IPAC-RS Newsletter

Upcoming Events of Interest

December 9 – 11, 2015, Drug Delivery to the Lungs Conference, Edinburgh, UK.

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.

IPAC-RS Activities

IPAC-RS Welcomes New Member

IPAC-RS is pleased to welcome AMCOR Flexibles as a new Associate Member.

IPAC-RS/RDD 2016

The program for the Joint IPAC-RS/RDD 2016 Symposium has been finalized. **Registration is now open!** Early bird fees will apply through January 22, 2016.

Cascade Impaction

The Cascade Impaction Working Group has completed a manuscript comparing Efficient Data Analysis and the Fine Particle Dose metric for controlling aerodynamic particle size distribution. When finalized, the paper will be submitted to the AAPS PharmSciTech.

Global Regulatory Review & Outreach (GRRO) European Union

GRRO EU has planned around a recent invitation from MHRA to IPAC-RS to discuss IPAC-RS projects, especially Human Factors and Instructions for Use. The IPAC-RS Planning Committee, Device Group, and Device Subgroups will also be involved in preparing for the 3-hour meeting. The date is yet to be determined.

IPAC-RS Strategic Plan 2016 - 2018

The IPAC-RS 2016-2018 Strategic Plan is being finalized based on feedback from the IPAC-RS Board of Directors. The document is expected to be finalized by the end of 2015.

2017 IPAC-RS/ISAM Organizing Committee

The Organizing Committee for the planned IPAC-RS/ISAM 2017 workshop has begun its work. Members are compiling a list of potential speakers and intend to focus on new scientific ideas and fresh areas of interest. Topics under consideration are patient compliance, electronic tools in conjunction with inhaler devices, regulatory compliance, specification setting and testing, manufacturing, supply chain, device-drug combination products, enhanced data, data interpolation, big data in clinical trial designs, and e-monitoring.

IPAC-RS Comments to USP and to FDA

- IPAC-RS submitted comments on USP chapters <5> and <1602> to USP.
- IPAC-RS submitted comments on FDA "eCTD TECHNICAL CONFORMANCE GUIDE".
- Representatives from the Device Working Group, OINDP Materials, and GRRO submitted comments to FDA on the draft guidance "Established Conditions: Reportable CMC Changes for Approved Drug and Biologic Products". You can view the comments here on the IPAC-RS website.

IPAC-RS Meeting with FDA

The IPAC-RS Combination Products Working Group meet with the FDA in July 2015 to discuss the IPAC-RS proposal submitted in formal comments, that legacy OINDP products be exempted from the FDA's Combination Products cGMP Regulations in 21 CFR Part 4. FDA acknowledged the high standards historically applied to OINDP development, and suggested a mapping-out of existing guidelines and development activities that essentially satisfy the requirements of 21 CFR Part 4. FDA was also interested in better understanding the practical

implications of the differences between the supplier controls described in 21 CFR Parts 210 and 211 and those described in Part 820. A follow-up discussion is planned by the IPAC-RS Combination Products WG.

IPAC-RS Board of Directors Meeting

The IPAC-RS Board of Directors met on 22-23 September 2015 in Lisbon, Portugal, hosted by Hovione. Invited speakers included Robert Price (University of Bath), who discussed his research, and Monika Fletcher, who leads a charitable organization whose efforts include educating patients and healthcare providers in the developing world about respiratory diseases and treatments.

Materials Working Group

The "Risk Management for Materials and Components Used in Orally Inhaled and Nasal Drug Products" paper has been published online in Pharmaceutical Research. Concepts from this paper were presented at Inhalation Asia in Shenyang, China on 10 September.

Modified Chi-Square Ratio (MCSR)

An IPAC-RS collaboration with the University of Florida has been launched. The group will study the MCSR tests combined with the Population Bioequivalence as recommended by FDA for determination of equivalence in Aerodynamic Particle Size Distributions.

GRRO China

On 8 September, GRRO China representatives met with NIFDC leaders in Beijing, China, including Dr. Baoming Ning, Deputy Director, Institute for Chemical Drug Control, and Dr. Huaxin Yang, Director, Institute for Chemical Drug Control. Other representatives from NIFDC, CDE, and the Chinese Pharmacopoeia were also present. Participants engaged in very good conversation on the IPAC-RS presentations. Dr. Stefan Leiner was also invited to speak at NIFDC's new campus launching ceremony on 24 September.

GRRO China representatives also traveled to Shenyang, China to attend Inhalation Asia 2015. Topics included TB and lung cancer treatment via inhaled route, nanoparticle delivery via inhalations, mechanisms of dissolutions and absorption, BE approaches, and materials quality. IPAC-RS hosted a panel on materials quality with Andrew Feilden, Zhenyu Wang, and Stefan Leiner, moderated by Lee Nagao. The session was very well attended and was the only session focused on the quality (and safety) aspects of inhalation drug development.

RS Connect

The IPAC-RS Secretariat has launched RSConnect, a new collaboration tool for IPAC-RS members. RS Connect will serve as the new document repository housing current working documents and will also allow members to collaborate and upload documents.

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.

External Developments

FDA Updates

- FDA has released draft recommendations for permitted daily exposure to the residual solvents trimethylamine and methylisobutylketone. The draft recommendations were prepared with ICH. Comments from industry are requested by December 15, 2015.
- FDA has extended the deadline for comments on the draft guidance Established Conditions: Reportable CMC Changes for Approved Drug and Biologic Products until January 4, 2016.

- FDA has announced a final guidance on Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route. The guidance intends to communicate to industry current CDER thoughts pertaining to safety data needed to support these drug products, increase uniformity within CDER on expectations for the nonclinical development of reformulated drug products or products being used by an alternate route, and encourage development of these products.
- FDA has announced a draft guidance on Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices and a draft guidance on General Considerations for Animal Studies for Medical Devices.

Medical Device Bills

Two device-focused bills are currently under consideration in the US Senate. The Combination Product Regulatory Fairness Act of 2015 intends to support faster FDA review of combination products; the Advancing Breakthrough Devices for Patients Act of 2015 would expedite the review process for novel medical devices that do not have an approved alternative.

USP – Russian Memorandum of Understanding (in Russian)
The US Pharmacopoeia and Russian drug and medical device regular *Roszdravnadzor* have signed a three-year Memorandum of Understanding (MOU). The agreement is an extension of a 2009 MOU and will enable collaboration on developing and implementing quality standards for medicines. According to USP, the MOU also encourages exchanges of staff, harmonization of important pharmaceutical requirements, and joint education.

CFDA on Medical Device Quality (in Chinese)
The China Food and Drug Administration has published a document on quality of the medical device supply chain, including details of procurement, storage, use, and maintenance of medic al devices. More information is available at Regulatory Focus.

ICH Organizational Changes
The ICH has changed its name to the “International Council for Harmonization” and formed a new Assembly and Management Committee. ICH expects these organizational reforms to welcome involvement from more international regulators.

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