

Fiscal Year (FY) 2026 Generic Drug Science and Research Initiatives Public Workshop

June 8, 2026

In-Person & Virtual Agenda (Day 1)

8:00 AM – 9:00 AM

Welcome

Sam Raney, PhD
Ahmed Zidan, PhD

Associate Director for Science & Chief Scientific Advisor, ORS/OGD/CDER/FDA
Sr. Research Pharmacologist, DPQR V/OPQR/OPQ/CDER/FDA

Opening Remarks

Alyson Bancroft, MPH
Darby Kozak, PhD
Sau (Larry) Lee, PhD

Director of Legislation, Policy & Alliances, Patients for Affordable Drugs
Deputy Director, OGD/CDER/FDA
Deputy Director of Pharmaceutical Quality, OPQ/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:

Ongoing Challenges with Nitrosamines Impurities

9:15 AM – 9:20 AM

Introduction

Co-Moderator:
Co-Moderator:

Dongmei Lu, PhD
Huzeyfe Yilmaz, PhD

Associate Director, DTP II/ORS/OGD/CDER/FDA
Supervisory Pharmaceutical Scientist (Act.), DPQR I/OPQR/OPQ/CDER

This session will include presentations and discussions related to the ongoing challenges with mitigating the formation of nitrosamine impurities, and related to identifying research that is needed to support a scientific understanding of the carcinogenicity risks associated with greater exposure to nitrosamine impurities.

9:20 AM – 9:30 AM

Nitrosamines in Drugs: A Regulatory Perspective on Research Progress and Opportunities

Robert Dorsam, PhD

Division Director, DPTR/OSCE/OGD/CDER/FDA

9:30 AM – 9:40 AM

Using In Vivo Transgenic Rodent (TGR) Data to Evaluate Mutagenic Potency

Robert Jolly, CPH, MPH, DABT

Sr. Advisor, Risk Assessment, Toxicology, Lilly Research Labs

9:40 AM – 9:50 AM

Overview of HESI Program and Research Initiatives

Joel Bercu, PhD, MPH, DABT

Executive Director, Gilead Sciences

9:50 AM – 10:00 AM

Deriving Scientifically Sound Acceptable Intake Limits for N-Nitroso-Bisoprolol by using Error-Corrected Sequencing (ECS) and Benchmark Dose (BMD) Analysis of In Vivo Mutagenicity Data – from Hazard Identification towards Human Risk Assessment

Stephanie Simon, PhD, ERT

Sr. Toxicologist, Associate Scientific Director, Merck (EMD Serono)

10:00 AM – 10:15 AM

Break

10:15 AM – 10:25 AM

Nitrosamine Mitigation Strategies: Insights from the FDA and Emerging Challenges

Diaa Shakleya, PhD

Sr. Research Scientist, DPQR V/OPQR/OPQ/CDER/FDA

10:25 AM – 10:35 AM

Antioxidants in Nitrosamine Risk Mitigation: Challenges and Considerations

Valerie Niddam-Hildesheim, PhD

Sr. Director, Global Nitrosamine Project Lead, Teva Pharmaceuticals

10:35 AM – 10:45 AM

Cracking the NDSRI Code: Mitigation in Generic Drugs, a Mission impossible?

Filip Geert A De Bock, PhD

Global Center of Excellence for Mutagenic Impurities Lead, Sandoz

10:45 AM – 10:55 AM

Analytical Methods for NDSRIs: Challenges & Troubleshooting

Houri Simonian, PhD

Sr. Director, Analytical Research and Development, Apotex

10:55 AM – 11:05 AM

Nitrosamine Risk of Recovered Solvents & NOx as Nitrosating Agent

Joerg Schlingemann, MB, PhD

Director, Global Quality Control Principal Expert, Merck (EMD Serono)

11:05 AM – 11:15 AM

The Role of Excipients in Nitrosamine Risk Mitigation: Nitrite Control and Scavengers

Ulrich Reichert, PhD, MDRA

Head of CDMO & Bioprocess Materials, Reg. Mgmt., Merck (MiliporeSigma)

11:15 AM – 12:00 PM

Public Comment Presentations

12:00 PM – 1:15 PM

Lunch Break

1:15 PM – 2:15 PM

Panel Discussion

Co-Moderator:
Co-Moderator:

Dongmei Lu, PhD
Huzeyfe Yilmaz, PhD

Associate Director, DTP II/ORS/OGD/CDER/FDA
Supervisory Pharmaceutical Scientist (Act.), DPQR I/OPQR/OPQ/CDER

Public Panelists:

Joel Bercu, PhD, MPH, DABT
Filip Geert A De Bock, PhD
Robert Jolly, CPH, MPH, DABT
Lance Molnar, PhD
Valerie Niddam-Hildesheim, PhD
Ulrich Reichert, PhD, MDRA
Joerg Schlingemann, MB, PhD
Stephanie Simon, PhD, ERT
Hourri Simonian, PhD

Executive Director, Gilead Sciences
Global Center of Excellence for Mutagenic Impurities Lead, Sandoz
Sr. Advisor, Risk Assessment, Toxicology, Lilly Research Labs
Head of Nonclinical Ops. and Risk Assessment, Global Pharm/Tox, Viatriis
Sr. Director, Global Nitrosamine Project Lead, Teva Pharmaceuticals
Head of CDMO & Bioprocess Materials, Reg. Mgmt., Merck (MiliporeSigma)
Director, Global Quality Control Principal Expert, Merck (EMD Serono)
Sr. Toxicologist, Associate Scientific Director, Merck (EMD Serono)
Sr. Director, Analytical Research and Development, Apotex

FDA Panelists:

Kelly Brant, PhD
Ee-Sunn (Joanne) Chia, PhD
Robert Dorsam, PhD
Diaa Shakleya, PhD

Master Toxicologist, DPTID/OID/OND/CDER/FDA
Division Director, DPQA X/OPQA II/OPQ/CDER/FDA
Division Director, DPTR/OSCE/OGD/CDER/FDA
Sr. Research Scientist, DPQR V/OPQR/OPQ/CDER/FDA

2:15 PM – 2:30 PM

Break

Session 2:

Using AI to Address Practical Challenges for Generic Drugs

2:30 PM – 2:35 PM

Introduction

Co-Moderator:
Co-Moderator:

Meng Hu, PhD
Qing Liu, PhD

Lead Chemical Engineer, DQMM/ORS/OGD/CDER/FDA
Deputy Director, DB I/OB/OGD/CDER/FDA

This session will gather insights on practical AI applications that can enhance generic drug development workflows, alongside industry perspectives on specific data integrity and standardization challenges that AI could effectively address. The session will also explore how AI can be strategically applied to improve the reliability and efficiency of the Inactive Ingredient Database (IID) and Maximum Daily Dose (MDD) datasets, particularly by addressing labor-intensive data quality challenges and reducing both the volume and review time of controlled correspondences related to IID levels and similar issues.

2:35 PM – 2:45 PM

AI and FDA's Inactive Ingredient Database

CDR Diana Solana-Sodeinde, PharmD Lead Program Coordinator, OB-IO/OGD/CDER/FDA

2:45 PM – 2:55 PM

Development of an AI Automation Tool to Facilitate Maximum Daily Dose Determination

Jing (Jenny) Wang, PhD Staff Fellow, DQMM/ORS/OGD/CDER/FDA

2:55 PM – 3:05 PM

Artificial Intelligence: Key to Address Practical Challenges for Generic Drugs

Arti Patel, MS Sr. Manager, Cosette Pharma

3:05 PM – 3:15 PM

AI/ML and Data Enablement in Generic Drug Manufacturing

Jeremy Evans, PhD Director, AI/ML Innovation in Pharmaceutical Manufacturing, USP

3:15 PM – 3:25 PM

GenAI Opportunity to Derisk and Accelerate Generic Product Development

Tushar Nitave, MS Staff Software Engineer, Vivpro Corp.

3:25 PM – 3:35 PM

AI-Assisted Generic Formulation and Nitrosamine Risk: Algorithmic Workflows

Sandip Tiwari, PhD Head of Technical Services, BASF

3:35 PM – 3:45 PM

Using AI to Address Practical Challenges for Generic Drugs: Using Digital Twins to Serve as RLD

Brooke Langevin, PhD Assistant Professor, University of Maryland, Baltimore

3:45 PM – 3:55 PM

AI/ML Regulatory Perspectives: Challenges and Considerations

Geng Tian, PhD Supervisory Research Officer, DPQR VI/OPQR/OPQ/CDER/FDA

3:55 PM – 4:05 PM

Advancing Pharmaceutical Quality System Assessment to Support ICH Q12 Implementation: Leveraging Evidence-Based AI Tools

Torrey Ward, PhD Consumer Safety Officer, DQI-II/OQS/OPQ/CDER/FDA

4:05 PM – 4:45 PM

Panel Discussion

Co-Moderator:

Meng Hu, PhD

Lead Chemical Engineer, DQMM/ORS/OGD/CDER/FDA

Co-Moderator:

Qing Liu, PhD

Deputy Director, DB I/OB/OGD/CDER/FDA

Public Panelists:

Jeremy Evans, PhD
Joga Gobburu, PhD
Brooke Langevin, PhD
Tushar Nitave, MS
Arti Patel, MS
Sandip Tiwari, PhD

Director, AI/ML Innovation in Pharmaceutical Manufacturing, USP
Professor, University of Maryland, Baltimore
Assistant Professor, University of Maryland, Baltimore
Staff Software Engineer, Vivpro Corp.
Sr. Manager, Cosette Pharma
Head of Technical Services, BASF

FDA Panelists:

Sharmista Chatterjee
Mihir Jaiswal, PhD
Robert Lionberger, PhD
CDR Diana Solana-Sodeinde, PharmD
Geng Tian, PhD
Jing (Jenny) Wang, PhD
Zhen Zhang, PhD
Torrey Ward, PhD

Division Director, DPMIII/OPMA/OPQ/CDER
Tech Liaison, PMS/OQA/OPQ/CDER/FDA
Director, ORS/OGD/CDER/FDA
Lead Program Coordinator, OB-IO/OGD/CDER/FDA
Supervisory Research Officer, DPQR VI/OPQR/OPQ/CDER/FDA
Staff Fellow, DQMM/ORS/OGD/CDER/FDA
Master Pharmacologist, DB I/OB/OGD/CDER/FDA
Consumer Safety Officer, DQI-II/OQS/OPQ/CDER/FDA

4:45 PM – 5:00 PM

Closing Remarks for Day 1

Robert Lionberger, PhD

Director, ORS/OGD/CDER/FDA

End of Day 1 at 5:00 PM

Fiscal Year (FY) 2026 Generic Drug Science and Research Initiatives Public Workshop

June 9, 2026

In-person & Virtual Agenda (Day 2)

9:00 AM – 9:05 AM

Welcome and Introduction to Day 2

Sam Raney, PhD
Ahmed Zidan, PhD

Associate Director for Science & Chief Scientific Advisor, ORS/OGD/CDER/FDA
Sr. Research Pharmacologist, DPQR V/OPQR/OPQ/CDER/FDA

Session 3:

Expanding Regulatory Flexibility with Bioequivalence Standards

9:05 AM – 9:15 AM

Introduction

Co-Moderator:
Co-Moderator:

Andrew Babiskin, PhD
Yan Wang, PhD

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

This session will explore research opportunities to enable more flexible, science-based bioequivalence (BE) approaches. Discussion will focus on moving beyond current criteria (e.g., Q1/Q2 sameness) toward mechanistic understanding, expanding biowaiver space and BCS classification, strengthening in vitro–in vivo linkage through robust in vitro characterization of formulation and manufacturing effects, leveraging predictive tools such as PBPK modeling, and identifying opportunities to support global harmonization of BE standards.

9:15 AM – 9:35 AM

Recent Developments and Experiences with Utilization of Non-Standard In-Vitro Characterization Tools to Demonstrate Bioequivalence between Reference and Test Drug Device Combination Products

Abhishek (Abhi) Gupta, PhD

Chief Scientific Officer, Transpire Bio

9:35 AM – 10:35 AM

Panel Discussion

Co-Moderator:
Co-Moderator:

Andrew Babiskin, PhD
Yan Wang, PhD

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

Public Panelists:

Tausif Ahmed, PhD
Allison Dunn, PharmD, MS
Abhishek (Abhi) Gupta, PhD, PMP
John Kirsch, PhD, RPh
Brandon Wood, BSc

Sr. VP & Head, Clinical Research & Biopharmaceutics, Mankind Pharma Ltd
Research Assistant Professor, University of Maryland SOP/CTM
Chief Scientific Officer, Transpire Bio
Head of Product Development, Viatrix
Sr. Director, Teva Pharmaceuticals

FDA Panelists:

Priyanka Ghosh, PhD
Myong-Jin Kim, PharmD
Bing Li, PhD
Pahala Simamora, PhD
Lei Zhang, PhD

Lead Pharmacologist, DTP I/ORS/OGD/CDER/FDA
Division Director, DTP II/ORS/OGD/CDER/FDA
Associate Director, OB/OGD/CDER/FDA
Division Director, DPQA IX/OPQA II/OPQ/CDER/FDA
Deputy Office Director, ORS/OGD/CDER/FDA

10:35 AM – 10:45 AM

Break

Session 4:

Facilitating Generic Drug Approvals by Improving Development and Regulatory Predictability

10:45 AM – 11:00 AM

Introduction

Co-Moderator:
Co-Moderator:

Markham Luke, MD, PhD
William Smith, PhD

Director, DTP I/ORS/OGD/CDER/FDA
Research Scientist, DPQR V/OPQR/OPQ/CDER/FDA

This session will focus on identifying scientific and technical challenges that contribute to multi-cycle reviews for certain complex generic drug products, with particular attention to dosage forms and analytical domains where multiple review cycles may occur. Discussions will center on identifying targeted research, enhanced quality management systems, methodological standardization, or new validation approaches that could reduce uncertainties related to product characterization or regulatory assessment. Panelists will also consider enhancements to current tools or approaches to address these challenges, and what additional scientific research should be prioritized.

11:00 AM – 11:10 AM	Characterizing the Complex: Validating Non-Compendial Methods, Comparing Q3, and Setting Acceptance Criteria for Complex Generic Drug Products	Brock Roughton, PhD	Division Director, DPQA XI/OPQAI/OPQ/CDER/FDA
11:10 AM – 11:20 AM	QMM as a Framework for Driving Operational Performance and Business Excellence	Eric Twum, PhD	Regulatory Specialist, DQI-II/OQS/OPQ/CDER/FDA
11:20 AM – 12:15 PM	Panel Discussion	Markham Luke, MD, PhD	Director, DTP I, ORS/OGD/CDER/FDA
<i>Co-Moderator:</i>		William Smith, PhD	Research Scientist, DPQR V/OPQR/OPQ/CDER/FDA
<i>Co-Moderator:</i>			
<i>Public Panelists:</i>		Clare Butler, PhD	Principal Product Development Scientist, Teva Global Inhalations
		Praveen Chappa, PhD	Group Head, Analytical Development, Sandoz
		Andrew Cooper, PhD	Sr. Director, Viatris / Mylan Pharma UK
		Niraj Mehta, PhD	Sr. VP of Global Quality Compliancy and Sustainability, Lupin
		Giuseppe Randazzo, MS	VP of Science and Regulatory Affairs, Association for Accessible Medicines
<i>FDA Panelists:</i>		Bob Berendt, PhD	Supervisory Pharmaceutical Scientist, DPQA V/OPQA I/OPQ/CDER/FDA
		Utpal Munshi, PhD	Division Director, DB I/OB/OGD/CDER/FDA
		Brock Roughton, PhD	Division Director, DPQA XI/OPQAI/OPQ/CDER/FDA
		Cameron Smith, PhD	Supervisory Pharmaceutical Scientist, DPQA IV/OPQA I/OPQ/CDER/FDA
		Eric Twum, PhD	Regulatory Specialist, DQI-II/OQS/OPQ/CDER/FDA

12:15 PM – 1:00 PM

Lunch Break

Session 5: Leveraging Generic Drug Industry Expertise & Insights for GDUFA Research & PSG Prioritization

1:00 PM – 1:05 PM

Moderator:

Introduction

Giuseppe Randazzo, MS

VP of Science and Regulatory Affairs, Association for Accessible Medicines

This session will explore new opportunities and approaches for industry experts to become more directly involved in the GDUFA research program, facilitating more hands-on participation with selecting research projects and potentially collaborating on the conduct of research activities. This session is also intended to facilitate industry feedback on what PSGs should be prioritized for development, and what type of details are helpful to include in PSGs (e.g., to clarify expectations about recommended tests & studies, as well as acceptable procedures for conducting them).

1:05 PM – 1:45 PM

Public Comment Presentations

1:45 PM – 2:45 PM

Moderator:

Panel Discussion

Giuseppe Randazzo, MS

VP of Science and Regulatory Affairs, Association for Accessible Medicines

Public Panelists:

Tausif Ahmed, PhD

Dennis Hall, BS, MA Ed, MBA

Uwe Niesner, PhD

Arti Patel, MS

James Polli, PhD

Anuj Kumar Saini, PhD

Brandon Wood, BSc

Sr. VP & Head, Clinical Research & Biopharmaceutics, Mankind Pharma Ltd

VP of Advanced Manufacturing & Technologies, U. S. Pharmacopeia (USP)

Head of Respiratory, Dermatology, Biologics & Regulatory Strategy, Viatris

Sr. Manager, Regulatory Affairs, Cosette Pharmaceuticals

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

Global Head of Clinical Management, Dr. Reddy's Laboratories

Sr. Director, Regulatory Affairs, Complex GRx, Teva Pharma USA, Inc

FDA Panelists:

Victoria Keck, VMD

Robert Lionberger, PhD

Sam Raney, PhD

Xiaoming Xu, PhD

Ahmed Zidan, PhD

Assoc. Director, GRx Stakeholder & Global Engagement (Act.), OGD/CDER/FDA

Director, ORS/OGD/CDER/FDA

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

Director, DPQR V/OPQR/OPQ/CDER/FDA

Sr. Research Pharmacologist, DPQR V/OPQR/OPQ/CDER/FDA

2:45 PM – 3:00 PM

Closing Remarks

Robert Lionberger, PhD

Director, ORS/OGD/CDER/FDA

End of Day 2 at 3:00 PM

Appendix of Abbreviations

Act.	Acting
Assoc.	Associate
AI	Artificial Intelligence
ANDA	Abbreviated New Drug Application
BCS	Biopharmaceutics classification system
BE	Bioequivalence
BMD	Benchmark Dose
BS/BSc	Bachelor of Science
CDER	Center for Drug Evaluation and Research
CDMO	Contract Development & Manufacturing Organization
CDR	Commander
CPH	Certified in Public Health
CRCG	Center for Research on Complex Generics
CTM	Center for Translational Medicine
DABT	Diplomate of the American Board of Toxicology
DB	Division of Bioequivalence
DQI	Division of Quality Intelligence
DPQA	Division of Product Quality Assessment
DPQR	Division of Product Quality Research
DPTID	Division of Pharmacology Toxicology for Infectious Diseases
DPTR	Division of Pharmacology Toxicology Review
DTP	Division of Therapeutic Performance
DQMM	Division of Quantitative Methods and Modeling
ECS	Error-Corrected Sequencing
ERT	Eurotox Registered Toxicologist
FDA	United States Food and Drug Administration
GenAI	Generative Artificial Intelligence
GDUFA	Generic Drug User Fee Amendments
GRx	Generic Drugs
HESI	Health and Environmental Sciences Institute
IID	Inactive Ingredient Database
Inc.	Incorporated
Ltd	Limited
MA Ed	Master of Education
MBA	Master of Business Administration
MB	Master of Biochemistry & Molecular Biology (Diplom-Biologe)
Mgmt.	Management
MD	Doctor of Medicine
MDD	Maximum Daily Dose
MDRA	Master of Drug Regulatory Affairs
ML	Machine Learning
MPH	Master of Public Health
MS	Master of Science
NDSRI	Nitrosamine Drug Substance Related Impurity
NOx	Nitrogen Oxides
OB	Office of Bioequivalence
IO	Immediate Office
OGD	Office of Generic Drugs
OID	Office of Infectious Diseases
OND	Office of New Drugs
OPQ	Office of Pharmaceutical Quality
OPQA	Office of Product Quality Assessment
OPQR	Office of Pharmaceutical Quality Research
Ops.	Operations
OQA	Office of Quality Assurance
OQS	Office of Quality Surveillance
ORS	Office of Research and Standards
OSCE	Office of Safety & Clinical Evaluation
PBPK	Physiologically Based Pharmacokinetics
PharmD	Doctor of Pharmacy
Pharm/Tox	Pharmacology and Toxicology
PhD	Doctor of Philosophy
PMP	Project Management Professional
PMS	Project Management Staff
pre-ANDA	Pre-Abbreviated New Drug Application
Prof.	Professor
PSG	Product-Specific Guidance
Reg.	Regulatory
RLD	Reference Listed Drug
RPh	Registered Pharmacist
SOP	School of Pharmacy
Sr.	Senior
TGR	Transgenic Rodent
UK	United Kingdom
USA	United States of America
USP	United States Pharmacopeia
VMD	Doctor of Veterinary Medicine
VP	Vice President