Bi-Annual Industry Regulatory Science Working Group Meeting
Meeting Minutes
March 23, 2022
10:00 AM to 11:30 AM
Zoom Meeting

10:00 AM – 10:05 AM: Introductions

Attendees**:**

FDA	**FDA** (*continued*)	**Industry**
Tiana Barnes	Markham Luke	John DiLoreto
Wendy Cai	Maria Monroy-Osorio	David Gaugh
Pinaki Desai	Savita Nigam	Brian McCormick
Rachel Dunn	Sam Raney	Cornell Stamoran
Karen Feibus	Sarah Rogstad	Molly Ventrelli
Jessie Floura	Rong Wang	
Xiaohua Huang	Miyoung Yoon	
Sarah Ibrahim	Lei Zhang	
Robert Lionberger	Liang Zhao	

10:05 AM – 10:45 AM: Discussion of Fiscal Year (FY) 2022 GDUFA Public Workshop Sessions

- Session 1: Overview by Robert Lionberger, PhD
- Session 2: Overview by Liang Zhao, PhD (covered by Miyoung Yoon, PhD)
- Session 3: Overview by Sam Raney, PhD
- Session 4: Overview by Rachel Dunn, PhD
- Session 5: Overview by Sarah Ibrahim, PhD
- Session 6: Overview by Markham Luke, MD, PhD
- Session 7: Overview by Karen Feibus, MD
- Session 8: Overview by Robert Lionberger, PhD

Dr. Robert Lionberger, Director of the Office of Research and Standards (ORS) within the Office of Generic Drugs (OGD), at the U.S. Food and Drug Administration (FDA) steered a discussion about the virtual fiscal year (FY) 2022 Generic Drug Science and Research Initiatives Public Workshop that will be held on May 9-10, 2022 ('the FY 2022 Workshop'). He provided the high-level overview of this year's workshop and its vision to focus on the next five years of the Generic Drug User Fee Amendments (GDUFA) research program at FDA.

Dr. Robert Lionberger further steered a discussion about Session 1 during the FY 2022 Workshop. This session will focus on generic drug industry perspectives about known and anticipated challenges with generic drug development and assessment, and opportunities for research to build scientific bridges across the knowledge gaps at the root of those challenges.

Dr. Miyoung Yoon, Team Lead in the Division of Quantitative Methods and Modeling within ORS/OGD, steered a discussion about Session 2 during the FY 2022 Workshop. This session, divided into two sub-sessions, will focus on discussing best practices and receiving industry feedback on modeling packages and novel artificial intelligence or machine learning approaches to facilitate generic drug development and assessment.

Dr. Sam Raney, Associate Director for Science in ORS/OGD steered a discussion about Session 3 during the FY 2022 Workshop. This session will feature prepared public comments and will provide an opportunity for attendees to contribute live comments via a virtual 'open microphone' session during which attendees can indicate their interest in speaking and be placed in a queue to have their microphone un-muted so that they can relay their comments. An FDA panel will be present to ask clarifying questions on the comments.

Dr. Rachel Dunn, Director of the Division of Pharmaceutical Analysis in the Office of Testing & Research (OTR) within the Office of Pharmaceutical Quality (OPQ) at FDA, steered a discussion about Session 4 during the FY 2022 Workshop. This session, divided into two sub-sessions, will focus on a range of scientific issues associated with excipients and impurities that impact generic drug development and assessment.

Dr. Sarah Ibrahim, Associate Director for Global Generic Drug Affairs in OGD, steered a discussion about Session 5 during the FY 2022 Workshop. This session will foster a discussion on scientific issues relevant to the global nature of generic drug development and focus on identifying what research could produce the information, models, or evidence needed to support global alignment of bioequivalence standards.

Dr. Markham Luke, Director of the Division of Therapeutic Performance I within ORS/OGD, steered a discussion about Session 6 during the FY 2022 Workshop. This session will focus on discussing what research is needed to clarify how product characterization tests, in vitro studies, and other novel methodologies recommended in FDA guidances should be implemented so that the results generated are compatible with FDA's expectations during the assessment of an abbreviated new drug application (ANDA).

Dr. Karen Feibus, Team Lead in the Division of Therapeutic Performance I within ORS/OGD, steered a discussion about Session 7 during the FY 2022 Workshop. This session will focus on discussing how the design of a user interface in a drug-device combination product might impact drug delivery, and what research would help improve approaches for identifying, categorizing and comparing differences between user interfaces, as well as addressing other scientific challenges impacting the development and assessment of generic drug-device combination products.

Dr. Robert Lionberger concluded this portion of the agenda by steering a discussion about Session 8 at the FY 2022 Workshop. This session will conclude the FY 2022 Workshop with a panel discussion that reflects upon the presentations and discussions throughout the preceding sessions of the workshop, and identifies what strategic research priorities are needed during the next 5 years of the GDUFA research program to address known and anticipated challenges impacting generic product development.

There was a general discussion from the meeting attendees that the FY 2022 Workshop topics are well aligned with the current issues and challenges impacting generic product development. Industry meeting attendees also expressed satisfaction with the faculty of speakers and panelists participating in the FY 2022 Workshop, who are subject matter experts well-suited to represent an important range of perspectives from across the generic drug industry, globally.

10:45 AM – 11:00 AM: Discussion on Industry Feedback (presenters, panelists, public comments, the docket)

Dr. Robert Lionberger steered a discussion on the different methods for industry to provide feedback and input relating to topics addressed during the FY 2022 Workshop. Dr. Lionberger and Dr. Raney emphasized that while some topics are explicitly noted to be within the scope of sessions on the agenda, FDA welcomes comments related to any topics that industry representatives consider to be important.

Dr. Lionberger and Dr. Raney summarized multiple ways in which comments may be provided, including:

1. *Reaching out directly to industry speakers/panelists on the agenda and requesting that they vocalize perspectives relating to their presentation topic, or relevant to a panel discussion*
2. *Utilizing the open microphone session during Session 3 of the FY 2022 Workshop*

3. *Submitting formal comments to the docket for this FY 2022 Workshop by June 10th*

11:00 AM – 11:15 AM: Proposed Revisions to Meeting Dates

Examples:

- Jul/Aug 2022: Bi-Annual Meeting focused on FY 23 Priorities
- Nov/Dec 2022: Bi-Annual Meeting focused on FY 23 Workshop

Dr. Sam Raney steered a discussion on the meeting schedule for the bi-annual industry meetings, proposing to schedule bi-annual meeting #1 in July/August (focused on discussing the science and research priority areas following the public workshop) and to schedule bi-annual meeting #2 in November/December (focused on the next GDUFA Public Workshop). Dr. Lionberger and Dr. Raney explained how the proposed schedule would provide greater opportunities for industry representatives to collaborate to a greater degree about details of the research priorities and of the GDUFA Workshop program. One consideration arising from this new meeting timeframe would be that we would have three (3) bi-annual meetings during 2022.

Dr. David Gaugh, Senior Vice President for Sciences and Regulatory at the Association for Accessible Medicines, noted that having an earlier meeting in July/August would provide the advantage of being only a short duration after the FY 2022 Workshop, which would make it easier to remember the discussions and incorporate the relevant feedback into the research priorities for the next year. The group decided to move toward this new meeting schedule. Dr. Gaugh also noted that the AAM GRX+Biosims Conference is typically held in November, and requested that the bi-annual meeting not be scheduled in conflict with the annual AAM GRX+Biosims Conference.

11:15 AM – 11:25 AM: Discussion of FY 2023 GDUFA Public Workshop Format

Dr. Sam Raney solicited feedback about any interest in a potential change to the format of future GDUFA public workshops. Specifically, he inquired whether there were any elements of the format, structure, or logistical timing of when certain aspects of the workshop are developed and finalized that was perceived as a limitation to being able to address emergent issues that may arise closer to the date of the meeting. Dr. Robert Lionberger mentioned that, currently, emergent issues can be addressed during the public comments session of the program, although prepared public comments are subject to advance planning.

Dr. David Gaugh and Brian McCormick, Vice President - Chief Regulatory Counsel, Head of Global Regulatory Policy at Teva Pharmaceuticals, both concurred that the current format and logistical processes for developing the annual public workshop programs works well, and that there is no need to change the process.

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

Dr. Sam Raney clarified the action items and target due dates.

- *FDA to identify dates for upcoming bi-annual meetings targeting one meeting in July/August and another in November/December*
- *Industry representatives to collaborate with industry colleagues to convey the multiple ways in which comments may be provided during and after the FY 2022 Workshop*

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