IPAC-RS Newsletter

Upcoming Events of Interest

February 19, 2016, FDA webinar to review the guidance on Applying Human Factors and Usability Engineering to Medical Devices.

April 17-21, 2016, RDD 2016, Phoenix, Arizona

April 21-22, 2016, IPAC-RS Symposium at RDD, Phoenix, Arizona

May 18 – 19, 2016, Inhalation & Respiratory Drug Delivery Congress, London, UK.

June 20 – 21, 2016, 2016 Annual Pharmaceutical Microbiology, Montreal, Canada.

November 4 - 6, 2016, Inhalation Drug Delivery Association (China) Scientific Conference 2016, Guangzhou, China

IPAC-RS Activities

IPAC-RS/RDD 2016

Registration for the Joint IPAC-RS/RDD 2016 Symposium is brisk and spaces are filling up fast. The room block cut-off date is ***March 18, 2016***, after which unreserved rooms will be released. We encourage you to make your reservation early as the room block often sells out before the stated cut-off date. In addition, IPAC-RS will be hosting a Networking Reception on April 21st, featuring a World Regulatory Roundtable with panelists from US, EU and Brazil. Don't miss this opportunity to mingle with colleagues and regulators.

IPAC-RS and MHRA Meeting

IPAC-RS met in-person with the MHRA on February 2, 2016. During the meeting, participants discussed approaches to Human Factors in OINDPs and other combination products, Instructions for Use for inhalers, device change management, and quality by design for OINDPs.

IPAC-RS 2016—2018 Strategic Plan

Read the new IPAC-RS 2016-2018 Strategic Plan for information on 2013—2015 accomplishments and impact, current workstreams and activities, and 2016—2018 goals.

IPAC-RS Comments to FDA

IPAC-RS will be preparing comments on the recently issued FDA human factors guidances (see below).

- Applying Human Factors and Usability Engineering to Medical Devices. [Guidance] [FR Notice] .
- List of Highest Priority Devices for Human Factors Review." [Draft Guidance] [FR Notice]
- Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development." [Draft Guidance] [FR Notice]

Cascade Impaction WG Submissions

The CI WG poster abstract focused on AIM's calibration traceability chains has been accepted by RDD 2016. The WG also submitted a manuscript comparing EDA and FPM as QC metrics to AAPS PharmSciTech (manuscript has been accepted). Another paper ("a roadmap for using AIM and EDA") will be submitted to the USP Pharmacopeial Forum shortly. Finally, a paper that examines discriminating ability of AIM to detect changes in MMAD, based on results of the IPAC-RS experiments, is under preparation. For background on Efficient Data Analysis (EDA) and Abbreviated Impactor Measurements (AIM), see the AIM/EDA Handbook.

IPAC-RS in Inhalation Magazine

IPAC-RS and other industry organizations are regularly highlighted by the online Inhalation magazine. Archival articles from the "Cross-Industry Organizations" column are now publically available here. The February 2016 *Inhalation article*, IPAC-RS: 15 Years of research advocacy and consensus building is now available.

External Developments

FDA Updates

- CDER is launching a pilot Clinical Outcome Assessment Compendium and has established a docket for receiving public input on the pilot. CDER is requesting comments by March 14, 2016. The pilot compendium is available here.
- CDRH has released a report on its 2016—2017 strategic priorities. These priorities include establishing a national evaluation system for medical devices, fostering meaningful patient engagement and use of patient input, and promoting a culture of quality within FDA and the medical device ecosystem.
- CDER has released its 2016 guidance agenda. The agenda includes a revised draft MDI/DPI CMC guidance.
- In January, FDA released draft guidance on Postmarket Management of Cybersecurity in Medical Devices.

Other

EMA Guideline

The European Medicines Agency recently finalized a "Guideline on the clinical investigation of medicinal products for the treatment of asthma". The guideline will be effective May 1, 2016. The current version of the guideline includes a section on the treatment of asthma in children, some considerations for the development of immunotherapy, and focuses on control-based management of the disease.

Interview on EMA Priorities

In a recent press briefing, EMA Executive Director Guido Rasi discussed his vision for the next five years. Dr. Rasi emphasized EMA's commitment to transparency, patient involvement, and research and development for medicines that address public health needs. He also stressed the importance of strong cooperation between the member states, the European Commission, and other international partners.

ISO 9001 (MDDI)

The Device Talk blog from Medical Device and Diagnostic Industry recently noted that the requirement for risk-based decision making is now explicit in the ISO 9001:2015 standard. This version also introduced several major quality management principles, including risk-based decision-making and "a system approach to management." The full standard is available here from ISO.

CHMP Forms Respiratory Drafting Group

The EMA's Committee for Medical Products for Human Use (CHMP) has decided to re-form the Respiratory Drafting Group (RDG) and has elected Karolina Törneke as its Chair.

NIH Strategic Plan

The US National Institutes of Health (NIH) recently released a 2016 – 2020 fiscal year strategic plan highlighting priorities and opportunities for the agency. Objectives described in the plan include the advancement of opportunities in biomedical research, fostering innovation, enhancing scientific stewardship, and excelling in the "science of science." Nanomedicinal research stands to benefit from several outlined NIH initiatives, including the ongoing BRAIN project.

**Inclusion of links to external articles or publications is for information only and does not represent IPAC-RS endorsement of any views expressed in these articles.*

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3M, Actavis, AstraZeneca, Boehringer-Ingelheim, Catalent, Chiesi, GlaxoSmithKline, Hovione, Lupin Pharmaceuticals, MannKind Corporation, Merck, Mylan, Novartis, Sunovion, Teva, Vectura

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For further information on IPAC-RS, see our website at: www.ipacrs.org