FDA-CRCG Workshop on Modeling and Artificial Intelligence (AI) in Generic Drug Development and Product Lifecycle Management: Regulatory Insights and Future Trends

Public Workshop
October 15-16, 2025
Agenda

Day 1 October 15

8:30 AM – 8:35 AM	**Welcome and Opening Remarks**	
	Anna Schwendeman, PhD	Co-Director, CRCG
8:35 AM – 8:50 AM	**FDA Opening Remarks**	
	Jeremy Walsh, BS	Chief AI Officer, OC, FDA

Session 1: Regulatory Perspectives and Opportunities

Session Lead: Dr. Lanyan (Lucy) Fang

This session underscores the critical importance of understanding global regulatory frameworks to responsibly harness AI in the lifecycle of drug development. By exploring the evolving standards, policies, and opportunities for AI integration, this session will highlight how regulatory landscape shapes the safe, effective, and innovative application of AI in advancing pharmaceutical innovation throughout the drug development lifecycle.

8:50 AM – 8:55 AM	***Speaker Introductions***	
	Lanyan (Lucy) Fang, PhD	Deputy Director, DQMM, ORS, OGD, FDA
8:55 AM – 9:15 AM	***FDA Guidance on the Use of AI in Drug Development and Regulatory Assessment***	
	Gabriel Innes, VMD, PhD	Assistant Director, Data Science and AI Policy, OMP, FDA
9:15 AM – 9:35 AM	***EMA AI Reflection Paper***	
	Luis Pinheiro, PharmD, MEpi	Senior Epidemiology Expert, European Medicines Agency
9:35 AM – 9:55 AM	***AI Use in Generic Drugs***	
	Robert Lionberger, PhD	Director, ORS, OGD, FDA
9:55 AM – 10:10 AM	***Coffee Break***	
10:10 AM – 11:05 AM	***Q&A Session with Panel***	
Moderator:	**Lanyan (Lucy) Fang, PhD**	Deputy Director, DQMM, ORS, OGD, FDA
Panelists:	**Tausif Ahmed, PhD**	Senior VP & Head of Clinical and Biopharmaceutics, Mankind Pharma
	Gabriel Innes, VMD, PhD	Assistant Director, Data Science and AI Policy, OMP, FDA
	B. Y. MiRa Jacobs, PhD	Division Director, DHP, DHCE, CDRH, FDA
	Robert Lionberger, PhD	Director, ORS, OGD, FDA
	Jinzhong (Jin) Liu, PhD	Acting Deputy Director, ODES, OND, FDA
	Luis Pinheiro, PharmD, MEpi	Senior Epidemiology Expert, European Medicines Agency
	Anil Sachdeva, MS	Vice President, Global Head Regulatory Affairs, Biocon
	Partha Roy, PhD	Director, OB, OGD, FDA

Session 2: AI Streamlining Workflows

Session Leads: Dr. James Clarke and Dr. Meng Hu

AI introduces new ways to enhance how we access, interpret, and apply knowledge. These technologies complement experts, helping them work more efficiently, consistently, and insightfully. This session will focus on the use of AI for streamlining workflows, which include, but are not limited to, regulatory writing or assessment, product development, and model development. We will delve into discussions on current practices in this area with real-world examples in which AI is being used to advance workflows relevant to promoting and accelerating generic drug development.

11:05 AM – 11:10 AM	***Speaker Introductions***	
	Meng Hu, PhD	Team Lead, DQMM, ORS, OGD, FDA

11:10 AM – 11:30 AM	***Harnessing AI for Transforming Generic Pharmaceutical Value Chain: A Regulatory-Focused Peptide Product Development Case Study***	
	Senthil Kumar S., MTech	Principal Product Manager, R&D, Digital & Process Excellence, Dr. Reddy's Lab
11:30 AM – 11:45 AM	***Generic Drug Structured Assessment-Bioequivalence and Advent of Artificial Intelligence Integration***	
	Rajan Jog, PhD	Senior Scientific Reviewer, DB I, OB, OGD, FDA
11:45 AM – 12:45 PM	***Lunch Break***	
12:45 PM – 1:05 PM	***Leveraging Generative AI to Support Regulatory Assessments***	
	Meng Hu, PhD	Team Lead, DQMM, ORS, OGD, FDA
1:05 PM – 1:15 PM	***Quantitative Systems Pharmacology at Scale with Generative AI***	
	Joshua Apgar, PhD	Vice President QSP Software, Certara
1:15 PM – 1:25 PM	***Accelerate. De-Risk. Succeed in the Age of AI***	
	Pravin Jadhav, PhD, MPH	CEO, Vivpro Corp
1:25 PM – 1:35 PM	***From Idea to Impact: Streamlining AI Integration Across the Enterprise***	
	Devin Pastoor, PhD	Chief Technology and Product Officer, A2-Ai
1:35 PM – 2:15PM	***Q&A Session with Panel***	
Moderator:	**Meng Hu, PhD**	Team Lead, DQMM, ORS, OGD, FDA
Panelists:	**Joshua Apgar, PhD**	Vice President QSP Software, Certara
	Sridevi Challa, MTech	Lead-Continuous Performance Improvement, Sandoz Development Center
	Lanyan (Lucy) Fang, PhD	Deputy Director, DQMM, ORS, OGD, FDA
	Pravin Jadhav, PhD, MPH	CEO, Vivpro Corp
	Rajan Jog, PhD	Senior Scientific Reviewer, DB I, OB, OGD, FDA
	Senthil Kumar S., MTech	Principal Product Manager, R&D, Digital & Process Excellence, Dr. Reddy's Lab
	Devin Pastoor, PhD	Chief Technology and Product Officer, A2-Ai
2:15 PM – 2:20 PM	***Closing Remarks for Virtual Audience***	
	Lanyan (Lucy) Fang, PhD	Deputy Director, DQMM, ORS, OGD, FDA

Session 3: Small Working Group Sessions (In-Person Only)

2:20 PM –3:10 PM — ***Regulatory Framework and Considerations for AI Tool Integration in Drug Development***

Session Leads: Dr. Eleftheria Tsakalozou and Dr. Eric Pang

In this collaborative session, in-person attendees will participate in focused discussions on applying AI tools in drug development and regulatory submissions, with particular emphasis on AI model validation, performance assessment, and documentation that demonstrates model reliability and relevance to the intended use.

3:10 PM – 3:20 PM — ***Coffee Break***

3:20 PM –4:10 PM — ***Opportunities for AI-Assisted Data Quality Assessment in Supporting Generic Drug Development and Regulatory Evaluation***

Session Lead: Dr. Nilufer Tampal

In this interactive session, in-person participants will engage in targeted case discussions on opportunities for leveraging AI-powered data quality assessment for generic drug development, by incorporating industry perspectives on using AI for data quality in ANDA submissions.

4:10 PM – 4:50 PM — ***In-person Summary***

Day 2 October 16

8:30 AM – 8:40 AM *Day 1 Summary*
Meng Hu, PhD Team Lead, DQMM, ORS, OGD, FDA

Session 4: AI Supporting Drug Development

Session Leads: Mr. Senthil Kumar and Dr. Jayanti Das

AI is becoming increasingly integral to the future of generic drug development. This session will explore how AI offers innovative solutions in transforming the generic drug development process by enhancing efficiency, accuracy, speed, cost, regulatory compliance, and to improve the quality of generic medicines. The session will delve into practical applications of AI within the generic drug domain, including predictive modeling for drug substance development, formulation optimization, intelligent data analysis for bioequivalence assessment, streamlining regulatory pathways, process optimization and scale-up, and post-market surveillance.

8:40 AM – 8:45 AM *Speaker Introductions*
Jayanti Das, PhD Research Scientist, DPQR VI, OPQR, OPQ, FDA

8:45 AM – 9:05 AM *Use Cases of GenAI Implementation in Generic Pharmaceutical Company*
Volodymyr Stus, MD Head of the Clinical Department, R&D PharOs Ltd

9:05 AM –9:25 PM *Maturity Framework to Accelerate AI Impact in CMC: Use Cases for Drug Substance and Drug Product*
Ian Houson, DPhil Programme Manager, Digital CMC CERSI, CMAC, University of Strathclyde

9:25 AM – 9:45 AM *Considerations of Pharmaceutical Manufacturing Process Models for Drug Product Development*
Katie Duncan, PhD Director, CMC Policy and Advocacy, GlaxoSmithKline

9:45 AM – 10:05 AM *Digital Regulatory Transformation: Where Innovation Meets Harmonization*
J. Paul Kirwan, PhD Senior Manager, Regulatory Affairs CMC. Amgen

10:05 AM – 10:20 AM *Coffee Break*

10:20 AM – 11:00 AM *Q&A Session with Panel*

Moderator:	**Jayanti Das, PhD**	Research Scientist, DPQR VI, OPQR, OPQ, FDA
Panelists:	**Christine Allen, PhD**	Full Professor, University of Toronto; CEO and Co-Founder, Intrepid Labs Inc.
	Katie Duncan, PhD	Director, CMC Policy and Advocacy, GlaxoSmithKline
	Ian Houson, DPhil	Programme Manager, Digital CMC CERSI, CMAC, University of Strathclyde
	J. Paul Kirwan, PhD	Senior Manager, Regulatory Affairs CMC, Amgen
	Volodymyr Stus, MD	Head of the Clinical Department, R&D PharOs Ltd
	Yan Wang, PhD	Deputy Division Director, DTP I, ORS, OGD, FDA
	Daniel Willett, PhD	Senior Research Scientist, DPQR II, OPQR, OPQ, FDA

Session 5: AI and Quantitative Medicine

Session Leads: Dr. Joga Gobburu and Dr. Rajanikanth Madabushi

Quantitative Medicine has long guided drug development by transforming biology into models, predictions, and decisions. Whether through pharmacometrics, systems pharmacology, or translational modeling, it has helped reduce uncertainty and increase precision across the drug lifecycle. Today, a new force is accelerating this transformation: Artificial Intelligence/Machine Learning. More than a buzzword, AI/ML approaches are becoming an indispensable extension of Quantitative Medicine—augmenting our ability to analyze massive, complex datasets, generate real-time insights, and simulate decisions at scale. In this session, we explore how AI is unlocking new possibilities for the entire lifecycle of drug development.

11:00 AM – 11:05 AM *Speaker Introductions*
Rajanikanth Madabushi, PhD Associate Director, Guidance & Scientific Policy at IO, OCP, OTS, FDA

11:05 AM – 11:20 AM *Digital Twins: What are They? How Can They Facilitate Drug Development?*
Adarsh Subbaswamy, PhD Assistant Professor, Center for Translational Medicine, UMB SOP

11:20 AM – 11:35 AM *AI-Driven Knowledge Management in PBPK Modeling: Challenges and Opportunities*
Vladmir Chupakhin, PhD Principal Scientist, Simulation Plus Inc.

11:35 AM – 11:50 AM *Role of AI/ML Approaches in New Drug Development and Evaluation*
Qi Liu, PhD, MStat, FCP Associate Director for Innovation & Partnership, OCP, OTS, FDA

11:50 AM –12:05 PM	***AI for Augmenting and Accelerating Computational Fluid Dynamics Predictions of Regional Lung Deposition***	
	Ross Walenga, PhD	Senior Chemical Engineer, DQMM, ORS, OGD, FDA
12:05 PM – 12:20 PM	***Using GenAI to Support Regulatory Applications and Product Lifecycle Management: Lessons Learned and Solutions***	
	Liang Zhao, PhD, MAS, MBA	Professor & VC, Dept Bioengineering & Therapeutic Sci, SOP & SOM UCSF
12:20 PM – 1:20 PM	***Lunch Break***	
1:20 PM – 2:00 PM	***Q&A Session with Panel***	
Moderator:	**Joga Gobburu, PhD, MBA**	Professor, SOP and SOM, UMB; Co-Founder, Vivpro Corp
Panelists:	**Andrew Babiskin, PhD**	Lead Pharmacokineticist, DQMM, ORS, OGD, FDA
	Vladmir Chupakhin, PhD	Principal Scientist, Simulation Plus Inc.
	Qi Liu, PhD, MStat, FCP	Associate Director for Innovation & Partnership, OCP, OTS, FDA
	Adarsh Subbaswamy, PhD	Assistant Professor, Center for Translational Medicine, UMB SOP
	Zhen Zhang, PhD	Master Pharmacologist, DB I, OB, OGD, FDA
	Ross Walenga, PhD	Senior Chemical Engineer, DQMM, ORS, OGD, FDA
	Liang Zhao, PhD, MAS, MBA	Professor & VC, Dept Bioengineering & Therapeutic Sci, SOP & SOM UCSF

Session 6: Small Working Group Sessions (In-Person Only)

2:00 PM –3:00 PM ***Mapping and Prioritizing Potential Opportunities and Challenges for AI-Driven Development of Quantitative Approaches in Support of Drug Development***

Session Leads: Dr. Rajanikanth Madabushi and Dr. Jayanti Das

In this collaborative session, in-person participants will join focused discussions on building and evaluating quantitative medicine models developed with AI tools. Guided by experienced moderators, they will explore the topics in depth through interactive Q&A.

3:00 PM – 3:30 PM	***Summary***	
	Meng Hu, PhD	Team Lead, DQMM, ORS, OGD, FDA
3:30 PM – 3:40 PM	***Closeout Workshop***	
	Robert Lionberger, PhD	Director, ORS, OGD, FDA

Appendix of Abbreviations

AI	Artificial Intelligence
BS or BSc	Bachelor of Science
CDRH	Center for Devices and Radiological Health
CEO	Chief Executive Officer
CERSI	Center of Excellence in Regulatory Science and Innovation
CMAC	Continuous Manufacturing and Advanced Crystallisation
CMC	Chemistry, Manufacturing, and Controls
CRCG	Center for Research on Complex Generics
DB	Division of Bioequivalence
Dept	Department
DHCE	Digital Health Center of Excellence
DHP	Digital Health Policy
DPhil	Doctor of Philosophy
DPQR	Division of Pharmaceutical Quality Research
DTP	Division of Therapeutic Performance
DQMM	Division of Quantitative Methods and Modeling
FCP	Fellow for Clinical Pharmacology
FDA	Food and Drug Administration
Inc	Incorporated
IO	Immediate Office
Lab	Laboratories
Ltd	Limited
MAS	Master of Applied Sciences
MBA	Master of Business Administration
MD	Doctor of Medicine
MEpi	Master of Epidemiology
MTech	Master of Technology
MPH	Master of Public Health
MS or MSci	Master of Science
OB	Office of Biostatistics
OC	Office of the Commissioner
OCP	Office of Combination Products
ODES	Office of Drug Evaluation Sciences
OGD	Office of Generic Drugs
OMP	Office of Medical Policy
OND	Office of New Drugs
OPA	Office of Public Affairs
OPQ	Office of Pharmaceutical Quality
OPQR	Office of Pharmaceutical Quality Research
ORS	Office of Regulatory Science
OTS	Office of Translational Sciences
PharmD	Doctor of Pharmacy
PhD	Doctor of Philosophy
QSP	Quantitative Systems Pharmacology
R&D	Research and Development
Sci	Sciences
SOM	School of Medicine
SOP	School of Pharmacy
UCSF	University of California, San Francisco
UMB	University of Maryland, Baltimore
VC	Vice Chair
VMD	Doctor of Veterinary Medicine