Bioequivalence Innovations for Generic Oral Products: Biowaivers, Bridging, and Development for Oncology and Discontinued Products

Public Workshop
May 5-6, 2026
Agenda

Day 1 May 5

8:30 AM – 8:35 AM **Welcome and Opening Remarks**
James Polli, PhD Co-Director, CRCG

8:35 AM – 8:50 AM **FDA Opening Remarks**
Robert Lionberger, PhD Director, ORS, OGD, FDA

Session 1: Bioequivalence Approaches for Oncology Oral Products
Session Leads: Dr. Jihong Shon, Dr. Tausif Ahmed
This session will highlight how FDA and industry approach bioequivalence decision-making for oral oncology products when ethical constraints, patient feasibility, and limited study options require the use of alternative evidence and clearly defined decision thresholds.

8:50 AM – 8:55 AM ***Speaker Introductions***
Tausif Ahmed, PhD Sr. VP & Head, Clinical Research and Biopharmaceutics, Mankind Pharma Ltd.

8:55 AM – 9:05 AM ***Industry Perspective on BE Assessment for Oncology Product: Balancing Challenges/Ethics and Evidence***
Anuj Kumar Saini, PhD Global Head, Global Clinical Management, Dr. Reddy's Laboratories Ltd.

9:05 AM – 9:15 AM ***From Ethics to Evidence: Regulatory Considerations for In Vivo BE Studies of Oncology Products***
Jihong Shon, MD, PhD Associate Director of Clinical Safety, DTP II, ORS, OGD, FDA

9:15 AM – 9:30 AM ***Optimizing Bioequivalence Trials on Oncology Patients***
Dejan Krajcar, MPharm, PhD Head Clinical Innovation, Clinical Pharmacology M&S, Sandoz Global Development

9:30 AM – 9:45 AM ***Enabling the Conduct of Patient Pharmacokinetics BE Studies Using Quantitative Medicine Approaches***
Yuqing Gong, PhD Lead Pharmacologist, DQMM, ORS, OGD, FDA

9:45 AM – 10:00 AM ***Leveraging Early Dissolution Risk Assessment and PBBM to Predict its Clinical Impact***
Lalit Kumar Khurana, PhD Senior Manager, Formulation R&D, Orals, Sun Pharmaceuticals Industries Ltd.

10:00 AM – 10:10 AM ***Advancing BCS-Based Biowaivers for Oncology Products Through Risk Assessment***
Emilija Fredro-Kumbaradzi, PhD Director, Biopharmaceutics & Statistics, Apotex Inc

10:10 AM – 10:20 AM ***BCS-Based Biowaivers for Oral Oncology Products: General Considerations, Challenges, and Case Studies***
Li Gong, MD, PhD Lead Pharmacologist, DB III, OB, OGD, FDA

10:20 AM – 10:30 AM ***PBPK Modeling to Support the Alternative BE Approaches for Oral Oncology Drugs***
Arindom Pal, PhD Pharmacokineticist, DQMM, ORS, OGD, FDA

10:30 AM – 10:50 AM ***Coffee Break***

10:50 AM – 11:20 AM ***Q&A Session with Panel***
Moderator: **Jihong Shon, MD, PhD** Associate Director of Clinical Safety, DTP II, ORS, OGD, FDA
Panelists:
Emilija Fredo-Kumbaradzi, PhD Director, Biopharmaceutics & Statistics, Apotex Inc
Li Gong, MD, PhD Pharmacokineticist, DQMM, ORS, OGD, FDA
Yuqing Gong, PhD Lead Pharmacologist, DQMM, ORS, OGD, FDA
Lalit Kumar Khurana, PhD Senior Manager, Formulation R&D, Orals, Sun Pharmaceuticals Industries Ltd.
Arshad H. Khuroo, PhD Head, Bioavailability & BE Division, Sun Pharmaceuticals Industries Ltd.
Dejan Krajcar, MPharm, PhD Head Clinical Innovation, Clinical Pharmacology M&S, Sandoz Global Development

	Arindom Pal, PhD	Pharmacokineticist, DQMM, ORS, OGD, FDA
	Anuj Kumar Saini, PhD	Global Head, Global Clinical Management, Dr. Reddy's Laboratories Ltd.
	Qi Zhang, PhD	Lead Pharmacologist, DTP II, ORS, OGD, FDA

Session 2: Nitrosamine-Driven Reformulation and Bioequivalence: Risk Assessment and Regulatory Decision-Making

Session Leads: Dr. Fang Wu, Dr. Emilija Fredro-Kumbaradzi

This session examines how nitrosamine-driven reformulation should be evaluated within BE frameworks, emphasizing scientific justifications, risk-based assessment, and when alternative BE evidence is appropriate, particularly for BCS IV immediate and modified release products.

11:20 AM – 11:25 AM	***Speaker Introductions***	
	Fang Wu, PhD	Senior Pharmacologist, DQMM, ORS, OGD, FDA
11:25 AM – 11:35 AM	***Decision Principles for Nitrosamine Impacted BCS IV Immediate or Modified-Release Products***	
	Rajkumar Boddu, PhD	Team Lead, Biopharmaceutics, Dr. Reddy's Laboratories Ltd.
11:35 AM – 11:45 AM	***Nitrosamine-Impacted Drug Products Containing BCS IV Drug Substances***	
	Shamema Nasrin, PhD	Research Scientist, DTP II, ORS, OGD, FDA
11:45 AM –12:00 PM	***Model Integrated Evidence to Support BE Assessment for Reformulated Nitrosamine-Impacted BCS IV Drug Products***	
	Yi-Hsien Cheng, PhD	Research Scientist, DQMM, ORS, OGD, FDA
12:00 PM – 12:15 PM	***Nitrosamine-Driven Reformulation in Oral Drug Products: From Root Cause Analysis to Practical Mitigation***	
	Blaž Robnik, PhD	Group Head Analytics, Sandoz Global Development, Sandoz
12:15 PM – 1:00 PM	***Lunch Break***	
1:00 PM – 1:15 PM	***PBPK Modeling-Based Evidence to Support BE Preservation Following Nitrosamine-Driven Reformulation of a Modified-Release BCS Class II Oral Drug Product***	
	Pradnya Shahapure, MPharm	Team Head, Biopharmaceutics (CPP), Sun Pharmaceuticals Industries Ltd.
1:15 PM – 1:30 PM	***Analysis of ANDA Submissions of Bridging Pre-and Post-Change Nitrosamine-Impacted Drug Products and Regulatory Experiences***	
	Min Guo, PhD	Pharmacokineticist, DB I, OB, OGD, FDA
1:30 PM – 2:00 PM	***Q&A Session with Panel***	
Moderator:	**Fang Wu, PhD**	Senior Pharmacologist, DQMM, ORS, OGD, FDA
Panelists:	**Rajkumar Boddu, PhD**	Team Lead, Biopharmaceutics, Dr. Reddy's Laboratories Ltd.
	Yi-Hsien Cheng, PhD	Research Scientist, DQMM, ORS, OGD, FDA
	Min Guo, PhD	Pharmacokineticist, DB I, OB, OGD, FDA
	Dongmei Lu, PhD	Associate Director, DTP II, ORS, OGD, FDA
	Shamema Nasrin, PhD	Research Scientist, DTP II, ORS, OGD, FDA
	Blaž Robnik, PhD	Group Head Analytics, Sandoz Global Development, Sandoz
	Pradnya Shahapure, MPharm	Team Head, Biopharmaceutics (CPP), Sun Pharmaceuticals Industries Ltd.
	Dan Snider, PhD	Head, Global R&D and Technical Quality, Viatris

Session 3 Discontinued RLDs and Unavailable Reference Standards: A Structural Barrier to Generic Access

Session Leads: Dr. Heather Boyce, Dr. Sivacharan Kollipara

This session frames discontinued RLDs and unavailable reference standards as a barrier to generic access, highlighting the public-health impact, regulatory constraints, and alternative approaches to resolve the problems.

2:00 PM – 2:05 PM	***Speaker Introductions***	
	Heather Boyce, PhD	Lead Pharmacokineticist, DTP II, ORS, OGD, FDA
2:05 PM – 2:25 PM	***Developing Generics for Discontinued RLDs and Missing RS: Overcoming the Barrier to Generic Access***	
	Suparna Mukherjee, MPharm	Director, Global Clinical Operations, Gx-Pharmacokinetics, US, Teva Pharmaceuticals
2:25 PM –2:35 PM	***Proactive PSG Development for Suitability Petition Enabled Generic Products: Innovative Regulatory Approaches Using Scientific Bridging Strategies***	
	Hye Lim Lim, PharmD	Pharmacologist, DTP II, ORS, OGD, FDA
2:35 PM –2:45 PM	***Alternative BE Approaches for Generic Immediate-Release Oral Solid Dosage Form Drug Products Development When RLD/RS are Unavailable***	
	CDR Yi Zhang, PhD	Regulatory Officer, DTP II, ORS, OGD, FDA

2:45 PM –3:00 PM	***Use of Innovator Studies and Virtual Reference Data for BE Assessment in the Case of Missing RLD***	
	Brooke Langevin, PhD	Assistant Professor, University of Maryland Baltimore
3:00 PM – 3:20 PM	***Pharmacokinetic Bridging to the RLD via Alternative Comparators***	
	Robert Hopefl, PharmD	Research Scientist, DQMM, ORS, OGD, FDA
	Wanjie Sun, PhD	Master Mathematical Statistician, DB VIII, OB, OTS, FDA
3:20 PM – 3:35 PM	***Use of Different Dosage Forms as Alternate Comparator Products in Generic Drug BE Studies: Regulatory Case Studies***	
	Pamela Garner Dorsey, PhD	Senior Pharmacologist, DB III, OB, OGD, FDA
3:35 PM – 4:05 PM	***Q&A Session with Panel***	
Moderator:	**Heather Boyce, PhD**	Lead Pharmacokineticist, DTP II, ORS, OGD, FDA
Panelists:	**Pamela Garner Dorsey, PhD**	Senior Pharmacologist, DB III, OB, OGD, FDA
	Yuqing Gong, PhD	Lead Pharmacologist, DQMM, ORS, OGD, FDA
	Robert Hopefl, PharmD	Research Scientist, DQMM, ORS, OGD, FDA
	Myong-Jin Kim, PharmD	Director, DTP II, ORS, OGD, FDA
	Brooke Langevin, PhD	Assistant Professor, University of Maryland Baltimore
	Hye Lim Lim, PharmD	Pharmacologist, DTP II, ORS, OGD, FDA
	Suparna Mukherjee, MPharm	Director, Global Clinical Operations, Gx-Pharmacokinetics, US, Teva Pharmaceuticals
	Wanjie Sun, PhD	Master Mathematical Statistician, DB VIII, OB, OTS, FDA
	CDR Yi Zhang, PhD	Regulatory Officer, DTP II, ORS, OGD, FDA
4:05 PM – 4:10 PM	***Closing Remarks for Virtual Audience***	
	Heather Boyce, PhD	Lead Pharmacokineticist, DTP II, ORS, OGD, FDA
4:10 PM – 4:20 PM	***Coffee Break***	

Session 4: Small Group Working Sessions (In-Person Only)

Session Leads: Dr. Jihong Shon, Dr. Yi-Hsien Cheng, Dr. Heather Boyce

In this collaborative session, in-person participants from Industry, Academia, and the FDA will actively engage in structured discussions that delve into the unique challenges and opportunities within the same topic areas as the three sessions from the earlier part of the day. Guided by experienced moderators, workshop participants will explore the selected topics with a focus on achieving meaningful outcomes to help move generic product development and regulatory assessment forward.

4:20 PM –5:40 PM Small Group Working Sessions addressing the topics below:

Topic 1. Bioequivalence Approaches for Oncology Oral Products
Topic 2: Nitrosamine-Driven Reformulation and Bioequivalence
Topic 3: Discontinued RLDs and Missing RS

Day 2 May 6

8:30 AM – 8:35 AM ***Introduction to Day 2***
James Polli, PhD Co-Director, CRCG

Summaries of Day 1 Small Group Working Sessions:

8:35 AM – 8:45 AM ***Topic 1. Bioequivalence Approaches for Oncology Oral Products***

8:45 AM – 8:55 AM ***Topic 2: Nitrosamine-Driven Reformulation and Bioequivalence***

8:55 AM – 9:05 AM ***Topic 3: Discontinued RLDs and Missing RS***

Session 5: When Is Dissolution Truly Biopredictive?
Session Leads: Dr. Hailing Zhang, Dr. Emilija Fredro-Kumbaradzi
This session highlights when dissolution data can credibly transition from a quality control tool to support a demonstration of BE, focusing on biorelevant/predictive dissolution, discriminating capabilities of the testing media/method, integration with modeling, evidence sufficiency, and common dissolution-based BE arguments.

9:05 AM – 9:10 AM ***Speaker Introductions***
Hailing Zhang, PhD Division Director, DPQA XII, OPQA II, OPQ, FDA

9:10 AM – 9:25 AM ***In Vitro Dissolution Technologies for Biopredictive Performance, Regulatory Perspective***
Hailing Zhang, PhD Division Director, DPQA XII, OPQA II, OPQ, FDA

9:25 AM – 9:40 AM ***Stories from Two Projects: Dissolution Methods Development for IVIVC of a High Biopharmaceutics Risk Product and Deconvolution-Based Analysis of Lower Biopharmaceutics Risk Products***
James Polli, PhD Professor, University of Maryland Baltimore

9:40 AM – 9:55 AM ***What is True Biopredictive Media and Approaches to Develop Biopredictive Dissolution***
Sivacharan Kollipara, PhD Vice President & Head, Biopharmaceutics, Dr. Reddy's Laboratories Ltd.

9:55 AM – 10:10 AM ***Establishing Fit-for-Purpose Dissolution Tests: Best Practices and Challenges in Integrating with PBPK/PBBM***
Deanna Mudie, PhD Senior Principal Scientist, PBPK R&D, Simulations Plus, Inc.

10:10 AM – 10:25 AM ***Predictive Dissolution and Modeling Approaches for Medium-Risk Oral Drug Products: Insights from a Lamotrigine ER Case Study***
Ahmed Zidan, PhD Senior Research Pharmacologist, DPQR V, OPQR, OPQ, FDA

10:25 AM – 10:45 AM ***Coffee Break***

10:45 AM – 11:15 AM ***Q&A Session with Panel***

Moderator:	**Ahmed Zidan, PhD**	Senior Research Pharmacologist, DPQR V, OPQR, OPQ, FDA
Panelists:	**Andrew Babiskin, PhD**	Deputy Division Director, DQMM, ORS, OGD, FDA
	Sivacharan Kollipara, PhD	Vice President & Head, Biopharmaceutics, Dr. Reddy's Laboratories Ltd.
	Deanna Mudie, PhD	Senior Principal Scientist, PBPK R&D, Simulations Plus, Inc.
	James Polli, PhD	Professor, University of Maryland Baltimore
	Sandra Suarez-Sharp, PhD	Global Head, Regulatory Strategies Center of Excellence, Simulations Plus, Inc.
	David B. Turner, PhD	Senior Scientific Advisor, Head of Mechanistic Oral Absorption Modeling, Certara Predictive Technologies UK Ltd. (Simcyp Division)
	Hailing Zhang, PhD	Division Director, DPQA XII, OPQA II, OPQ, FDA

Session 6: Regulatory Acceptance of Alternative Approaches
Session Leads: Dr. Ahmed Zidan, Dr. Sivacharan Kollipara
This session explores strategies for achieving regulatory acceptance when using alternative approaches to establish bioequivalence in challenging scenarios.

11:15 AM – 11:20 AM ***Speaker Introductions***
Ahmed Zidan, PhD Senior Research Pharmacologist, DPQR V, OPQR, OPQ, FDA

11:20 AM – 11:30 AM ***Session Introduction***
Lei Zhang, PhD, FAAPS Deputy Director, ORS, OGD, FDA

11:30 AM – 11:50 AM	***Using Covariates as an Aid to Establishing BE***	
	Jack Cook, PhD	Senior Vice President, Clinical Pharmacology, A2-Ai, LLC
11:50 AM – 12:05 PM	***Model-Based BE Approach to Resolve BE Failures from Outliers***	
	Yasvanth Ashokraj, PhD	Director, Biopharmaceutics & Pharmacokinetics, Cipla Ltd.
12:05 PM – 12:20 PM	***Regulatory Review of Alternative Approaches: Lessons from Submissions and Pre-Engagement Forums***	
	Zhen Zhang, PhD	Master Pharmacologist, DB I, OB, OGD, FDA
12:20 PM – 1:15 PM	***Lunch Break***	
1:15 PM – 1:30 PM	***Navigating Alternative BE Approaches for High-Risk Drug Products***	
	Qi Zhang, PhD	Lead Pharmacologist, DTP II, ORS, OGD, FDA
1:30 PM – 1:45 PM	***Virtual BE Assessment for Crizotinib Pediatric Dosage Form in Pediatric Subjects Using PBPK Modeling***	
	Kazuko Sagawa, PhD	Research Fellow, Drug Product Design & Supply, Pfizer Global R&D
1:45 PM – 2:00 PM	***Regulatory Experience of Using Totality of Evidence Including PBPK Modelling to Support Alternative BE Approaches***	
	Fang Wu, PhD	Senior Pharmacologist, DQMM, ORS, OGD, FDA
2:00 PM – 2:30 PM	***Q&A Session with Panel***	
Moderators:	**Sivacharan Kollipara, PhD**	Vice President & Head, Biopharmaceutics, Dr. Reddy's Laboratories
	Ahmed Zidan, PhD	Senior Research Pharmacologist, DPQR V, OPQR, OPQ, FDA
Panelists:	**Yasvanth Ashokraj, PhD**	Director, Biopharmaceutics & Pharmacokinetics, Cipla Ltd.
	Jack Cook, PhD	Senior Vice President, Clinical Pharmacology, A2-Ai, LLC
	Lanyan (Lucy) Fang, PhD	Division Director, DQMM, ORS, OGD, FDA
	Bing Li, PhD	Associate Director for Science, OB, OGD, FDA
	Kazuko Sagawa, PhD	Research Fellow, Drug Product Design and Supply, Pfizer Global R&D
	Fang Wu, PhD	Senior Pharmacologist, DQMM, ORS, OGD, FDA
	Lei Zhang, PhD, FAAPS	Deputy Director, ORS, OGD, FDA
	Qi Zhang, PhD	Lead Pharmacologist, DTP II, ORS, OGD, FDA
	Zhen Zhang, PhD	Master Pharmacologist, DB I, OB, OGD, FDA
2:30 PM – 2:40 PM	***Closing Remarks for Virtual Audience***	
	Lei Zhang, PhD, FAAPS	Deputy Director, ORS, OGD, FDA

Session 7: Small Group Working Sessions (In-Person Only)

Session Leads: Dr. Hailing Zhang, Dr. Ahmed Zidan

In this collaborative session, in-person participants from Industry, Academia, and the FDA will actively engage in structured discussions that delve into the unique challenges and opportunities within the same topic areas as the two sessions from the earlier part of the day. Guided by experienced moderators, workshop participants will explore the selected topics with a focus on achieving meaningful outcomes to help move generic product development and regulatory assessment forward.

Topic 4: When is Dissolution Truly Biopredictive?
Topic 5: Regulatory Acceptance of Alternative Approaches

2:40 PM –3:20 PM	Small Group Working Session addressing the topics above.
3:20 PM – 3:35 PM	***Coffee Break***
3:35 PM – 4:15 PM	Small Group Working Session addressing the topics above.

Day 2 Working Group Session Summaries

4:15 PM – 4:25 PM	***Topic 4: When is Dissolution Truly Biopredictive?***	
4:25 PM – 4:35 PM	***Topic 5: Regulatory Acceptance of Alternative Approaches***	
4:35 PM – 4:45 PM	***Closeout Workshop for In-Person Audience***	
	Lei Zhang, PhD, FAAPS	Deputy Director, ORS, OGD, FDA

Appendix of Abbreviations

ANDA	Abbreviated New Drug Application
BCS	Biopharmaceutics Classification System
BE	Bioequivalence
CDR	Commander
CPP	Critical Process Parameters
CRCG	Center for Research on Complex Generics
DB	Division of Bioequivalence
DPQA	Division of Product Quality Assessment
DPQR	Division of Pharmaceutical Quality Research
DTP	Division of Therapeutic Performance
DQMM	Division of Quantitative Methods and Modeling
EVP	Executive Vice President
FDA	Food and Drug Administration
Inc	Incorporated
IVIVC	In Vitro In Vivo Correlation
Ltd	Limited
MD	Doctor of Medicine
MPharm	Master of Pharmacy
M&S	Modeling and Simulation
OB	Office of Bioequivalence
OB	Office of Biostatistics
OGD	Office of Generic Drugs
OPQ	Office of Pharmaceutical Quality
OPQA	Office of Product Quality Assessment
OPQR	Office of Pharmaceutical Quality Research
ORISE	Oak Ridge Institute for Science and Education
ORS	Office of Research and Standards
OTS	Office of Translational Sciences
PBPK	Physiologically Based Pharmacokinetic
PhD	Doctor of Philosophy
PK	Pharmacokinetics
PSG	Product Specific Guidance
R&D	Research and Development
RLD	Reference Listed Drug
RS	Reference Standard
VP	Vice President