Bi-Annual Industry Regulatory Science Working Group Meeting
Meeting Minutes
August 28, 2024
1:00 PM to 2:30 PM ET
Zoom Meeting

1:00 PM – 1:10 Introductions
Attendees:

FDA	**FDA** (continued)	**Industry**
Ahmed Zidan Andrew Babiskin Bryan Newman Dongmei Lu Heather Boyce Jessie Floura Layan (Lucy) Fang Lei Zhang Markham Luke Maria Monroy-Osorio Namrata Trivedi	Rachel Dunn Robert Lionberger Sam Raney Sarah Ibrahim Sarah Rogstad Sruthi King William (Bill) Chong Yang Yuan Yuqing Gong Zhen Zhang	**AAM** Brian McCormick Giuseppe Randazzo Scott Kuzner **Apotex** Martin Ehlert **Fresenius-Kabi** Molly Ventrelli

1:10 PM – 1:40 PM Brief Review of Industry Input on FY 2025 GDUFA Science & Research Priorities During Fiscal Year (FY) 2024 GDUFA Public Workshop Sessions

Dr. Sam Raney provided an overview of the FY 2024 GDUFA Public Workshop, discussing the overarching structure of the workshop, faculty presentations, public comment presentations, and panel discussions.

Dr. Raney then facilitated a discussion summarizing the input received during each session of the public workshop. Designated representatives from FDA summarized the key feedback received from workshop faculty and the public for each session of the workshop. There was generally concurrence among workshop faculty, including representatives from industry and FDA, and the public about the research areas that should be prioritized for FY 2025.

The sessions for the FY 2024 GDUFA Public Workshop discussed were:

- Session 1: Nitrosamine Drug Substance-Related Impurities (NDSRIs)
  Session summary by Dr. Sruthi King and Dr. Dongmei Lu

  Areas of Focus: Safety assessments; bioequivalence (BE) for reformulated products; analytical methods for NDSRI detection; and product quality challenges
- Session 2: Predictive Tools for Generic Product Development and Assessment
  Session summary by Dr. Lanyan (Lucy) Fang and Dr. Ahmed Zidan

  Areas of Focus: Model-integrated evidence (MIE) for BE; artificial intelligence (AI); and machine learning tools

- Session 3: Public Comments
  Session summary by Dr. Sam Raney

  Areas of focus: Characterization of complex active pharmaceutical ingredients and impurities, including immunogenicity assays; development of biorelevant in vitro methods to assess drug release from long-acting dosage forms; research on the users and context of use for drug-device combination products; development of biopredictive dissolution methods for oral dosage forms; and the integration of in silico and in vitro methods to characterize Q3 attributes of complex products.

- Session 4: Drug-Device Combination Products
  Session summary by Dr. William Chong

  Areas of focus: Minor vs. other design differences and justifications for each; challenges with comparative use human factor studies (i.e., sample size determination and statistical methods); research and applications of human factor studies within the regulatory space.

1:40 PM – 2:10 PM Discussion of Draft FY 2025 GDUFA Science & Research Priorities

Dr. Raney illustrated how the feedback provided to FDA during the FY 2024 GDUFA Public Workshop guided the development of the FY 2025 GDUFA Science and Research Priorities. Prior to the meeting, the draft FY 2025 Research Priorities were shared with meeting attendees.

Dr. Raney displayed the draft FY 2025 priorities and, in coordination with FDA session leads, illustrated how and where feedback from the FY 2024 GDUFA Public Workshop was incorporated. Dr. Raney noted that some FY 2024 GDUFA research Priorities were largely unchanged for FY 2025 because the feedback to FDA indicated that those research areas continued to be a priority.

The proposed eight priority (8) areas for the FY 2025 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

Dr. Raney requested input from industry attendees in the Bi-Annual meeting on the proposed FY 2025 GDUFA Science and Research Priorities.

- Mr. Brian McCormick recommended exploring alternatives to the current design or analysis of comparative use human factors studies with prospective generic drug-device combination products, and to assess additional approaches to justify the acceptability of "other" design differences.
- Mr. McCormick recommended prioritizing research to expand the eligibility for both, biopharmaceutics classification system (BCS)-based biowaivers and additional strength biowaivers, for immediate release oral drug products.
- Mr. Giuseppe Randazzo requested to consult with industry stakeholders about research to develop innovative study designs for PK BE studies in patients, such as those with reduced or sparse sampling for oncology products, and those involving adaptive designs. Also related to this, Dr. Fang and Dr. Robert Lionberger provided context for this potential new research priority. Dr. Fang also provided a link to the recently published FDA publication titled *Landscape Analysis of Generic Availability for Oncologic Drugs | Therapeutic Innovation & Regulatory Science* (https://link.springer.com/article/10.1007/s43441-023-00562-w)

Dr. Raney invited the attendees to email FDA with any additional feedback relating to the proposed FY 2025 GDUFA Science and Research Priorities so that it can be considered and potentially incorporated into the final version.

2:10 PM – 2:25 PM Discussion of FY 2025 GDUFA Public Workshop

Dr. Raney facilitated a discussion on the FY 2025 GDUFA Public Workshop, noting that the meeting is tentatively scheduled for June 3-4, 2025, and will tentatively be a hybrid meeting (in-person at FDA White Oak campus, and virtual). Dr. Raney also noted that the next bi-annual working group meeting is scheduled for October 30th, 2024, and would focus on the planning of FY 2025 GDUFA Public Workshop. In the meantime, FDA will work closely with industry partners (i.e., through CRCG, AAM, USP) to identify potential discussion topics and faculty for the workshop.

2:25 PM – 2:30 PM Review of meeting outcomes and proposed actions

Dr. Raney offered a brief review of the meeting outcomes and the next steps.

- FDA will revise the proposed FY 2025 GDUFA Science and Research Priorities to address comments received during this bi-annual meeting and share the revised version with all attendees by mid-September 2024.
- Mr. Randazzo would coordinate any additional feedback or suggested revisions to the proposed FY 2025 GDUFA Science and Research Priorities by the end of September 2024.
- FDA will continue to collaborate with AAM, CRCG, USP, and other industry partners to identify potential topics and faculty for the FY 2025 GDUFA Public Workshop.
- The next bi-annual working group meeting will be on October 30th, 2024, to discuss the FY 2025 GDUFA Public Workshop.

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