June 2019

IPAC-RS Newsletter

IPAC-RS Activities

- Presentations from the **IPAC-RS/ISAM workshop on Digital Health** are now available.
- IPAC-RS Knowledge Network on **QBD of Analytical Methods**, with input from GRRO-Europe and other pertinent groups, are preparing IPAC-RS comments on the new consultation paper from the UK MHRA.
- The **Analytical Methods KN** discussed updates from ICH groups revising the Q2 (method validation) and drafting the Q14 (analytical method lifecycle) guidelines.
- IPAC-RS is preparing comments on a draft **EMA guideline for quality requirements of drug-device combination products**. In addition to reviewing the guideline from the inhalation-products perspectives, IPAC-RS also plans to coordinate with EFPIA/EBE/CPC and ELSIE, who are also interested in the guideline.
- GRRO-North America reviewed two **draft documents from Health Canada**:
    - Draft Guidance Document: Identifying and Labelling Medicinal Ingredients in New Drug Products
    - Draft Guidance Document: Generic Drug Equivalence: Medicinal Ingredients
- An IPAC-RS Subgroup for the European Medical Device Regulations (MDR) Analysis is conducting a survey related to **MDR Rule 20**. The results are intended for inclusion, in summary form, in a "rapid communication" being prepared by the Subgroup, for publicizing next month due to the overall MDR deadline. The MDR Subgroup has also reviewed a recent **"Q&A" on Notified Bodies** published by the European Commission and other related updates.
- **PK Batch-To-Batch Variability** Discussion Group is preparing a white paper for the IPAC-RS Board and membership about statistical approaches for assessing equivalence.
- Materials WG is conducting an IPAC-RS **Biocompatibility Survey** Please consider taking this survey if you have solid experience in working with or conducting biocompatibility testing for OINDP, and are familiar with the standards and guidelines used for such testing, and/or have experience

Upcoming IPAC-RS Teleconferences

June 26 Plume Characterization WG

June 28 GRRO Brazil

June 28 GRRO NA Group

July 9 IPAC-RS/RDD 2020 Organizing Committee

July 10 IPAC-RS MDR Subgroup

July 11 CI WG

July 11 Materials WG

July 12 HF Subgroup

July 16 GRRO China

July 17 GRRO EU

July 17 Planning Committee

July 23 GRRO Brazil

July 24 IPAC-RS/RDD 2020 Organizing Committee Session 3

July 24 Plume Characterization WG

July 26 GRRO NA Group

responding to regulators on issues related to this testing.

- Planning for the RDD/IPAC-RS **2020 Joint Symposium** is gaining momentum. One of the three sessions is completed. Six regulators have been invited to another session. There will also be a networking reception with a series of talks and activities. Further information is available here. The main RDD conference is still open to proposal for podium talks (**by August 1, 2019**), and poster abstracts (by Jan-13, 2020).
- The IPAC-RS **Cascade Impaction** WG's paper about best-practice CI for DPIs has been published in AAPS PharmSciTech (2019) 20: 206.
- GRRO-China is leading preparations for **IPAC-RS/NIFDC(China) workshop** in the Fall 2020.
- GRRO-Brazil and the PBE WG continue to plan and prepare for a PBE webinar to present to Anvisa in Fall 2019.
- GRRO-Brazil is inviting Anvisa to discuss the recently published Resolution RDC 278 and Normative Instruction 33.

External Activities

U.S. FDA

- FDA paper on PBPK modeling, including for respiratory drugs.
- FDA program for breakthrough devices.

North America

- US NIH: Rethinking inhaled steroids for mild persistent asthma.
- Digital Technology: Electronic Inhaler Monitoring Reduces Hospitalizations, ER Visits in Patients with COPD.
- Canada is stepping up regulatory oversight of medical devices.

Europe

- UK MHRA Device Director John Wilkinson highlighted key priorities for the agency and industry in a recent interview: He plans to retire this October.
- UK published considerations for MDR in light of potential Brexit.
- Ireland and Germany expressed concern over MDR/Notified Bodies.
- TÜV SÜD/Germany became a second designated Notified Body (besides BSI/UK): On the other hand, two prominent NBs indicated they would not pursue MDR designation: a UK-based LRQA and Swiss notified body (NB) QS Zürich AG. Despite mounting concerns about the capacity of available designated NBs to handle the increased/new review and

assessment workload necessitated by MDR (coming into effect next Spring), the EU Health Commissioner reiterated the May-2020 deadline and in a webcast recording.

China

- The China Center for Medical Device Evaluation (CMDE) is publicly seeking participants to assist in developing guidelines related to three guidelines for the “physical and chemical evaluation of medical devices.” These guidelines would accompany other leachables study related guidelines on application of a toxicological concern threshold, and method development.
- The China Center for Drug Evaluation (CDE) opened a public consultation on a draft guideline addressing "Real World Evidence Supporting Fundamental Considerations for Drug Development.”

Brazil

- Anvisa has approved the first inhalable insulin in Brazil. See here for press release.
- Anvisa has an open public consultation CP 632/2019 on analytical laboratories, which deals with the proposed Resolution on the operation of laboratories that conduct analyses of products and services subject to health surveillance. Anvisa is collecting comments to inform the development of the Resolution. The deadline to submit comments is 25 June.
- On June 18-19, Anvisa hosted a symposium on New Pharmaceutical Boundaries. The symposium theme was new frontiers in manufacturing technology, regulatory sciences, and pharmaceutical quality systems. Anvisa partnered with Sindusfarma and IPS-FIB to host the event.
- Public Consultation 653/2019 on Guidelines for GMP for Medicines was published on May 25.

International

- ICH adopted Leachables and Extractables as a new topic for harmonization/standardization.
- ICH added regulatory observers from four new countries: Argentina, Israel, Jordan, and Saudi Arabia.

Recent Publications of Interest

- Inhaler use errors and therapeutic equivalence.
- Pressurized Metered Dose Inhaler Technology: Manufacturing.

- Best-practice cascade impaction testing of DPIs.
- Patients perspectives on inhaled corticosteroids' discontinuation.
- In-silico methods for generic drug-device combination products.
- Robert Califf (former FDA Commissioner) and co-authors, on cybersecurity and medical misinformation.
- Express Scripts (a large US-based a prescription benefit plan company) is developing a digital therapeutics formulary.

Recent and Upcoming Meetings

- ISPE Annual Meeting
  27-30 October 2019
  Las Vegas, NV
- Inhalation Asia
  13-15 November 2019
  Hong Kong
- IPAC-RS/RDD Joint Symposium
  April 2020

LinkedIn

IPAC-RS is now on LinkedIn. Ask to join the group today!