

**Bi-Annual Industry Regulatory Science Working Group Meeting
Meeting Minutes
December 8, 2022
3:00 to 4:30 PM EST
Zoom Meeting**

3:00 PM – 3:10 PM: Introductions

Attendees:

FDA	FDA (continued)	Industry
Robert Lionberger Lei K. Zhang Sam Raney Jessie Floura Liang Zhao Markham Luke Sarah Ibrahim Sarah Rogstad	Joshua Huang Bryan Newman Miyoung Yoon Pinaki Desai Rachel Dunn Savita Nigam Maria Monroy-Osorio	David Gaugh – AAM (absent) John DiLoreto – BPTF Gil Roth – PBOA Molly Ventrelli – Fresenius-Kabi - AAM Scott Kuzner – AAM Giuseppe Randazzo – AAM Kiran Krishnan – Apotex Brian McCormick – Teva Scott Kuzner – AAM Cornell Stamoran - PBOA

3:10 PM – 4:00 PM: Discussion of FY 2023 GDUFA Public Workshop (May 11-12, 2023)

Dr. Sam Raney led a discussion reviewing industry input on tentative topics and sessions for the FY23 GDUFA Public workshop.

- It was agreed that issues relating to either 1) model-integrated evidence (MIE), or 2) artificial intelligence (AI) tools, would be integrated within the context of use relevant to each session’s topic area, rather than having a separate session dedicated to MIE and AI.
- The general format for each session was discussed, preferring shorter presentations (e.g., 15 minutes) and substantial time for a live panel discussion (e.g., 45 minutes).

Each prospective workshop session was discussed, with a focus on identifying suitable expert faculty for each session who could discuss current research in each field and identify what new research is needed.

- Day 1, Session 1 – Oral Products
 - Sub-Session A will focus on impurities, such as nitrosamines.
 - Sub-Session B will focus on oral routes, biowaivers, and global harmonization, among other topics.
- Day 1, Session 2 – Parenteral (Injectable) Products
 - Sub-Session A will focus on API characterization.
 - Sub-Session B will focus on topics such as Long-Acting Injectables (LAIs) and excipients.
 - Within both sessions, the goal is to include discussion on challenges industry faces when implementing recommendations from FDA.

- Day 2, Session 3 – Inhalation Products
 - Prior to the FY23 GDUFA Public Workshop, on April 20-21, 2023, FDA and the Center for Research on Complex Generics (CRCG) will be hosting a workshop to discuss current challenges and opportunities for generic inhalation products.
 - The distinct scope for the session during the FY23 GDUFA Public Workshop will be to discuss what new research is needed to enhance the efficiency of bioequivalence approaches for complex generic inhalation products.
- Day 2, Session 4 – Topical Products
 - This session will focus on what new research is needed to enhance the efficiency of bioequivalence approaches for complex generic topical products.
 - Topics will include Q3 characterization and challenges relating to conducting IVPT studies.
- Day 2, Session 5 – Public Comments & Discussion
 - This session will accommodate public comments.
 - Public comments received prior to the workshop, relevant to the topic area of Sessions 1-4 above, may be scheduled into the relevant session.

4:00 PM – 4:25 PM: Discussion of FY 2023 GDUFA Public Workshop Program

- It was discussed and agreed that the FY2023 GDUFA Public Workshop would be a hybrid meeting, where the speakers and panelists would be in-person at the FDA’s Great Room (White Oak, Maryland). All faculty would ideally be participating in-person.
- The target date by which to identify faculty was agreed to be January 30, 2023, to afford sufficient time for session leads to coordinate faculty and for the presenters to prepare presentations.
- The finalization of industry presenters and panelists would be coordinated through the CRCG and faculty nominations by industry would be sent directly to the CRCG via Dr. Randazzo.

4:25 PM – 4:30 PM: Review of Meeting Outcomes and Proposed Action Items

Review of action items:

- Industry and FDA will solicit faculty nominations, targeting to identify all faculty by January 30, 2023. Industry nominations will be provided to the CRCG via Dr. Giuseppe Randazzo.
- FDA will develop the agenda for the FY2023 GDUFA Public Workshop.
- Any additional industry input for the agenda will be sent to Dr. Sam Raney.
- The next working group meeting will be scheduled for August 2023 to discuss the outcomes of the FY2023 workshop and review the FY2024 Research Initiatives & Priorities.
- During FY 2023, we are transitioning from a Fall/Spring bi-annual meeting schedule to a Summer/Winter schedule, where the Winter meeting is focused on discussing the next year’s GDUFA public workshop, and the Summer meeting is focused on discussing the outcomes from the GDUFA public workshop and the research priorities for the next fiscal year.

Dr. Robert Lionberger concluded the meeting and thanked all attendees for their participation.