Bi-Annual Industry Regulatory Science Working Group Meeting
Meeting Minutes
November 17, 2025
8:00 AM to 9:30 AM
Microsoft Teams Meeting

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

FDA	**FDA** (continued)	**Industry**
Ahmed Zidan (absent) Andrew Babiskin Bryan Newman Cameron Smith Dongmei Lu Huzeyfe Yilmaz Jessie Floura (absent) Jihong Shon (absent) Lanyan (Lucy) Fang Lei Zhang (absent) Maria Monroy-Osorio	Markham C. Luke Namrata Trivedi (absent) Nilufer Tampal (absent) Robert Lionberger Sam Raney Sarah Ibrahim (absent) William Smith Yan Wang Yang Yuan (absent) Zhen Zhang	**AAM** Giuseppe Randazzo Scott Kuzner

Mr. Randazzo explained that for today's meeting, only he and Dr. Kuzner will represent industry due transitioning representation associated with the GDUFA IV negotiations. For future Bi-Annual Industry-FDA Working Group Meetings, additional industry attendees will be invited.

8:10 AM – 8:20 AM Finalization of Meeting Minutes for August 6, 2025, Bi-Annual Industry Meeting

Dr. Sam Raney solicited any feedback on the meeting minutes from the August 6, 2025, Bi-Annual Industry Meeting. Mr. 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 2026 GDUFA Public Workshop (June 8-9, 2026)

Dr. Sam Raney led a discussion on the FY 2026 GDUFA Public Workshop scheduled for June 8-9, 2026. Mr. Randazzo confirmed that, at this time, no conflicts have been identified with the June 8-9, 2026 dates. Dr. Raney verified that the FDA Great Room has been reserved for the FY 2026 GDUFA Public Workshop on June 8-9, 2026, and that FDA would work to facilitate the plans for the workshop accordingly.

- ***Reflections on the Format & Content of the FY 2025 GDUFA Public Workshop***

Dr. Raney provided a brief review of the format used for the FY 2025 Public Workshop, which included an opening session with remarks from OPQ and OGD on regulatory science impact, followed by Dr. Lionberger providing an overview or the GDUFA research portfolio across the eight GDUFA research priority areas. Dr. Raney provided a brief overview of the individual sessions for the FY 2025 GDUFA Public Workshop. Dr. Raney mentioned that the FY 2025 workshop ran late into the afternoon on the first day and noted the potential implications on the convenience of live attendance for virtual attendees in different time zones.

- ***Discussion of Potential Components of the FY 2026 GDUFA Public Workshop***

Dr. Raney walked through the program of the FY 2025 GDUFA Public Workshop to discuss elements that would be of interest to retain or revise for the FY 2026 GDUFA Public Workshop.

1) FDA Update on Activity in FY25 GDUFA Research Priority Areas
    - Overview of current research portfolio in each of the 8 priority areas

    Mr. Randazzo agreed with Dr. Raney that this overview is very worthwhile and beneficial to industry.

2) Sessions Focused on Selected Topics (see proposed session topics below)
    - Discussion of emerging and ongoing challenges for generic product development and assessment, and associated new research needed in selected areas

    Dr. Raney explained that some potential sessions would be discussed as part of the next part of the agenda.

3) Public Comments and/or Industry Panel Session
    - Open forum for public comments and/or industry perspectives

    Dr. Raney explained how in previous years, sessions afforded time for open public comments from industry and the public, or consisted of an industry panel to help identify what research discussed during the workshop should be prioritized. Following clarification about this from Dr. Raney, AAM attendees acknowledged that the purpose of this workshop should focus on identifying what research should be prioritized to facilitate the development or assessment of generic products.

Mr. Randazzo requested clarification on the difference between the public comments referenced on this agenda item "3)" and the public comments on the next agenda item "4)". Dr. Raney explained that one format provided unstructured time for any workshop attendee to come up to a microphone and speak, whereas another format involved scheduled time for prepared public comment presentations. Mr. Randazzo noted that it was prudent to afford opportunities for interested parties to pose questions, provide comments, or recommend research for consideration.

4) Public Comments & Presentations on Proposed New Research in Priority Areas
   - Open forum for public comments and scientific presentations of proposed research ideas to address GDUFA research priorities

   Dr. Raney clarified that this session would be a structured session with prepared presentations that are requested (in advance) in response to the Federal Register notice of this meeting.

- ***Potential Session Topic Areas for FY 2026 GDUFA Public Workshop***

Dr. Raney highlighted potential topic areas for scientific sessions (listed in the agenda) where discussions about new research may be needed. Mr. Randazzo commented that he had received positive feedback from industry about sessions on nitrosamines, on using artificial intelligence to address practical challenges, and on expanding regulatory flexibility.

- Leveraging Insights & Experience from Industry Experts for GDUFA Research
  Dr. Raney explained this session could explore how the generic drug industry might enhance its engagement with the design and selection of research projects, potentially by serving on proposal review committees, serving on expert committees that guide research projects, or leveraging the capabilities for industry labs to conduct activities that support the research. Mr. Randazzo noted generic industry support for helping to translate research activities into practical benefits that ultimately facilitate the approval of generic products.

- Evaluating Industrial Priorities for Product Specific Guidance (PSG) Development
  Dr. Raney clarified this session would focus on better understanding industry needs and interests when identifying which PSGs to develop and identifying what content and format of PSGs is most needed and most helpful. Mr. Randazzo noted that this session would be very beneficial. The possibility of combining the first and second session topics together was discussed. Dr. Raney and Mr. Randazzo agreed to have additional discussions on how to best structure the scope and content of the session to best serve the goals of the workshop.

- Addressing Ongoing Challenges with Impurities such as Nitrosamines
  Dr. Raney explained that a session on nitrosamines would facilitate discussions about ongoing challenges with mitigating the formation of nitrosamines as well as discussions on how to efficiently establish evidence that could justify higher acceptable intake limits. Mr. Randazzo confirmed industry interest in these topics and noted the value of global harmonization for standards being developed in this area.

- Expanding Regulatory Flexibility with Bioequivalence Standards
  Dr. Raney alluded to Mr. Randazzo's earlier comment that the generic drug industry was supportive of this session and discussed potential presentation topics such as expanding eligibility criteria for innovative bioequivalence approaches, broadening biowaiver eligibility, and addressing situations without available reference standards. Mr. Randazzo confirmed that these topics were a high priority and of broad industry interest.

- Using AI to Address Practical (e.g., IID/MDD) Challenges for Generic Drugs
  Dr. Raney alluded to Mr. Randazzo's earlier comment about having received positive feedback from industry about this session. Potential topics that might be within the scope of this session included improvements to the inactive ingredient database, and the maximum daily dose information. Mr. Randazzo confirmed strong industry support for this session.

- Advancing Characterization Methods and Standards for Product Quality
  Dr. Raney explained that this session would focus on clarifying technical challenges related to the conduct or assessment of novel product quality and performance tests. Mr. Randazzo suggested analyzing submissions with product quality deficiencies over the past few years and identifying any patterns or common deficiencies to support a discussion about how product quality deficiencies can be mitigated.

Dr. Raney summarized this part of the discussion noting that while the proposed session topics generally appeared to be compatible with generic industry needs and interests, the specific scope and content of individual sessions would require refinement. Dr. Raney requested any final feedback on the potential session topics. No additional feedback was received.

9:00 AM – 9:25 AM Discussion of FY 2026 GDUFA Public Workshop Planning/Logistics

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

Dr. Raney asked attendees for feedback about having a hybrid (in-person and virtual) workshop. Mr. Randazzo agreed that the hybrid structure is optimal.

- ***Collaborative planning process with the Center for Research on Complex Generics (CRCG)***

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

- ***Workshop planning timeframes***

Dr. Raney proposed that as an action item from the current meeting, representatives from FDA, AAM, and the CRCG would work together to refine the scope and content of the proposed workshop sessions, and to map out a process and timeline to identify faculty and confirm their participation.

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 proceed to finalize the meeting minutes from the August 6, 2025 Bi-Annual 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 2026 GDUFA Public Workshop, to include an overview of the current research portfolio, sessions focused on the topic areas discussed above, and opportunities for public comments and industry feedback through presentations and panel discussions. Over the next few weeks, FDA, AAM, USP and CRCG will work collaboratively to identify faculty members who can represent perspectives from the generic drug industry.

Mr. Randazzo requested clarity from Dr. Lionberger about the distinction between topics discussed during the current Bi-Annual meeting and GDUFA IV negotiation meetings. Dr. Lionberger clarified that while this Bi-Annual meeting is focused on planning the FY 2026 GDUFA Public Workshop, the GDUFA IV negotiation meetings are focused on matters and discussions that would relate directly to the FDA's GDUFA IV commitment letter.

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