Bi-Annual Industry Regulatory Science Working Group Meeting
Meeting Minutes
October 30, 2024
8:00 AM to 9:30 AM
Zoom Meeting

8:00 AM – 8:10 AM Introductions
Attendees:

FDA	**FDA** (continued)	**Industry**
Ahmed Zidan Andrew Babiskin Bryan Newman Diana Vivian (absent) Fallon Smalls (absent) Heather Boyce (absent) Huzeyfe Yilmaz Jessie Floura Jihong Shon Lanyan (Lucy) Fang Lei Zhang Manar Al-Ghabeish (absent) Maria Monroy-Osorio	Markham C. Luke Namrata Trivedi (absent) Rachel Dunn (absent) Robert Lionberger Rong Wang (absent) Sam Raney Sarah Ibrahim Sarah Rogstad (absent) William Smith Yan Wang Yang Yuan Zhen Zhang	**AAM** David Gaugh (absent) Giuseppe Randazzo Scott Kuzner **Apotex** Kiran Krishnan **Teva Pharmaceuticals** Brian McCormick **Fresenius-Kabi** Molly Ventrelli

8:10 AM – 8:20 AM Finalization of Meeting Minutes for August 28, 2024, Bi-Annual Industry Meeting

Dr. Sam Raney solicited any feedback on the meeting minutes for the August 28, 2024, Bi-Annual Industry Meeting. Dr. Randazzo confirmed industry partners reviewed the meeting minutes and had no further comments or edits. Dr. Raney thanked the industry partners for their review and stated FDA would proceed to post the final meeting minutes.

8:20 AM – 9:00 AM FY 2025 GDUFA Public Workshop (June 3-4, 2025)

Dr. Sam Raney led a discussion on the FY 2025 GDUFA Public Workshop tentatively scheduled for June 3-4, 2025, and asked if there were any concerns with this date. Dr. Randazzo mentioned that on June 4, 2024, there were tentative plans to hold a quarterly GDUFA III implementation meeting but indicated that he would work to move that implementation meeting. No further concerns were noted with these dates and the FY 2025 GDUFA Public Workshop was confirmed to be held on June 3-4, 2025.

- ***Reflections on the Format & Content of the FY 2024 GDUFA Public Workshop***

Dr. Raney provided a brief review of the format used for the FY 2024 GDUFA Public Workshop, noting that the FY 2024 workshop had an unusually large number of public comment presentations, and a introduced a new format with parallel FDA and Public panelists who participated during the entire session. Dr. Randazzo commented that the format worked very well, and the panel size allowed for conversation and dialogue. It was noted that several public comment presentations seemed to be

promotional in nature, appearing to advocate for FDA to contract with major consulting firms to build artificial intelligence systems. The group recommended that, for the FY 2025 GDUFA Public Workshop, public comment presentations aligned with scope of the workshop would be invited to present their comments during the workshop, and those comments that did not appear to be in scope would be invited to submit their comments via the docket. Dr. Krishnan noted that relevant feedback related to nitrosamines which was provided to FDA through public comments was appropriately considered by FDA and incorporated into an FDA Guidance for Industry that was published quickly following the meeting.

Dr. Raney asked for industry feedback on the physical layout of the two parallel panels, with industry on one panel and FDA on the other, intended to allow for dialogue between panelists and presenters. Dr. Lionberger clarified that the goal of the FDA panel was for FDA to have designated experts participating throughout the session to listen to input and to ask clarifying questions. Dr. Krishnan provided feedback on the panel member selection and how discussions sometimes would go on tangents outside of the scope and focus of this workshop. Dr. Krishnan recommended selecting panel members who are more closely associated with the day-to-day challenges from generic drug developers. It was agreed that FDA, AAM, and the CRCG will work together to identify suitable faculty for the FY 2025 GDUFA Public Workshop and will take the feedback provided in relation to the FY 2024 GDUFA Public Workshop into account

- ***Discussion of Potential Components of the FY 2025 GDUFA Public Workshop***

Dr. Raney walked through the program of the FY 2024 GDUFA Public Workshop to discuss elements that would be of interest retain or revise for the FY 2025 GDUFA Public Workshop.

1. FDA Update on Activity in FY24 GDUFA Research Priority Areas
    a. In FY 2024, the workshop opened with Dr. Lionberger providing an update and overview of the current research portfolio associated with the research priorities.
    b. Dr. Randazzo stated that this presentation during the opening session was very useful for industry to understand the status of research activities in GDUFA priority areas. Dr. Krishnan and Dr. Ventrelli concurred with Dr. Randazzo's comments.
    c. The group recommended retaining this update in the program for the FY 2025 GDUFA Public Workshop.
2. Sessions Focused on Selected Scientific Topics
    a. The group recommended retaining sessions on specific topic areas (and the selected scientific topics for these sessions were discussed later in the meeting).
3. Public Comments and/or Industry Panel Session (General Discussion)
    a. The group was amenable to an open forum for public comments, to the extent that relevant comments would be provided.
    b. Dr. Randazzo questioned whether public comments were appropriate to segregate into a separate session, distinct from the scientific topic sessions. Dr. Lionberger clarified that the session focused on public comments was intended for FDA to be able to receive general feedback from industry that may not be associated with any of the specific scientific topic areas for which dedicated sessions were scheduled. Dr. Randazzo understood and agreed with Dr. Lionberger. Dr. Kuzner suggested revising the session title for the FY 2025 workshop to clarify that the focus would be on soliciting Generic Industry Feedback.
4. Public Comments & Presentations on Proposed New Research in Priority Areas
    a. The group discussed having an open forum for public comments and scientific presentations of proposed research ideas to address GDUFA research priorities

b. These comments would be focused and separated based on the selected scientific topics and presentations would focus on potential new research to prioritize in each topic area.

- ***Potential Session Topic Areas for FY 2025 GDUFA Public Workshop***

Dr. Raney identified three potential scientific sessions to discuss where new research may be needed, with a theme of clarifying implementation details and potential guidance recommendations for:

1. Complex APIs & Immunogenicity, including Iron Products
2. Complex Products, including Inhalation Products, DDCPs, & Complex Injectables
3. M13A, including BCS Class IV, and Parallel Approaches for MR Products

Dr. Raney requested feedback from industry partners on these proposed topics. The group concurred that discussions relating to research on modeling and simulation would be integrated into each of the three sessions above, rather than having a separate session focused on modeling and simulation.

Dr. Krishnan emphasized the importance of soliciting industry feedback about their experience and the specific challenges they have encountered when attempting to implement test methods that were developed as part of the research already conducted, as well as discussing how some of these challenges were overcome, to allow for greater transparency in discussions and to glean better insights about improved approaches for implementing future research outcomes. Dr. Randazzo further emphasized that inhalation products have been a hot topic in industry and suggested that having a session focused on this topic area would be very beneficial. Dr. Lionberger provided clarification about the strategic way different research priority areas were featured each year.

Dr. Raney concluded discussion on this agenda topic and stated that FDA would utilize three the topics above to begin structuring the workshop sessions and overall layout. The group agreed that over the next six weeks, FDA, AAM, and the CRCG would work together to identify faculty with expertise in these topic areas.

9:00 AM – 9:25 AM Discussion of FY 2025 GDUFA Public Workshop Planning/Logistics

- ***Hybrid (in-person + virtual) workshop format***

Dr. Raney asked attendees for feedback on having an in person and virtual workshop. Dr. Randazzo agreed that the hybrid structure is optimal. Dr. Raney clarified that the aspiration would be for all faculty to attend in person and Dr. Lionberger further added that a key aim was to maximize the quality of industry input by having faculty attend in person.

- ***Collaborative planning process with the CRCG***

Dr. Raney stated that over the past few years working with CRCG to identify faculty has been helpful and in FY 2024 we also received input from the United States Pharmacopeia (USP). Dr. Randazzo and Dr. Ventrelli agreed with continuing this coordination of industry perspectives through the CRCG and USP.

- ***Workshop planning timeframes***

Dr. Raney proposed that, ideally over the next six weeks, FDA, AAM, USP and the CRCG would work together to identify faculty and confirm their participation (ideally before the December holidays). The goal would be to begin faculty planning sessions in January 2025.

9:00 AM – 9:30 AM Review of meeting outcomes and proposed actions

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

- FDA will finalize the meeting minutes from the August 28, 2024 Bi-Annual Industry Meeting.
- FDA will draft the meeting minutes from today's meeting and share with industry partners for feedback prior to finalization.
- FDA will begin planning for the FY 2025 GDUFA Public Workshop, to include an overview of the current research portfolio, sessions focused on areas of interest discussed above, and opportunities for industry feedback during session presentations and panel discussions. Over the next six weeks, FDA, AAM, USP and the CRCG will work collaboratively to identify faculty members who can represent perspectives from the generic drug industry.

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