

Fiscal Year (FY) 2025 Generic Drug Science and Research Initiatives Public Workshop

June 3-4, 2025

In-Person & Virtual

Agenda (Day 1)

8:00 AM – 9:00 AM

Welcome

Sam Raney, PhD

Associate Director for Science & Chief Scientific Advisor, ORS, OGD, CDER, FDA

Opening Remarks

Susan Rosencrance, PhD

Deputy Super Office Director, OPQ, CDER, FDA

Ilun Murphy, MD

Super Office Director, OGD, CDER, FDA

Overview of the GDUFA Science and Research Program

Robert Lionberger, PhD

Director, ORS, OGD, CDER, FDA

9:00 AM – 9:15 AM

Break

Session 1:

Assessment Challenges with Complex Active Ingredients: Peptides & Oligonucleotides

9:15 AM – 09:20 AM

Introduction

Co-Moderator:

Cameron Smith, PhD

Supervisory Pharmaceutical Scientist, DPQA IV, OPQA I, OPQ, CDER, FDA

Co-Moderator:

Yan Wang, PhD

Deputy Division Director, DTP I, ORS, OGD, CDER, FDA

This session will include presentations on proposed research to improve the characterization of active ingredients, impurities, and immunogenicity for generic drugs with complex active ingredients, with a focus on peptide and oligonucleotide products. Throughout the session, a panel of representatives from the generic drug industry and the FDA will have the opportunity to interact with presenters to clarify and discuss the applications and utility of the proposed research.

09:20 AM – 09:35 AM

Immunogenicity Risk Assessment of Peptides: Progress and Remaining Challenges

Eric Pang, PhD

Senior Chemist, DTP I, ORS, OGD, CDER, FDA

09:35 AM – 09:50 AM

Generic Oligonucleotides – Challenges and Opportunities

Likan Liang, PhD

Supervisory Pharmaceutical Scientist, DPQA X, OPQA II, OPQ, CDER, FDA

09:50 AM – 10:10 AM

Challenges in Immunogenicity Risk Assessment for Complex Active Ingredients

MK Pananchukunnath, MCP

Chief Scientific Officer, Biocon Ltd.

10:10 AM – 10:30 AM

Research Initiatives for Harmonization of Immunogenicity Risk Assessments for Generic Peptides

Andrew Graves, MS, SCYM

Director, Immunogenicity Assessment, Teva Pharmaceutical Industries Ltd.

10:30 AM – 10:50 AM

Immunogenicity of Oligonucleotides

Sudhir Agrawal, DPhil

President, ARNAY Sciences; Affiliate Professor, University of Mass.

10:50 AM – 11:10 AM

Immunological Challenges Associated with Nucleic Acid-Based Therapeutics

Raman Bahal, PhD

Associate Professor, Univ. of Connecticut

11:10 AM – 11:25 AM

Break

11:25 AM – 12:00 PM

Panel Discussion

Co-Moderator:

Cameron Smith, PhD

Supervisory Pharmaceutical Scientist, DPQA IV, OPQA I, OPQ, CDER, FDA

Co-Moderator:

Yan Wang, PhD

Deputy Division Director, DTP I, ORS, OGD, CDER, FDA

Public Panelists:

Sudhir Agrawal, DPhil,

President, ARNAY Sciences; Affiliate Professor, Univ. of Massachusetts

Raman Bahal, PhD

Associate Professor, University of Connecticut

Andrew Graves, MS, SCYM

Director, Immunogenicity Assessment, Teva Pharmaceutical Industries Ltd.

MK Pananchukunnath, MCP

Chief Scientific Officer, Biocon Ltd.

<i>FDA Panelists:</i>	Jae Lee, PhD Mohanraj Manangeeswaran, PhD Paresma Patel, PhD Kui Yang, PhD	Staff Fellow, DQMM, ORS, OGD, CDER, FDA Senior Research Scientist, DPQR IV, OPQR, OPQ, CDER, FDA Division Director, DPQA XIX, OPQA III, OPQ, CDER, FDA Senior Research Scientist, DPQR II, OPQR, OPQ, CDER, FDA
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12:00 PM – 12:55 PM **Lunch Break**

Session 2: *Tackling Formulation Sameness and Advancing In Vitro Characterization for Bioequivalence of Complex Generic Products*

12:55 PM – 1:00 PM <i>Co-Moderator:</i> <i>Co-Moderator:</i>	Introduction Bryan Newman, PhD Ahmed Zidan, PhD	Lead Pharmacologist, DTP I, ORS, OGD, CDER, FDA Senior Research Pharmacologist, DPQR V, OPQR, OPQ, CDER, FDA
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This session will cover challenges and innovations in demonstrating bioequivalence for complex generics, focusing on formulation sameness and in vitro characterization. Topics include method standardization for inhaled and nasal products, biopredictive methods, and in silico modeling. Presentations will highlight microstructural techniques, mechanistic PBBM-PBPK models, and modeling of long-acting injectables. Emphasis will be placed on integrating novel tools into option-based approaches to support regulatory assessments of complex products such as orally inhaled drugs and DDCPs. Throughout the session, a panel of representatives from the generic drug industry and the FDA will discuss the applications and utility of the proposed research.

1:00 PM – 1:10 PM	Challenges with Method Standardization for Inhalation and Nasal Drug Products Susan Boc, PhD	Pharmacokineticist, DTP I, ORS, OGD, CDER, FDA
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1:10 PM – 1:20 PM	Biopredictive In Vitro Characterization to Correlate Quality Attributes to In Vivo Performance Hailing Zhang, PhD	Division Director, DPQA XII, OPQA II, OPQ, CDER, FDA
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1:20 PM – 1:30 PM	Advancing In Silico Methods & Understanding the Impact of Compositional Differences on Performance Ross Walenga, PhD	Senior Chemical Engineer, DQMM, ORS, OGD, CDER, FDA
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1:30 PM – 1:45 PM	Research Opportunities to Support Further PSG Development for Orally Inhaled Products Andrew Cooper, PhD	Sr. Director, Development for In-Vitro Performance Lead, Viatrix Inc.
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1:45 PM – 2:00 PM	Enhanced PBPK-Based IVIVE Method to Support the Development of Pulmonary Drug Products Maxime Le Merdy, PhD	Director, PBPK Research and Collaboration, Simulations Plus
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2:00 PM – 2:15 PM	Microstructural Techniques for Demonstrating Bioequivalence in Dry Powder Inhalers Nuria Manzano Jurado, BSc	Specialist, R&D Pharma Services, Nanopharm
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2:15 PM – 2:30 PM	Application of Mechanistic PBPK Modeling to Understand Drug Release from PLGA-Based Solid Implants Naresh Mittapelly, PhD	Research Scientist II, Certara UK Ltd, United Kingdom
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2:30 PM – 2:45 PM	The Utility of In Silico Modelling and Substitution Risk for Generic Orally Inhaled Drugs Clare Butler, BSc, PhD	Principal Product Development Scientist, Respiratory R&D, Teva Pharma
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2:45 PM – 3:15 PM <i>Co-Moderator:</i> <i>Co-Moderator:</i>	Panel Discussion Bryan Newman, PhD Ahmed Zidan, PhD	Lead Pharmacologist, DTP I, ORS, OGD, CDER, FDA Senior Research Pharmacologist, DPQR V, OPQR, OPQ, CDER, FDA
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<i>Public Panelists:</i>	Clare Butler, BSc, PhD Andrew Cooper, PhD Maxime Le Merdy, PhD Nuria Manzano Jurado, BSc Naresh Mittapelly, PhD	Principal Product Development Scientist, Respiratory R&D, Teva Pharma Senior Director, Development for In-Vitro Performance Lead, Viatrix Director, PBPK Research and Collaboration, Simulations Plus Specialist, Analytical Development, R&D, Nanopharm Research Scientist II, Certara UK Ltd, United Kingdom
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<i>FDA Panelists:</i>	Andrew Babiskin, PhD Elizabeth Bielski, MS, PhD Dhaval Gaglani, PhD Wenlei Jiang, PhD Xiaojian Jiang, PhD Xiaoming Xu, PhD	Lead Pharmacokineticist, DQMM, ORS, OGD, CDER, FDA Senior Pharmacologist, DTP I, ORS, OGD, CDER, FDA Supervisory chemist, DPQA V, OPQA I, OPQ, CDER, FDA Senior Adviser for Innovation and Strategic Outreach, ORS, OGD, CDER, FDA Deputy Division Director, DB II, OB, OGD, CDER, FDA Director, DPQR V, OPQR, OPQ, CDER, FDA
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3:15 PM – 3:30 PM **Break**

Session 3: *Future Horizons for Assessing the Bioequivalence of Complex Products: Challenges in the Next Five Years*

3:30 PM – 3:35 PM

Co-Moderator:
Co-Moderator:

Introduction

Bryan Newman, PhD
Ahmed Zidan, PhD

Lead Pharmacologist, DTP I, ORS, OGD, CDER, FDA
Senior Research Pharmacologist, DPQR V, OPQR, OPQ, CDER, FDA

This session will highlight the anticipated challenges and opportunities for the assessment of bioequivalence and quality for complex products over the next several years. Topics discussed will include the need for and design of in vivo studies, FDA perspectives on the current and future quality and bioequivalence challenges, the evolving regulatory and policy landscapes for complex products, the role of machine learning in device taxonomy, and considerations around irritation studies for TDS products. Throughout the session, a panel of representatives from the generic drug industry and the FDA will discuss the applications and utility of the proposed research.

3:35 PM – 3:45 PM

Establishing Equivalence of TDS and OIDs

Priyanka Ghosh, PhD

Lead Pharmacologist, DTP I, ORS, OGD, CDER, FDA

3:45 PM – 3:55 PM

FDA's Perspectives on Current Quality and Bioequivalence Challenges for Complex Products

Andre O'Reilly Beringhs, PhD
Renishkumar Delvadia, PhD

Staff Fellow, DTP I, ORS, OGD, CDER, FDA
Senior Staff Fellow, DPQA VIII, OPQA II, OPQ, CDER, FDA

3:55 PM – 4:10 PM

Challenges and Opportunities for Complex Generic Products

Brandon Wood, BSc

Sr. Director, RA I & Combination Products Liaison, Teva Pharma USA, Inc.

4:10 PM – 4:25 PM

Evolving Technologies Shaping New Research Needs for Future Pulmonary and Nasal Generics

Carla Vozone, PharmD, MBA

Vice President Specialty Drug Delivery, Catalent Pharma Solutions

4:25 PM – 4:40 PM

A Taxonomy for Categorizing User Interface Design in Medical Device Development: Human Factors Application, Development Opportunities, and Potential Integration of AI and Machine Learning

Megan Conrad, PhD
Mary Beth Privitera, MDes, PhD

Associate Professor of Mechanical Engineering, University of Detroit Mercy
Professor, Biomedical Engineering, University of Cincinnati

4:40 PM – 4:50 PM

Industry Insight: Clarity and Consistency for Complex Generics

Russell J. Rackley, PhD

Global Head, Clinical Pharmacology, Viatris

4:50 PM – 5:25 PM

Panel Discussion

Co-Moderator:
Co-Moderator:

Bryan Newman, PhD
Ahmed Zidan, PhD

Lead Pharmacologist, DTP I, ORS, OGD, CDER, FDA
Senior Research Pharmacologist, DPQR V, OPQR, OPQ, CDER, FDA

Public Panelists:

Megan Conrad, PhD
Mary Beth Privitera, MDes, PhD
Russell J. Rackley, PhD
Carla Vozone, PharmD, MBA
Brandon Wood, BSc

Associate Professor of Mechanical Engineering, University of Detroit, Mercy
Professor, Biomedical Engineering, University of Cincinnati
Global Head, Clinical Pharmacology, Viatris
Vice President Specialty Drug Delivery, Catalent Pharma Solutions
Sr. Director, RA I & Combination Products Liaison, Teva Pharma USA, Inc.

FDA Panelists:

Robert Berendt, PhD
Andrew Clerman, MD, PhD
Lanyan (Lucy) Fang, PhD
Bing Li, PhD
Kimberly Witzmann, MD
Rob Lionberger, PhD

Supervisory Chemist, DPQA V, OPQA I, OPQ, CDER, FDA
Acting Lead Physician, DTP I, ORS, OGD, FDA
Deputy Division Director, DQMM, ORS, OGD, CDER, FDA
Expert Pharmacologist, Associate Director for Science, OB, OGD, CDER, FDA
Deputy Director, OSCE, OGD, CDER, FDA
Director, ORS, OGD, CDER, FDA

5:25 PM – 5:30 PM

Closing Remarks for Day 1

Ahmed Zidan, PhD

Senior Research Pharmacologist, DPQR V, OPQR, OPQ, CDER, FDA

End of Day 1 at 5:30 PM

Fiscal Year (FY) 2025 Generic Drug Science and Research Initiatives Public Workshop

June 3-4, 2025

In-person & Virtual Agenda (Day 2)

Session 4: Implementation of the M13A Guidance: Lessons Learned and Advances for Immediate Release Products

9:00 AM – 9:05 AM

Co-Moderator:

Co-Moderator:

Introduction

Dongmei Lu, PhD

Associate Director, DTPII, ORS, OGD, CDER, FDA

Nilufer Tampal, PhD

Associate Director, OB, OGD, CDER, FDA

Following the recent publication and implementation of the FDA's M13A guidance, significant gaps persist concerning critical formulation and manufacturing attributes of high-risk products. This session aims to provide valuable insights into areas that could benefit from further discussion and research, facilitating the successful implementation of M13A for oral IR products. The faculty presentations will focus on technical and scientific aspects from both regulatory and research perspectives, which can be incorporated into systematic risk assessments of IR products. These additional considerations may enhance the comprehensive evaluation of bioequivalence for solid oral IR drug products.

9:05 AM – 9:25 AM

Amorphous Solid Dispersion (ASD) Products and Potential Alternative BE Approaches

Girish Nihalani, MS

Associate Director, Product Development at Hikma Pharmaceuticals USA Inc.

9:25 AM – 9:45 AM

Dissolution of Amorphous Solid Dispersions and Absorption of Poorly Soluble Drugs

Geoff G. Z. Zhang, PhD, FAAPS

Founder, Chief Technical Director, ProPhysPharm LLC

9:45 AM – 10:05 AM

Modeling & Simulation Tools as Alt. BE Approaches for BCS IV & High-Risk Prods: Generic Industry Perspective

Sivacharan Kollipara, MS

Head, Biopharmaceutics, Dr. Reddy's Laboratories Ltd., India

10:05 AM-10:25 AM

Advancing IVIVC in Lipid-Based Formulations: Addressing In Vitro Dissolution Challenges for BA Correlations

Sandip Tiwari PhD

Head of Technical Services, Pharma Solutions, NA, BASF Corporation

10:25 AM-10:45 AM

Enhancing Patient BE Studies Using Model-Integrated Evidence (MIE)

Yuqing Gong, PhD

Senior Pharmacologist, DQMM, ORS, OGD, CDER, FDA

10:45 AM – 11:00AM

Break

11:00 AM – 11:40 AM

Panel Discussion

Co-Moderator:

Co-Moderator:

Dongmei Lu, PhD

Associate Director, DTP II, CDER, FDA

Nilufer Tampal, PhD

Associate Director, OB, OGD, CDER, FDA

Public Panelists:

Emilija Fredro-Kumbaradzi, PhD

Director, Biopharmaceutics and Statistics, Global R&D, Apotex Inc.

Sivacharan Kollipara, MS

Head, Biopharmaceutics, Dr. Reddy's Laboratories Ltd.

Girish Nihalani, MS

Associate Director, Product Development at Hikma Pharmaceuticals USA Inc.

Russell J. Rackley, PhD

Global Head, Clinical Pharmacology, Viatris Inc.

Sandip Tiwari, PhD

Head of Technical Services, Pharma Solutions, NA, BASF Corporation

Geoff G. Z. Zhang, PhD, FAAPS

Founder, Chief Technical Director, ProPhysPharm LLC

FDA Panelists:

Hazem Ali, PhD

Senior Chemist, DPQA II, OPQA I, OPQ, CDER, FDA

Bhagwant Rege, PhD

Division Director, DPQA VI, OPQA I, OPQ, CDER, FDA

Diana Vivian, PhD

Associate Division Director, DBII, OB, OGD, CDER, FDA

Fang Wu, PhD

Senior Pharmacologist, DQMM, ORS, OGD, CDER, FDA

Lei K. Zhang, PhD

Deputy Director, ORS, OGD, CDER, FDA

Qi Zhang, PhD

Lead Pharmacologist, DTP II, ORS, OGD, CDER, FDA

11:40 AM – 1:00 PM

Lunch Break

Session 5: Challenges and Opportunities for Modified Release Generic Products

1:00 PM – 1:05 PM

Co-Moderator:

Co-Moderator:

Introduction

Dongmei Lu, PhD

Nilufer Tampal, PhD

Associate Director, DTPII, CDER, FDA

Associate Director, OB, OGD, CDER, FDA

This session will discuss issues identified from the ongoing effort to establish globally consistent standards for evaluating generic MR products, different considerations in bioequivalence perspectives, potential approaches to resolve the identified issues, and further directions of the future research to achieve the global and consistent standards for MR drug products.

1:05 PM – 1:25 PM

Considerations for Additional Strength Waivers of MR Products

James E. Polli, PhD

Co-Director, CRCG and Prof., University of Maryland

1:25 PM – 1:45 PM

Unlocking Strength Scaling for Extended-Release Tablet Development: Research Gaps and Opportunities

Jie Shen, PhD

Associate Professor of Pharmaceutical Sciences, Northeastern University

1:45 PM – 2:05 PM

Advancing Generic MR Product Development Using Tiny-TIMsg to Predict In Vivo Performance

Lieke van den Elsen, PhD

Scientific Advisor, InnoGI Technologies

2:05 PM-2:25 PM

Criteria to Decide Whether pAUCs Are Appropriate BE Metrics and Alternatives When They Are Not

Charles E. DiLiberti, MS

President, Montclair Bioequivalence Services, LLC

2:25 PM-2:45 PM

Opportunities and Challenges with IR/MR Dosage Forms in Lipid-Based Formulations

Karunakar (Karu) Sukuru, RPh, PhD

Global VP, Pharma Product Development, Catalent Pharma Solutions

2:45 PM- 3:05 PM

Quality Control of 3D Printed Controlled Release Dosage Forms in Distributed Manufacturing Networks

Stephen Hoag, PhD

Professor, University of Maryland at Baltimore

3:05 PM – 3:20 PM

Break

3:20 PM – 4:00 PM

Co-Moderator:

Co-Moderator:

Panel Discussion

Dongmei Lu, PhD

Nilufer Tampal, PhD

Associate Director, DTPII, CDER, FDA

Associate Director, OB, OGD, CDER, FDA

Public Panelists:

Charles E. DiLiberti, MS

Lieke van den Elsen, PhD

Stephen Hoag, PhD

James E. Polli, PhD

Jie Shen, PhD

Karunakar Sukuru, RPh, PhD

President, Montclair Bioequivalence Services, LLC

Scientific Advisor, InnoGI Technologies

Professor, University of Maryland at Baltimore

Professor, University of Maryland

Associate Professor of Pharmaceutical Sciences, Northeastern University

Global VP, Pharma Product Development, Catalent Pharma Solutions

FDA Panelists:

Manar Al-Ghabeish, PhD

Yuqing Gong, PhD

Likan Liang, PhD

Hailing Zhang, PhD

Zhen Zhang, PhD

Ahmed Zidan, PhD

Senior Pharmacologist, DTP II, ORS, OGD, CDER, FDA

Senior Pharmacologist, DQMM, ORS, OGD, CDER, FDA

Supervisory Pharmaceutical Scientist, DPQAX, OPQA II, OPQ, CDER, FDA

Division Director, DPQA XII, OPQA II, OPQ, CDER, FDA

Master Pharmacologist, DB I, OB, OGD, CDER, FDA

Senior Research Pharmacologist, DPQRV, OPQR, OPQ, CDER, FDA

Closing Session

4:00 PM – 4:15 PM

Challenges and Opportunities Related to the Development of Generic Drugs

Anna Schwendeman, PhD

Co-Director, CRCG and Prof., Univ. of Michigan

4:15 PM – 4:30 PM

Closing Remarks

Robert Lionberger, PhD

Director, ORS, OGD, CDER, FDA

End of Day 2 at 4:30 PM

Appendix of Abbreviations

AI	Artificial Intelligence
Alt.	Alternative
ASD	Amorphous Solid Dispersion
BCS	Biopharmaceutics classification system
BA	Bioavailability
BE	Bioequivalence
BS/BSc	Bachelor of Science
CDER	Center for Drug Evaluation and Research
CRCG	Center for Research on Complex Generics
Dev	Development/Developing
DDCP	Drug-Device Combination Product
DPhil	Doctor of Philosophy
DQMM	Division of Quantitative Methods and Modeling
DPQA II	Division of Product Quality Assessment II
DPQA V	Division of Product Quality Assessment V
DPQA VI	Division of Product Quality Assessment VI
DPQA VIII	Division of Product Quality Assessment VIII
DPQA X	Division of Product Quality Assessment X
DPQA XII	Division of Product Quality Assessment XII
DPQA XIX	Division of Product Quality Assessment XIX
DPQR V	Division of Product Quality Research V
DTP I	Division of Therapeutic Performance I
DTP II	Division of Therapeutic Performance II
DQMM	Division of Quantitative Methods and Modeling
FAAPS	Fellow of the American Association of Pharmaceutical Scientists
FDA	United States Food and Drug Administration
Inc.	Incorporated
IR	Immediate Release
IVIVC	In Vitro-In Vivo Correlation
IVIVE	In Vitro to In Vivo Extrapolation
Ltd.	Limited
LLC	Limited Liability Company
MBA	Master of Business Administration
MCP	Master of Clinical Pharmacy (MClinPharm)
MD	Doctor of Medicine
MDes	Master of Design
MP	Master of Pharmacy (MPharm)
MPH	Master of Public Health
MR	Modified Release
MS/MSc	Master of Science
NA	North America
OB	Office of Bioequivalence
OCP	Office of Clinical Pharmacology
OGD	Office of Generic Drugs
OIDP	Orally Inhaled Drug Product
OPP	Opportunity/Opportunities
OPQ	Office of Pharmaceutical Quality
OPQA I	Office of Product Quality Assessment I
OPQA II	Office of Product Quality Assessment II
OPQR	Office of Pharmaceutical Quality Research
ORS	Office of Research and Standards
pAUC	Partial Area-Under-Curve
PBBM	Physiologically Based Biopharmaceutics Modeling
PBPK	Physiologically Based Pharmacokinetics
Pharma	Pharmaceuticals
PhD	Doctor of Philosophy
PI	Principal Investigator
PLGA	Poly(Lactic-co-Glycolic) Acid Copolymer
Prods	Products
Prof.	Professor
PSG	Product-Specific Guidance
RA	Regulatory Affairs
R&D	Research and Development
RPh	Registered Pharmacist
SCYM	Specialist in Cytometry
Sr.	Senior
TDS	Transdermal Delivery Systems
UK	United Kingdom
Univ.	University
USA	United States of America
VP	Vice President