

# 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 II/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

### *Overview of HESI Program and Research Initiatives*

Joel Bercu, PhD, MPH, DABT

Executive Director, Gilead Sciences

9:40 AM – 9:50 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

9:50 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 – 11:30 AM

### *Public Comment Presentations*

11:30 AM – 12:30 PM	<b>Panel Discussion</b>	
<i>Co-Moderator:</i>	Dongmei Lu, PhD	Associate Director, DTP II/ORS/OGD/CDER/FDA
<i>Co-Moderator:</i>	Huzeyfe Yilmaz, PhD	Supervisory Pharmaceutical Scientist (Act.), DPQR I/OPQR/OPQ/CDER
<i>Public Panelists:</i>	Joel Bercu, PhD, MPH, DABT	Executive Director, Gilead Sciences
	Filip Geert A De Bock, PhD	Global Center of Excellence for Mutagenic Impurities Lead, Sandoz
	Robert Jolly, CPH, MPH, DABT	Sr. Advisor, Risk Assessment, Toxicology, Lilly Research Labs
	Lance Molnar, PhD	Head of Nonclinical Ops. and Risk Assessment, Global Pharm/Tox, Viatris
	Valerie Niddam-Hildesheim, PhD	Sr. Director, Global Nitrosamine Project Lead, Teva Pharmaceuticals
	Ulrich Reichert, PhD, MDRA	Head of CDMO & Bioprocess Materials, Reg. Mgmt., Merck (MiliporeSigma)
	Joerg Schlingemann, MB, PhD	Director, Global Quality Control Principal Expert, Merck (EMD Serono)
	Stephanie Simon, PhD, ERT	Sr. Toxicologist, Associate Scientific Director, Merck (EMD Serono)
	Houri Simonian, PhD	Sr. Director, Analytical Research and Development, Apotex
<i>FDA Panelists:</i>	Kelly Brant, PhD	Master Toxicologist, DPTID/OID/OND/CDER/FDA
	Ee-Sunn (Joanne) Chia, PhD	Division Director, DPQA X/OPQA II/OPQ/CDER/FDA
	Robert Dorsam, PhD	Division Director, DPTR/OSCE/OGD/CDER/FDA
	Diaa Shakleya, PhD	Sr. Research Scientist, DPQR V/OPQR/OPQ/CDER/FDA
12:30 PM – 1:30 PM	<b>Lunch Break</b>	

## Session 2: *Using AI to Address Practical Challenges for Generic Drugs*

1:30 PM – 1:35 PM	<b>Introduction</b>	
<i>Co-Moderator:</i>	Meng Hu, PhD	Lead Chemical Engineer, DQMM/ORS/OGD/CDER/FDA
<i>Co-Moderator:</i>	Qing Liu, PhD	Deputy Director, DB I/OB/OGD/CDER/FDA
	<p>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.</p>	
1:35 PM – 1:45 PM	<b>AI and FDA's Inactive Ingredient Database</b>	
	CDR Diana Solana-Sodeinde, PharmD	Lead Program Coordinator, OB-IO/OGD/CDER/FDA
1:45 PM – 1:55 PM	<b>Development of an AI Automation Tool to Facilitate Maximum Daily Dose Determination</b>	
	Jing (Jenny) Wang, PhD	Staff Fellow, DQMM/ORS/OGD/CDER/FDA
1:55 PM – 2:05 PM	<b>Artificial Intelligence: Key to Address Practical Challenges for Generic Drugs</b>	
	Arti Patel, MS	Sr. Manager, Cosette Pharma
2:05 PM – 2:15 PM	<b>AI/ML and Data Enablement in Generic Drug Manufacturing</b>	
	Jeremy Evans, PhD	Director, AI/ML Innovation in Pharmaceutical Manufacturing, USP
2:15 PM – 2:25 PM	<b>GenAI Opportunity to Derisk and Accelerate Generic Product Development</b>	
	Tushar Nitave, MS	Staff Software Engineer, Vivpro Corp.
2:25 PM – 2:35 PM	<b>AI-Assisted Generic Formulation and Nitrosamine Risk: Algorithmic Workflows</b>	
	Sandip Tiwari, PhD	Head of Technical Services, BASF
3:35 PM – 3:45 PM	<b>Using AI to Address Practical Challenges for Generic Drugs: Using Digital Twins to Serve as RLD</b>	
	Brooke Langevin, PhD	Assistant Professor, University of Maryland, Baltimore
2:45 PM – 2:55 PM	<b>AI/ML Regulatory Perspectives: Challenges and Considerations</b>	
	Geng Tian, PhD	Supervisory Research Officer, DPQR VI/OPQR/OPQ/CDER/FDA
2:55 PM – 3:05 PM	<b>Advancing Pharmaceutical Quality System Assessment to Support ICH Q12 Implementation: Leveraging Evidence-Based AI Tools</b>	
	Torrey Ward	Consumer Safety Officer, DQI-II/OQS/OPQ/CDER/FDA
3:05 PM – 3:15 PM	<b>Break</b>	

3:15 PM – 3:45 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

Director, AI/ML Innovation in Pharmaceutical Manufacturing, USP

Joga Gobburu, PhD

Professor, University of Maryland, Baltimore

Brooke Langevin, PhD

Assistant Professor, University of Maryland, Baltimore

Tushar Nitave, MS

Staff Software Engineer, Vivpro Corp.

Arti Patel, MS

Sr. Manager, Cosette Pharma

Sandip Tiwari, PhD

Head of Technical Services, BASF

*FDA Panelists:*

Sharmista Chatterjee, PhD

Division Director, DPMIII/OPMA/OPQ/CDER/FDA

Mihir Jaiswal, PhD

Tech Liaison, PMS/OQA/OPQ/CDER/FDA

Robert Lionberger, PhD

Director, ORS/OGD/CDER/FDA

CDR Diana Solana-Sodeinde, PharmD

Lead Program Coordinator, OB-IO/OGD/CDER/FDA

Geng Tian, PhD

Supervisory Research Officer, DPQR VI/OPQR/OPQ/CDER/FDA

Jing (Jenny) Wang, PhD

Staff Fellow, DQMM/ORS/OGD/CDER/FDA

Zhen Zhang, PhD

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

Torrey Ward

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

3:45 PM – 4:00 PM

**Closing Remarks for Day 1**

Robert Lionberger, PhD

Director, ORS/OGD/CDER/FDA

**End of Day 1 at 4:00 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  
Andrew Cooper, PhD  
Allison Dunn, PharmD, MS  
Abhishek (Abhi) Gupta, PhD, PMP  
Brandon Wood, BSc

Sr. VP & Head, Clinical Research & Biopharmaceutics, Mankind Pharma Ltd  
Sr. Director, Viatris / Mylan Pharma UK  
Research Assistant Professor, University of Maryland SOP/CTM  
Chief Scientific Officer, Transpire Bio  
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	<b>Characterizing the Complex: Validating Non-Compendial Methods, Comparing Q3, and Setting Acceptance Criteria for Complex Generic Drug Products</b> Brock Roughton, PhD	Division Director, DPQA XI/OPQAI/OPQ/CDER/FDA
11:10 AM – 11:20 AM	<b>QMM as a Framework for Driving Operational Performance and Business Excellence</b> Eric Twum, PhD	Regulatory Specialist, DQI-II/OQS/OPQ/CDER/FDA
11:20 AM – 12:15 PM	<b>Panel Discussion</b> Co-Moderator: Markham Luke, MD, PhD Co-Moderator: William Smith, PhD	Director, DTP I, ORS/OGD/CDER/FDA Research Scientist, DPQR V/OPQR/OPQ/CDER/FDA
<b>Public Panelists:</b>	Clare Butler, PhD Praveen Chappa, PhD Andrew Cooper, PhD Niraj Mehta, PhD	Principal Product Development Scientist, Teva Global Inhalations Group Head, Analytical Development, Sandoz Sr. Director, Viatrix / Mylan Pharma UK Sr. VP, Global Quality Compliance and Sustainability, Lupin
<b>FDA Panelists:</b>	Bob Berendt, PhD Utpal Munshi, PhD Brock Roughton, PhD Cameron Smith, PhD Eric Twum, PhD	Supervisory Pharmaceutical Scientist, DPQA V/OPQA I/OPQ/CDER/FDA Division Director, DB I/OB/OGD/CDER/FDA Division Director, DPQA XI/OPQAI/OPQ/CDER/FDA Supervisory Pharmaceutical Scientist, DPQA IV/OPQA I/OPQ/CDER/FDA 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

**Introduction**

**Moderator:**

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 – 1:50 PM

**Public Comment Presentations**

1:50 PM – 2:50 PM

**Panel Discussion**

**Moderator:**

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, Advanced Manufacturing & Technologies, U. S. Pharmacopeia (USP)  
Head of Respiratory, Dermatology, Biologics & Regulatory Strategy, Viatrix  
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

2:50 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