Fiscal Year (FY) 2026 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

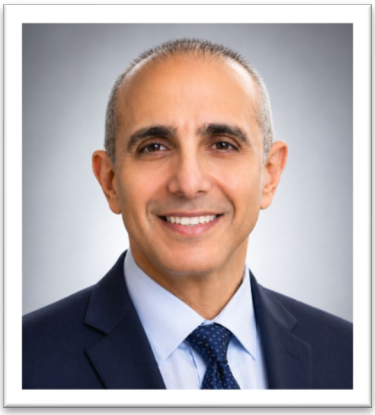
ORS|OGD|CDER|FDA

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.

Ahmed Zidan, PhD

Senior Research Pharmacologist

DPQR V|OPQR|OPQ|CDER|FDA



Dr. Ahmed Zidan is Senior Research Pharmacologist in the Office of Pharmaceutical Quality (OPQ), Center for Drug Evaluation and Research (CDER), U.S. FDA, serving as a subject matter expert supporting OPQ and the Office of Generic Drugs (OGD) in research and assessment activities. His work focuses on advancing risk-based, mechanistic bioequivalence approaches that integrate in vitro performance, pharmacokinetics, and quality attributes to inform regulatory decision-making. He contributes to cross-functional initiatives including predictive dissolution and in vitro–in vivo linkage, alternative BE approaches, lifecycle quality assessment, and AI/ML applications. Dr. Zidan has authored many OPQR research reports, and over 120 peer-reviewed publications and has led FDA research on complex topical, oral, and inhalation products and advanced manufacturing, contributing to regulatory guidances and science-based assessment strategies for innovative and generic drug development.

Alyson Bancroft, MPH
Director of Legislation, Policy & Alliances,
Patients for Affordable Drugs NOW

Ms. Alyson Bancroft spearheads the policy portfolio of Patients For Affordable Drugs. Her expertise guides the team's work on legislative and regulatory proposals to make prescription drugs more affordable. Aly joined P4AD from Health GAP, where she led the organization's engagement with Congress and the Executive Branch, pushing for global access to quality HIV care. Previous roles in health advocacy bolstered her insights for coalition building and lowering drug prices. Early in her career, Aly coordinated diabetes camps in Haiti, the Dominican Republic, and the United States. Additionally, she served as an AmeriCorps VISTA at the Medicare Rights Center. Aly completed six years on the Board of Directors for Universities Allied for Essential Medicines. She currently sits on the Community Advisory Panel for the Medicines Patent Pool. She has lived with type one diabetes for over 30 years and holds a Master of Public Health from the University of North Carolina at Chapel Hill

Darby Kozak, PhD
Deputy Director
OGD|CDER|FDA

Dr. Darby Kozak is the Deputy Director for the Office of Generic Drugs (OGD) where he serves as a senior agency advisor in the development and implementation of FDA policies and long-range objectives for generic drug scientific programs and activities, including the development of a strategic plan for the Generic Drug Program. Dr. Kozak started his FDA career in April 2015 as a reviewer, team lead, and then deputy division director in OGD's Office and Research and Standards where he helped develop new analytical methods and equivalence evaluation methodologies for complex generic drug substances and parenteral, ophthalmic, otic, and inhalation formulations. Prior to joining the FDA, Dr. Kozak was Chief Scientist for Izon Science and Research Fellow at The University of Queensland's Australian Institute for Bioengineering and Nanotechnology. Dr. Kozak has a B.Sc. in Chemical Engineering from the University of Washington (Seattle, WA) and Ph.D. in Chemistry from the University of Bristol (United Kingdom).

Sau (Larry) Lee, PhD
Deputy Office Director
OPQ|CDER|FDA

Dr. Lee is currently Deputy Super Office Director for Pharmaceutical Quality who oversees research, quality surveillance, policy, and quality assurance functions in CDER's Office of Pharmaceutical Quality. Dr. Lee has been with the FDA since 2005, serving as a regulatory scientist, team lead, Associate Director for Science, Deputy Office Director, Office Director, and Deputy Super Office Director of Science. He has provided exemplary leadership in developing OPQ science, research and testing programs to support quality assessment, inspection, surveillance, and policy. In 2016, Dr. Lee was appointed to the Senior Biomedical Research Service (SBRS) because of his extensive regulatory and scientific contributions to manufacturing science, complex drug substances and products, and emerging pharmaceutical technologies. Prior to joining the FDA, Dr. Lee received a B.S. degree in Chemical Engineering from the University of Virginia with a minor in Materials Science and a Ph.D. in Chemical Engineering from Princeton University.

Robert Lionberger, PhD
Director
ORS|OGD|CDER|FDA

Dr. Robert Lionberger serves as Director of the Office of Research and Standards (ORS) in the Office of Generic Drugs (OGD). Dr. 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 meetings, product specific guidance and correspondence responses. He received his undergraduate degree from Stanford University in Chemical Engineering, and a PhD from Princeton University in Chemical Engineering. After his PhD, he conducted post-doctoral research in Australia in the Department of Mathematics and Statistics at the University of Melbourne. Prior to joining the FDA 23 years ago, he was an Assistant Professor of Chemical Engineering at the University of Michigan.

Session 1

Addressing Ongoing Challenges with Nitrosamines Impurities

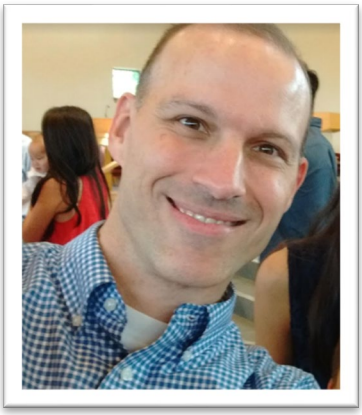
Dongmei Lu, PhD
Associate Director
DTP II|ORS|OGD|CDER|FDA

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 on oral dosage forms in bioequivalence perspective 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*.

Huzeyfe Yilmaz, PhD
Supervisory Pharmaceutical Scientist (Acting)
DPQR II|OPQR|OPQ|CDER|FDA

Dr. Huzeyfe Yilmaz is a Supervisory Pharmaceutical Scientist in the Division of Pharmaceutical Quality Research (DPQRII) within Office of Pharmaceutical Quality. At FDA, Dr. Yilmaz has led numerous research initiatives focused on pharmaceutical characterization and served as a subject matter expert in various working groups and committees. He received his PhD degree in Material Science from Washington University in St. Louis.

Robert Dorsam, PhD
Division Director
DPTR|OSCE|OGD|CDER|FDA



Dr. Robert (Bob) Dorsam is Director for the Division of Pharmacology/Toxicology Review (DPTR) which is responsible for the safety assessment of impurities and excipients in generic drugs. Bob earned his Ph.D. in Pharmacology from Temple University School of Medicine and conducted postdoctoral research at the National Institutes of Health (NIH). He joined the FDA where he performed Pharm/Tox review for oncology products and over-the-counter (OTC) products in the Office of New Drugs (OND). He then joined the Office of Generic Drugs (OGD) where he held various leadership roles and helped to build OGD's Pharmacology/Toxicology team. As Director of DPTR, Bob is committed to advancing several technical areas of Pharm/Tox review, promoting process-improvement, and contributing to innovations in review tools. Bob has been a member of the CDER Nitrosamine Task Force since its inception. He has presented on nitrosamines in various forums and is also an active member of review teams that conduct safety assessments on nitrosamines.

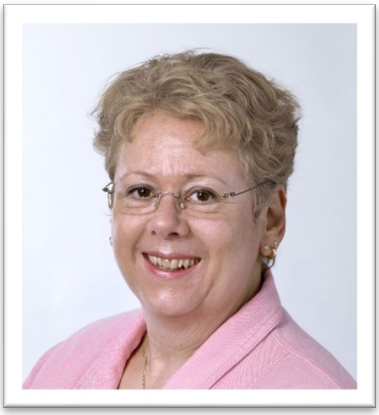
Robert Jolly, CPH, MPH, DABT
Senior Advisor, Risk Assessment, Toxicology
Lilly Research Labs

Dr. Bob Jolly graduated with a degree in pharmacology and toxicology from the University of Wisconsin, Madison. He later received a CPH and an MPH in Environmental Science from the University of Indiana. Bob has worked in the field of Toxicology for over thirty years starting his career in investigative toxicology and moving to human health risk assessment toxicologist in 2010. He is currently a Senior Advisor in the Toxicology group at Eli Lilly and Company where he has worked since 2002. He is a "Diplomate of the American Board of Toxicology (DABT)" with certification since 2012. Bob has coauthored over 50 peer reviewed publications and most recently has published several manuscripts on the toxicology of nitrosamines.

Joel Bercu, PhD, MPH DABT
Executive Director
Gilead Sciences

Dr. Joel Bercu MPH, DABT is an Exec. Director in the Nonclinical Safety and Pathobiology group at Gilead Science and has over 25 years of public health / toxicology experience in pharmaceuticals. His mission while at these positions is to protect the safety of staff, patients, and the environment. He leads the Environmental and Occupational Toxicology (EOT) group at Gilead. Part of the remit of the of the EOT group is pharmaceutical safety impurity assessments (including mutagenic / carcinogenic impurities), QSAR assessments of impurities for ICH M7 compliance, and the safety evaluation of potential nitrosamine impurities. Prior to joining Gilead Sciences, he has worked at Eli Lilly and Amgen. He is a member of the Society of Toxicology and the Risk Assessment, Occupational and Public Health (where he served as President, and Endowment Steward), Computational Toxicology and Medical Devices Specialty Sections, and American College of Toxicology (ACT). He is currently on the ICH M7 Nitrsoamine Addendum Expert Working Group (EWG) and leads several external committees such as chairing the IQ/Drusafe Impurities Working Group and leading the Nitrosamine Research Program at the Health and Environmental Sciences Institute (HESI). He received his BS from Texas A&M University, MPH from University of Texas – Houston School of Public Health, PhD from Indiana University, and is a Diplomate of the American Board of Toxicology (DABT).

Stephanie Simon, PhD, ERT
Senior Toxicologist
Associate Scientific Director, Merck (EMD Serono)



Dr. Stephanie Simon is a molecular biologist and board-certified toxicologist (ERT) with over 20 years of industry experience at Merck Healthcare KGaA in Darmstadt, Germany. She has a diploma degree in biology from the Technical University of Darmstadt and earned her PhD in Natural Sciences from the University of Heidelberg. Throughout her career at Merck, she has held multiple roles within the Department of Chemical and Preclinical Safety, spanning quality assurance, study direction and laboratory management, and several years leading the Genetic Toxicology group. In her current position as Senior Toxicologist within Chemical Toxicology, she has a particular focus on the risk assessment of impurities including nitrosamines and supports workplace safety and manufacturing processes by deriving health-based exposure limits. She is recognized both internally and externally as an expert in genetic toxicology and nitrosamine assessment and actively contributes to national and international scientific working groups, including the HESI GTTC and ICH M7.

Diaa Shakleya, PhD
Senior Research Scientist (Pharmacologist)
DPQR V|OPQR|OPQ|CDER|FDA

Dr. Diaa Shakleya is a Senior Research Scientist within the Office of Pharmaceutical Quality/FDA. His areas of expertise include drug products quality, opioids, and regulated bioanalysis and pharmaceutical analysis. In his current role, Dr. Shakleya leads regulatory science research work related to nitrosamine impurities, including projects related to Mitigation strategies to reduce the risk of the NDSRI impurities in pharmaceutical drug products and effect of excipients on the formation of nitrosamines. Dr. Shakleya also leads the Opioids research project on the risk associated with opioids and opioids antagonists and creating an in vitro surrogate model platform to assess in vivo permeation and risk associated with the vaping opioids. Diaa has been with the FDA for over 12 years. Prior to joining FDA, Dr. Shakleya served as an associate director with biotech company where he led a group of scientists in preclinical evaluation of small drug molecules under drug discovery program. Diaa received his Ph.D. degree in Pharmaceutical Sciences from Mumbai University, India and Postdoctoral Fellowship from West Virginia University. Dr. Shakleya has over 65 peer-reviewed publications and more than 150 scientific podium and poster presentations

Valerie Niddam-Hildesheim, PhD
Senior Director, Global Nitrosamine Project Lead
Global Nitrosamine Project Lead, Teva Pharmaceuticals

Dr. Valerie Niddam Hildesheim is Senior Director and Global Nitrosamines Project Lead at Teva, leading global nitrosamine risk-management strategy and execution across commercial and R&D products. She established governance and technical guidance across Teva's network, supporting Teva's global manufacturing and R&D network (>30 sites). She led the mitigation strategy and implementation for Finished Products since 2020 in collaboration with suppliers and internal stakeholders to support timely, science-based decision-making and regulatory submissions. She also represents Teva in nitrosamines-related engagements with health authorities and industry consortia, ensuring scientifically grounded, objective, and compliant communication. Dr. Niddam Hildesheim brings 25+ years of pharmaceutical R&D and development leadership, including management of complex cross-functional global programs in Finished Products development. She previously led Teva API's Chemical Department, overseeing process development, scale-up, and lifecycle support while managing a multidisciplinary team. She is an inventor on 50+ patents and a peer-reviewed author. She earned her PhD in Medicinal Chemistry from the University of Aix Marseille II, France followed by two post-doctoral positions.

Filip Geert A De Bock, PhD
Global Center of Excellence for Mutagenic Impurities Lead
Sandoz

Dr. Filip De Bock has a PhD in (Bio)Medical Sciences and more than 15 years of industry experience in clinical and preclinical development, safety, toxicology and impurity management. For the last 5 years, Filip is leading the Center of Excellence for Mutagenic Impurities and Nitrosamines in Sandoz, which is a cross-functional team responsible for drug substance ICH M7 mutagenic impurities assessments and drug substance and product Nitrosamine Risk Assessments. Filip has in depth expertise on mutagenic impurities, N-nitrosamines, Cohort of Concern impurities, ICH M7 and nitrosamine guidelines, risk/hazard assessments, nitrosamine root cause investigations and remediation/mitigation strategy development and execution. Filip is representing APIC in the ICH M7 working group and is representing Sandoz in several industry working groups (MfE, CGPA) on nitrosamine related topic.

Houri Simonian, PhD
Senior Director, Analytical Research and Development,
Apotex

Dr. Houri Simonian is the Senior Director of Analytical R&D at Apotex, where she leads global teams in Canada and India across Solid and Liquid Dosage Forms. With over 25 years of experience in the pharmaceutical industry, Houri began her career in medicinal chemistry before transitioning to product development, with a strong emphasis on analytical development and regulatory compliance. Her expertise spans method development, validation, and lifecycle management, supporting global regulatory submissions and ensuring product quality and safety. Houri holds a PhD in Organic Chemistry from the University of Nottingham, UK.

Joerg Schlingemann, PhD
Director, Global Quality Control Principal Expert
Merck Healthcare KGaA (EMD Serono)

Dr. Joerg Schlingemann is a director and principal expert for quality control systems within Merck KGaA's/EMD Serono's healthcare quality unit. He studied molecular biology in Uppsala and Heidelberg, where he completed a doctorate degree at the German Cancer Research Center in 2005. He has 17 years of experience in the pharmaceutical industry from various roles within quality control and quality assurance. Since late 2019, Joerg has been leading Merck's analytical activities for N-nitrosamines, based on which he has authored or co-authored several scientific publications dealing with analytical challenges, NDMA in metformin, nitrite in excipients and the prevalence of NDSRIs. Joerg is an advocate of scientific collaboration, data sharing and expressive visualization of data. He is married and has three children.

Ulrich Reichert, PhD, MDRA
Head of CDMO & Bioprocess Materials, Regulatory Management
Merck KGaA

Dr. Ulrich Reichert, M.D.R.A., is Head of CDMO and Bioprocess Materials, Regulatory Management at Merck Life Science KGaA, Darmstadt, Germany. He leads a global team providing regulatory support for the manufacturing of active substances and biologic drug substances, including worldwide site registration of manufacturing facilities. With more than 25 years of regulatory and quality experience supporting materials used in active substances of both chemical and biological origin, he brings deep expertise to his current role. Ulrich is a pharmacist with a PhD (Dr. rer. nat.) in Medicinal Chemistry from the University of Berlin and a Master of Drug Regulatory Affairs (M.D.R.A.) from the University of Bonn. He is an active contributor to international regulatory and scientific bodies. He chairs the IPEC Europe Nitrosamine Task Force, is a member of the ICH M7 subgroup on nitrosamine impurities, serves on two expert groups of the European Pharmacopoeia (EDQM), and is a member of the pharmacopoeia committee on medicinal chemistry at BfArM (Germany's health authority).

Lance Molnar, PhD
Head of Nonclinical Ops. and Risk Assessment, Global Pharm/Tox
Viatris

Dr. Lance Molnar has a Ph.D. in Pharmacology & Toxicology and currently holds the role of Head of Nonclinical Operations and Risk Assessment within Viatris' Global Pharmacology and Toxicology Department. He has approximately 20 years of industry experience, including simple and complex generics, branded development and biologics/biosimilars. Among his responsibilities are the risk and safety assessment of impurities from various sources (drug substance/product, solvents, excipients, leachables, etc.), and he has served on several impurities-focused ICH Expert Working Groups for Q3C, Q3D, Q3E and M7 (nitrosamines addendum) as a safety expert. Current focus of his work includes methodologies for de-risking nitrosamine safety concerns within drug products, standardization of PDE assessments, and leveraging existing data for safety risk analysis.

Kelly Brant, PhD
Master Toxicologist
DPTID|OID|OND|CDER|FDA

Dr. Kelly Brant is a master toxicologist at US Food and Drug Administration (FDA) in the Center for Drug Evaluation and Research. Dr. Brant received her MPH and PhD in toxicology from the University of Michigan School of Public Health. She is a board-certified toxicologist with over 10 years of experience at US FDA regulating pharmaceuticals. Dr. Brant is a subject matter expert on nitrosamine safety, serving as a member of the FDA/CDER nitrosamine safety team, the HESI Genetic Toxicology Technical Committee Nitrosamine Research Program, and the FDA ICH M7 nitrosamine addendum Expert Working Group. She has served on multiple US FDA Pharm/Tox subcommittees (Reproductive and Developmental Toxicology SC, Education SC) and is the current co-chair of the CDER PTCC Nitrosamine Working Group. Outside of her FDA activities, Dr. Brant has served in several professional societies and is the past president of the Allegheny-Erie Regional Chapter of the Society of Toxicology (SOT). Prior to joining the FDA, Dr. Brant was a Research Professor at the University of Pittsburgh.

Ee-Sunn (Joanne) Chia, PhD
Division Director
DPQA X|OPQA II|OPQ|CDER|FDA

Dr. Joanne Chia serves as Division Director of the Division of Product Quality Assessment X within the Office of Product Quality Assessment II at the U.S. Food and Drug Administration. She oversees experienced drug product assessors who provide critical support for Generic Drug User Fee Act (GDUFA) activities and regulatory review processes. Dr. Chia holds a Ph.D. in Chemical Engineering from Princeton University and a Bachelor of Science in Chemical Engineering from the University of Virginia.

Session 2

Using AI to Address Practical Challenges for Generic Drugs

Meng Hu, PhD
Lead Chemical Engineer
DQMM|ORS|OGD|CDER|FDA

Dr. Meng Hu received both his Bachelor of Engineering in Biomedical Engineering and Ph.D. in Physics from the Zhejiang University, China. He joined the FDA's Office of Generic Drugs in 2015 and currently serves as a team lead in the Division of Quantitative Methods and Modeling under the Office of Research and Standards. His main research interests include the development and application of advanced data analytics tools (including AI/ML/LLM) to promote business and process intelligence in government, big data management, generation of real-world evidence, and quantitative methods to facilitate assessment for in-vitro bioequivalence study.

Qing Liu, PhD
Deputy Director
DB I|OB|OGD|CDER|FDA

Dr. Qing Liu is the Deputy Division Director in the Division of Bioequivalence I, Office of Generic Drugs within the FDA's Office of Generic Drugs. She has over 10 years of experience in the assessment of bioequivalence for abbreviated new drug applications, controlled correspondences, citizen petitions, product-specific guidance and protocols submitted to the Agency. In her current role, Dr. Liu works with a group of scientists on complex generic drug products, such as nasal/orally-inhaled drug products, long-acting injectables, topicals and ophthalmic suspensions.

CDR Diana Solana-Sodeinde, PharmD, MPH
Lead Program Coordinator for the FDA Inactive Ingredient Program
OB-IO|OGD|CDER|FDA

CDR Diana Solana-Sodeinde, is currently serving as the Lead Program Coordinator for the FDA Inactive Ingredient Database (IID) program, operated by the Immediate Office of the Office of Bioequivalence within the Office of Generic Drugs (OGD) at the Food and Drug Administration (FDA). CDR Solana-Sodeinde received a doctorate degree in Pharmacy (Pharm.D.) from Howard University, Washington DC in 2007; a master's certificate in Project Management from the George Washington University, Washington DC in 2015; and a master's degree in Public Health- Global Health concentration (MPH-GH) from the Liberty University, Lynchburg, VA in 2021. Upon graduation from pharmacy school, CDR Solana-Sodeinde worked as a Pharmacist at the Johns Hopkins Hospital, Baltimore, Maryland

prior to joining the United States Public Health Service as a Pharmacy Officer in 2008. Since 2008, CDR Solana-Sodeinde worked at FDA in OGD's Office of Bioequivalence and served in different roles as Regulatory Health Project Manager from 2008 to 2013; Supervisory Project Manager from 2013 to 2016; Associate Director of Regulatory Affairs from 2016 to 2023; and then, transitioned in 2023 to lead the FDA IID program that was transferred from the Office of Pharmaceutical Quality to OGD on June 1, 2024.

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

Dr. Jing (Jenny) Wang is currently a Staff Fellow working at the Data Analytics Team of the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS), Office of Generic Drugs (OGD), CDER/FDA. Since her joining the DQMM in 2020, she has been utilizing quantitative analytics approaches and artificial intelligence (AI) techniques to support regulatory review efficiency and bioequivalence assessment. Her areas of expertise include Agentic AI application development, pharmacometrics, machine learning algorithms, and Bayesian methods. She received her Ph.D. in Rehabilitation Science from the University of Pittsburgh and received both her Bachelor and Mater degrees in Biomedical Engineering, from the Xi'an Jiaotong University, China.

Arti Patel, MS
Senior Manager, Regulatory Affairs
Cosette Pharma

Ms. Arti Patel is a Global Regulatory Affairs leader with 15+ years of experience driving end-to-end regulatory strategy, approvals, and lifecycle management across the U.S., EU, and emerging markets. In her current role at Cosette Pharmaceuticals Inc, she is responsible for and leading the projects of complex new drug products from development, execution and submission of the applications (i.e. IND/NDA/ANDA) and following queries from the Agency. Prior to this, she spent a decade with Torrent Research Centre and managed submission of applications and life cycle management of multiple projects. She has also gained hand on experience of analytical skills at Cadila Healthcare Ltd. She has earned degree of Master Pharmacy in Quality Assurance at Ganpat University. Overall, she has established strong track record of cross-functional leadership, regulatory risk mitigation, and aligning regulatory pathways with business objectives to accelerate market access. She is also engaged in AI-driven regulatory innovation and digital transformation in pharmaceutical development and submissions.

Jeremy Evans, PhD
Director
U.S. Pharmacopeia (USP)

Dr. Jeremy Evans serves as the Director of AI/ML Innovation for Pharmaceutical Manufacturing at US Pharmacopeia. In his role, he applies his expertise in simulation and modelling to advance innovations that support the development of cutting-edge drug manufacturing techniques. With nearly two decades of experience, Jeremy specializes in designing and delivering data-driven, machine learning, and artificial intelligence solutions in the biopharmaceutical and related industries. Prior to joining USP, Jeremy worked cross-sector as a lead informatics and data science technical consultant with an R&D and engineering focus. He has a Ph.D. in physical chemistry.

Tushar Nitave, MS
Staff Software Engineer
Vivpro Corp.

Mr. Tushar Nitave brings over five years of data science and software engineering expertise to his role as a Staff Software Engineer at Vivpro Corp.. He currently leads the engineering team for REGAIN, an AI-based solution for regulatory document creation, and holds a Master's in Computer Science from the Illinois Institute of Technology.

Sandip Tiwari, PhD
Head of Technical Services - Pharma Solutions, North America
BASF

Dr. Sandip B. Tiwari Dr. Sandip Tiwari is a pharmaceutical scientist and industry leader with over 26 years of experience in formulation science and drug product development. He currently serves as Head of Technical Services for Pharma Solutions (North America) at BASF, where he leads scientific initiatives focused on translating formulation science across small molecule and biopharmaceutical modalities into predictive, regulatory relevant solutions. His work centers on integrating data driven and model informed approaches into drug product development to improve formulation design, dissolution performance, and risk based decision making.Throughout his career spanning BASF, Teva Pharmaceuticals, Colorcon, and Zydus Cadila, Dr. Tiwari has contributed to the development and commercialization of multiple drug products and enabling technologies across global markets. He has deep expertise in complex oral dosage forms, excipient functionality, and scalable manufacturing, and is advancing the application of mathematical modeling and AI assisted workflows to proactively assess and mitigate risks such as nitrosamine formation. An active scientific leader and mentor, Dr. Tiwari has authored over 100 publications, presentations, and patents, and currently serves as Chair of the AAPS Formulation & Delivery Community, advancing data enabled, science driven approaches in pharmaceutical development

Brooke Langevin, PhD
Assistant Professor
University of Maryland, Baltimore

Dr. Brooke Langevin is an Assistant Professor in the Department of Practice, Sciences, and Health Outcomes Research. Dr. Langevin is a pharmacometrician and translational scientist whose work focuses on applying quantitative modeling and simulation to inform drug development and support therapeutic decision-making in data-limited settings, including special populations and rare diseases. Her research integrates population pharmacokinetics, physiologically based pharmacokinetic modeling, and model-informed approaches to better understand drug exposure and support evidence generation. This work also extends to the use of data-driven and AI-informed frameworks to support quantitative decision-making in areas such as precision dosing, bioequivalence, and regulatory science. She has a BS in Chemical and Biomolecular Engineering from Johns Hopkins University and a PhD in Pharmaceutical Sciences from the University of Maryland, Baltimore.

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

Lieutenant Commander Geng (Michael) Tian, Ph.D., serves as a Supervisory Research Officer in the Office of Pharmaceutical Quality within the Center for Drug Evaluation and Research at FDA. Dr. Tian serves as a technical liaison, collaborating with industry, academia, and other government agencies on FDA extramural research programs to advance the development and implementation of innovative manufacturing technologies that ensure drug quality. He actively contributes to regulatory guidance development, supports IND, NDA, and ANDA consults, and participates in Agency workgroups, presentations, and peer-reviewed publications. He currently serves as Vice Chair of ASME V&V 80 and is a member of the FDA Emerging Technology Program (ETP), FDA AI Council, and FDA Advanced Manufacturing Council.

Torrey Ward
Consumer Safety Officer
DQI II|OQS|OPQ|CDER|FDA

Ms. Torrey Ward joined the FDA in 2020 as an Investigator with the Office of Inspections and Investigations (OII) in the Kansas City District conducting complex inspections of pharmaceutical establishments. In 2023, Torrey transferred to CDER's Office of Pharmaceutical Quality, Office of Quality Surveillance where she monitors drug manufacturing sites and product quality-related signals for mitigation of public health issues; evaluates and reports data on pharmaceutical quality and drug availability for internal business partners and external stakeholders, and collaborates with those partners to develop innovative surveillance approaches that facilitate data-driven and risk-based decision-making.

Session 2 – Panel Discussion

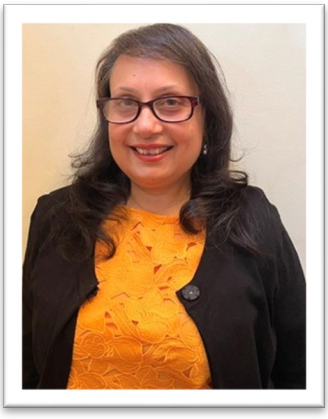
Meng Hu, PhD *See biography at page 11*
Qing Liu, PhD *See biography at page 11*
Jeremy Evans, PhD *See biography at page 13*

Joga Gobburu, PhD
Professor
University of Maryland, Baltimore

Dr. Joga Gobburu is Professor with the School of Pharmacy and the School of Medicine, University of Maryland, Baltimore, MD, USA. He held various positions at the US FDA between 1998 and 2011. He has experience with overseeing the review of 1000s of Investigational New Drug Applications (INDs), over 250 New Drug and Biological Licensing Applications, numerous FDA Guidances and policies pertaining to drug approval and labeling. He received numerous awards from FDA and other professional organizations. He has published over 180 papers and book chapters. He is co-founder of PumasAI Inc., and Vivpro Corporation.

Brooke Langevin, PhD *See biography at page 14*
Tushar Nitave, MS *See biography at page 13*
Arti Patel, MS *See biography at page 12*
Sandip Tiwari, PhD *See biography at page 13*

Sharmista Chatterjee, PhD
Division Director
DPMA III|OPMA|OPQ|CDER|FDA



Dr. Sharmista Chatterjee is currently the Division Director in Division of Pharmaceutical Manufacturing Assessment III, within FDA's Office of Pharmaceutical Manufacturing Assessment (OPMA). Sharmista has been with the FDA since 2006. During her tenure she has been actively involved in many agency initiatives that include Quality by Design (QbD), FDA-EMA QbD pilot program, Emerging Technology Program (ETP), KASA, NIR guidance, Continuous Manufacturing, and in the Framework for Regulatory Advanced Manufacturing Evaluation (FRAME). Prior to joining the agency in 2006, she spent around 10 years in industry. Her industry experience was primarily in process development and modeling in diverse areas that ranged from consumer goods to pharmaceuticals with companies such as United Technologies Corporation (now Raytheon), Procter and Gamble (P&G), and Forest Laboratories (now Allergan). She received a bachelor's degree in Chemical Engineering from Indian Institute of Technology and a PhD in Chemical Engineering with a co-major in Biomedical engineering from Iowa State University

Mihir Jaiswal, PhD
Visiting Scientist,
PMS|OQA|OPQ|CDER|FDA

Dr. Mihir Jaiswa, is a senior leader at the U.S. Food and Drug Administration (FDA) specializing in artificial intelligence, advanced analytics, and enterprise digital transformation. He currently leads AI adoption initiatives within the Center for Drug Evaluation and Research (CDER), driving the implementation of generative AI and data-driven solutions to enhance regulatory decision-making, operational efficiency, and public health outcomes. With over a decade of experience at the intersection of data science, operations research, and regulations, Dr. Jaiswal has led high-impact programs including drug supply chain surveillance during the COVID-19 pandemic, inspection modernization, and enterprise analytics platform development. His work focuses on translating emerging technologies into scalable, real-world applications within complex, highly regulated environments. Dr. Jaiswal has been recognized with multiple FDA honors, including the Center Director's Special Citation and the Generative AI Impact Award, for advancing innovative solutions that strengthen national public health infrastructure. He is a published author and speaker on AI, analytics, and regulatory innovation, with a particular focus on operationalizing AI—driving adoption, governance, and measurable impact at enterprise scale.

Robert Lionberger, PhD *See biography at page 3*
CDR Diana Solana-Sodeinde, PharmD *See biography at page 11*
Geng Tian, PhD *See biography at page 14*
Jing (Jenny) Wang, PhD *See biography at page 12*

Zhen Zhang, PhD
Master Pharmacologist
DB I|OB|OGD|CDER|FDA

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 numerous complex bioequivalence challenges and played a key role in the development of several FDA general guidances. Dr. Zhang earned his Ph.D. in Pharmacology from the University of Wisconsin-Madison.

Torrey Ward *See biography at page 14*

Closing Remarks for Day 1

Robert Lionberger, PhD *See biography at page 3*

Fiscal Year (FY) 2026 Generic Drug Science and Research Initiatives Public Workshop Speaker, Panelist, And Moderator Biographies

In order of appearance on Agenda

Day 2

Welcome & Introduction

Sam Raney, PhD *See biography at page 1*

Ahmed Zidan, PhD *See biography at page 1*

Session 3

Expanding Regulatory Flexibility with Bioequivalence Standards

Andrew Babiskin, PhD
Deputy Division Director
DQMM|ORS|OGD|CDER|FDA

Dr. Andrew Babiskin is the Deputy Division Director of 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.

Yan Wang, PhD
Deputy Division Director
DTP I|ORS|OGD|CDER|FDA

Dr. Yan Wang is the Deputy Division Director in the Division of Therapeutic Performance I (DTP-I), ORS, OGD at the U.S. Food and Drug Administration. The division advances regulatory science to support generic drug development and establish standards for demonstrating therapeutic equivalence. Since joining FDA in 2013, Dr. Wang has served in multiple scientific and leadership roles, including as a subject matter expert in complex long-acting drug products and Team Lead for the Complex Drug Substance and Complex Formulation Team. Her work focuses on analytical methods, in vitro characterization, and drug release testing for complex drug products. Her expertise spans complex parenteral, ophthalmic, otic, intravaginal, and intrauterine products, with an emphasis on linking formulation and manufacturing to product performance and bioequivalence

Abhishek (Abhi) Gupta, PhD, PMP
Chief Scientific Officer
Transpire Bio

Dr. Abhishek Gupta, Ph.D., PMP, 'Abhi', is Transpire Bio's Chief Scientific Officer (CSO). Dr. Gupta is responsible for the scientific direction of Transpire Bio. As a member of the leadership team, Dr. Gupta is responsible for providing the strategic and operational leadership to develop and implement the company's scientific strategy, overall product portfolio, and conceptualization and introduction of new product opportunities. Dr. Gupta is also responsible for the evaluation of new product opportunities and M&A to expand existing business and create new business. Dr. Gupta is a seasoned and accomplished bio-pharmaceutical executive with over 26 years of product development experience across dosage forms, with over 20 years focused primarily on inhalation drug-device combination products. Dr. Gupta's time in industry has included leadership positions at Novartis Pharmaceuticals, Nektar Therapeutics, Cardinal Health, Lupin, and his most recent position at Cipla as the SVP & Head of R&D, North America. Dr. Gupta has successfully led the product development and approval of several branded and generic dosage forms, including small molecules, polypeptides, proteins, and biologics for registration in the US and EU. Dr. Gupta is a graduate of Harvard Business School's business analytics program. Dr. Gupta has a Ph.D. in Pharmaceutical Sciences from the University of Arizona, US, with a focus on Pharmaceutics, Analytical, and Material Sciences. He is a certified project management professional (PMP) through the Project Management Institute (PMI) of America and has a Bachelor's in Pharmacy (B. Pharm.) from India. Dr. Gupta has over 50 peer-reviewed publications and numerous granted and filed patents.

Session 3 – Panel Discussion

Andrew Babiskin, PhD *See biography at page 17*
Yan Wang, PhD *See biography at page 17*

Tausif Ahmed, PhD
Senior Vice-President
Mankind Pharma LTD

Dr. Tausif Ahmed is currently working as Sr. Vice President & Head-Clinical Research & Biopharmaceutics Department at Mankind Pharma Limited, Delhi, India. He is responsible for managing all Bioequivalence studies, preclinical Tox and Phase I-IV clinical trials supporting global complex generic products and NCEs/NBEs at Mankind. Prior to joining Mankind, Dr. Tausif worked as Sr. VP Bioequivalence and CT at Aizant Drug Research solution Pvt., Ltd. Hyderabad, India. In past he has worked as Vice President & Head-Biopharmaceutics & Bioequivalence in the Global Clinical Management group, IPDO at Dr. Reddy's Laboratories Limited (DRL), Hyderabad. He was responsible for managing all Bioequivalence studies supporting global complex generic products at DRL. He was also involved in PK/Modelling and Simulation activities supporting global generic development. Prior to joining DRL, he was Associate Director and Head-DMPK (preclinical discovery, Clinical dev., and Generic) & Dy. Test Facility Mgt. GLP toxicology dept. at Piramal Enterprises Limited, Mumbai. Dr. Ahmed has been associated with different pharmaceutical companies such as Dr. Reddy's Research Foundation (DRF), Ranbaxy Research Laboratories (Sun Pharma) and Sai Life Sciences Limited in past. He obtained M.S. in Pharmaceutics from NIPER and Ph.D. in Pharmaceutical Medicine (specialization: Biopharmaceutics and PK/PD) from Hamdard University (Ranbaxy sponsored). He has been working in the field of drug discovery, development, phase I-IV, and generic BA-BE studies for more than 24 years. His area of specialization includes DMPK, metabolite-ID, population PK, PK-PD modelling, and simulation, generic BA/BE studies and GLP bioanalysis. In recent years his focus is on use PBBM/PBPK modelling in generic drug development. He has extensive experience in outsourcing preclinical and clinical studies to CROs both in and outside of India. Dr. Ahmed has contributed to >15 IND filings, multiple ANDAs, and Phase I-IV regulatory submissions, nationally and globally. He has co-authored two book chapters and over 80 publications and multiple international presentations. He has worked with different regulatory agencies like USFDA, EMA, CDSCO, ANVISA, NMPA in the area of innovative BE strategies/Modeling & Simulation and have joint publications with these agencies. Dr. Ahmed is a guest faculty at Hamdard University, NMIMS (Mumbai), NIPER, and various other universities in India. He has also supervised many Master's and Ph.D. students.

Allison Dunn, PharmD, MS
Research Assistant Professor
University of Maryland School of Pharmacy, Center for Translational Medicine

Dr. Allison Dunn is a Research Assistant Professor at the University of Maryland School of Pharmacy and investigator within the Center for Translational Medicine. Her research focuses on pharmacometrics and model-informed drug development, with applications spanning clinical pharmacology, regulatory science, and complex generics. Dr. Dunn has worked on implementing novel model-informed bioequivalence approaches to address bioequivalence challenges for long-acting injectable products and has contributed to regulatory strategy and quantitative modeling efforts across multiple therapeutic areas.

Abhishek (Abhi) Gupta, PhD, PMP *See biography at page 18*

Brandon Wood, BSc
Senior Director, Regulatory Affairs, Complex Gx
Teva Pharmaceuticals USA, Inc.

Mr. Brandon Wood is an accomplished regulatory affairs leader with 15+ years of experience in the pharmaceutical industry, specializing in complex generic drug development. As Senior Director of Regulatory Affairs at Teva Pharmaceuticals USA, Inc., he leads regulatory strategy, submissions, and lifecycle management for complex generics spanning complex APIs, long acting injectables, respiratory therapies, combination products, and non sterile complex products. Brandon has played a pivotal role in advancing and securing approvals for complex generic submissions, including GLP 1–based therapies, navigating scientific, CMC, and regulatory challenges to enable first to market or highly differentiated generic outcomes. Since joining Teva in 2018, he has driven regulatory strategies for some of the company's most technically demanding programs, building on prior experience in regulatory affairs, quality assurance, and R&D at CorePharma and Impax Laboratories, and an early technical foundation as a chemist at West Ward Pharmaceuticals. He holds a B.S. in Chemistry with a concentration in Organic Chemistry from Monmouth University.

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

Dr. Priyanka Ghosh is a lead pharmacologist within the Division of Therapeutic Performance, ORS, OGD. Her areas of expertise include products in dosed on skin and other mucosal tissues. 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 and is the co-chair of the Bioequivalence Standards for Topicals Committee within OGD. 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.

Myong-Jin Kim, PharmD
Division Director
DTP II|ORS|OGD|CDER|FDA

Dr. Myong Jin Kim serves as Director of the Division of Therapeutic Performance II within the Office of Research and Standards, Office of Generic Drugs at CDER/FDA. Since joining the FDA in 2001, she has held several key positions, including Deputy Director of the Division of Quantitative Methods and Modeling and Team Leader in the Office of Clinical Pharmacology.
Dr. Kim earned her Bachelor of Science degree in Chemistry from the Georgia Institute of Technology. She went on to receive her Doctor of Pharmacy degree from Temple University School of Pharmacy and completed a two-year postdoctoral fellowship in clinical pharmacology at Bassett Healthcare, a major teaching affiliate of Columbia University College of Physicians and Surgeons, in New York.

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

Dr. Bing Li is the Associate Director for Science in the Office of Bioequivalence within the Office of Generic Drugs at the U.S. Food and Drug Administration (FDA). In this role, she provides scientific leadership and expertise in the assessment of bioequivalence (BE) studies submitted through Abbreviated New Drug Applications (ANDAs) and oversees the scientific initiatives within the Office of Bioequivalence. Dr. Li is an Expert Pharmacologist at the FDA, specializing in the bioequivalence of aerosolized drug products. Before joining the FDA in 2004, Dr. Li was a Research Investigator at Bristol-Myers Squibb. She earned her Ph.D. in Pharmaceutical Sciences from the University of Wisconsin–Madison in 2001, and her bachelor's degree in Medicinal Chemistry from Peking University, China, in 1990.

Pahala Simamora, PhD
Division Director
DPQA IX|OPQA II|OPQ|CDER|FDA

Dr. Pahala Simamora serves as the Director of the Division of Product Quality Assessment IX (DPQA IX), within the Office of Product Quality Assessment II (OPQA II), OPQ/CDER at the FDA. His division oversees the quality assessment of regulatory submissions under both the GDUFA and PDUFA programs, including those involving radiopharmaceutical drug products. Dr. Simamora has played an important role in several key FDA initiatives. These include the Abbreviated New Drug Application (ANDA) Integrated Quality Assessment process, which streamlines the review of generic drug submissions; the Framework for Regulatory Advanced Manufacturing Evaluation (FRAME), which explores innovative regulatory approaches for mobile and advanced manufacturing technologies; and the Knowledge Aided and Structured Assessment (KASA) initiative, which advances structured quality assessments of generic drug applications. Before joining the FDA in 2010, Dr. Simamora brought with him 14 years of pharmaceutical industry experience, with deep expertise in formulation development, process development, and manufacturing scale-up - a foundation that continues to inform his regulatory and scientific leadership at the Agency.

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

Dr. Lei Zhang serves as the Deputy Director of Office of Research and Standards within Office of Generic Drugs at the Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). She oversees the Generic Drug User Fee Amendments (GDUFA) science and research program to ensure the therapeutic equivalence of generic drug products. Dr. Zhang was previously Senior Advisor for Regulatory Programs and Policy in the Office of Clinical Pharmacology at CDER, FDA. Dr. Zhang is an accomplished professional with more than 27 years of combined experience in the areas of drug research, development and regulatory review and approval. She has contributed to numerous guidance development and research projects focused on science-based regulatory decision making. Before joining FDA in 2002, she worked at Bristol Meyers Squibb as a Research Investigator and Preclinical Candidate Optimization Team Leader. Dr. Zhang is an Adjunct Professor in the Department of Bioengineering and Therapeutic Sciences, University of California at San Francisco (UCSF), Schools of Pharmacy and Medicine. Dr. Zhang received her Ph.D. in Biopharmaceutical Sciences from UCSF. She is currently the Rapporteur for the ICH M13 Expert Working Group that is developing harmonized guidelines on bioequivalence (BE) for immediate-release solid oral dosage form drugs including M13A, M13B and M13C. Dr. Zhang was inducted American Association of Pharmaceutical Scientists (AAPS) Fellow in 2013. She received the American Society for Clinical Pharmacology and Therapeutics (ASCPT) Malle Jurima-Romet Mid-Career Leadership Award in 2023. She is a member of ASCPT, ISSX, ACCP, and AAPS. She serves/has served various volunteer and leadership roles in these organizations. She has published more than 140 peer-reviewed papers and book chapters.

Session 4

Facilitating Generic Drug Approvals by Improving the Predictability of Regulatory Expectations

Markham Luke, MD, PhD
Director
DTP I|ORS|OGD|CDER|FDA

Dr. Markham C. Luke, MD, PhD, FAAD, is a Supervisory Physician and Director of the Division of Therapeutic Performance (DTP1) in the FDA's Office of Generic Drugs. Since 1998, he has held leadership roles at the FDA focusing on complex generic drugs, dermatology, device evaluation, and cosmetics. He is a board-certified dermatologist with research expertise in dermato-pharmacology and drug-device combinations

William Smith, PhD
Research Scientist
DPQR V|OPQR|OPQ|CDER|FDA

Dr. William C. Smith is a Research Scientist in the Division of Product Quality Research working on complex drug formulations from topicals to injectables and implantable polymeric devices. Dr. Smith manages the DPQR Micromeritics "Particle Size" Lab with research focusing on advanced manufacturing and the physicochemical characterization of nano- and micro-scale materials to support regulatory assessment and review, and evaluation of drug product quality. Dr. Smith received his B.S. degree in Chemistry from the Evergreen State College. In 2017, he was a guest researcher at the Leibniz Institute for Polymer Research (IPF) in Dresden, Germany. He earned his Ph.D. in 2019 from the Colorado School of Mines, where his doctoral work focused on the development of advanced separation techniques for the characterization of complex polymers and colloidal nanomaterials.

Brock Roughton, PhD
Division Director
DPQA XI|OPQA II|OPQ|CDER|FDA

Dr. Brock Roughton is the acting director of Division of Pharmaceutical Quality Assessment XI, Office of Pharmaceutical Assessment II, Office of Pharmaceutical Quality (OPQ). He manages staff in drug product quality assessment across the drug product lifecycle, from initial IND submission to post-approval changes for ANDAs. He joined FDA in 2014 as a drug product quality assessor and then team lead and branch chief in the former Office of Lifecycle Drug Products. His assessment experience covers a variety of complex dosage forms, and he has presented on complex quality topics at external forums including SBIA, DIA, and AAM. Brock supports the preANDA program to clarify regulatory expectations for complex generic drugs, serving as OPQ chair in PDEV meetings and as a subject-matter expert for PSG development. He holds a BS in Chemical and Biochemical Engineering from Colorado School of Mines and a PhD in Bioengineering from University of Kansas.

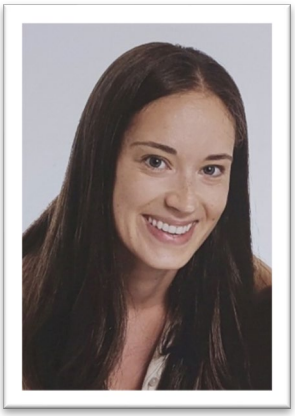
Eric Twum, PhD
Regulatory Specialist
DQI II|OQS|OPQ|CDER|FDA

Dr. Eric Twum is a Regulatory Specialist in the Office of Pharmaceutical Quality in the FDA's Center for Drug Evaluation and Research. Eric has experience supporting the evaluation of pharmaceutical quality systems, analyzing post-market surveillance data, and helping advance FDA's Quality Management Maturity (QMM) program and holds a PhD in Computational Biology from George Mason University.

Session 4 – Panel Discussion

Markham Luke, MD, PhD *See biography at page 23*
William Smith, PhD *See biography at page 23*

Clare Butler, PhD
Principal Product Development Scientist
Teva Pharmaceuticals



Dr. Clare Butler holds a BSc and PhD in Pharmacology from University College Dublin and works as a Principal Scientist within Teva's Global Inhalation team. She has extensive experience in analytical method development and validation, with a strong focus on realistic and clinically relevant approaches to in vitro–in vivo correlation. Her expertise spans in vivo preclinical models and mechanistic modelling, supporting the development and understanding of inhaled pharmaceutical products.

Praveen Chappa, PhD
Group Head – Analytical Development
Sandoz

Dr. Praveen Chappa serves as the Group Head of Material Science and Special Analytics at the Sandoz Development Centre, Hyderabad, India, supporting oral solid dosage form development programs. His expertise includes de formulation, preformulation, and sameness characterization, enabling robust development strategies and science based decision making. He leads impurity risk assessments and defines control strategies for elemental impurities, nitrosamines, extractables and leachables (E&L), degradation products, and polymorphism. He also oversees analytical method development, validation, and technology transfer to ensure regulatory compliance and effective product lifecycle management. With 16 years of pharmaceutical industry experience, including roles at Mylan, Fresenius Kabi, Dr. Reddy's Laboratories, and Novugen, he has supported development programs ranging from simple to complex generics. He holds a PhD in Chemistry from SRM Institute of Science and Technology, Tamil Nadu, India.

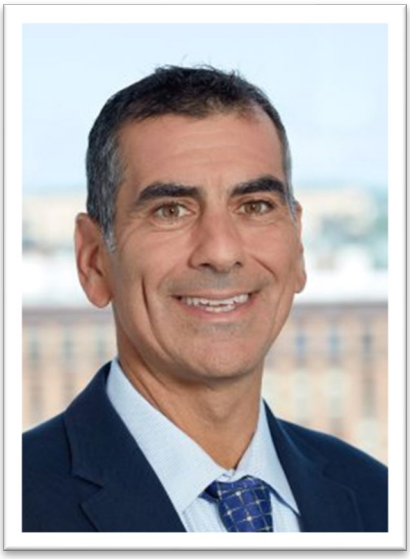
Andrew Cooper, PhD
Respiratory Bioequivalence Strategy Lead
Viartis/Mylan Pharma UK

Dr. Andrew Cooper's current role is Respiratory Bioequivalence Strategy Lead in Viatris R&D, based in Sandwich, UK. He holds a Ph.D in Pharmaceutical Analysis from University of Bath and has broad industrial experience of analytical chemistry supporting complex dosage form development. His roles have been focused on respiratory product development for around 20 years. He has long held interests at the CMC-clinical interface, in understanding the relevance of in-vitro tests to in-vivo performance and of in-vivo studies informing product development. He is also committed to regulatory engagement supporting the development of science-based bioequivalence strategies for respiratory products which facilitate patient access to high-quality medicines.

Niraj Mehta, PhD
Senior VP – Quality Compliance and Sustainability
Lupin

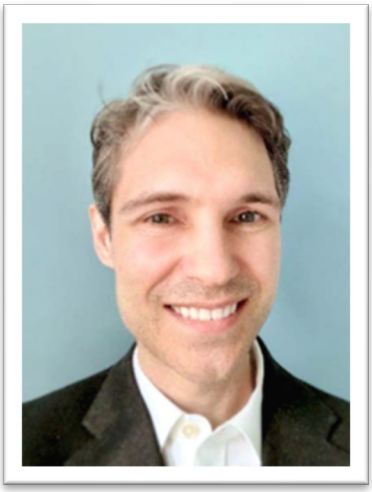
Dr. Niraj Mehta is the Senior Vice President of Quality Compliance and Sustainability at Lupin Pharmaceuticals Inc., where he leads the global Quality Compliance organization. In this role, he oversees auditing, investigations, GMP training, permanent inspection readiness, regulatory intelligence, and governance of Quality Council activities and metrics. Prior to joining Lupin, Dr. Mehta served as Executive Director and Global Quality Lead for Strategic Programs and Regulatory Intelligence within Merck's Manufacturing Division, where he was responsible for external policy management and execution of enterprise-wide quality compliance programs, including the enablement of a Quality Management Maturity framework. Earlier in his career, he spent over a decade at the U.S. Food and Drug Administration in roles within the Center for Drug Evaluation and Research and the Office of the Commissioner, where he supported global regulatory initiatives, including facilitating the adoption and implementation of the U.S.–EU Mutual Recognition Agreement. Dr. Mehta holds a Bachelor's Degree in Biology from Penn State University, and a Ph.D. in Pharmacology and Molecular Sciences from the Johns Hopkins University School of Medicine.

Giuseppe Randazzo, MS
VP - Science and Regulatory Affairs
Association for Accessible Medicines



Mr. Giuseppe Randazzo is Senior Vice President of Sciences and Regulatory Affairs at the Association for Accessible Medicines (AAM) representing manufacturers of generic and biosimilar medicines. Prior to joining the association, Giuseppe worked on a global pharmaceutical company's policy and regulatory team, where he collaborated across multiple areas including drug and policy development, user fee agreement negotiations, and engagement with industry and trade organizations. Before that, Giuseppe spent nearly 15 years at the FDA, where he last served as an Office Director in Office of Pharmaceutical Quality within CDER. During his FDA tenure, he also held roles in new drug review, compliance, and played a key role in establishing a product quality office in coordination with the generic drugs program. Giuseppe holds a B.A. in Chemistry and Physical Science Education from The Pennsylvania State University and an M.S. in Regulatory Science from The Johns Hopkins University.

Bob Berendt, PhD
Supervisory Pharmaceutical Scientist
DPQA V|OPQA I|OPQ|CDER|FDA



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-device 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.

Utpal Munshi, PhD
Division Director
DB I|OB|OGD|CDER|FDA

Dr. Utpal M. Munshi is the Division Director of the Division of Bioequivalence I (DBI) in the Office of Bioequivalence, Office of Generic Drugs, CDER, FDA. Dr. Munshi has had a variety of technical and administrative roles since joining DBI in 2007. He currently leads a team of scientists responsible for the regulatory assessment of the bioequivalence section of Abbreviated New Drug Applications (ANDA) and other stakeholder submissions. In addition, Dr. Munshi has contributed to the development and implementation of Agency guidances and has led multiple teams in the assessment of complex generic drug products and other challenging regulatory science issues. Dr. Munshi received his Ph.D. in Biological Chemistry from the University of Michigan and then undertook post-doctoral training at the National Cancer Institute in Frederick, Maryland before joining DBI.

Brock Roughton, PhD *See biography at page 24*

Cameron Smith, PhD
Supervisory Pharmaceutical Scientist
DPQA IV|OPQA I|OPQ|CDER|FDA

Dr. Cameron Smith is a Supervisory Pharmaceutical Scientist in the Division of Product Quality Assessment IV (DPQAIV) within the Office of Product Quality Assessment I (OPQAI)/Office of Pharmaceutical Quality (OPQ). Dr. Smith started his FDA career in October 2014 as a drug product quality assessor. In his current role he manages and mentors a team of drug product quality assessors 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 organic 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.

Eric Twum, PhD *See biography at page 24*

Session 5

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

Giuseppe Randazzo, MS *See biography at page 27*

Session 5 – Panel Discussion

Tausif Ahmed, PhD *See biography at page 19*

Dennis Hall, BS, MA Ed, MBA
VP, Advanced Manufacturing & Technologies
U. S. Pharmacopeia (USP)

Mr. Dennis Hall is Vice President of Advanced Manufacturing Technologies at the United States Pharmacopeia (USP), where he is shaping the future of how medicines are made, tested, and supplied. He leads initiatives that apply advanced manufacturing and quality technologies to solve systemic challenges in drug production and supply chains to strengthen resilience, accelerate innovation, and rebuild U.S. manufacturing competitiveness. With more than two decades at USP, Dennis has driven transformation across strategy, analytics, manufacturing services, and global growth, consistently turning complex problems into scalable, industry-level solutions. He is a founding board member of the Alliance for Building Better Medicine, advancing a national vision for affordable, high-quality medicines through next-generation manufacturing. Dennis holds an MBA from the University of Maryland Smith School of Business, a master's degree in education from the College of William and Mary, and a bachelor's degree in physics from Clarion University of Pennsylvania.

Uwe Niesner, PhD
Head of Respiratory, Dermatology, Biologics & Regulatory Strategy
Viatris

Dr. Uwe Niesner is the Head of Respiratory, Derms & Biologics Regulatory Strategy at Viatris. Uwe has more than 15 years of experience in Global Regulatory Affairs covering innovator molecules and biologics in various stages of development, generic programs, biosimilars, and established brands. Prior to joining Viatris in 2015, he worked for Abbott and Solvay Pharmaceuticals in various regulatory roles of increasing responsibility. Uwe holds a Dr. rer. nat. degree (a PhD) in biochemistry from the Humboldt University in Berlin, Germany. Uwe is an expert in navigating high-stakes submissions for complex generic pharmaceuticals globally, focused on science-based efficient regulatory pathways to accelerate market access.

Arti Patel, MS *See biography at page* 12

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

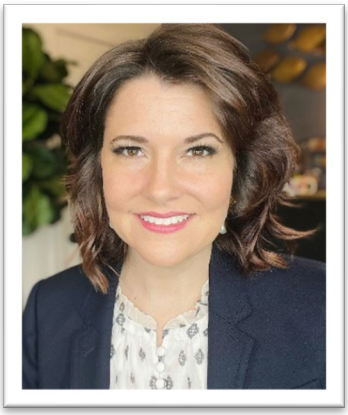
Dr. James Polli is Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics at University of Maryland. His research interest is oral drug absorption, involving laboratory and clinical research. He has served as the advisor to 26 PhD graduates. He is co-Director of the Center for Research on Complex Generics, an FDA-funded collaborative agreement with the Agency. He is Director of the online M.S. in Regulatory Science program. He is a fellow of the American Association for Pharmaceutical Scientists (AAPS) and served as an editor of Pharmaceutical Research for 12 years. He is the 14th recipient of the American Pharmacists Association Takeru Higuchi Research Prize. He was the recipient of the 2024 American Association of Colleges of Pharmacy Volwiler Research Achievement Award, the 2024 FFQM Pearls of Bioequivalence Award, the 2022 AAPS Global Leadership Award, the 2026 Philadelphia College of Pharmacy Alumni Award for Excellence in Research, and the 2021 TOPRA Education Award. He is a member of the University of Maryland General Clinical Research Center Advisory Committee and the University of Maryland institutional review board (IRB).

Anuj Kumar Saini, PhD
Global Head-Global Clinical Management
Dr. Reddy's Laboratories Ltd.

Dr. Anuj Kumar Saini is the Global Head – Global Clinical Management at Dr. Reddy's Laboratories Limited, Hyderabad, India. He leads global preclinical and clinical development strategy and operations, with oversight across biopharmaceutics, clinical operations, immunogenicity, biostatistics and data management, medical writing, program management, bio-innovation, and external collaborations. With over 22 years of experience across the pharmaceutical industries and contract research organizations, including 17 years in senior leadership roles, Dr. Saini brings deep expertise in the development of small molecules, peptides, biosimilars, complex injectable and drug-device combination products, respiratory therapies, topical, and transdermal formulations. His work spans preclinical through late-phase clinical development, with strong strengths in PK/PD, immunogenicity, PBPK modelling, and global regulatory submissions. Dr. Saini is passionate about delivering data-driven development strategies that enable efficient global product approvals while meeting the highest scientific and regulatory standards.

Brandon Wood, BSc *See biography at page 20*

Victoria Keck, DVM
Acting Associate Director for Generic Drug Stakeholder and Global Engagement
OGD|CDER|FDA



Dr. Victoria "Vickie" Keck serves as Acting Associate Director for Generic Drug Stakeholder and Global Engagement at the FDA's Office of Generic Drugs (OGD), where she leads outreach and international collaboration efforts to advance generic drug regulatory science and policy. In this role, she builds strategic partnerships with industry, scientific communities, and international regulatory agencies, and directs OGD's participation in global harmonization initiatives. Vickie brings nearly 25 years of experience at the intersection of science, medicine, and regulatory decision-making. Grounded in laboratory animal and comparative medicine, she applies a One Health framework — recognizing the interconnectedness of human, animal, and environmental health — to translational and regulatory science. Her work has spanned pharmacology/toxicology review, international scientific exchange, and complex cross-agency issues such as nitrosamine risk assessment. A recognized leader and collaborator, Vickie has developed and launched an international scientific exchange programs and served as a mentor and leader at FDA for over a decade. She holds a VMD from the University of Pennsylvania School of Veterinary Medicine, a master's in biotechnology/bioinformatics from Johns Hopkins University, and completed a residency in laboratory animal/comparative medicine at Vanderbilt University Medical Center.

Robert Lionberger, PhD *See biography at page 3*
Sam Raney, PhD *See biography at page 1*

Xiaoming Xu, PhD
Director
DPQR V|OPQR|OPQ|CDER|FDA

Dr. Xiaoming Xu is a Division Director in the Office of Pharmaceutical Quality Research (OPQR) at the U.S. Food and Drug Administration (FDA), where he leads regulatory science initiatives supporting complex drug products, nanomaterials, and advanced pharmaceutical manufacturing. His work focuses on strengthening the scientific foundation for modern manufacturing approaches, including continuous manufacturing, advanced process control, and data-driven quality assessment. Dr. Xu plays a key leadership role in the implementation of the Generic Drug User Fee Amendments (GDUFA) III as co-lead of the Complex Product-Specific Guidance (PSG) Working Group, where he promotes the integration of regulatory research into guidance development for complex drug products. He is an active member of the FDA Nanotechnology Task Force and leads international collaborations and standards-development efforts related to nanotechnology-enabled pharmaceutical products. He serves on the editorial board of the International Journal of Pharmaceutics and is an elected Fellow of the Controlled Release Society (CRS) and the American Association of Pharmaceutical Scientists (AAPS). Dr. Xu received his B.S. and M.S. in Pharmaceutics from China Pharmaceutical University and earned his Ph.D. in Pharmaceutical Sciences from the University of Connecticut.

Ahmed Zidan, PhD *See biography at page 1*

Closing Remarks

Robert Lionberger, PhD *See biography at page 3*

FDA Offices Abbreviations

CDER	Center for Drug Evaluation and Research
DB	Division of Bioequivalence
DQI	Division of Quality Intelligence
DPMA	Division of Pharmaceutical Manufacturing Assessment
DPQA	Division of Product Quality Assessment
DPQR	Division of Product Quality Research
DPTID	Division of Pharmacology Toxicology for Infectious Diseases
DPTR	Division of Pharmacology Toxicology Review
DTP	Division of Therapeutic Performance
DQMM	Division of Quantitative Methods and Modeling
FDA	United States Food and Drug Administration
OB	Office of Bioequivalence
IO	Immediate Office
OGD	Office of Generic Drugs
OID	Office of Infectious Diseases
OND	Office of New Drugs
OPMA	Office of Pharmaceutical Manufacturing Assessment
OPQ	Office of Pharmaceutical Quality
OPQA	Office of Product Quality Assessment
OPQR	Office of Pharmaceutical Quality Research
OQA	Office of Quality Assurance
OQS	Office of Quality Surveillance
ORS	Office of Research and Standards
OSCE	Office of Safety & Clinical Evaluation
PMS	Project Management Staff