Fiscal Year (FY) 2022 Generic Drug Science and Research Initiatives Public Workshop (Virtual)

May 9, 2022

Final Agenda (Day 1)

8:00 AM – 8:15 AM	**Opening Remarks**	
	Robert Lionberger, PhD	Director, ORS, OGD, FDA
8:15 AM – 8:30 AM	**Welcome to the FY 2022 Generic Drug Science and Research Initiatives Public Workshop**	
	Sally Choe, PhD	Director, OGD, FDA

Session 1: *The Next 5 Years of the Generic Product Science and Research Program*

This session opens the workshop with presentations providing several industry perspectives about the challenges impacting generic product development that are the most critical to address during the next 5 years of FDA's GDUFA Science and Research program. The presentations will discuss challenges associated with several prominent scientific issues impacting generic product development, and suggest how each of these issues might be addressed by focused research initiatives.

8:30 AM – 8:45 AM	***Industry Interview Feedback on the Main Challenges in the Development of Complex Generics***	
	Anna Schwendeman, PhD	Co-Director, CRCG
8:45 AM – 9:00 AM	***An Industry Perspective on Generic Product Development Challenges & Research Priorities for the Next 5 Years - I***	
	Bob Iser, MS	Sr. VP, Global Quality Management, Amneal Pharm.
9:00 AM – 9:15 AM	***An Industry Perspective on Generic Product Development Challenges & Research Priorities for the Next 5 Years - II***	
	Kiran Krishnan, PhD	Sr. VP, Global Regulatory Affairs, Apotex Inc.
9:15 AM – 9:30 AM	***An Industry Perspective on Generic Product Development Challenges & Research Priorities for the Next 5 Years - III***	
	Janet Vaughn, BS	VP, North America Generic Regulatory Affairs, Teva Pharm.
9:30 AM – 9:45 AM	***Advancing Development of Complex Generics to Improve Patient Access to Medicines***	
	Rosario Lobrutto, PhD	Executive Director, Head of Scientific Affairs, Sandoz Inc.
9:45 AM – 10:00 AM	***Coffee Break***	

Session 2: *Implementing Practical and Efficient Model-Integrated BE Approaches*

This session will focus on how a broader adoption of modeling by generic drug developers could overcome bioequivalence (BE) challenges that are otherwise difficult to resolve. Presentations and panel discussions about the practical implementation of model-integrated evidence (MIE) to support a demonstration of BE will focus on best practices for the development of model-integrated BE (Session 2A), the utilization of model master file packages (Session 2A), and paths to leverage artificial intelligence and machine learning in support of generic drug development and assessment (Session 2B). Industry feedback will be sought to elucidate barriers impacting the practical implementation of modeling within generic drug development programs, exploring research that may help overcome those hurdles in contexts of specific interest to generic industry representatives. Discussion of such contexts may include generating model-informed evidence to support waivers for additional strengths that may not be proportionally formulated, assessing when fed pharmacokinetics (PK) BE studies may potentially be waived, and exploring the feasibility of potential alternatives to vehicle placebo treatment arms in comparative clinical endpoint BE studies for generic products.

Sub-Session 2A: Best Practices to Leverage Model-Integrated Evidence and Model Master File Packages to Bring Generics to Market

During this session, generic industry representatives who have successfully incorporated model-integrated evidence (MIE) into their drug development paradigms will describe and discuss the practical utility and best practices for developing mechanistic physiologically based pharmacokinetic (PBPK) modeling and population pharmacokinetic (Pop PK) modeling to inform regulatory decision making. To further the discussion, this session will then explore the concept of model master files to facilitate the implementation of MIE. FDA is seeking input from industry, academia, and commercial experts in modeling to further develop this concept and to support the feasibility of implementing this concept. Questions to be addressed will include: What is the definition of model-master files? What is included in model-master files? Would they be platform specific? How will ANDA applicants share these model-master files with FDA?

10:00 AM – 10:10 AM	***PBPK Model for Modified-Release Capsules: Development, Validation and Establishment of In Vitro In Vivo Relationship for BE Prediction of Formulations with Different Dissolution Rates***	
	Rebeka Jereb, PhD	Clinical Scientist, Sandoz Inc.
10:10 AM – 10:20 AM	***Research Related to Model Master Files to Establish the Concept and Details for Practical Implementation of Model-Integrated BE Packages in Regulatory Submissions***	
	Andy Hooker, PhD	Prof. of Pharmacometrics, Uppsala Univ.
10:20 AM – 10:30 AM	***Attributes of Models that Facilitate Model Reusability: Implications for Acceptance***	
	Amin Rostami, PhD	Prof. of Systems Pharmacology, Univ. of Manchester / CSO, Certara
10:30 AM – 10:40 AM	***Legal Considerations on Modeling Sharing and Implications on Model Master Files***	
	David Feigal, Jr., MD, MPH	Partner, NDA Partners
10:40 AM – 10:50 AM	***Best Practices to Leverage Model-Integrated Evidence and Model Master File Packages to Bring Complex Generics to Market***	
	Liang Zhao, PhD	Director, DQMM, ORS, OGD, FDA
10:50 AM – 11:40 AM	Panel Discussion	
Moderator:	**Liang Zhao, PhD**	Director, DQMM, ORS, OGD, FDA

Panelists:	**Géraldine Cellière, PhD**	VP, Application, Simulations Plus, Lixoft Division
	David Feigal, Jr., MD, MPH	Partner, NDA Partners
	Joga Gobburu, PhD	Prof. & Director, Center for Translational Medicine, Univ. of Maryland
	Andy Hooker, PhD	Prof. of Pharmacometrics, Uppsala Univ.
	Rebeka Jereb, PhD	Clinical Scientist, Sandoz Inc.
	Robert Lionberger, PhD	Director, ORS, OGD, FDA
	Carl Peck, MD	Adj. Prof., Schools of Pharmacy & Medicine, UCSF / Consultant, NDA Partners
	Amin Rostami, PhD	Prof. of Systems Pharmacology, Univ. of Manchester / CSO, Certara
	Partha Roy, PhD	Director, OB, OGD, FDA
	Yu Chung Tsang, PhD	CSO, Biopharmaceutics and Biostatistics, Apotex Inc.
	Raja Velagapudi, PhD	Executive Director, Pharmaceutical Dev. & Clinical Dev., Sandoz Inc.

Sub-Session 2B: Artificial Intelligence and Machine Learning for Generic Drug Development and Assessment

The application of artificial intelligence (AI) and machine learning (ML) methodologies to generic drug development and assessment is sufficiently advanced stage that the implementation of these tools can meaningfully enhance the efficiency and effectiveness of generic drug development and assessment, thereby potentially reducing time, cost, and risk. Presentations and discussion during the panel will illustrate the recent advancements in AI, ML, and other areas that can streamline generic drug development and ANDA assessment, conveying real-world experience and the efforts by the FDA to collaboratively explore applications for generics with industry representatives and technology developers.

11:40 AM – 11:50 AM	***Leveraging Artificial Intelligence and Machine Learning to Support Regulatory Efficiency – Current Progress***	
	Meng Hu, PhD	Team Lead, DQMM, ORS, OGD, FDA
11:50 AM – 12:00 PM	***Digital Twins Powered by Machine Learning for Real Time Insights in Pharmaceutical R&D and Manufacturing***	
	Sridevi Challa, MTech	Team Lead, Formulation Development, Sandoz, a Novartis Division
12:00 PM – 12:30 PM	Panel Discussion	
Moderator:	**Lanyan Fang, PhD**	Deputy Director, DQMM, ORS, OGD, FDA
Panelists:	**Sridevi Challa, MTech**	Team Lead, Formulation Development, Sandoz, a Novartis Division
	Sunny Chapel, PhD	CSO, Amador Bioscience/CEO, A2PG
	Meng Hu, PhD	Team Lead, DQMM, ORS, OGD, FDA
	Ravi Iyer, PhD	Sr. Director, Head Real World Evidence Strategy, Global HEOR, Teva Pharm.
	Laura Kleiman, PhD	Founder and CEO, Reboot Rx
	Bing Li, PhD	Associate Director for Science, OB, OGD, FDA
	Mark Sale, MD	EVP, Pharmacometrics, Certara
12:30 PM – 1:00 PM	***Lunch Break***	

Session 3: *Public Comments*

1:00 PM – 1:05 PM	***A Need for Biorelevant/Biopredictive In Vitro Release Methodologies for LAI, Inhalation, and Other Complex Generic Drug Products***	
	Raja Velagapudi, PhD	Executive Director, Clinical Development, Sandoz
1:05 PM – 1:10 PM	***Remediation of Complex Nitrosamines***	
	Valerie Niddam-Hildesheim, PhD	Sr. Director, Glob. Nitrosamines Proj. Lead, Glob. Med. Affrs & PV, Teva Pharm.
1:10 PM – 1:15 PM	***Understanding Endogenous Nitrosation -vs- Impact of Nitrosamine Impurities in Pharmaceuticals***	
	Aloka Srinivasan, PhD	Principal and Managing Partner, RAAHA, LLC
1:15 PM – 1:20 PM	***Transitioning to Green Propellants and the Potential Impact on Generic Drugs***	
	Janet Vaughn, BS	VP, North America Generics Regulatory Affairs, Teva Pharm.
1:20 PM – 1:25 PM	***Expectations from GDUFA III – Expanding the Span, Aligning all the Partners***	
	Raghuram Pannala, PhD	Sr. VP, Corp. Qual. Comp., Pharmacovig. & Reg. Affrs at ScieGen Pharm. Inc.
1:25 PM – 1:45 PM	Virtual, live 'open microphone' for public comments on any topics of interest to any attendee	
Moderator:	**Sarah Rogstad, PhD**	Senior Scientific Advisor, OTR, OPQ, FDA
Panelists:	**Rachel Dunn, PhD**	Director, DPA, OTR, OPQ, FDA
	Robert Lionberger, PhD	Director, ORS, OGD, FDA
	Tom O'Connor, PhD	Deputy Director, OTR, OPQ, FDA
	Andre Raw, PhD	Associate Director for Science and Communication, OLDP, OPQ, FDA
	Partha Roy, PhD	Director, OB, OGD, FDA
1:45 PM – 2:00 PM	***Coffee Break***	

Session 4: *Excipient Effects*

The presentations and panel discussions during this session will focus on a wide range of scientific issues impacting generic product development and assessment that are associated with excipients and impurities. These issues specifically include, but are not limited to, excipient identity, grade and interchangeability; mixtures, heterogeneity & purity considerations; critical material attributes; impurities & pharm-tox issues; and excipient effects on bioavailability.

Sub-Session 4A: Harmful Impurities Such as Nitrosamines: Contamination and Strategies to Mitigate Their Formation

Presenters and panelists will discuss excipient issues related to the presence of harmful impurities such as nitrosamines and discuss strategies to mitigate the formation of nitrosamine impurities. Discussions will encompass pharmacological and toxicological considerations, and BE implications for formulation changes that can mitigate nitrosamine formation. Questions addressed (in the presentations and panel discussion) will include: How do excipients contribute to nitrosamine formation? What are the challenges and considerations when assessing the risk of excipient contributions to nitrosamine formation, from a quality and safety standpoint? How may excipients inhibit the formation of nitrosamine contaminants? What research should be done to address concerns about BE risks, if products are reformulated to include a nitrosation inhibitor? What strategy(ies) should FDA use to investigate these issues? Which excipients and/or drug products should be prioritized?

2:00 PM – 2:05 PM	***Session Introduction***	
	Sruthi King, PhD	Deputy Director, DPTR, OSCE, OGD, FDA
	Andre Raw, PhD	Associate Director for Science and Communication, OLDP, OPQ, FDA
2:05 PM – 2:15 PM	***Nitrite in Excipients Pre-Competitive Data Sharing Initiative***	
	Grace Kocks, BSc (Hons)	Principal Application Scientist, Lhasa Ltd.
2:15 PM – 2:25 PM	***Exploration of Forward-Looking Ideas for Inhibiting Nitrosamine Formation in Drug Products***	
	Kausik Nanda, PhD	Associate Principal Scientist, Merck & Co.
2:25 PM – 2:35 PM	***Data Gaps and Evolving Areas in Controlling Nitrosamine Formation: Drug Products and Substances***	
	Martin Ehlert, PhD	VP, Global API R&D, Apotex Inc.
2:35 PM – 2:45 PM	***Analytical Methods for Nitrosamines in Pharmaceuticals: Progress, Pitfalls and Prospects***	
	Jingyue (Jan) Yang, PhD	Sr. Research Scientist, DPA, OTR, OPQ, FDA
2:45 PM – 2:55 PM	***Safety & Risk Assessment of Excipient Contributions to Nitrosamine Formation***	
	Bob Dorsam, PhD	Director, DPTR, OSCE, OGD, FDA
2:55 PM – 3:25 PM	Panel Discussion	
Co-Moderator:	**Sruthi King, PhD**	Deputy Director, DPTR, OSCE, OGD, FDA
Co-Moderator:	**Andre Raw, PhD**	Associate Director for Science and Communication, OLDP, OPQ, FDA
Panelists:	**Khondoker Alam, PhD**	Sr. Staff Fellow, DQMM, ORS, OGD, FDA
	Bob Dorsam, PhD	Director, DPTR, OSCE, OGD, FDA
	Martin Ehlert, PhD	VP, Global API R&D, Apotex Pharm.
	David Kellehan, PhD	Sr. Manager, Global Technical Services, Viatris
	Grace Kocks, PhD	Principal Application Scientist, Lhasa Ltd.
	Kausik Nanda, PhD	Pharmaceutical Scientist, Merck Pharm.
	Jingyue (Jan) Yang, PhD	Sr. Research Scientist, DPA, OTR, OPQ, FDA
3:25 PM – 3:40 PM	***Coffee Break***	

Sub-Session 4B: Characterization of Excipients for Complex Dosage Forms

Presenters and panelists will discuss challenges related to the detailed characterization of excipients, their roles in different dosage forms (e.g., liposomes, polymeric materials, suspensions, etc.) and considerations impacting how excipient identity, grade, purity, variability, and other factors may influence critical material attributes and impact the potential interchangeability of excipients. Questions addressed (in the presentations and panel discussion) will include: How should Critical Quality Attributes be chosen/defined for excipients used in complex dosage forms? What are the specific characteristics that must be in place to achieve equivalent performance in a generic product? For example, polymers like poly(lactic-co-glycolic acid) (PLGA) have been characterized in great detail – what other excipients need that level of detail to aid in generic drug development? What is considered sufficient characterization for polymeric excipients (e.g., in transdermal systems, vaginal systems, intrauterine systems, and subcutaneous implants)? What is considered to be the same?

3:40 PM – 3:50 PM	***Characterization of Excipients in Complex Dosage Forms – FDA Research Highlights and Goals***	
	Tom O'Connor, PhD	Deputy Director, OTR, OPQ, FDA
3:50 PM – 4:00 PM	***Current Limitations and Challenges in Characterization of Excipients in Complex Dosage Forms & Future Directions***	
	Dama Venugopala Rao, PhD	Analytical Expert, Dr. Reddy's Laboratories Ltd.
4:00 PM – 4:30 PM	Panel Discussion	
Moderator:	**Wenlei Jiang, PhD**	Senior Advisor for Innovation and Strategic Outreach, ORS, OGD, FDA
Panelists:	**Darby Kozak, PhD**	Deputy Director, DTP I, ORS, OGD, FDA
	Brendan Muldoon, BSc, PhD	Sr. Director, R&D, Teva Pharm.
	Tom O'Connor, PhD	Deputy Director, OTR, OPQ, FDA
	Dama Venugopala Rao, PhD, MBA	Lead, Structural Characterization and Analytical, Dr. Reddy's Laboratories Ltd.
	Ahmed Zidan, PhD	Sr. Staff Fellow, DPQR, OTR, OPQ, FDA

Fiscal Year (FY) 2022 Generic Drug Science and Research Initiatives Public Workshop (Virtual)

May 10, 2022

Final Agenda (Day 2)

Session 5: *The Global Nature of the Generic Drug Industry*

This session will foster a discussion of scientific issues relevant to the global nature of the generic drug industry, including scientific issues relevant to the harmonization of international BE recommendations and study designs. The presentations and panel discussions will compare and contrast the BE standards in different international regulatory jurisdictions, discuss barriers to harmonization, and consider what research could produce the information, models, or evidence needed to overcome these barriers and support global alignment.

8:00 AM – 8:15 AM	***Current Challenges to Complex Generic Drug Development Under Divergent Global Regulations***	
	Michael Banks, MSc	Sr. Vice President, Global Head Regulatory Affairs, Teva Pharm.
8:15 AM – 8:30 AM	***Challenges in Clinical Development for Orally Inhaled Drug Products for the United States and Europe***	
	Bill Brashier, MD	Group Head, Respiratory Clinical Development, Novartis Healthcare Pvt. Ltd.
8:30 AM – 8:45 AM	***Expansion of Biowaivers and Global Development of Generic Products***	
	Les Benet, PhD	Prof. of Bioeng. & Ther. Sciences, Schools of Pharmacy and Medicine, UCSF
8:45 AM – 9:00 AM	***What Elements of Modeling and Simulation May Support Global Submissions?***	
	Amin Rostami, PhD	Prof. of Systems Pharmacology, Univ. of Manchester / CSO, Certara
9:00 AM – 9:15 AM	***Single Global Development: A Key to Unlocking Access***	
	Susana Almeida, PhD	Clinical Development & Safety Director, Medicines for Europe
9:15 AM – 9:30 AM	***Challenges and Opportunities for Global Development***	
	Kevin Blake, MD, PhD	Translational Sciences Sr. Specialist, SEGD, European Medicines Agency
9:30 AM – 9:45 AM	***How Can Scientific Advancements Help Align Global Development of Complex Generic Products?***	
	Wenlei Jiang, PhD	Senior Advisor for Innovation and Strategic Outreach, ORS, OGD, FDA
9:45 AM – 10:15 AM	Panel Discussion	
Moderator:	**Sarah Ibrahim, PhD**	Associate Director for Global Generic Drug Affairs, OGD, FDA
Panelists:	**Susana Almeida, PhD**	Clinical Development & Safety Director, Medicines for Europe
	Michael Banks, MSc	Sr. Vice President, Global Head Regulatory Affairs, Teva Pharm.
	Les Benet, PhD	Prof. of Bioeng. & Ther. Sciences, Schools of Pharmacy and Medicine, UCSF
	Kevin Blake, MD, PhD	Translational Sciences Sr. Specialist, SEGD, European Medicines Agency
	Bill Brashier, MD	Group Head, Respiratory Clinical Development, Sandoz Inc.
	Siddharth Chachad, MD	EVP & Head, Global Clinical Management, Dr. Reddy's Laboratories Ltd.
	Wenlei Jiang, PhD	Senior Advisor for Innovation and Strategic Outreach, ORS, OGD, FDA
	Amin Rostami, PhD	Prof. of Systems Pharmacology, Univ. of Manchester / CSO, Certara
10:15 AM – 10:30 AM	***Coffee Break***	

Session 6: *Implementing GDUFA Science in Product Development and ANDAs*

This session will discuss what additional 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 ANDA assessment. The presentations and panel discussion will identify some of the technical challenges and uncertainties associated with generating information and data submitted in ANDAs, and explore what research and collaborations may help to establish the suitability of methods developed and implemented by generic drug developers, clarify approaches to validate novel methodologies, or help standardize best practices for the development of suitable test procedures, study designs, model integrated evidence, or other matters impacting deficiencies and the number of ANDA review cycles.

10:30 AM – 10:35 AM	***Session Introduction***	
	Markham Luke, MD, PhD	Director, DTP I, ORS, OGD, FDA
10:35 AM – 10:45 AM	***From the Bench to Approval: the Role of GDUFA Research in Promoting Complex Generics***	
	Yan Wang, PhD	Team Lead, DTP I, ORS, OGD, FDA
10:45 AM – 10:55 AM	***Identification of Research Needs During Product Development Prior to ANDA Submission***	
	Priyanka Ghosh, PhD	Acting Team Lead, DTP I, ORS, OGD, FDA
10:55 AM – 11:05 AM	***Identify Research Needs to Accelerate Product-Specific Guidance (PSG) Development for Complex Products***	
	Xiaoming Xu, PhD	Lab Chief, Branch III, DPQR, OTR, OPQ, FDA
11:05 AM – 11:15 AM	***Identification of Research Opportunities from ANDA Submissions Related to BE for Orally Inhaled Drug Products***	
	Ke Ren, PhD	Deputy Director, DB-III, OB, OGD, FDA
11:15 AM – 11:30 AM	***Implementing GDUFA Science in Product Development and ANDAs: Realizations and Recommendations***	
	Brandon Wood, BSc	Associate Director, Regulatory Affairs, Generic Steriles, Teva Pharm.
11:30 AM – 11:45 AM	***Implementing GDUFA Science: Industry Perspectives***	
	Meenakshi Jain, MPharm	Director and Head, Development Regulatory Center, Sandoz Inc. (India)
11:45 AM – 12:30 PM	Panel Discussion	
Moderator:	**Markham Luke, MD, PhD**	Director, DTP I, ORS, OGD, FDA

Panelists:	**William Chong, MD**	Director, OSCE, OGD, FDA
	Priyanka Ghosh, PhD	Acting Team Lead, DTP I, ORS, OGD, FDA
	Meenakshi Jain, MPharm	Director and Head, Development Regulatory Center, Sandoz Inc. (India)
	Utpal Munshi, PhD	Director, DB-I, OB, OGD, FDA
	Patrick Vallano, PhD	Head of Innovative Programs, R&D, Viatris
	Yan Wang, PhD	Team Lead, DTP I, ORS, OGD, FDA
	Brandon Wood, BSc	Associate Director, Regulatory Affairs, Generic Steriles, Teva Pharm.
	Xiaoming Xu, PhD	Lab Chief, Branch III, DPQR, OTR, OPQ, FDA

12:30 PM – 1:00 PM ***Lunch Break***

Session 7: *Drug-Device Combination Products*

This session will discuss what research may further elucidate how the design of a user interface in a drug-device combination product might impact drug delivery; how research can improve and standardize approaches for identifying differences in user interfaces and for categorizing them as "minor" vs. "other" and how best to conduct comparative use human factors studies, and other scientific challenges impacting the development and assessment of generic drug-device combination products. The presentations will illustrate various types of scientific issues that arise for generic drug-device combination products. The panel discussion will explore what research may help to establish principles and criteria for acceptability that can provide a predictable and consistent framework for the successful development and assessment of generic drug-device combination products.

1:00 PM – 1:05 PM	***Session Introduction***	
	Karen Feibus, MD	Team Lead, DTP I, ORS, OGD, FDA
1:05 PM – 1:20 PM	***Pre-ANDA Evaluation of Drug Delivery Device Constituent***	
	Betsy Ballard, MD	Medical Officer, ORS, OGD, FDA
1:20 PM – 1:40 PM	***Comparative Use Trials and Human Factors***	
	Irene Chan, PhD	Deputy Director, DMEPA, OMEPRM, OSE, FDA
1:40 PM – 1:55 PM	***URRA and Root Cause Analysis: The Secret Ingredients for Effective Comparative Use Human Factors Studies***	
	Melissa Lemke, PhD	Founder, Human Ability Designs
1:55 PM – 2:10 PM	***Building a Taxonomy for Consistent Determination of Design Differences in Combination Products***	
	Mary Beth Privitera, PhD	Principal, Human Factors & Research, HS Design
2:10 PM – 2:25 PM	***Opportunities to Leverage Device Functional Assessment for Classifying and Evaluating User Interface Differences***	
	Hailey Fehrenbach, MS	Industrial and Human Factors Engineer, Battelle Memorial Institute
2:25 PM – 2:40 PM	***Insufficient Published Literature Related to the Usability of Device Constituent Parts***	
	Tracy VonBriesen, RN, MS	Director, Clinical Development, Fresenius Kabi
2:40 PM – 3:30 PM	Panel Discussion	
Moderator:	**Karen Feibus, MD**	Team Lead, DTP I, ORS, OGD, FDA
Panelists:	**Betsy Ballard, MD**	Medical Officer, ORS, OGD, FDA
	Irene Chan, PhD	Deputy Director, DMEPA, OMEPRM, OSE, FDA
	Melissa Lemke, PhD	Founder, Human Ability Designs
	Mary Beth Privitera, PhD	Principal, Human Factors & Research, HS Design
	Hailey Fehrenbach, MS	Industrial and Human Factors Engineer, Battelle Memorial Institute
	Tracy VonBriesen, RN, MS	Director, Clinical Development, Fresenius Kabi
	Chirag Walawalkar, BBE	Associate Director, Combination Products & Device R&D, Teva Pharm.
	Yaping Zhu, PhD	Exec. Director, Device Dev. & Inhalation Dev., Sandoz Inc., a Novartis Division

3:30 PM – 3:45 PM ***Coffee Break***

Session 8: *Panel Discussion on The Next 5 Years*

This session brings the workshop to a close with a panel discussion during which panelists will reflect upon the presentations and discussions throughout the preceding sessions of the workshop, and identify what strategic research priorities are needed to address the challenges impacting generic drug development that are the most critical during the next 5 years of the GDUFA research program. Long-term strategic perspectives from industry representatives may be provided by individuals from specific generic pharmaceutical companies, or those who have synthesized feedback from numerous industry representatives (e.g., representatives from an industry association, a center for research, industry consultants, etc.)

3:45 PM – 4:45 PM	Panel Discussion	
Moderator:	**Robert Lionberger, PhD**	Director, ORS, OGD, FDA
Panelists:	**Kevin Blake, MD, PhD**	Translational Sciences Sr. Specialist, SEGD, European Medicines Agency
	Bob Iser, MS	Sr. VP, Global Quality Management, Amneal Pharm.
	Kiran Krishnan, PhD	Sr. VP, Global Regulatory Affairs, Apotex Corp.
	Rosario Lobrutto, PhD	Executive Director, Head of Scientific Affairs, Sandoz Inc.
	Jason Rodriguez, PhD	Director, DCDA, OTR, OPQ, FDA
	Anna Schwendeman, PhD	Co-Director, CRCG
	Janet Vaughn, BS	VP, North America Generic Regulatory Affairs, Teva Pharm.
	Róisín Wallace	Head of Global Device Development, Viatris
4:45 PM – 5:00 PM	**Closing Remarks**	
	Robert Lionberger, PhD	Director, ORS, OGD, FDA

Appendix of Abbreviations

Adj.	Adjunct
Affrs.	Affairs
BBE	Bachelor in Biomedical Engineering
BE	Bioequivalence
Bioeng.	Bioengineering
BSc.	Bachelor of Science
CDER	Center for Drug Evaluation and Research
Co.	Company
Comp.	Compliance
Corp.	Corporate
CRCG	Center for Research on Complex Generics
CSO	Chief Scientific Officer
DB-I	Division of Bioequivalence I
DB-III	Division of Bioequivalence III
DCDA	Division of Complex Drug Analysis
Dev.	Development
Dev/Ops	Development and Operations
DMEPA	Division of Medication Error Prevention and Analysis
DPA	Division of Pharmaceutical Analysis
DQMM	Division of Quantitative Methods and Modeling
DPQR	Division of Product Quality Research
DPTR	Division of Pharmacology/Toxicology Review
DTP I	Division of Therapeutic Performance I
EVP	Executive Vice President
Exec.	Executive
FDA	United States Food and Drug Administration
GDUFA	Generic Drug User Fee Amendments
Glob.	Global
HEOR	Health Economics and Outcomes Research
Inc.	Incorporated
LLC	Limited Liability Corporation
MBBS	Bachelor of Medicine, Bachelor of Surgery
MD	Doctor of Medicine
Med.	Medical
MPharm	Master of Pharmacy
MS	Master of Science
MTech	Master of Technology
OB	Office of Bioequivalence
OGD	Office of Generic Drugs
OLDP	Office of Lifecycle Drug Products
OMEPRM	Office of Medication Error Prevention and Risk Management
OPQ	Office of Pharmaceutical Quality
ORS	Office of Research and Standards
OSCE	Office of Safety and Clinical Evaluation
OSE	Office of Surveillance and Epidemiology
OTR	Office of Testing and Research
Pharm.	Pharmaceuticals
Pharmacovig.	Pharmacovigilance
PhD	Doctor of Philosophy
Prof.	Professor
Proj.	Project
Pvt.	Private
Qual.	Quality
R&D	Research and Development
Reg.	Regulatory
SEGD	Scientific Evidence Generation Department
Sr.	Senior
Ther.	Therapeutic
UCSF	University of California, San Francisco
Univ.	University
URRA	Use Related Risk Analysis
VP	Vice President