informal discussions on a range of scientific issues related to bioequivalence approaches in the US, EU, Canada, China, India and Brazil. A number of University of Florida graduate students also attended and assisted at the event. IPAC-RS has formed a writing committee to prepare a series of scientific articles for a peer-reviewed journal based on the conference proceedings. Final presentations are accessible via www.ipacrs.org.

Cascade Impaction Workshop at RDD 2015

The IPAC-RS Cascade Impaction Working Group will sponsor a brief, 60-minute workshop at RDD Europe 2015 to be held May 5-8 in Nice, France. The proposal for the workshop is titled “Abbreviated Impactor Measurement (AIM) and Effective Data Analysis (EDA) of Aerodynamic Particle Size Data from Orally Inhaled Products (OIP): How to Link with the Product Lifecycle.”

IPAC-RS/ISAM Workshop in conjunction with 2015 ISAM Congress

IPAC-RS and ISAM are planning a joint workshop to be held in conjunction with the 2015 ISAM Congress in Munich, Germany. The workshop will take place on May 31st. Tentative topics include patient adherence and device design; patient handling studies; instructions for use; electronic device features and mobile applications; device changes; quality by design; and device regulation.

New IPAC-RS website launched

In spring 2014, IPAC-RS launched a new website, www.ipacrs.org, which incorporates a completely-revamped layout with easy access to information about news, events and publications. The site also includes member resources, including member-only publications and a participant directory.

IPAC-RS is interested in growing the membership of the organization. If your company is interested in joining, please visit our website, www.ipacrs.org, for more information.

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