Bi-Annual Industry Regulatory Science Working Group Meeting
Meeting Minutes
November 17, 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 Sruthi King Sarah Ibrahim Robert Lionberger Lei K. Zhang Sam Raney Sarah Rogstad Jessie Floura Liang Zhao Markham Luke Layan (Lucy) Fang Maria Monroy-Osorio	Manar Al-Ghabeish Tiana Barnes (absent) Heather Boyce Rachel Dunn Bryan Newman Andre Raw Fallon Smalls (absent) Namrata Trivedi Diana Vivian Yang Yuan (absent) Ahmed Zidan Rong Wang	**AAM** Brian McCormick David R. Gaugh Giuseppe Randazzo Scott Kuzner **PBOA** Gil Roth **BPTF** Joel Carpenter **Apotex** Ripen Misri

10:10 AM – 11:00 AM: FY 2024 GDUFA Public Workshop (May 20-21, 2024)
Dr. Sam Raney initiated a discussion on the FY 2024 GDUFA Public Workshop (which is scheduled for May 20-21, 2024), and about the potential components of the FY 2024 GDUFA Public Workshop

- The sessions of the FY 2023 GDUFA Public Workshop were discussed, and it was agreed that during the opening session of the workshop it would be ideal if FDA could provide an overview of the current research portfolio across each of the eight (8) GDUFA science and research priority areas.
- It was also decided to expand the time allocated to public comments, in lieu of a session dedicated to a panel discussion with industry representatives
- The topic areas for the scientific field-specific sessions of the workshop were discussed in depth. Dr. Raney presented a brief summation of the ecosystem in which the workshop will be happening and where specific topics have been recently discussed or where they are going to be discussed in future meetings. The summary presented covered workshops in 2022, 2023, and 2024 hosted by the FDA or in collaboration with the Center for Research on Complex Generics (CRCG):

2022 Workshops

2022 CRCG Workshops

In Vitro Release Test (IVRT) and In Vitro/In Vivo Correlation (IVIVC) of Complex Generic Ophthalmic, Injectable, Implantable, and Inserted Products
Best Practices for Utilizing Modeling Approaches to Support Generic Product Development
Formulation Characterization and Cutaneous Pharmacokinetics to Facilitate Generic Topical Product Development
Excipients and Formulation Assessments of Complex Generic Products: Best Practices and Lessons Learned

2022 GDUFA Public Workshop Sessions

Best Practices to Leverage Model-Integrated Evidence and Model Master File Packages to Bring Generics to Market
Artificial Intelligence and Machine Learning for Generic Drug Development and Assessment
Harmful Impurities Such as Nitrosamines: Contamination and Strategies to Mitigate Their Formation
Characterization of Excipients for Complex Dosage Forms
The Global Nature of the Generic Drug Industry
Implementing GDUFA Science in Product Development and ANDAs
Drug-Device Combination Products

2023 Workshops:

2023 CRCG Workshops

Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products
DDCP 101 – Identifying, Developing, and Evaluating Generic Drug Device Combination Products (DDCP)
Mitigation Strategies for Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generics
Advances in PBPK Modeling and its Regulatory Utility for Oral Drug Product Development
Characterization of Complex Excipients and Formulations

2023 GDUFA Public Workshop Sessions

Development of Efficient Methods for Generics to Address Impurities Such as Nitrosamines
Enhancing the Efficiency of Bioequivalence Approaches for Generic Oral Products
Enhancing the Efficiency of Bioequivalence Approaches for Generic Products with Complex Active Ingredients
Enhancing the Efficiency of Bioequivalence Approaches for Generic Dosage Forms and Formulations
Enhancing the Efficiency of Bioequivalence Approaches for Complex Generic Inhalation Products
Enhancing the Efficiency of Bioequivalence Approaches for Complex Generic Topical Products

2024 Workshops:

2024 CRCG Workshops

Drug-Device Combination Products: Updates and Challenges in Demonstrating Generic Substitutability
Considerations and Potential Regulatory Applications for a Model Master Files
Scientific and Regulatory Considerations for Assessment of Immunogenicity Risk for Generic Peptide and Oligonucleotide Drug Products
Updates on Approaches to Acceptable Intakes of NDSRIs and Bioequivalence Assessment for Reformulated Drug Products
Navigating the Transition to Low Global Warming Potential Propellants

- As part of the summation, Dr. Raney presented an overview of the GDUFA III priorities and where they were discussed over the course of the past 3 years.

	2022 Workshops		**2023** Workshops		**2024** Workshops	
GDUFA III Priority	CRCG	GDUFA	CRCG	GDUFA	CRCG	GDUFA
1 Nitrosamines		✓	✓	✓	✓	
2 Peptides & Oligos				✓	✓	
3 LAIs & Polymers	✓	✓	✓	✓		
4 Inhalation & Topical	✓$_{T}$	✓$_{I,P,T}$	✓$_{I}$	✓$_{I,P,T}$	✓$_{P}$	
5 DDCPs		✓	✓		✓	
6 Oral & Parenteral	✓	✓	✓	✓		
7 Modeling	✓	✓		✓	✓	
8 AI/ML Tools		✓				

✓$_{T}$ = Topical BE ✓$_{I}$ = Inhalation BE ✓$_{P}$ = Propellants ✓ = Presentation(s) - Not a Dedicated Session

- Dr. Lionberger encouraged the group to consider dedicating scientific sessions during the workshop to a subset of the 8 research priority areas where new research needs would be productive to discuss. Based on FDA's experience, as well as feedback to FDA from industry, the following 5 areas appeared to be potential candidates for such scientific sessions.

1. Nitrosamines (and Data to Determine Acceptable Intake Limits)
2. Peptide Immunogenicity (and Impurity Limits)
3. Drug-Device Combination Products (Device Similarity/Human Factors)
4. Predictive Tools Needed for Generic Product Development & Assessment
5. Transition to Low Global Warming Potential Propellants

- Following substantial discussion among meeting attendees, it was decided that scientific sessions should be developed that focus on the following topic areas:
    1. Nitrosamines (and Data to Determine Acceptable Intake Limits)
    2. Predictive Tools Needed for Generic Product Development & Assessment
    3. Drug-Device Combination Products (Device Similarity/Human Factors)

11:00 AM – 11:25 AM: Discussion of FY 2024 GDUFA Public Workshop Planning/Logistics

Dr. Sam Raney initiated a discussion on the planning and logistics for the FY 2024 GDUFA Public Workshop.

- It was decided that the format of the workshop would be hybrid, with both in-person and virtual attendees, and with workshop faculty participating in person to the greatest extent possible
- It was also decided that the process for nominating industry presenters and panelists would be that industry nominations would be sent directly to Dr. Giuseppe Randazzo, who would coordinate with CRCG, and that CRCG would actively reach out to generic industry stakeholders to identify presenters and panelists from industry and academia where none were otherwise nominated
- Dr. Randazzo suggested that we limit the number of panelists to facilitate a productive dialogue and to allow for in-depth discussions
- Dr. Lionberger concurred and clarified that FDA panelists have a distinct role compared with public panelists (who are typically from industry and academia), and he proposed structuring the FDA and public panelists in a manner that helps public panelists discuss and provide input about what new research should be prioritized, while FDA panelists listen and ask questions to clarify the scientific challenges impacting generic product development and assessment

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.

- Dr. Randazzo and Dr. Raney will coordinate with CRCG to discuss faculty nominations
- The next working group meeting will tentatively be scheduled in August 2024, and will focus on discussing feedback to FDA during the FY24 GDUFA Public Workshop and corresponding updates to the FY 2025 GDUFA Science and Research Priorities.

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