# Fiscal Year (FY) 2024 Generic Drug Science and Research Initiatives Public Workshop

May 20-21, 2024

In-person & Virtual

## Agenda (Day 1)

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| 8:00 AM – 9:00 AM | ***Welcome and Opening Remarks*** | |
| *Moderator:* | Sarah Rogstad, PhD | Senior Scientific Advisor, OPQR, OPQ, CDER, FDA |
| *Presenters:* | Darby Kozak, PhD | Deputy Director, OGD, CDER, FDA |
| | Michael Kopcha, PhD | Director, OPQ, CDER, FDA |
| | Robert Lionberger, PhD | Director, ORS, OGD, CDER, FDA |
| 9:00 AM – 9:15 AM | ***Coffee Break*** | |

## Session 1: *Nitrosamine Drug Substance-Related Impurities (NDSRIs)*

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| 9:15 AM – 10:00 AM | ***Public Comment Presentations on NDSRIs*** | |
| *Co-Moderator:* | Sruthi King, PhD | Deputy Division Director, DPTR, OSCE, OGD, CDER, FDA |
| *Co-Moderator:* | Dongmei Lu, PhD | Policy Lead, DRG, OPPQ, OPQ, CDER, FDA |

This session will include multiple in-person and virtual 5-minute public comment presentations and 15-minute faculty presentations on proposed research relating to NDSRIs. Throughout the session, an in-person 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.

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| 10:00 AM – 10:15 AM | ***N-Nitrosamine SAR Modeling of Potency – Current Status and Future Needs*** | |
| | Kevin P. Cross, PhD | VP, Regulatory Science, PI, FDA Research Collaborations, Instem |
| 10:15 AM – 10:30 AM | ***N-Nitrosamine Drug Impurity Research at FDA/NCTR: Assessing the Mutagenicity of N-Nitrosamines and NDSRIs*** | |
| | Xilin Li, PhD | Visiting Scientist, DGMT, NCTR, FDA |
| 10:30 AM – 10:45 AM | ***NDMA and Beyond: A Biased Kinetic Model to Assess Nitrosation Risk in Solid Drug Products*** | |
| | Dr. Ian W. Ashworth | Principal Scientist, Chemical Development, AstraZeneca, Macclesfield, UK |
| 10:45 AM – 11:00 AM | ***CMC Considerations and Bridging Bioequivalence Studies of Reformulated Products Impacted by Nitrosamines*** | |
| | Martin Ehlert, PhD | Vice-president, API R&D, Apotex Inc. |
| 11:00 AM – 11:15 AM | ***Physiologically Based Pharmacokinetic Absorption Modeling to Support BCS Based Waiver of In Vivo BE Studies*** | |
| | Fang Wu, PhD | Senior Pharmacologist, DQMM, ORS, OGD, CDER, FDA |
| 11:15 AM – 11:30 AM | ***Nitrosamine Impurities: Beyond a Compendial Standard - Learnings from USP's Nitrosamines Exchange Community*** | |
| | Naiffer Romero, MSc, MPH | Principal Scientist, Scientific Affairs - US Pharmacopeia |
| 11:30 AM – 12:00 PM | ***Panel Discussion*** | |
| *Co-Moderator:* | Sruthi King, PhD | Deputy Division Director, DPTR, OSCE, OGD, CDER, FDA |
| *Co-Moderator:* | Dongmei Lu, PhD | Policy Lead, DRG, OPPQ, OPQ, CDER, FDA |
| *Public Panelists:* | Tausif Ahmed MS, PhD | VP & Head, Biopharmaceutics & Bioequivalence, GCM, Dr. Reddy's Laboratories Ltd. |
| | Ian W. Ashworth, PhD | Principal Scientist, Chemical Development, AstraZeneca, Macclesfield, UK |
| | Kevin P. Cross, PhD | VP, Regulatory Science, PI, FDA Research Collaborations, Instem |
| | Martin Ehlert, PhD | Vice-president, API R&D, Apotex Inc. |
| | Naiffer Romero, MSc, MPH | Principal Scientist, Scientific Affairs - US Pharmacopeia |
| | Daniel Snider, PhD | Head, Global Quality Systems IT Quality/Technical Quality, Viatris |
| *FDA Panelists:* | Robert Dorsam, PhD | Director, DPTR, OSCE, OGD, CDER, FDA |
| | Naomi Kruhlak, PhD | Scientific Lead, DARS, OCP, OTS, CDER, FDA |
| | Bing V. Li, PhD | Associate Director for Science, OB, OGD, CDER, FDA |
| | Xilin Li, PhD | Visiting Scientist, DGMT, NCTR, FDA |
| | Bhagwant Rege, PhD | Division Director, DPQA VI, OPQA I, OPQ, CDER, FDA |
| | Diaa Shakleya, PhD | Senior Research Scientist, DPQR, OPQR, OPQ, CDER, FDA |
| | Matthew D. Vera, PhD | Supervisory Chemist, DPQA II, OPQA I, OPQ, CDER, FDA |
| | Fang Wu, PhD | Senior Pharmacologist, DQMM, ORS, OGD, CDER, FDA |
| 12:00 PM – 12:45 PM | ***Lunch Break*** | |

## **Session 2:** *Predictive Tools for Generic Product Development and Assessment*

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|---|---|---|
| 12:45 PM – 2:15 PM | ***Public Comment Presentations on Predictive Tools for Generic Product Development and Assessment*** | |
| *Co-Moderator:* | Lanyan (Lucy) Fang, PhD | Deputy Division Director, DQMM, ORS, OGD, CDER, FDA |
| *Co-Moderator:* | Ahmed Zidan, PhD | Senior Staff Fellow, DPQR V, OPQR, OPQ, CDER, FDA |

This session will include multiple in-person and virtual 5-minute public comment presentations and 15-minute faculty presentations on proposed research relating to modeling and simulation, artificial intelligence and machine learning, and novel ways to support a demonstration of bioequivalence for inhalation products. Throughout the session, an in-person 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.

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| 2:15 PM – 2:30 PM | ***Coffee Break*** | |
| 2:30 PM – 3:30 PM | ***Public Comment Presentations on Predictive Tools for Generic Product Development and Assessment (Contd.)*** | |
| 3:30 PM – 3:45 PM | ***Advancing the Use of Model-Integrated Evidence in Generic Drug Development and Assessment*** | |
| | Liang Zhao, PhD | Director, DQMM, ORS, OGD, CDER, FDA |
| 3:45 PM – 4:00 PM | ***Integration of Simulation, In Vitro and Clinical Methods to Support Complex Drug Product Development*** | |
| | William Ganley, PhD | Senior Specialist, Nanopharm Ltd. (an Aptar Pharma company) |
| 4:00 PM – 4:15 PM | ***PBPK Modeling of Locally Acting Drug Products: Identifying and Addressing Factors Affecting Extrapolation*** | |
| | Jessica Spires, PhD | Principal Scientist, Simulation Plus |
| 4:15 PM – 4:30 PM | ***Digital Twins and In-silico Trials to Support the Approval Process of Complex Generics*** | |
| | Jan de Backer, PhD, MBA | Chief Executive Officer, Fluidda |
| 4:30 PM – 5:00 PM | ***Panel Discussion*** | |
| *Co-Moderator:* | Lanyan (Lucy) Fang, PhD | Deputy Division Director, DQMM, ORS, OGD, CDER, FDA |
| *Co-Moderator:* | Ahmed Zidan, PhD | Senior Staff Fellow, DPQRV, OPQR, OPQ, CDER, FDA |
| *Public Panelists:* | Robert Bies, PhD | Prof. & Assoc. Dean, School of Pharmacy and Pharmaceutical Sciences, Univ. at Buffalo |
| | Clare Butler, PhD | Principal Product Development Scientist, Teva |
| | Andrew Cooper, PhD | Senior Director, Mylan Global Respiratory Group, Mylan Pharma UK (Viatris) |
| | Jan de Backer, PhD, MBA | Chief Executive Officer, Fluidda |
| | William Ganley, PhD | Senior Specialist, Nanopharm Ltd. (an Aptar Pharma company) |
| | Sivacharan Kollipara, PhD | Team Lead, Biopharmaceutics, Dr. Reddy's Laboratories Ltd. |
| | Jessica Spires, PhD | Principal Scientist, Simulation Plus |
| | Ping Zhao, PhD | Senior Program Officer, Bill & Melinda Gates Foundation |
| *FDA Panelists:* | Dhaval Gaglani, PhD | Supervisory chemist, DPQAV, OPQAI, OPQ, CDER, FDA |
| | Meng Hu, PhD | Team Lead, DQMM, ORS, OGD, CDER, FDA |
| | Rebecca Moody, PhD | Pharmaceutical scientist, OPQAII, OPQ, CDER, FDA |
| | Zhen Zhang, PhD | Master Pharmacologist, DBI, OB, OGD, CDER, FDA |
| | Liang Zhao, PhD | Director, DQMM, ORS, OGD, CDER, FDA |
| | Jayanti Das, PhD | Research Scientist, DPQRVI, OPQR, OPQ, CDER, FDA |
| | Bryan Newman, PhD | Lead Pharmacologist, DTP-I, ORS, OGD, CDER, FDA |

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**Agenda (Day 2)**

## **Session 3:** *Public Comments*

8:00 AM – 11:15 AM — ***Public Comment Presentations and Open Public Comments***

*Moderator:* Sam Raney, MS, PhD — Associate Director for Science & Chief Scientific Advisor, ORS, OGD, CDER, FDA

This session will include multiple in-person and virtual 5-minute public comment presentations and 15-minute faculty presentations on proposed research relating to complex APIs, complex products, immunogenicity, oral products, real world evidence, and other topics. This session will also accommodate impromptu public comments from in-person attendees within the time available. Throughout the session, an in-person 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.

11:15 AM – 11:30 AM — ***Coffee Break***

11:30 AM – 11:45 AM — ***Industry Interview Feedback on the Main Challenges in the Development of Complex Generics***

Anna Schwendeman, PhD — Co-Director, CRCG and Prof., Univ. of Michigan

11:45 AM – 12:00 PM — ***Perspective of the U.S. Pharmacopeia on the Research Needed to Address Scientific Challenges for Generic Drugs***

Prabhakar Reddy, PhD — Director, Pharmaceutical Sciences, United States Pharmacopeia

12:00 PM – 12:30 PM — ***Panel Discussion***

*Moderator:* Sam Raney, MS, PhD — Associate Director for Science & Chief Scientific Advisor, ORS, OGD, CDER, FDA

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| *Public Panelists:* | Tausif Ahmed, MS, PhD | VP & Head, Biopharmaceutics & Bioequivalence, GCM, Dr. Reddy's Laboratories Ltd. |
| | Pradeep Dabhi, PhD | Co-Founder and Chief Scientific Officer, Cutyx Research |
| | William Ganley, PhD | Sr. Specialist, Nanopharm, an Aptar Pharma company |
| | Andrew Graves, MS | Director, Immunogenicity Assessment, Specialty Bioanalytics, Teva |
| | Ripen Misri, PhD | Sr. Director, Liquids & Specialty Dosage Forms, Global R&D, Apotex Inc. |
| | Prabhakar Reddy, PhD | Director, Pharmaceutical Sciences, United States Pharmacopeia |
| | Anna Schwendeman, PhD | Co-Director, CRCG and Prof., Univ. of Michigan |
| | Thomas Tice, PhD | Sr. Director, Global Strategic and Technical Marketing, Health Care, Evonik Corp. |
| *FDA Panelists:* | Meng Hu, PhD | Team Lead, DQMM, ORS, OGD, CDER, FDA |
| | Yan Wang, PhD | Acting Deputy Director, DTP I, ORS, OGD, CDER, FDA |
| | Eric Pang, PhD | Senior Chemist, DTP I, ORS, OGD, CDER, FDA |
| | Cameron Smith, PhD | Supervisory Chemist, DPQA-IV, OPQA-I, OPQ, CDER, FDA |
| | Daniela Verthelyi, PhD | Supervisory Biologist, DPQR-IV, OPQR, OPQ, CDER, FDA |
| | Deyi Zhang, PhD | Senior Chemist, DTP I, ORS, OGD, CDER, FDA |
| | Lei Zhang, PhD | Deputy Director, ORS, OGD, CDER, FDA |

12:30 PM – 1:30 PM — ***Lunch Break***

## **Session 4:** *Drug-Device Combination Products*

1:30 PM – 1:40 PM — ***Public Comment Presentations on Drug Device Combination Products***

*Moderators:* William Chong, MD — Director, OSCE, OGD, CDER, FDA

Katharine Feibus, MD — Team Leader, Device Evaluation Team, DTP I, ORS, OGD, CDER, FDA

This session will include a virtual 5-minute public comment presentation and 20-minute in-person faculty presentations on proposed research relating to drug-device combination products. Throughout the session, an in-person 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.

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| 1:40 PM – 2:00 PM | ***Comparative Use Human Factors Studies: Challenges and Recommendations*** | |
| | Brandon Wood, BS | Director of Regulatory Affairs, Generic Steriles (Teva Pharmaceuticals USA, Inc.) |
| 2:00 PM – 2:20 PM | ***We Muddled Our Way Through the CUHF Process, Now What Does It Mean?*** | |
| | Melissa Lemke, MS | Regulatory Human Factors Engineering Advisor, Human Ability Designs, LLC |
| 2:20 PM – 2:40 PM | ***Comparative Threshold Analysis – So Near, Yet So Far …*** | |
| | Vivek Viswanathan, PhD | Manager, Research & Development, Rubicon Research Canada Ltd. |
| | Daliya Bharati, MS | Director, Regulatory Affairs and Intellectual Property, Advagen Pharma, Ltd. |
| 2:40 PM – 3:00 PM | ***Industry Perspective: Development of Generic Emergency Use Products*** | |
| | Amy Lukau, BA, BS | Senior Human Factors Lead, Kindeva Drug Delivery |
| 3:00 PM – 3:20 PM | ***It's Hip to be Square: Demonstrating Equivalency without Inferiority in CUHF Studies*** | |
| | Heidi Mehrzad, MS | CEO and Human Factors Expert, HFUX Research, LLC |

3:20 PM – 3:35 PM ***Coffee Break***

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| 3:35 PM – 4:15 PM | ***Panel Discussion*** | |
| *Moderator:* | William Chong, MD | Director, OSCE, OGD, CDER, FDA |
| *Public Panelists:* | Daliya Bharati, MS | Director, Regulatory Affairs and Intellectual Property, Advagen Pharma, Ltd. |
| | Tim Briggs, MSc | Senior Principal Human Factors Engineer Global Device Development, Viatris |
| | Megan Conrad, PhD | Associate Professor of Mechanical Engineering, Univ. of Detroit Mercy |
| | Amy Lukau, BA, BS | Senior Human Factors Lead, Kindeva Drug Delivery |
| | Heidi Mehrzad, MS | CEO and Human Factors Expert, HFUX Research, LLC |
| | Melissa Lemke, MS | Regulatory Human Factors Engineering Advisor, Human Ability Designs, LLC |
| | Manoj Pananchukunnath, MP | Chief Scientific Officer, Scientific Affairs, Biocon Ltd. |
| | Vivek Viswanathan, PhD | Manager, Research & Development, Rubicon Research Canada Ltd. |
| | Brandon Wood, BS | Director of Regulatory Affairs, Generic Steriles, Teva Pharmaceuticals USA, Inc. |
| *FDA Panelists:* | Robert Berendt, PhD | Supervisory Chemist, DPQA V, OPQA I, OPQ, CDER, FDA |
| | Ariane O. Conrad, PharmD | Associate Director for Human Factors, DMEPA I, OMEPRM, OSE, CDER, FDA |
| | Katharine Feibus, MD | Team Leader, Device Evaluation Team, DTP I, ORS, OGD, CDER, FDA |
| | Jason Flint, MBA, PMP | Deputy Director, DMEPA I, OMEPRM, OSE, CDER, FDA |
| | Kyran Gibson, BS | Biomedical Engineer and Lead Reviewer, DHT IIIC, OHT III, OPEQ, CDRH, FDA |
| | Stella Grosser, PhD | Director, DB VIII, Office of Biostatistics, OTS, CDER, FDA |
| | Edna Termilus, MD, MPH | Associate Director, DCR, OSCE, OGD, CDER, FDA |

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| 4:15 PM – 4:30 PM | ***Closing Remarks*** | |
| | Robert Lionberger, PhD | Director, ORS, OGD, CDER, FDA |

# Appendix of Abbreviations

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| API | Active Pharmaceutical Ingredient |
| Assoc. | Associate |
| BCS | Biopharmaceutics classification system |
| BE | Bioequivalence |
| BS | Bachelor of Science |
| CDER | Center for Drug Evaluation and Research |
| CDRH | Center for Devices and Radiological Health |
| CEO | Chief Executive Officer |
| CMC | Chemistry and manufacturing controls |
| CRCG | Center for Research on Complex Generics |
| CUHF | Comparative use human factors |
| DARS | Division of Applied Regulatory Science |
| DB VIII | Division of Biostatistics VIII |
| DCR | Division of Clinical Review |
| DGMT | Division of Genetic and Molecular Toxicology |
| DHT IIIC | Division of Health Technology IIIC |
| DMEPA I | Division of Medication Error Prevention and Analysis I |
| 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 |
| DPQR V | Division of Product Quality Research V |
| DPTR | Division of Pharmacology/Toxicology Review |
| DRG | Division of Regulations and Guidance |
| DTP I | Division of Therapeutic Performance I |
| FDA | United States Food and Drug Administration |
| GCM | Global Clinical Management |
| Inc. | Incorporated |
| IT | Information Technology |
| Ltd. | Limited |
| LLC | Limited Liability Company |
| MBA | Master of Business Administration |
| MD | Doctor of Medicine |
| MP | Master of Pharmacy (MPharm) |
| MPH | Master of Public Health |
| MS/MSc | Master of Science |
| NCTR | National Center for Toxicological Research |
| NDMA | N-nitrosodimethylamine |
| NDSRI | Nitrosamine drug substance related impurity |
| OB | Office of Bioequivalence |
| OCP | Office of Clinical Pharmacology |
| OGD | Office of Generic Drugs |
| OHT III | Office of Health Technology III |
| OMEPRM | Office of Medication Error Prevention and Risk Management |
| OPEQ | Office of Product Evaluation and Quality |
| OPPQ | Office of Policy for Pharmaceutical Quality |
| OPQ | Office of Pharmaceutical Quality |
| OPQA I | Office of Product Quality Assessment I |
| OPQR | Office of Pharmaceutical Quality Research |
| ORS | Office of Research and Standards |
| OSCE | Office of Safety and Clinical Evaluation |
| OSE | Office of Surveillance and Epidemiology |
| OTS | Office of Translational Sciences |
| PBPK | Physiologically Based Pharmacokinetics |
| PhD | Doctor of Philosophy |
| PI | Principal Investigator |
| Prof. | Professor |
| R&D | Research and Development |
| SAR | Structure Activity Relationship |
| Sr. | Senior |
| UK | United Kingdom |
| Univ. | University |
| USP | United States Pharmacopeia |
| VP | Vice President |