Fiscal Year (FY) 2025 Generic Drug Science and Research Initiatives Public Workshop Speaker, Panelist, And Moderator Biographies

In order of appearance on Agenda

Day 1

Welcome & Introduction

Sam Raney, PhD
Associate Director for Science & Chief Scientific Officer
Office of Research and Standards (ORS) | Office of Generic Drugs (OGD) |
Center for Drug Evaluation and Research (CDER) | FDA

Dr. Sam Raney is the Associate Director for Science and Chief Scientific Advisor in the FDA's Office of Research and Standards and Office of Generic Drugs, where he oversees the research portfolio of FDA's generic drug research program. He has over 30 years of experience in pharmaceutical drug development, specializing in topical and transdermal products, and producing numerous research manuscripts, review articles, book chapters and patents. He has been a researcher and adjunct professor within academia, was the longest serving Chair of the AAPS Topical and Transdermal Community, has been a principal or sub investigator on over 400 pharmaceutical product studies, has held senior management roles in industry, serves on multiple expert committees and panels for the U.S. Pharmacopeia, and is frequently invited to speak at scientific meetings around the world. Dr. Raney holds a Bachelor's Degree in Molecular Biophysics & Biochemistry from Yale University, and a Ph.D. in Biochemistry & Molecular Biology from the University of British Columbia in Canada.

Susan Rosencrance, PhD
Deputy Super Office Director
Office of Pharmaceutical Quality (OPQ) | CDER

Dr. Susan Rosencrance serves as the Deputy Director for Science in CDER's Office of Pharmaceutical Quality (OPQ). She is performing this role in addition to serving as the Director for the Office of Product Quality III, also within OPQ. She has spent more than 25 years at the FDA serving in a variety of senior roles including the Acting Director for CDER's Office of Generic Drugs in 2022-2023, Director for the Office of Lifecycle Drug Products in OPQ from 2015-2022, as well as the Deputy Director for Generic Drug Chemistry from 2013-2015 in CDER's former Office of Pharmaceutical Science. Before joining the FDA, Susan worked in a drug discovery program at Merck in Rahway, New Jersey. She holds a B.S. in Biochemistry and a Ph.D. in Chemistry and completed her dissertation research in protein modeling at the NIH Laboratory for Biophysical Chemistry.

Iilun Murphy, MD
Director
OGD | CDER

Dr. Iilun Murphy is the Director of the Office of Generic Drugs (OGD) in the FDA's Center for Drug Evaluation and Research (CDER). Appointed in June 2023, she leads the office responsible for reviewing and approving abbreviated new drug applications, ensuring the safety and efficacy of generic drugs for the American public. Dr. Murphy's FDA career began in 2007 as a medical officer in CDER's Office of New Drugs, Division of Gastroenterology Products. She broadened her expertise by joining the Center for Tobacco Products in 2011, where she contributed to expanding the Office of Science. In January 2020, she returned to CDER as OGD's Deputy Director for Clinical and Regulatory Affairs before assuming her current directorship. A board-certified pediatrician, Dr.

Murphy also serves as an assistant clinical professor of pediatrics at The George Washington University School of Medicine. Her educational background includes a bachelor's degree from Cornell University, a medical degree from Stanford University, and pediatric training from the Boston Combined Residency Program, affiliated with Harvard Medical School and Boston University School of Medicine.

Robert Lionberger, PhD
Director
ORS|OGD|CDER

Dr. Robert Lionberger leads OGD's implementation of the GDUFA science and research commitments including internal research activities and external research grants and collaborations to ensure the therapeutic equivalence of generic drug products. ORS also provides pre-submission advice on complex generics through pre-ANDA (Abbreviated New Drug Application) meetings and product-specific guidance and correspondence responses. He received his undergraduate degree from Stanford University in Chemical Engineering, and a Ph.D. from Princeton University in Chemical Engineering. He conducted post-doctoral research in Australia in the Department of Mathematics and Statistics at the University of Melbourne. Prior to joining the FDA 20 years ago, he was an Assistant Professor of Chemical Engineering at the University of Michigan.

Session 1

Assessment Challenges with Complex Active Ingredients: Peptides & Oligonucleotides

Cameron Smith, PhD
Supervisory Pharmaceutical Scientist
Division of Product Quality Assessment IV (DPQAIV)|Office of Product Quality I (OPQAI)|
OPQ|CDER

Dr. Cameron Smith is a Supervisory Chemist in the Office of Product Quality Assessment I/Office of Pharmaceutical Quality in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration. In this role he manages and mentors a team of CMC reviewers engaged in the assessment of pre- and post-market applications. Prior to his Agency tenure, he spent 15 years in the pharmaceutical industry as a medicinal chemist, primarily at Merck Research Laboratories in Rahway, NJ and before that at OSI Pharmaceuticals in Durham, NC. Cameron completed his Ph.D. studies in chemistry at the University of Cambridge in Cambridge, UK and followed this up with postdoctoral studies at the University of Utah in Salt Lake City, UT. He obtained his undergraduate degree at Monash University in Melbourne, Australia.

Yan Wang, PhD
Deputy Division Director
Division of Therapeutic Performance I (DTP I)|ORS|OGD|CDER

Dr. Yan Wang is the Deputy Director in the Division of Therapeutic Performance I (DTP-I), Office of Research and Standards (ORS) in the Office of Generic Drugs (OGD). DTP-I is responsible for facilitating pre-application development of generic drugs by conducting and promoting regulatory science research to establish standards to ensure therapeutic equivalence of new generic drug products. Yan has been at the U.S. Food and Drug Administration since 2013. Prior to her current role, Yan served in various roles, including as the subject matter expert in the area of complex long-acting drug

products, and as the Team Lead for the Complex Drug Substance and Complex Formulation Team in ORS/DTP-1. Yan has research interests in developing new analytical methods, in vitro characterization, and drug release testing methodologies for complex drug products. She specializes in complex parenteral, ophthalmic, otic, intravaginal, and intrauterine formulations.

Eric Pang, PhD
Senior Chemist
DTP I|ORS|OGD|CDER

Dr. Eric Pang specializes is in the analysis of peptide and large molecule drugs. In his current role as the senior chemist and subject matter expert, he is involved with the development of policy to support the review of generic peptide products. He is mainly responsible for drafting product specific guidances of complex drug products, responding to queries submitted through controlled correspondences and pre-ANDA meeting requests, and supporting the Agency's responses to citizen petitions. He is also managing several regulatory science projects related to generic complex drug substances and products. Eric has over eleven years of experience in the Agency as a research chemist, a CMC reviewer and a policy lead.

Likan Liang, PhD
Supervisory Pharmaceutical Scientist
Division of Product Quality Assessment X (DPQAX)|Office of Product Quality II (OPQAII)|
OPQ|CDER

Dr. Likan Liang is a Unit Supervisor in the Division of Product Quality Assessment X, Office of Product Quality Assessment II, Office of Pharmaceutical Quality, CDER, FDA. Dr. Liang served as the OPQ chair in reviews of many oligonucleotide pre-ANDAs and contributed to the development of many published product specific guidance for generic oligonucleotides. Dr. Liang has been a quality assessor in the previous immediate release, modified release, and liquid drug product review divisions. Prior to join the FDA in 2013, Dr. Liang has worked in the pharmaceutical industry for about 16 years, in areas including API synthesis, formulation development of various dosage forms and complex products, as well as process development, scale up, and commercial scale manufacturing of modified-release drug products. Dr. Liang has a Ph.D. degree in organic chemistry.

Manoj Kumar (MJ) Pananchukunnath, MCP
Chief Scientific Officer
Biocon, Ltd.

Mr. Manoj Kumar Pananchukunnath is the Chief Scientific officer at Biocon Limited and is responsible for R&D, Regulatory Sciences, IPR, Clinical, Program and Portfolio Management functions since 2020. Manoj brings over two and a half decades of extensive experience in end-to-end product development and regulatory sciences across US, EU, CA, JP, AU, BR, ROW and Emerging markets for both Active Ingredients (API) and Dosage forms. He carries a wide range of experience across various types of active ingredients and multiple dosage forms especially in Drug-Device combination products, Injectable, Peptide, Fermentation and Oligonucleotide. He drives product development across several geographies from aiding conception of ideas to development and finally managing the life cycle from submission to approval and commercialization. Manoj has played an important role in setting and expanding facilities for development and manufacturing and has managed multinational teams across US, EU and other countries. He has over 25 patents and patent applications generated over the many different areas over the years. He has managed cost centers of order of ~90 million USD annually.

Andrew Graves, MS, SCYM
Director, Immunogenicity Assessment
Teva Pharmaceutical Industries Limited

Mr. Andrew Graves serves as the Director of Immunogenicity Assessment for Teva Pharmaceuticals. In his role, Andrew leads a talented group of immunologists supporting innovative and complex generic pharmaceutical candidate programs, spanning nonclinical in vivo studies, human clinical studies, and in vitro immunogenicity prediction studies. Andrew specializes in the development and validation of complex immunoassays. Before joining Teva in 2021, Andrew's scientific career began at Aeras, where he led assay development activities supporting clinical vaccine studies. He then moved to FlowMetric, where he served as Associate Director of Lab Operations. Andrew holds a BS degree in biotechnology from the Rochester Institute of Technology, an MS in immunology from the University of Rochester, and earned his Specialist in Cytometry certification in 2016.

Sudhir Agrawal, Dphil
President, ARNAY Sciences
Affiliate Professor, Department of Medicine, University of Massachusetts

Dr. Sudhir Agrawal is the founder and president of ARNAY Sciences and serves as an affiliate professor in the Department of Medicine at UMass Chan Medical School. Over the past three decades, his research interests have encompassed the discovery and development of RNA therapeutics, including antisense and immunotherapy. He concentrates on the chemical biology of oligonucleotides to advance RNA therapeutics. He has introduced gapmer antisense for the targeted knockdown of RNA and modified RNA antisense for splice modulation, which are widely utilized in both approved antisense drugs and candidates currently under development. Recently, he has introduced spatial cyclic structures of oligonucleotides to enhance RNA therapeutics. He has published over 300 research papers, is a co-inventor on more than 400 patents worldwide, and has edited four books on oligonucleotide chemistry and antisense technology. Currently, he sits on the scientific advisory boards of several biotechnology companies. He earned his D.Phil. in Chemistry and conducted postdoctoral research at MRC's Laboratory of Molecular Biology in Cambridge, UK. In 2022, the Oligonucleotide Therapeutic Society awarded him the Lifetime Achievement Award.

Raman Bahal, PhD
Associate Professor
University of Connecticut

Dr. Raman Bahal serves as an associate professor in the department of pharmaceutical sciences at the University of Connecticut. Dr. Bahal's research lab integrates chemical biology of nucleic acid analogues and new polymeric delivery strategies to target genetic diseases and various kinds of cancer. His group's major research interests include (1) selective targeting of microRNA and mRNA using antisense based scaffolds delivered via nanotechnology, (2) exploring the design and engineering of genome targeted nucleic acid analogues towards next-generation human therapeutics, and (3) selective targeting of tumor cells in tumor microenvironment using novel peptide and peptidomimetics based modules Dr. Bahal received his doctorate degree from Carnegie Mellon University.

Jae (Mike) Lee, PhD
Staff Fellow
Division of Quantitative Methods and Modeling (DQMM)|ORS|OGD|CDER

Dr. Jae (Mike) Lee is a chemical engineer in the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards, Office of Generic Drugs, CDER/FDA. Prior to joining the FDA in 2021, he was a postdoctoral fellow in the Department of Mechanical Engineering at Johns

Hopkins University. Mike received his B.A. in Applied Mathematics from the University of California, Berkeley, and his Ph.D. in Mathematics from the University of North Carolina at Chapel Hill. His research has been in developing physics-based models of bioprosthetic heart valves, drug dissolution in human stomach, and orally inhaled drug products. His recent research has been on developing and application of advanced methods in areas of large language model, AI/ML, data analytics, and in silico immunogenicity assessment to help facilitate bioequivalence assessments.

Mohanraj Manangeeswaran, PhD
Senior Research Scientist
Division of Product Quality Research IV (DPQRIV)|Office of Pharmaceutical Quality Research (OPQR)|
OPQ|CDER

Dr. Mohanraj Manangeeswaran is a Senior Research Scientist in the Office of Product Quality Research and has more than 20 years of research experience in the areas of infectious disease and immunology and over 12 years regulatory experience in dealing with product quality and immunogenicity assessments of therapeutic proteins, complex peptide, and oligonucleotide drugs. Dr. Manangeeswaran received his Ph.D from the University of Madras, India and completed his joint post-doctoral fellowship with FDA and Boston Children's Hospital (Harvard Medical School). He has extensive experience in the development and validation of bioassays needed to monitor and control process and product related impurities in peptide drug products and he has received multiple awards from FDA recognizing his research and regulatory excellence.

Paresma Patel, PhD
Division Director
Division of Product Quality Assessment XIX (DPQAXIX)|Office of Product Quality III (OPQAIII)|
OPQ|CDER

Dr. Paresma (Pinky) Patel is a Division Director in CDER's Office of Pharmaceutical Quality, Office of Product Quality Assessment III. In this role, she leads assessment groups responsible for the evaluation of chemistry, manufacturing, and controls (CMC) information with a focus on drug substance quality throughout clinical development to submission of marketing applications. She served as a supervisor, supporting the oncology and anti-viral clinical divisions, prior to transitioning to her current role. Prior to FDA, she worked as a medicinal chemist at the National Institutes of Health. Dr. Patel completed her Ph.D. in organic chemistry at The Scripps Research Institute and postdoctoral fellowship at the California Institute of Technology.

Kui Yang, PhD
Senior Research Scientist
Division of Product Quality Research II (DPQRII)|OPQR|OPQ|CDER

Dr. Kui Yang is a Senior Research Scientist in the Office of Pharmaceutical Quality Research (OPQR) within the Office of Pharmaceutical Quality (OPQ) at FDA. She specializes in mass spectrometry of complex products, with a current focus on synthetic oligonucleotides. Her research centers on the characterization of complex active ingredients and impurities to provide scientific inputs on drug quality questions. She received a Ph.D. degree in Chemical Engineering from Tianjin University. Prior to joining FDA in 2016, Dr. Yang was an Instructor in Medicine at Washington University School of Medicine, where she had over ten years of experience in mass spectrometry-based lipidomics and biomarker research in diabetes, heart disease and Alzheimer's disease.

Session 2

Tackling Formulation Sameness and Advancing In Vitro Characterization for Bioequivalence of Complex Generic Products

Bryan Newman, PhD
Lead Pharmacologist
DTP I|ORS|OGD|CDER

Dr. Bryan Newman is a lead pharmacologist and team lead for inhalation and nasal drug products in the Division of Therapeutic Performance 1 (DTP-1), Office of Research and Standards (ORS), under the Office of Generic Drugs (OGD). Dr. Newman's work focuses on developing product-specific guidances along with addressing controlled correspondences, citizen petitions, consults, and pre-ANDA meeting requests. He also serves as a project officer and contracting officer's representative for regulatory science research initiatives related to inhalation and nasal drug products. Dr. Newman received his B.S. degree from Louisiana State University in Biochemistry and his M.S. and Ph.D. degrees from the University of Michigan in Pharmaceutical Science.

Ahmed Zidan, PhD
Senior Research Pharmacologist
DPQRV|OPQR|OPQ|CDER

Dr. Ahmed Zidan is a Senior Research Pharmacologist at the Division of Pharmaceutical Quality Research (V) of Office of Pharmaceutical Quality of CDER. Ahmed leads the topical and transdermal drug products laboratories of DPQR and provides hands-on trainings to reviewers on various topics including transdermal delivery systems, in vitro release, and permeation testing of pharmaceuticals, and preformulation consideration for development of topical and oral drug products. Dr. Zidan also leads OPQR research efforts supporting the development of general and product-specific guidance documents, review strategies for pre-ANDAs and ANDAs and citizen petitions for topical drug products. Ahmed is the government liaison Expert of USP committee of complex excipients. His research activities and collaborations produced more than 120 peer reviewed publications and book chapters. Ahmed completed his bachelor's and master's degree in pharmaceutical sciences at Zagazig University, and his doctoral degree in Pharmaceutical Sciences (Drug delivery) at Howard University.

Susan Boc, PhD
Pharmacokineticist
DTP I|ORS|OGD|CDER

Dr. Susan Boc is a Pharmacokineticist in the Division of Therapeutic Performance 1 in the Office of Research and Standards and specializes in inhalation and nasal drug products. She is responsible for the development of product-specific guidances for generic drug development, reviewing and responding to controlled correspondences, pre-ANDA meeting requests, and internal consults. She also manages research projects on developing new analytical methods and in vitro characterization for inhalation drug products. Prior to joining the FDA, she spent over 8 years in the pharmaceutical industry working in the development of drug products for oral inhalation. She received her B.S. in Biochemistry from University of California, Los Angeles, and her Ph.D. in Pharmaceutical Sciences from Virginia Commonwealth University.

Hailing Zhang, PhD
Division Director
DPQAXII|OPQAII|OPQ|CDER

Dr. Hailing Zhang is the division director of Division of Product Quality Assessment XII (DPQA XII) in Office of Product Quality Assessment II (OPQA II), Office of Pharmaceutical Quality (OPQ). Dr. Hailing Zhang obtained her Ph.D. in Organic Chemistry and Physical Organic Chemistry from Emory University (Atlanta, GA). She was an associate professor of Pharmaceutical Science in College of Pharmacy at Mercer University (Atlanta, GA) before joined in FDA in 2014. In her current role as the Division Director of DPQA XII in OPQA II, Hailing is leading a team of talented Pharmacokineticists to provide Biopharmaceutic assessment and approval for various submissions.

Ross Walenga, PhD
Senior Chemical Engineer
DQMM|ORS|OGD|CDER

Dr. Ross Walenga joined the FDA in 2015 as an Oak Ridge Institute for Science and Education (ORISE) Fellow. He is currently a Senior Chemical Engineer at the Division of Quantitative Methods and Modeling at the Office of Research and Standards. He began his career at Virginia Polytechnic Institute and State University (Virginia Tech), where he earned a Bachelor Science in Aerospace Engineering. He later earned his Ph.D. in Engineering (mechanical track) from Virginia Commonwealth University in 2014, where he also spent seven months as a postdoctoral fellow prior to joining the FDA. His research interests include computational fluid dynamics modeling of orally inhaled, nasal, ophthalmic, and dermal drug products to answer questions pertaining to bioequivalence.

Andrew Cooper, PhD
Senior Director, Development for In Vitro Performance Lead
Viatris, Inc.

Dr. Andrew Cooper studied at University of Bath in the UK. He gained broad experience of API and complex dosage form development during 14 years with Pfizer Global R&D. Andrew joined Mylan Global Respiratory Group (now within Viatris) in 2012 as Analytical R&D lead. In 2022 he took on a new role, responsible for leading studies supporting development of inhaled products for in-vivo performance. He has specific interests in understanding the relevance of in-vitro tests to in-vivo performance and bioequivalence strategies for inhaled products.

Maxime Le Merdy, PhD
Director, PBPK Research and Collaboration
Simulation Plus

Dr. Maxime Le Merdy serves as the Director of Research and Collaborations at Simulations Plus, a global leader in innovative modeling and simulation software for pharmaceutical research and development. He earned his Pharm.D. from Paris University in 2015 and completed his Ph.D. in 2022. In 2017, Dr. Le Merdy joined the U.S. Food and Drug Administration (FDA) as a postdoctoral fellow in the Division of Quantitative Methods and Modeling within the Office of Generic Drugs. During his time at the FDA, he specialized in physiologically based pharmacokinetic (PBPK) modeling for locally acting drug products, contributing to the advancement of non-oral PBPK methodologies and publishing several papers in this domain.

Nuria Manzano Jurado, BSc
Specialist, R&D Pharma Services
NanoPharm

Ms. Nuria Manzano Jurado is an Analytical Specialist at NanoPharm and subject matter expert in alternative bioequivalence for inhaled and nasal drug products. She has lead development, validation and testing using a range of novel methods and supported preANDA and post-submission meetings between FDA and NanoPharm customers. She also contributed to two FDA contracts investigating microstructural characterization for orally inhaled and nasal drug products and has presented her work at a range of international conferences.

Naresh Mittapelly, PhD
Research Scientist II
Certara UK LTD, United Kingdom

Dr. Naresh Mittapelly is a Senior Research Scientist at Certara UK Ltd, Predictive Technologies, where he has been working since 2021. Currently, he leads the modeling efforts for the Long-Acting Injectable (LAI) module in the Simcyp Simulator platform and is involved in the development of the Virtual Bioequivalence (VBE) module. Naresh holds a PhD in Pharmaceutical Sciences from the Central Drug Research Institute, Lucknow, India, where his research focused on the development and testing of suspension-based long-acting injectables and transdermal patch delivery systems. He also holds a master's degree in Pharmaceutics from the Birla Institute of Technology and Science (BITS), Pilani, Rajasthan, India. At Certara, Naresh contributed to the Simcyp R project, the development of LAI models. He is involved in an FDA grant-funded project aimed at developing in vitro–in vivo correlations (IVIVCs) for polymer-based solid implants. He also supports consultancy projects that utilize LAI models to study long-acting injectable formulations and support regulatory submissions. Prior to joining Certara, Naresh worked as a Deputy Manager at Cipla R&D, where he was responsible for developing complex injectable formulations

Clare Butler, BSC, PhD
Principal Product Development Scientist, Respiratory R&D
Teva Pharmaceuticals Ireland

Dr. Clare Butler completed both undergraduate and doctoral degrees in Pharmacology at University College Dublin (UCD). She began her pharmaceutical career at Sanofi (Waterford, Ireland), focusing on analytical method development and technical transfer for lyophilized products. Dr. Buter has been working with Teva Pharmaceuticals (Global Respiratory R&D, Waterford, Ireland) for almost 7 years, where she currently serves as principal product development scientist concentrates on leading an in vitro-in vivo correlation (IVIVC) initiative for global respiratory, involving mechanistic PBPK and semi-empirical lung deposition modelling and realistic method development and validation. In doing so, the goal is to enhance the development of respiratory products for lung diseases and deliver quality generic inhalation products to patients.

Andrew Babiskin, PhD
Lead Pharmacokineticist
DQMM|ORS|OGD|CDER

Dr. Andrew Babiskin is a Lead Pharmacokineticist in the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS), Office of Generic Drugs, CDER. He previously led the Locally-acting Physiologically Based Pharmacokinetic Modeling Team and the Quantitative Clinical Pharmacology Team in DQMM. Dr. Babiskin's expertise lies in modernization of bioequivalence evaluation practices through model-integrated evidence. Dr. Babiskin received his

B.S. degree from the University of Maryland (College Park) in Chemical Engineering and his M.S. and Ph.D. degrees from the California Institute of Technology in Chemical Engineering. He joined the FDA in 2012 as an ORISE postdoctoral fellow in the OGD Science Staff (now ORS) and became an employee within DQMM in 2014.

Elizabeth Bielski, MS, PhD
Senior Pharmacologist
DTP I|ORS|OGD|CDER

Dr. Elizabeth Bielski is a Senior Pharmacologist working at Division of Therapeutic Performance-I (DTP-I), Office of Research and Standards (ORS), Office of Generic Drugs (OGD), Center of Drug Evaluation and Research (CDER) at the FDA and has been with DTP-I since 2018. Her areas of expertise involve orally inhaled and nasal drug products (OINDPs). She is actively involved in regulatory guidance development and research initiatives to promote generic drug development of OINDPs. Elizabeth completed her Ph.D. in Chemical Engineering from Wayne State University (Detroit, MI, USA) in 2018. She also received her Master of Science in Biomedical Engineering in 2012 and her Bachelor of Science in Biomedical Physics Honors with University Honors in 2011 from Wayne State University.

Dhaval Gaglani, PhD
Supervisory Chemist
DPQAV|OPQAI|OPQ|CDER

Dr. Dhaval Gaglani started his FDA career as a review chemist in the Office of Generic Drugs (OGD) in 2010, and since then served multiple roles in OGD and OPQ with increasing responsibilities. He is currently serving as the Supervisory Pharmaceutical Scientist in the Office of Product Quality Assessment I (OPQA I)/Division of Product Quality Assessment V. His Unit is responsible for drug product quality assessment of Abbreviated New Drug Applications (ANDAs) for pre-marketing and post-marketing applications. Dhaval and members of his unit are Subject Matter Experts in quality assessment of Generic Inhalation products (DPIs, MDIs, Nasal Powders, and Soft mist inhalers). In his role, he oversees and provides pre-submission advice on complex generics including Inhalation products through pre-ANDA (Abbreviated New Drug Application) meeting requests and controlled correspondence. Dhaval currently serves on the working group revising the 2018 draft quality guidance for MDIs and DPIs, and Agency working group involved in regulatory aspects related to the Next Generation Propellants (NGP). He and his work unit also participate in regulatory science research, USP liaison for Aerosol subcommittee and other activities associated with Inhalation products. Prior to joining the FDA in 2010, he spent 12 years in pharmaceutical industry (both brand and generic) with industrial experience in product and process development, product scale-up, process validation, and technology transfer. Dhaval earned his master's degree in Pharmaceutics and Industrial Pharmacy from Long Island University, and a bachelor's degree in pharmacy from the University of Pune, India.

Wenlei Jiang, PhD
Senior Advisor for Innovation and Strategic Outreach
ORS|OGD|CDER

Dr. Wenlei Jiang is a Senior Biomedical Research and Biomedical Product Assessment Service (SBRBPAS) Expert and currently serves as Senior Advisor for Innovation and Strategic Outreach in the Office of Research and Standards/Office of Generic Drugs. She is leading complex product classification and research, promoting global harmonization of bioequivalence criteria, and developing opportunities for scientific outreach. She is current US Co-Chair for Global Bioequivalence Harmonization Initiative (GBHI) to facilitate science-driven regulations in the field

of bioequivalence assessment. She also chairs International Pharmaceutical Regulator Programme (IPRP) Nanomedicine Working Group, and supports ICH M13, generic drug cluster, and other global regulatory affairs activities. She serves at National Cancer Institute (NCI) Nanotechnology Characterization Laboratory (NCL) Scientific Oversight Committee and was the immediate past Chair for Product Quality Research Institute (PQRI) Steering Committee. Prior to joining FDA, she was at Novartis Pharmaceutical Corporation where her responsibilities included formulation development of conventional liquid and solid dosage forms, as well as advanced parenteral drug delivery systems. She received her PhD in Pharmaceutics and Pharmaceutical Chemistry from The Ohio State University.

Xiaojian Jiang, PhD
Deputy Division Director
Division of Bioequivalence II (DBII)|Office of Bioequivalence (OB)|OGD|CDER

Dr. Xiaojian Jiang received her Ph.D. in Pharmaceutical Sciences from the University of Maryland, Baltimore. As a Divisional management and tertiary reviewer of complex BE issues, Dr. Jiang has successfully addressed numerous key scientific/regulatory issues of complex topical dosage forms, locally acting GI products, long acting injectables as well as nasal and inhalation products. She has presented and published on a range of complex regulatory, scientific issues including Adaptive design approach for BE studies, deficiencies associated with IVRT, IVIVC issue and case studies, BE approaches for locally acting drug products, highly variable drug products, in vitro dissolution testing, and in vitro BE approaches for nasal spray products.

Xiaoming Xu, PhD
Director
DQPRV|OPQR|OPQ|CDER

Dr. Xiaoming Xu serves as a Division Director in the Office of Pharmaceutical Quality Research in FDA, where he leads multiple regulatory research areas such as complex formulations, nanomaterials, and advanced manufacturing. In support of GDUFA III implementation, Xiaoming co-leads the complex PSG working group, with a focus of better integrating research in complex PSG development. He is also a member of FDA Nanotechnology Task Force and is responsible for developing international collaborative programs and standards in areas related to nanotechnology. Xiaoming is an editorial board member of the International Journal of Pharmaceutics. He received his B.S. and M.S. degrees in Pharmaceutics from China Pharmaceutical University and Ph.D. degree in Pharmaceutical Sciences from University of Connecticut.

Session 3

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

Bryan Newman, PhD
Lead Pharmacologist
DTP I|ORS|OGD|CDER

See biography above.

Ahmed Zidan, PhD
Senior Research Pharmacologist
DPQRV|OPQR|OPQ|CDER

See biography above.

Priyanka Ghosh, PhD
Lead Pharmacologist
DTP I|ORS|OGD|CDER

Dr. Priyanka Ghosh is a lead pharmacologist within the Division of Therapeutic Performance, ORS, OGD. Her areas of expertise include products in the topical and transdermal drug delivery area. In her current role, Dr. Ghosh leads regulatory science research initiatives related to topical, transdermal and transmucosal drug products, under the GDUFA regulatory science program. Dr. Ghosh also leads the development of general and product-specific guidances, review strategies for industry meeting requests and citizen petitions. Prior to joining FDA, Dr. Ghosh completed her Bachelor's degree in Biotechnology from West Bengal University of Technology (India) and a Ph.D. in Pharmaceutics and Drug Design from the University of Kentucky.

Andre O'Reilly Beringhs, PhD
Staff Fellow
DTP I|ORS|OGD|CDER

Dr. Andre O'Reilly Beringhs is a pharmaceutical scientist specializing in pharmaceutics and regulatory affairs. He earned his Ph.D. in Pharmaceutical Sciences from the University of Connecticut in 2021, following Master's and Bachelor's degrees in pharmacy from the Federal University of Santa Catarina, Brazil. Dr. Beringhs has made significant contributions to the development of advanced drug delivery systems and nanotechnology-based therapeutics. Within FDA, Dr. Beringhs serves as a staff fellow/pharmacologist within the Office of Research and Standards, Office of Generic Drugs, where he applies his expertise to navigate complex regulatory and scientific issues pertaining to the therapeutic performance of complex ophthalmic and nanoparticle-based injectable products.

Renishkumar Delvadia, PhD
Senior Staff Fellow
DPQAVIII|OPQAII|OPQ|CDER

Dr. Renishkumar Delvadia is a pharmaceutical scientist with over a decade of regulatory and research experience at the U.S. Food and Drug Administration (FDA). His work spans drug development, regulatory review, and applied research in drug-device combination and complex products, with a particular focus on inhalation and nasal drug delivery systems. Dr. Delvadia currently serves as a Senior Reviewer in the Office of Pharmaceutical Quality, FDA. In this role, he evaluates the quality aspects of a wide range of drug products and frequently serves as the technical lead, with a focus on complex combination products, pulmonary therapies, abuse-deterrent formulations, and emergency-use drugs. Prior to his current position, Dr. Delvadia worked in the Office of Research and Standards within the Office of Generic Drugs, where he contributed to regulatory guidance development, pre-ANDA consultations, and research advancing bioequivalence methodologies for generic inhalation and nasal drug-device combination products. Dr. Delvadia earned his Ph.D. in Pharmaceutical Sciences from Virginia Commonwealth University, where his research focused on development of realistic in vitro models for in vivo prediction of regional aerosol drug deposition. He previously worked in R&D at Sun Pharmaceutical Advanced Research Centre, India, developing dry powder inhaler products. He has authored over 60 peer-reviewed publications, several scientific presentations, and has received multiple FDA awards for scientific and regulatory contributions.

Brandon Wood, BSc
Senior Director, Regulatory Affairs I & Combination Products Liaison
Teva Pharmaceuticals USA, Inc.

Mr. Brandon Wood is a Senior Director, Regulatory Affairs I & Combination Products Liaison for Teva Pharmaceuticals USA, Inc. In this role Brandon leads a group of regulatory professionals and oversees the filing of applications for generic parenteral products. He specializes in the development of generic applications for complex products such as peptides, oligonucleotides, iron colloids, long-acting injectables, and drug-device combination products. As the combination products liaison Brandon provides consultation on applications for drug-device combination products, mentors, and trains staff on drug-device combination product regulatory requirements, provides representation in cross-functional initiatives and strategy discussions specific to drug-device combination products, and communicates current affairs and trends in the drug-device combination product space to relevant departments within his organization. Brandon has been a regulatory professional for 12+ years and prior to joining Teva in 2018 served various regulatory and quality assurance R&D positions for CorePharma and Impax Laboratories working on both sterile and non-sterile products. Before starting his regulatory career Brandon worked as a chemist for West-Ward Pharmaceuticals supporting raw material and bulk release activities, analytical research projects, data review, and investigative writing. Brandon has a B.Sc. in Chemistry from Monmouth University (West Long Branch, NJ) with a specific concentration in Organic Chemistry.

Carla Vozone, PharmD, MBA
Vice President Specialty Drug Delivery
Catalent Pharma Solutions

Dr. Carla Vozone is Vice President of Specialty Drug Delivery at Catalent Pharma Solutions, where she leads the business segment of pulmonary and nasal delivery, and bioavailability technologies. Carla is responsible for Business Development and Commercial Operations and leads Inhalation Product Development. Carla holds a PharmD and MSc in Pharmaceutical Technology from the Pharmacy School, University of Lisbon, a Masters in Business Administration with a specialization in Pharmaceutical Management from Rutgers Business School, New Jersey. Carla is board member at IPAC-RS, the leading industry consortium on regulatory science of orally inhaled and nasal drugs, having served as Vice-Chair and Chair from 2019 to 2021.

Megan Conrad, PhD
Associate Professor of Mechanical Engineering
University of Detroit, Mercy

Dr. Megan Conrad is an Associate Professor of Mechanical Engineering at the University of Detroit Mercy. Her most recent research focuses on evaluating user interface design features and improving human factors assessments of drug-device combination products (DDCPs). Through an FDA-funded project, her research team developed a user interface design taxonomy and proposed modified comparative use human factors methods for gaining FDA approval of generic DDCPs. Dr. Conrad's other research interests center around assessing human performance in healthy and disabled populations as it pertains to therapy, work, and product design. She aims to identify device design features and therapeutic techniques allowing individuals to remain independent at home and work. Dr. Conrad earned a PhD in Biomedical Engineering from Marquette University. She also holds an MS in Systems Engineering from UPenn and a BS in Industrial Engineering from Marquette. She has received extramural funding as PI or co-I on projects supported by the AHA, FDA, NIH, and NSF. At Detroit Mercy, she leads the Eick Center for Assistive Technology, acts as Director of the Biomedical Design Program, and teaches courses related to Biomedical Engineering, Human Factors, and Product Design.

Mary Beth Privitera, MDes, PhD
Professor, Biomedical Engineering
University of Cincinnati

Dr. Mary Beth Privitera, M.Design, FIDSA, is a Professor at the University of Cincinnati's Department of Biomedical Engineering and works collaboratively among the Colleges of Medicine, Engineering and Design. She is Principal of Design & Human Factors for Sentiar, a medical device company specializing in augmented reality devices guiding physicians during cardiac ablation procedures with an interactive, real-time, 3D interface as well as a consultant to the medical device industry through Know Why Design, LLC. Additionally, she serves as faculty and co-chair of the Association for the Advancement of Medical Instrumentation's Human Engineering Committee. She has worked professionally as a consultant to the medical device industry for over 30 years on devices which are intended for use across the practice of medicine and intended for home use. Her current research focuses on applied ergonomics and design interpretation. She has conducted contextual inquiry studies internationally with results intended to inform the design. She has been involved in the development of surgical tools, diagnostic equipment, combination products, software as medical device, clinical decision support software, as well as intraprocedural augmented reality. Her research funding has been supported by NIH, the Gates Foundation and FDA CDER Division. She has authored many peer reviewed articles and books titled "Contextual Inquiry for Medical Device Design," promoting best practices for phase zero medical device development. Her 2nd book, edited and written in collaboration with AAMI Human Factors faculty is titled "Applied Human Factors in Medical Device Design." This book aims at bringing all references and best practices together in one resource compendium. Her current efforts include preparing the 2nd edition of this book intended for publication in 2026.

Russel Rackley, PhD
Global Head, Clinical Pharmacology
Viatris, Inc.

Dr. Russel Rackley is Global Head, Clinical Pharmacology, Viatris Inc. He has a demonstrated history of working in the pharmaceuticals industry and an understanding of global health authority expectations. He holds a BS in Pharmacy and a PhD in Pharmaceutics from the University of Tennessee, Memphis and has over 36 years of Industry experience in pharmaceutical development, including: 7 years as a research scientist at Ciba-Geigy Corporation in the departments of Biopharmaceutics and Clinical Pharmacokinetics; 5 years as Director of Biopharmaceutics at Purepac Pharmaceutical Co.; and the last 24 years at Viatris (formerly Mylan Pharmaceuticals Inc.). Areas of expertise include assisting in formulation development with respect to in vitro screening and relevance to in vivo performance, as well as design and reporting of clinical pharmacokinetic and bioequivalence studies. Experience includes supporting development of small to complex molecules, in simple to complex formulations, for oral, topical, transdermal, and injectable routes of delivery. Responsibilities include serving as a global resource for the development of products to be registered world-wide. More recent appointments include representative to the International Council for Harmonisation (ICH), on behalf of the International Generic and Biosimilar Medicines Association (IGBA), in the Generic Discussion Group to support development of bioequivalence guidance and serving as Topic Lead for IGBA within the ICH M13 Expert Working Group.

Robert (Bob) Berendt, PhD
Supervisory Chemist
DPQAV|OPQAI|OPQ|CDER

Dr. Robert (Bob) Berendt is a supervisory pharmaceutical scientist in the Office of Product Quality Assessment I (OPQA I) within the Office of Pharmaceutical Quality (OPQ). Dr. Berendt and members

of his unit are subject matter experts in quality assessment of generic drug-device combination products formulated as solid polymeric systems, including intravaginal and intrauterine systems, implants, and transdermal and topical delivery systems (TDS). In his role, he oversees and contributes to the risk-based assessment of controlled correspondence, pre-ANDA meeting requests, ANDA submissions, and Type IV DMFs. He and his work unit also participate in guidance development, regulatory science research, and working group activities associated with drug-de combination products. Prior to joining OPQ as a quality assessor, Dr. Berendt was a laboratory chemist in the FDA's Office of Testing and Research, supporting regulatory review and policy activities. He earned his doctorate in pharmaceutical chemistry from the University of Kansas, where he focused on solid-state characterization of pharmaceutically relevant systems using solid-state NMR spectroscopy.

Andrew Clerman, MD
Acting Lead Physician
DTP I|ORS|OGD|CDER

Dr. Andrew Clerman is a Senior Physician and Team Lead (acting) in OGD's Office of Research and Standards Division of Therapeutic Performance I where he leads the Device Evaluation Team. The Device Evaluation Team conducts pre-ANDA reviews and oversees research initiatives that involve drug-device combination product user interfaces. Before joining OGD, Andrew was a clinical reviewer in the Office of New Drugs Division of Pulmonology, Allergy and Critical Care. He maintains clinical board certifications in Internal Medicine, Pulmonary Disease, and Critical Care Medicine, and obtained a PhD in Molecular Microbiology and Immunology from the University of Maryland, Baltimore.

Lanyan (Lucy) Fang, PhD
Deputy Division Director
DQMM|ORS|OGD|CDER

Dr. Lanyan (Lucy) Fang serves as Deputy Director of the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards, Office of Generic Drugs (OGD), CDER/FDA. Dr. Fang leads OGD's modeling and simulation and data analytics program and has established herself as the FDA expert in the use of quantitative clinical pharmacology approaches in the review and regulation of generic drugs. Prior to her OGD career, Lucy worked as senior clinical pharmacology reviewer in the FDA's Office of Clinical Pharmacology and senior pharmacokineticist in Merck. Lucy obtained her PhD in Pharmaceutical Sciences from The Ohio State University and is a graduate of the Excellence in Government Fellows program (2014-2015).

Bing Li, PhD
Expert Pharmacologist & Associate Director for Science
OB|OGD|CDER

Dr. Bing Li serves as the Associate Director for Science for Office of Bioequivalence within the Office of Generic Drugs at CDER/FDA. In this role, she provides scientific leadership and expertise for the assessment of the bioequivalence studies submitted by pharmaceutical industry through Abbreviated New Drug Applications (ANDAs) and oversees the scientific programs including guidance development and implementation in Office of Bioequivalence. Dr. Li is an Expert Pharmacologist at the FDA in the area of bioequivalence of aerosolized drug products. Prior to joining FDA in 2004, she was a Research Investigator at Bristol-Myer-Squibb where her responsibilities included formulation identification, development, and optimization for oral solid dosage form formulations. Dr. Bing V. Li received her Ph.D. in Pharmaceutical Sciences from University of Wisconsin at Madison in 2001, and a bachelor's degree in Medicinal Chemistry in 1990 in Beijing University, China

Kimberly Witzmann, MD
Deputy Director
Office of Safety and Clinical Evaluation (OSCE)|OGD|CDER

Dr. Kimberly Witzmann is a physician, and the Deputy Director for the Office of Safety and Clinical Evaluation within the Office of Generic Drugs (CDER), at FDA. The Office of Safety and Clinical Evaluation (OSCE) addresses issues related to clinical safety, substitutability, and therapeutic equivalence throughout the generic product's lifecycle. As the Deputy Office Director, Dr. Witzmann is responsible for concentrating on complex, long-range and emerging issues impacting the clinical evaluation of generic drug products in ANDAs; she serves as the authority on clinical review considerations and complex combination products. She is committed to making safe and effective generic drugs available to the American public. Dr. Witzmann has been with OGD for more than 10 years, also serving as the acting Deputy Director in the Office of Bioequivalence (OB), and before that, as the team leader for the inhalation, nasal, and generic drug-device combination products team, in the Office of Research and Standards. During her time in OGD, Dr. Witzmann has focused on communications with industry regarding complex drug product development. She has spoken at national meetings discussing user interface considerations for complex generic combination products, as well as development for generic orally inhaled and nasal combination drug products; she has been a co-author on several medical articles published in peer-reviewed journals that discuss the scientific and regulatory challenges and opportunities associated with complex generic product development. She has been with FDA-CDER for almost 16 years, having spent her first 5 years in CDER's Office of New Drugs. Prior to joining FDA in 2009, Dr. Witzmann was an assistant Professor of pediatrics at Children's National Medical Center in Washington, DC, where she practiced pediatric pulmonology. She has prior experience as an expert lecturer and member of medical advisory boards and has served as a primary investigator on several clinical research protocols involving lung diseases.

Robert Lionberger, PhD
Director
ORS|OGD|CDER

See biography above.

Closing Remarks for Day 1

Ahmed Zidan, PhD
Senior Research Pharmacologist
DPQRV|OPQR|OPQ|CDER

See biography above.

Fiscal Year (FY) 2025 Generic Drug Science and Research Initiatives Public Workshop Speaker, Panelist, And Moderator Biographies

In order of appearance on Agenda

Day 2

Session 4

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

Dongmei Lu, PhD
Associate Director of Regulatory Sciences
DTPII|ORS|OGD|CDER

Dr. Dongmei Lu obtained her PhD degree in Pharmaceutical Sciences from University of North Carolina at Chapel Hill. Her extensive industry experience includes pre-formulation and formulation at GlaxoSmithKline, Wyeth, and Pfizer. Dr. Lu served as a reviewer and team leader in the Office of Bioequivalence within the Office of Generic Drugs before transitioning to the Office of Policy for Pharmaceutical Quality in OPQ. There, she developed numerous policies, notably the guidance for nitrosamine-impacted products. Currently, Dr. Lu oversees the research portfolio and activities in DTPII/ORS. Dr. Lu's expertise is recognized widely, as evidenced by her role as an FDA Expert supporting ICH M13A and 13B global harmonization efforts. She is also a member of the FDA Biopharmaceutic Classification Systems Committee. Additionally, Dr. Lu contributes to several professional organizations, serving as a member of the PQRI Biopharmaceutics Technical Committee, FDA Liaison for USP nitrosamine and relevant research areas, and as an Editorial Advisory Board Member for the journal of AAPS Open.

Nilufer Tampal, PhD
Associate Director
OB|OGD|CDER

Dr. Nilufer Tampal is the Associate Director for Scientific Quality in the Office of Bioequivalence (OB) within the Office of Generic Drugs (OGD). In this role, Dr. Tampal develops strategies and oversees implementation of data quality and the scientific integrity of bioequivalence data submitted in ANDAs. She is the subject matter expert in Bioanalytical Methods and Data Integrity in OGD, among other areas of generic drugs and has held various leadership positions in OB for the last 15 years. Dr. Tampal represents the FDA as the Topic Leader on the ICH M13A, M13B, and M13C Expert Working Groups for developing the harmonized M13 guideline. As the Rapporteur for the ICH Generic Drug Discussion Group, she facilitated the identification and scoping of bioequivalence topic areas for harmonized guidelines on solid oral IR and MR dosage forms. Dr. Tampal received her Ph.D. in Toxicology from the University of Kentucky.

Girish Nihalani, M.S
Associate Director, Product Development
Hikma Pharmaceuticals USA Inc

Mr. Girish Nihalani is an Associate Director of Formulation Development at Hikma Pharmaceuticals USA Inc. based at Columbus, Ohio where he leads Formulation Development Team for Development of ANDA, NDA and value proposition products. Prior to joining Hikma, he has worked at leading organizations such as Teva, Cipla, Dr. Reddy’s, FDC, Inventia. He has over 20 years of experience in

the pharmaceutical industry in formulation development and process scale up specifically modified release solid oral dosage forms. Mr. Nihalani earned his Masters Degree in Pharmaceutical Sciences from Bombay College of Pharmacy, Mumbai University in 2005. He has developed multiple drug products as ANDA such as bi-layer tablets, Amorphous Solid Dispersions, ER/DR Pellets, matrix based systems, nanotechnology, MUPS, abuse deterrent, etc. He has specific interest in in-vitro in-vivo correlations for BCS class II and IV drugs. He has played a critical role in responding to deficiency letters to support regulatory decision making for ANDA. Mr. Nihalani to his name has multiple publications including patent applications. He is a member of AAPS and serves as reviewer of peer reviewed journals. In his free time, Mr. Nihalani enjoys playing tennis and swimming.

Geoff G. Z. Zhang, PhD, FAAPS
Founder &Chief Technical Director
ProPhysPharm LLC

Dr. Geoff G. Z. Zhang is the Founder and Chief Technical Director of ProPhysPharm; an adjunct professor of the Department of Industrial and Molecular Pharmaceutics (IMPH) at Purdue University since 2016; and a Fellow of American Association of Pharmaceutical Scientists since 2011. He has contributed broadly to Physical Pharmacy, specifically in the areas of salt and polymorph screening, co-crystallization and crystal engineering, characterization and crystallization of amorphous solids, physical chemistry of supersaturated solutions and the design of amorphous solid dispersions. He has published 124 peer-reviewed articles, reviews, and book chapters; given 77 invited talks at conferences, universities, pharmaceutical companies, and FDA; and presented 157 posters. Prior to founding ProPhysPharm in 2024, he spent 26 years at Abbott/AbbVie. He is a co-inventor of over 170 patents/applications including composition of matter, crystal form, formulation, processing, and method of use on clinical candidates and marketed products. He received his B.Sc. in Physical Chemistry from Fudan University, and Ph.D. in Pharmaceutics from University of Minnesota Twin Cities.

Sivacharan Kollipara, MS
Head, Biopharmaceutics
Dr. Reddy's Laboratories Ltd., India

Mr. Sivacharan Kollipara is currently working as Head, Biopharmaceutics department in the Global Clinical Management group, IPDO at Dr. Reddy’s Laboratories Limited (DRL), Hyderabad. He is responsible for biopharmaceutics evaluation, bioequivalence risk assessment, and bioequivalence prediction for conventional as well as complex generic products at DRL. He is also involved in PK modeling and simulations activities supporting generic drug development of various immediate release, modified release, and complex products at DRL and involved in utilizing novel PBPK and PBBM modeling approaches for regulatory justifications for various markets. Prior to joining DRL, Mr. Kollipara was Principal Scientist (Global Pharmaceutical Development) at Novartis Healthcare Pvt Ltd., Hyderabad. Previously he also has been associated with Ranbaxy Research Laboratories, Gurgaon (Metabolism and Pharmacokinetics). He obtained Masters in Pharmaceutical Sciences from BITS, Pilani, Rajasthan, India and currently pursuing Ph.D. Mr. Kollipara is also Chair Person, Scientific Planning Committee for SOPHAS (Society of Pharmacometrics & Health Analytics). Overall Mr. Kollipara has an experience of 18 years in the field of drug discovery, development and generic product development, bioanalytical method development and validation, PK data modelling and simulations. He has authored/co-authored more than 40 peer-reviewed publications and is scientific reviewer for many peer-reviewed journals. His research interests include PBPK/PBBM modeling, virtual bioequivalence simulations, IVIVC/R, drug-drug interactions, dissolution/bioequivalence safe space, bio-predictive dissolution methodologies, biowaivers, novel statistical tools for dissolution similarity analysis and food effect evaluations.

Sandip Tiwari, PhD
Head of Technical Services, Pharma Solutions NA
BASF Corporation

Dr. Sandip B. Tiwari is an accomplished leader in the pharmaceutical industry with over 25 years of experience, currently serving as the Head of Technical Services – Pharma Solutions North America at BASF. In this pivotal role, he leads innovative efforts to provide advanced solutions that address complex formulation and processing challenges for (bio)pharmaceutical companies. His career spans diverse roles at major companies, including Teva Pharmaceuticals, Actavis, Allergan, Colorcon Inc., and Zydus Cadila as well as academic engagements at Northeastern University, Boston, MA. Dr. Tiwari has made substantial contributions to pharmaceutical science, authoring a highly regarded Desk Book of Pharmaceutical Dissolution Science, alongside nine book chapters and monographs, and over 100 research publications, abstracts, and patents. His expertise encompasses dosage form design, scale-up of formulations, dissolution science, mathematical modeling, excipients, and new drug delivery technologies. Recognized for his expertise, Dr. Tiwari has been appointed as Vice Chair of the American Association of Pharmaceutical Scientists (AAPS) In Vitro Release & Dissolution Testing (IVRDT) Community for 2025. He will transition to Chair in 2026 and Past Chair in 2027.

Yuqing Gong, PhD
Senior Pharmacologist
DQMM|ORS|OGD|CDER

Dr. Yuqing Gong is currently a Senior Pharmacologist at the Quantitative Clinical Pharmacology Team in the Division of Quantitative Methods and Modeling, Office of Research and Standards, Office of Generic Drugs, Center for Drug Evaluation and Research/FDA. Her research focuses on utilizing quantitative tools such as population pharmacokinetics, modeling and simulations, to address specific questions relate to generic drug development process and/or regulatory decision making. Before joining the FDA, she received comprehensive trainings in pharmaceutical sciences with focuses on drug delivery, pharmacokinetics, and drug-drug interactions. Dr. Gong received her Ph.D. degree in Pharmaceutical Sciences at the University of Tennessee Health Science Center (Memphis, TN, US) in 2020. Her Ph.D. thesis work was to develop a nanoformulation for antiretroviral drugs to suppress the viral load in the central nervous system across the blood-brain barrier.

Emilija Fredro-Kumbaradzi, PhD
Director, Biopharmaceutics and Statistics, Global R&D
Apotex Inc.

Dr. Emilija Fredro-Kumbaradzi is Director of Biopharmaceutics and Statistics at Apotex. She is responsible for Biopharmaceutics aspects in the development of generic drug products. Her work spans dissolution science, in vitro comparisons, in silico modeling, and biowaiver justifications, ensuring alignment with global regulatory standards. She also oversees clinical research activities related to bioequivalence studies and clinical study design, with a focus on regulatory strategy and scientific integrity. With over 20 years at Apotex, Dr. Fredro-Kumbaradzi brings extensive experience in the biopharmaceutic evaluation of solid oral dosage forms. She holds a Ph.D. in Pharmaceutical Sciences from the University of Skopje, Macedonia, where she previously served as a Professor of Pharmaceutical Technology.

Russell J. Rackley, PhD
Global Head, Clinical Pharmacology
Viatris Inc.

See biography above.

Hazem Ali, PhD
Senior Chemist
DPQAII|OPQAI|OPQ|CDER

Dr. Hazem Ali is a review chemist in the Office of Product Quality Assessment I/OPQ/FDA since 2014. Before joining the FDA, he had over 15 years of research experience on utilization of statistical modeling and experimental designs for formulation development and characterization of modified-release solid oral dosage forms, self-emulsifying drug delivery systems, and nanoparticles. He is a recipient of postdoctoral scholarship at the University of Texas Medical Branch where he developed drug-loaded polymeric nanoparticles and studied their passage across in vitro models of placental tissues. His research was funded by T32 grant from the National Institutes of Health, and he is a recipient of postdoctoral fellowship at the University of California San Diego where he developed enzyme-loaded silica nanoparticles and studied their effects on in vitro models of ovarian cancer. Dr. Ali has Bachelor of Pharmacy from Mansoura University, Egypt and Ph.D. in Pharmaceutics from University of Louisiana at Monroe, USA.

Bhagwant Rege, PhD
Division Director
DPQAVI|OPQAI|OPQ|CDER

Dr. Bhagwant Rege is the Division Director for Biopharmaceutics in CDER/OPQ/OPQA I at the FDA. His division at FDA is responsible for assessment of clinically relevant in vitro release specifications for drug products, in vitro-in vivo correlations (IVIVC), physiologically-based biopharmaceutics models (PBBM), scientific bridging strategies, biowaivers, and BCS classification requests. Prior to his current position, he served as a Division Director for CDER/OPQ/OLDP/ Division of Immediate and Modified Release Products III. Before joining the FDA in 2010, he worked in industry for many years in oral biopharmaceutics and formulation development groups. Bhagwant has served as a team leader and review chemist in the Office of Generic Drugs where he was part of the team that developed the QbD examples for the generic industry. He is a member of the FDA Emerging Technology Team (ETT) and ICH Q12 Expert/Implementation Working Group. He served as FDA liaison on the USP expert committee on dosage forms general chapter (2015-2020). Bhagwant received his BS and MS in pharmacy from the University of Mumbai, India and a Ph.D. in Pharmaceutical Sciences from the University of Maryland, Baltimore.

Diana Vivian, PhD
Associate Division Director
DBII|OB|OGD|CDER

Dr. Diana Vivian joined the Division of Bioequivalence II (DBII) in 2014 and has served as the Associate Director of DBII since 2019. Dr. Vivian has bioequivalence interests in diverse areas such as complex topical dosage forms, nasal and inhalation products, and the Biopharmaceutics Classification System (BCS). She is currently the co-chair of the CDER-wide BCS Committee. She received her Bachelor of Science degree in Chemical Engineering from the University of Maryland, College Park and her Ph.D. in Pharmaceutical Sciences from the University of Maryland, Baltimore.

Fang Wu, PhD
Senior Pharmacologist
DQMM|ORS|OGD|CDER

Dr. Fang Wu is a senior pharmacologist reviewer and scientific lead for oral Physiologically-based Pharmacokinetic modeling in Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS), Office of Generic Drugs (OGD) in FDA. Dr. Wu has been with FDA for more than 13 years. She is responsible for using modeling and simulations tools for reviewing pre-abbreviated new drug applications (pre-ANDA) meeting packages, ANDA consults and controlled correspondences. Prior to joining DQMM, Dr. Fang Wu was a biopharmaceutics reviewer for more than 4 years and responsible for NDA and ANDA reviews. She has been a principal and co-principal investigator for multiple FDA research projects and involved in several guidance working groups and grant review panels.

Lei K. Zhang, PhD
Deputy Director
ORS|OGD|CDER

Dr. Lei Zhang is the Deputy Director of the Office of Research and Standards (ORS) in the Office of Generic Drugs (OGD) at the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER). In this role, she oversees the implementation of the GDUFA science and research program, supporting the development and approval of therapeutically equivalent generic drug products. Dr. Zhang brings over 26 years of experience in drug research, development, and regulatory review. Prior to her current position, she served as Senior Advisor for Regulatory Programs and Policy in the Office of Clinical Pharmacology at CDER. She has played a pivotal role in advancing regulatory science through her contributions to numerous guidance documents and research initiatives. Before joining the FDA in 2002, Dr. Zhang was a Research Investigator and Team Leader at Bristol Myers Squibb. She earned her Ph.D. in Biopharmaceutical Sciences from the University of California, San Francisco (UCSF), where she currently serves as an Adjunct Professor in the Department of Bioengineering and Therapeutic Sciences. Dr. Zhang is currently the Rapporteur for the ICH M13 Expert Working Group, leading the development of harmonized guidelines on bioequivalence for immediate-release solid oral dosage forms (M13A, M13B, and M13C). She previously served as the U.S. FDA Topic Lead for the ICH Generic Drug Discussion Group (GDG). Dr. Zhang was inducted as a Fellow of the American Association of Pharmaceutical Scientists (AAPS) in 2013. She has authored more than 140 peer-reviewed publications and book chapters. Her work continues to shape regulatory policy and enhance access to high-quality generic medicines.

Qi Zhang, PhD
Lead Pharmacologist
DTPII|ORS|OGD|CDER

Dr. Qi Zhang is a Lead Pharmacologist at the U.S. Food and Drug Administration (FDA), currently serving as the Immediate Release Drug Product Team Leader in the Division of Therapeutic Performance II within the Office of Research and Standards (ORS) at the Center for Drug Evaluation and Research (CDER). With over 9 years of experience at the FDA, Dr. Zhang has established herself as an expert in Biopharmaceutics and Pharmacokinetics (PK). Her expertise spans a wide range of areas, including the Biopharmaceutics Classification System (BCS), bioequivalence, biowaiver and bridging strategies, dissolution/drug release of high-risk drug products, and complex drug products including GI locally acting formulations and extended-release depot injections. Dr. Zhang leads a multidisciplinary team responsible for regulatory reviews, product-specific guidance (PSG) development, and research related to immediate release drug products. A key contributor to the implementation of ICH M13A guidance, Dr. Zhang has led efforts in developing data analytics tools

to expedite provisional BCS classification and created a Biopharmaceutics risk assessment framework. Her work has been crucial in supporting FDA's commitment to science-based regulatory harmonization. Prior to her current role, Dr. Zhang served as a Senior Biopharmaceutics Reviewer in the Office of New Drug Products within the FDA. Her experience also includes academic positions at Tulane University School of Medicine and Indiana University School of Medicine. Dr. Zhang holds a Ph.D. in Pharmacology from Huazhong University of Science and Technology, where she also earned her M.Sc. in Pharmaceutical Chemistry and B.Sc. in Pharmaceutical Science.

Session 5

Challenges and Opportunities for Modified Release Generic Products

Dongmei Lu, PhD
Associate Director
DTPII|ORS|OGD|CDER

See biography above.

Nilufer Tampal, PhD
Associate Director
OB|OGD|CDER

See biography above.

James E. Polli, PhD
Co-Director, Center for Research on Complex Generics (CRCG)
Professor, University of Maryland

Dr. James Polli is Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics at University of Maryland. His research interest is oral drug absorption, involving laboratory and clinical research. A major focus in the last several years is poorly water soluble drugs, with studies on amorphous solid dispersion formulation, surfactant-mediated drug dissolution, and characterization of a hollow fiber system as a part of a dissolution/permeation system. He has served as the advisor to 25 PhD graduates and is Director of the online University of Maryland M.S. in Regulatory Science program. He is co-Director of the Center for Research on Complex Generics. He is a fellow of the American Association for Pharmaceutical Scientists (AAPS) and served as an editor of Pharmaceutical Research for 12 years.

Jie Shen, PhD
Associate Professor of Pharmaceutical Sciences
Northeastern University

Dr. Jie Shen is currently an Associate Professor in the Department of Pharmaceutical Sciences at Northeastern University. She earned her Ph.D. in Pharmaceutical Sciences from China Pharmaceutical University, Nanjing, China. Dr. Shen's research centers on the development and characterization of complex drug formulations, bioequivalence assessment strategies, and in vitro-in vivo correlation (IVIVC). Her work spans a range of complex dosage forms, including nanocarriers, long-acting injectables/implants, locally-acting semisolids, and modified-release oral formulations, targeting hard-to-treat conditions such as cancer, infectious diseases, substance use disorders, and ocular diseases.

She has received several prestigious honors, including the IPEC-Americas Foundation Emerging Researcher Award and the 2025 Gerald Schumacher Pharmacy Faculty Award. She previously serves as Chair of the AAPS In Vitro Release and Dissolution Testing Community and the Controlled Release Society's (CRS) Diversified Products: Delivery Beyond Pharma (C&DP) Division. She also serves on the editorial boards of several leading peer-reviewed journals.

Lieke van den Elsen, PhD
Scientific Advisor
InnoGI Technologies

Dr. Lieke van den Elsen has a background in Pharmaceutical Sciences and obtained her PhD in Immunopharmacology at Utrecht University (Utrecht, The Netherlands). After 10 years of postdoctoral training in New Zealand and Australia, Lieke joined InnoGI Technologies (Delft, The Netherlands) in 2023. As a Scientific Advisor at InnoGI Technologies, she oversees multiple projects in the field of drug development, collaborating closely with customers in the pharmaceutical industry.

Charles E. DiLiberti, MS
President
Montclair Bioequivalence Services, LLC

Mr. Charlie DiLiberti has over 40 years' experience in the pharmaceutical industry, much of which (17 years) was at Barr Laboratories (later acquired by Teva Pharmaceuticals). Charlie built and oversaw Barr's bioequivalence and pharmacokinetics program for generic drugs, small molecule proprietary drugs, and biologics. Charlie left his position as Vice President of Biopharmaceutics at Teva Women's Health Research in 2010 to start his own firm, Montclair Bioequivalence Services, LLC, which provides consulting services around the world in generic, innovative, and biological drug development. Charlie has given numerous public presentations, in the US and internationally, on a wide variety of topics. In 2018, along with several colleagues, Charlie co-founded Scientists Advancing Affordable Medicines, Inc. (SAAMnow®). Charlie holds a BA in Biochemical Sciences from Princeton University and an MS in Chemistry from Stevens Institute of Technology.

Karunakar (Karu) Sukuru, RPh, PhD
Global Vice President, Pharma Product Development & Head-Scientific Advisory
Catalent Pharma Solutions

Dr. Karunakar Sukuru is a distinguished leader in the pharmaceutical industry, with over three decades of experience in Drug Product and Technology Development. At Catalent, he oversees the development of small molecule Rx products, guiding a team of over 850 scientists across 14 sites on four continents. Karu's role involves managing a robust pipeline of 100s of new molecules, utilizing diverse drug delivery technologies including Lipid Based Drug Delivery Systems (LBDDS). Karunakar has a proven track record in product development and technical oversight of numerous Contract Development and Manufacturing Organizations (CDMOs) globally. He has developed patented innovative controlled-release platform technologies in softgel dosage forms using LBDDS. He holds several granted patents and has over 20 pending patent applications, particularly in modified shell, fill technologies and lyophilization techniques for biologic products. Before joining Catalent in 2016, Karunakar held key positions at Endo Pharmaceuticals, Banner Pharmacaps (in India and USA), and Natco Pharma in India, demonstrating his extensive leadership in the field. He is actively involved in professional organizations, including the American Association of Pharmaceutical Scientists (AAPS), Controlled Release Society (CRS), Society for Pharmaceutical Dissolution Science (SPDS), and serves as an expert committee member at USP, for the last 10 years where he contributes to setting pharmaceutical standards. Karunakar obtained his M.Pharm., Ph.D., in Pharmaceutical Technology

from Indian Institute of Technology, Banaras Hindu University, India. He is also a registered Pharmacist (R.Ph.) in Delaware, USA.

Stephen W. Hoag, PhD
Professor
University of Maryland, Baltimore

Dr. Stephen Hoag is a professor at the University of Maryland, Baltimore School of Pharmacy. His research focuses on oral delivery systems, controlled release polymers, and excipient functionality. He is also involved in stability and excipient testing, 3D printing, and developing abuse deterrent formulations (ADF). He frequently uses Raman and Near-Infrared (NIR) spectroscopy in Process Analytical Technology (PAT) applications. Dr. Hoag directs the School of Pharmacy's GMP facility and is a member of several groups, including NIPTE, the Steering Committee for the Handbook of Pharmaceutical Excipients, and the editorial board of the Journal of Pharmaceutical Development Technology. He is also an AAPS Fellow.

Manar Al-Ghabeish, PhD
Senior Pharmacologist
DTPII|ORS|OGD|CDER

Dr. Manar Al-Ghabeish serves as a senior pharmacologist in the Division of Therapeutic Performance II within the Office of Research and Standards (ORS) of the Office of Generic Drugs (OGD). As a member of the modified release oral team in ORS/OGD, Dr. Al-Ghabeish contributes to the development and revision of product-specific guidance for modified oral drug products. Additionally, she reviews and responds to internal consultations, pre-ANDA meeting requests, and controlled correspondences pertaining to the demonstration of bioequivalence in generic drugs. Dr. Al-Ghabeish also functions as the project officer for several regulatory science research initiatives focused on oral solid drug products. Prior to her current role in OGD, Dr. Al-Ghabeish held positions as a Regulatory Research Scientist and Product Quality Assessor in the Office of Pharmaceutical Quality Research (OPQR) within the Office of Pharmaceutical Quality (OPQ). Her research endeavors concentrated on abuse-deterrent formulations, locally acting gastrointestinal drugs, and the characterization of complex drug products. Dr. Al-Ghabeish obtained her B.S. in Pharmacy and M.S. in Pharmaceutical Sciences from the University of Jordan. She subsequently earned her Ph.D. in Pharmaceutics from the University of Iowa.

Yuqing Gong, PhD
Senior Pharmacologist
DQMM|ORS|OGD|CDER

See biography above.

Likan Liang, PhD
Supervisory Pharmaceutical Scientist
DPQAX|OPQAII|OPQ|CDER

See biography above.

Hailing Zhang, PhD
Division Director
DPQAXII|OPQAII|OPQ|CDER

See biography above.

Zhen Zhang, PhD
Master Pharmacologist
DBI|OB|OGD|CDER

Dr. Zhen Zhang is a Master Pharmacologist in the Division of Bioequivalence I, Office of Bioequivalence, within the FDA's Office of Generic Drugs (OGD). His extensive expertise includes data analysis, modeling and simulation, dissolution studies, and topical product evaluations. Dr. Zhang leads efforts to modernize data analysis tools within the Office of Bioequivalence, significantly enhancing the efficiency of bioequivalence reviews. He also co-leads OGD's Oral PBPK Expert Committee. Over the course of his career, Dr. Zhang has addressed complex bioequivalence challenges and played a key role in the development of several FDA general guidances. For his significant contributions, Dr. Zhang has received many individual and group awards at both the FDA and CDER levels. Dr. Zhang earned his Ph.D. in Pharmacology from the University of Wisconsin-Madison.

Ahmed Zidan, PhD
Senior Research Pharmacologist
DQPRV|OPQR|OPQ|CDER

See biography above.

Wrap-Up & Closing

Anna Schwendeman, PhD
Co-Director, CRCG
Professor, University of Michigan

Dr. Anna Schwendeman is the Larry and Ann Hsu Professor of Pharmacy and Pharmaceutical Sciences and department Chair at the University of Michigan. Her research focuses on optimizing high-density lipoprotein (HDL) nanoparticles for the treatment of atherosclerosis, sepsis, and drug delivery purposes. In 2016, she cofounded EVOQ Therapeutics (www.evoqtherapeutics.com), a company focused on using HDL nanodiscs to deliver immunotherapies to improve the lives of individuals fighting autoimmune diseases. Dr. Schwendeman received her B.S. from Moscow Institute of Physics and Technology and her Ph.D. in Pharmaceutics from The Ohio State University. Prior to starting her academic career in 2012, Dr. Schwendeman spent 12 years in the pharmaceutical industry at Cerenis Therapeutics, Pfizer, and Esperion Therapeutics. She was involved in discovering and translating HDL drugs for clinical trials. She successfully submitted FDA INDs for seven different products, including nanoparticles, liposomes, recombinant proteins, peptides, and small molecules. Her laboratory's research in regulatory sciences focuses on the analytical characterization of liposomes, polymer microspheres, peptides, and biosimilar products. Dr. Schwendeman is a co-Director of the FDA-sponsored Center for Research in Complex Generics (CRCG, http://www.complexgenerics.org) and an Associate Editor for Nanomedicine NBM and Eur. J. Pharm and Biopharm.

Robert Lionberger, PhD
Director
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See biography above.