Bi-Annual Industry Regulatory Science Working Group Meeting
Meeting Minutes
August 30, 2023
10:00 AM to 11:30 AM EST
Zoom Meeting

10:00 AM – 10:10 AM: Introductions
Attendees:

FDA	FDA (*continued*)	Industry
Iilun Murphy Robert Lionberger Lei K. Zhang (absent) Sam Raney Sarah Rogstad Sarah Ibrahim Jessie Floura Liang Zhao Markham Luke Layan (Lucy) Fang (absent) Manar Al-Ghabeish Tiana Barnes Heather Boyce (absent) Pinaki Desai Rachel Dunn (absent) Priyanka Ghosh	Xiaohua (Joshua) Huang Qing Liu (absent) Bryan Newman Andre Raw (absent) Fallon Smalls (absent) Cameron Smith Namrata Trivedi Eleftheria Tsakalozou (absent) Diana Vivian (absent) Ross Walenga Rong Wang(absent) Yan Wang Fang Wu (absent) Yang Yuan Deyi Zhang (absent) Ahmed Zidan (absent)	**AAM** Kiran Krishnan Brian McCormick Janet Vaughn (absent) David R. Gaugh (absent) Giuseppe Randazzo Scott Kuzner **PBOA** Gil Roth Cornell Stamoran (absent) **BPTF** Joel Carpenter (absent) **Apotex** Ripen Misri Kiran Krishnan **Teva** Raphael Nudelman

10:10 AM – 10:45 AM: Brief Review of Industry Input on FY 2024 GDUFA Science & Research Priorities
Dr. Sam Raney initiated a discussion of industry input received from FY 2023 GDUFA Public Workshop, held on May 11-12, 2023, and how the input was considered in the development of the draft FY 2024 GDUFA Science and Research Priorities.

- Different representatives from FDA summarized the key input received from industry during each session of the workshop.
- A discussion ensured for each session and attendees from industry generally concurred with the research needs identified, or provided further input that was incorporated into the corresponding research FY 2024 priorities.
- The sessions of the FY 2023 GDUFA Public Workshop discussed were:
    - Session 1A: Reviewed by Sarah Rogstad, PhD
    - Session 1B: Reviewed by Manar Al-Ghabeish, PhD
    - Session 2A: Reviewed by Cameron Smith, PhD
    - Session 2B: Reviewed by Yan Wang, PhD

- Session 3: Reviewed by Ross Walenga, PhD
- Session 4: Reviewed by Priyanka Ghosh, PhD
- Session 5: Reviewed by Robert Lionberger, PhD

Dr. Robert Lionberger observed that throughout the workshop there was often an overlap between the priority areas, particularly relating to the integration of in silico, in vitro, and in vivo evidence that collectively supports a demonstration of bioequivalence, and he requested input from industry partners about their general industry perspectives on research priorities for generic drugs.

Dr. Kiran Krishnan concurred with FDA's summations of industry feedback during the workshop and agreed with Dr. Lionberger's observations. Dr. Giuseppe Randazzo expanded on the need for global harmonization and the challenges faced by generic drug developers to satisfy all the separate regulatory requirements across different regions.

10:45 AM – 11:05 AM: Discussion of Draft FY 2024 GDUFA Science & Research Priorities
Dr. Robert Lionberger and Dr. Sam Raney steered a discussion on the draft FY 2024 GDUFA Science & Research Priorities, detailing the changes incorporated from industry feedback and internal FDA review.

- Dr. Lionberger noted that during the FY 2023 GDUFA Public Workshop, as in each annual GDUFA Public Workshop, selected priority areas were discussed in detail to allow for the most pressing challenges to be discussed in that year.
- Dr. Lionberger walked through the eight (8) priority areas of the FY 2024 GDUFA Science & Research Priorities, indicated how each priority area incorporated key industry feedback from the FY 2023 GDUFA Public Workshop and from other CRCG and FDA workshops, and requested input from industry members.
- The proposed eight priority (8) areas for the FY 2024 GDUFA Science & Research Initiatives:
    1. Develop Methods for Generics to Address Impurities such as Nitrosamines
    2. Enhance the Efficiency of Bioequivalence Approaches for Complex Active Ingredients
    3. Enhance the Efficiency of Bioequivalence Approaches for Complex Dosage Forms and Formulations
    4. Enhance the Efficiency of Bioequivalence Approaches for Complex Routes of Delivery
    5. Enhance the Efficiency of Bioequivalence Approaches for Complex Drug-Device Combination Products
    6. Improve the Efficiency of Bioequivalence Approaches for Oral and Parenteral Generic Products
    7. Facilitate the Utility of Model-Integrated Evidence (MIE) to Support Demonstration of Bioequivalence
    8. Expand the Use of Artificial Intelligence (AI) and Machine Learning (ML) Tools

Following the discussion and concurrence, it was agreed that FDA would work to finalize the FY 2024 GDUFA Science & Research Priorities.

- Dr. Randazzo requested that as revisions may be suggested, they be forwarded to him to share with industry members for comment.

- Dr. Lionberger invited any additional feedback relating to the priorities could be sent to FDA via email so that it can be considered and potentially incorporated into the final version.

11:05 AM – 11:25 AM: Discussion of FY 2024 GDUFA Public Workshop (May 20-21, 2024)
Dr. Raney steered a discussion on the planning for the FY 2024 GDUFA Public Workshop, tentatively scheduled for May 20 – 21, 2024.

- Dr. Randazzo noted that CRCG played a key role last year, helping to identify the faculty for the FY 2023 workshop; he suggested collaborating with CRCG again for the FY 2024 GDUFA Public Workshop.
- Dr. Raney concurred and agreed that FDA would work with Dr. Randazzo and CRCG over the coming months.
- It was discussed and agreed that a hybrid (in-person and virtual) workshop format was preferred with faculty predominantly participating in person, and that all sessions should be scheduled in series across 2 days (no parallel breakout sessions).
- The number of speakers and faculty members was discussed. Dr. Randazzo and Dr. Krishnan agreed that panel discussions were productive but cautioned that too many panelists could make it challenging for each one to make meaningful contributions within the time allotted.
- Dr. Randazzo shared comments and feedback he had received in relation to potential topics for the FY 2024 GDUFA Public Workshop, including:
    - Improving predictive dissolution methods for oral products
    - Characterizing the stability of complex formulations and active ingredients
    - Advancing methods to assess the immunogenicity of complex active ingredients
    - Exploring patient centric approaches and improving patient experiences with generic products
- Dr. Ripen Misri also provided input in relation to potential topics for the FY 2024 GDUFA Public Workshop, including:
    - Modeling-based approaches to support a demonstration of bioequivalence for long acting injectable products
    - Mitigating challenges with the conduct and analysis of in vivo bioequivalence studies

11:25 AM – 11:30 AM: Review of Meeting Outcomes and Proposed Action Items

Review of action items:

- FDA will progress the FY 2024 GDUFA Science & Research Priorities toward finalization
- FDA will collaborate with AAM & CRCG to plan the FY 2024 GDUFA Public Workshop
- The next working group meeting will be scheduled for November 2023 to discuss the FY 2024 GDUFA Public Workshop.

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