December 2023

NEWSLETTER

IPAC-RS Activities

- IPAC-RS prepared and submitted to USP consortium's comments on USP chapter <429> "Particle Size Analysis by Laser Light Diffraction" [PF 49(5)]. Final copy is available here on the IPAC-RS website.
- A summary of the questions discussed during the October 11th, IPAC-RS Workshop on the Transition to LGWP Propellants for MDIs are available on the workshop webpage. In addition, a summary of the IPAC-RS Survey - Stakeholder Perspectives on Switching Current pMDIs to New Propellants is available here.
- On December 4-5, the IPAC-RS Board of Directors met in-person before the DDL conference in Edinburgh, UK. On the first day, the Board discussed developments related to LGWP propellants, inhaled and nasal biologics, and nitrosamines. On the second day, the Board heard presentations from the IPAC-RS Nasal Working Group as well as invited guests - Professor Regina Scherließ (Kiel University) and Professor Ben Forbes (King's College London). The meeting wrapped up with an update from Inhalanda (EDQM), by Jan Olof Svensson (AstraZeneca), and a networking lunch the European Pharmaceutical Aerosol Group (EPAG).
- Planning has started for an IPAC-RS Biologics Workshop -2024. The Organizing Committee is chaired by Chris Gruenloh (PPD), Alan Watts (Catalent), and Chris Vernall

(Intertek). The workshop will have a dual goal of discussing scientific and regulatory challenges for inhaled and nasal biologics, and to develop a proposal for the structure of a collaborative industry initiative focused on those topics. The workshop will be open to the public, details to come soon. ***If you are interested in joining the Organizing Committee to help plan for the Workshop, please contact the Secretariat.***

Regulatory Developments

United States

- Final:
  - Federal Register: TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances
  - CBER/CDER final guidance: COVID-19: Developing Drugs and Biological Products for Treatment or Prevention
- FDA CDER revised a number of draft product-specific bioequivalence guidances (PSG), including the following:
  - Albuterol Sulfate (pMDI)
  - Budesonide; Formoterol Fumarate Dihydrate (pMDI)
  - Fluticasone Propionate (pMDI)
  - Fluticasone Propionate; Salmeterol Xinafoate (pMDI)
  - Levalbuterol Tartrate (pMDI)
  - Mometasone Furoate (pMDI)
  - Tiotropium Bromide (DPI)
- CDRH Final Guidance published: Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions
- FDA announces OPQ reorganization to alleviate 'long-standing pain points' | RAPS
- USP PF 49(6) (76) published for comment by January 31, 2024:
  - ⟨1040⟩ Quality Considerations of Plasmid DNA as a Starting Material for Cell and Gene Therapies.
- President Biden Announces New Actions to Strengthen America's Supply Chains, Lower Costs for Families, and Secure Key Sectors.
- US plans to establish an AI Institute under NIST, as announced at the Global Summit on AI Safety. Part of its mission will be developing standards, including for biotech and related industries.

Europe & UK

- EMA's responses to public comments, and a final version of the Q&A document have been published at Questions and answers on data requirements when transitioning to low global warming potential (LGWP) propellants in oral pressurised metered dose inhalers - Scientific guideline

International

- The International Society for Aerosols in Medicine (ISAM) is starting planning for its 2025 Congress. The ISAM Congress Organizing Committee is being assembled. If you are a member of ISAM, you are welcome to join and help with the planning.

Recent Publications of Interest

- Revisiting the Landscape of Potential Small and Drug Substance Related Nitrosamines in Pharmaceuticals - Journal of Pharmaceutical Sciences
- Advanced approaches to overcome biological barriers in respiratory and systemic routes of administration for enhanced nucleic acid delivery to the lung: Expert Opinion on Drug Delivery
- Design of experiment (DoE) as a quality by design (QbD) tool to optimise formulations of lipid nanoparticles for nose-to-brain drug delivery: Expert Opinion on Drug Delivery

Reports and Recordings from Recent Meetings

- USP Forum "**Conversations with USP: Approaches to Developing + Revising General Chapters**" was held on November 13, 2023. USP speakers explained that chapters numbered above 1000 are not mandatory even when they are referenced in the mandatory below-1000 chapters. Alternative methods are allowed after validation, and directed users to chapter 1225 "Validation of Analytical Procedures" (where the previous requirement for the alternate method to be "*equivalent or better*" has been changed to "*comparable*"). Stimuli articles could be submitted by anyone; a USP staff liaison will be appointed to manage the review and publication.

Future Events (Webinars and Conferences)

- Drug Delivery to the Lungs (DDL). Wednesday-Friday, December 6-8, 2023. Edinburgh, UK.
- CRCG FDA Workshop: Characterization of Complex Excipients/Formulations. December 7-8, 2023. In-person and virtual.
- FDA Public workshop: Biomarker-driven Drug Development for Allergic Diseases and Asthma. Agenda found here. February 22, 2024. In-person and virtual.
- RDD 2024. May 5-9, 2024. Tucson, AZ. **Poster Abstract Submissions Deadline:** January 22, 2024.
- **Call for speakers open**! Drug Delivery Summit 2024. February 28 - 29, 2024. Los Angeles, California.
- FDA Public Workshop: Enhancing Adoption of Innovative Clinical Trial Approaches. March 19-20, 2024. In-person and virtual.
- PQRI/EUFEPS Global Bioequivalence Harmonisation Initiative (GBHI): 6th International Workshop – GBHI 2024. April 16-17, 2024. To be held at USP (Rockville, MD). Registration to open soon.
- PQRI/FDA Workshop: Challenges and Opportunities for Modified Release Oral Drug Product Development; Forum for Stakeholder Engagement (to follow GBHI 2024) April 18, 2024 at USP.
- ATS 2024. May 17-22, 2024. San Diego, CA.
- CRCG events planned for 2024 (details found here):
    - Drug-Device Combination Products: Updates and Challenges in Demonstrating Generic Substitutability – March 14-15, 2024
    - Scientific and Regulatory Considerations for Assessment of Immunogenicity Risk for Generic Peptide and Oligonucleotide Drug Products: Present State and Future Directions – October 7-8, 2024.
    - Updates on Approaches to Acceptable Intakes of Nitrosamine Drug Substance Related Impurities (NDSRIs) and Bioequivalence Assessment for Reformulated Drug Products – November 7, 2024.
    - Navigating the Transition to Low Global Warming Potential Propellants – December 4-5, 2024.

Upcoming IPAC-RS Teleconferences

December 4-5	IPAC-RS Board of Directors Hybrid meeting (Edinburgh, Scotland)
December 8	OINDP Materials
December 11	IPAC-RS LGWP Propellants Workshop (II) Organizing Committee
December 12	Cascade Impaction GRRO-Alternate Propellants

December 14	Materials & Propellants Quality Considerations PQDS Core
December 15	Change Management
December 18	GRRO Europe IPAC-RS Planning Committee
December 19	GRRO China
December 20	GRRO North America

Please visit the IPAC-RS Pharmaceutical Aerosols Resource Center (PARC). Feel free to share with those who might find it useful and send the Secretariat your suggestions for additional resources and links to include on that page.

Follow us on Linkedin to stay

up-to-date on news and events.

** 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.*

This newsletter is prepared by the IPAC-RS Secretariat for IPAC-RS Members. If you would like to ask a question, make a comment or suggestion, or subscribe or unsubscribe from the newsletter, please contact the IPAC-RS Secretariat at: +1-202-230-5607 or info@ipacrs.org. For further information: www.ipacrs.org