Fiscal Year (FY) 2024 Generic Drug Science and Research Initiatives Public Workshop Speaker, Panelist, And Moderator Biographies

In order of appearance on Agenda

Sarah Rogstad, PhD
Senior Scientific Advisor, OPQR/OPQ/CDER/FDA

Dr. Sarah Rogstad is a Senior Scientific Advisor in the Office of Pharmaceutical Quality Research (OPQR) in the Office of Pharmaceutical Quality (OPQ). She received her Ph.D. in Pharmacology from the University of Colorado and her B.S. in Biology-Chemistry from Harvey Mudd College. She joined FDA in 2014. Her expertise is in mass spectrometry of protein, peptides, and complex products.

Darby Kozak, PhD
Deputy Director, OGD/CDER/FDA

Dr. Darby Kozak is the Deputy Director for the Office of Generic Drugs where he serves as a senior advisor in the development and implementation of FDA policies and long-range objectives for generic drug scientific programs and activities. Prior to joining the FDA in 2014, Darby was Chief Scientist for Izon Science and a Research Fellow at the University of Queensland's Australian Institute for Bioengineering and Nanotechnology. Darby received his B.Sc. in Chemical Engineering from the University of Washington (Seattle, WA) and Ph.D. in Chemistry from the University of Bristol (United Kingdom).

Michael Kopcha, PhD
Director, OPQ/CDER/FDA

Michael Kopcha, Ph.D., R.Ph. is the Director of the FDA's Office of Pharmaceutical Quality (OPQ). This office has over 1,300 staff responsible for assuring the availability of quality medicines for the American public through assessment, inspection, surveillance, research, and policy. OPQ contributes to the assessment of nearly every type of human drug marketing application including New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and Biologics License Applications (BLAs), including 351(k) applications (i.e., biosimilars). OPQ also performs the quality assessment of Investigational New Drug Applications (INDs) and establishes quality standards for over-the-counter drug products and facilities. Prior to joining the FDA, Dr. Kopcha amassed more than 25 years of experience in major and mid-sized innovator, generic, drug/device, and over-the counter (OTC) pharmaceutical and consumer health companies. He developed expertise in areas including formulation and process development, product scale-up, process validation, technology transfer, project

management, change management, and off-shoring/outsourcing. Dr. Kopcha most recently served as Vice President, and global research and development franchise head, for cough, cold, and respiratory products at Novartis Consumer Health, Inc. Dr. Kopcha earned his doctorate and master's degrees in pharmaceutical science, and a bachelor's degree in pharmacy from Rutgers University. He also served as an adjunct assistant professor in the Department of Pharmaceutics at Ernest Mario School of Pharmacy at Rutgers.

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

Robert Lionberger, Ph.D., 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.

Sruthi King, PhD,
Deputy Director, DTPR/OSCE/OGD/CDER/FDA

Sruthi King earned her Ph.D. in pharmacology from Georgetown University and completed postdoctoral training at Stanford University in the Department of Dermatology. Sruthi joined the U.S. Food and Drug Administration in 2008 as a pharmacologist in the Division of Gastroenterology and Inborn Error Products within the Office of New Drugs and in 2015, joined OGD as a Pharm/Tox team leader in the Division of Clinical Review. Sruthi now serves as Deputy Director in the Division of Pharmacology/Toxicology Review in the Office of Safety and Clinical Evaluation within the OGD. Sruthi has been a member of the CDER nitrosamine task force since 2017 and serves on several working groups within FDA and internationally to establish guidance and harmonize approaches related to nitrosamine safety assessments.

Dongmei Lu, PhD
Policy Lead, OPPQ/OPQ/CDER/FDA

Dr. Dongmei Lu obtained her PhD degree in Pharmaceutical Sciences from University of North Carolina at Chapel Hill. She has pre-formulation and formulation working experience in GlaxoSmithKline, Wyeth and Pfizer. Before joining Office of Policy for Pharmaceutical Quality, she was a team leader in Office of Bioequivalence in Office of Generic Drugs. In OPPQ, Dongmei has been working on the policies of nitrosamine-impacted products. She was the primary author of the FDA guidance for industry "Control of Nitrosamine Impurities in Human Drugs". Dongmei also led a couple of FDA sponsored research projects on nitrosamine mitigations. Dongmei serves as a member of PQRI Biopharmaceutics Technical Committee.

Kevin P. Cross, PhD
Vice President, Regulatory Science FDA Research Collaborations & Principal Investigator Instem

Kevin P. Cross, Ph.D., is the Vice-President of Regulatory Science at Instem where he is Principal Investigator of U.S. FDA/instem research collaborations. He has been developing chemoinformatics tools and products for over 40 years. He is involved in several collaborative efforts creating in silico protocols and procedures for performing chemical hazard and risk assessments for regulatory purposes as well as developing and assessing the performance of QSAR models. He has published over 45 papers and 3 book chapters.

Xilin Li, PhD
Visiting Scientist, DGMPT/NCTR/FDA

Dr. Li is a toxicologist working at the National Center for Toxicological Research (NCTR), U.S. FDA, leading multiple studies in genotoxicity assessment for products safety. He received his doctoral degree in Environmental Health from Indiana University in 2018, where he investigated the mode of action of chemical-induced liver tumorigenesis in rodents and its human relevance. He also led research projects to exam the role of xenobiotics in the pathogenesis and progression of non-alcoholic fatty liver diseases. After graduation, he joined the Division of Genetic and Molecular Toxicology at NCTR, where he studies a broad range of topics in genotoxicity and chemical carcinogenicity. He leads multiple projects utilizing molecular biology tools and in vitro models to examine FDA-relevant chemicals for their mutagenicity and for determining the mechanisms underlying the induced genetic toxicity. His work has been incorporated into guidance documents for the industry by authorities such as the FDA, Health Canada, and the European Medicines Agency (EMA). He has authored/co-authored over 30 publications including peer-reviewed articles and/or book

chapters. He has been an active member of professional organizations including the Society of Toxicology (SOT), Environmental Mutagenesis and Genomic Society (EMGS), and Health and Environmental Sciences Institutions (HESI). He also serves as an editorial board member of multiple scientific journals.

Ian W. Ashworth, PhD
Principal Scientist, Chemical Development, AstraZeneca, Macclesfield, UK

Ian is currently Principal Scientist Physical Organic Chemistry in Chemical Development at AstraZeneca. He earned a BSc in Chemistry from Durham University and a Ph.D. in Chemistry at Cambridge University with Tony Kirby. HIs doctoral studies on intramolecular catalysis in phosphonoacetate hydrolysis started an ongoing interest in pH dependent kinetics. Dr. Ashworth started his industrial career in Zeneca's Process Studies Group, where he spent his early career working to apply physical organic chemistry to agrochemical and speciality chemical processes to build process understanding. Since 2005 Ian has worked for AstraZeneca in Chemical Development to apply physicochemical concepts to support drug substance process development. During this this time he has developed an interest in degradation chemistry across the drug substance - drug product interface. Since 2019 a significant focus has been understanding the formation of nitrosamines during drug substance processing and leading the Nitrosamine Formation sub team of the IQ Consortium's Nitrosamine Working Group to drive the science behind nitrosamine risk assessments. A significant focus has been the development of kinetics based tools to support API and drug product RAs.

Marthin Ehlert, PhD
Vice President, API R&D, Apotex Inc

Martin Ehlert obtained a B.Sc. in Applied Chemistry at McMaster University in 1987 and a Ph.D. in Chemistry at the University of British Columbia in 1992. In 1994, Dr. Ehlert commenced his career in the pharmaceutical industry at Phytogen Life Sciences working in the areas of API process development, engineering and production operations. In 1998, he joined Apotex Pharmachem Inc., serving in various capacities within API R&D and operations. In 2015, Dr. Ehlert moved to Apotex Inc. and currently holds the role of Vice President, Global API R&D.

Fang Wu, PhD
Senior Pharmacologist, DQMM/ORS/OGD/CDER/FDA

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 12 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.

Naiffer Romero, MSc, MPH
Principal Scientist, Scientific Affairs, US Pharmacopeia

Naiffer has more than 20+ years of pharmaceutical industry experience. In his 15 years tenure with USP, he has served several roles: Lead scientist in performance testing compendial reference standards development, Manager in charge of LATAM Compendial engagement and education with users and national regulatory bodies. Naiffer is also a certified USP Education instructor. Naiffer's journey with USP continued in 2020 when he joined the Scientific Affair performance cell. Here, he spearheads scientific outreach and technical engagement for the LATAM & US region on critical national health priority topics. His broad pharmaceutical expertise encompasses Analytical development, salt and polymorph selection, Development of dissolution methods, IVIVC modeling, and impurity analytical strategy. However, his true passion lies in the field of nitrosamine impurities, where he is a recognized subject matter expert with several publications. He also plays a crucial role as a member of USP's Nitrosamine workstream Committee and as a community manager for 'Nitrosamine Exchange', a knowledge community hosted by USP in All-things Nitrosamines Impurities. Naiffer also liaises technical discussions on pharmacopeial collaboration, including the International Meeting of World Pharmacopeias (part of WHO) and international compendial discussion groups (PDG), and is a member of several regional regulatory agencies' nitrosamines working groups.

Tausif Ahmed, PhD, MS
Vice President & Head, Biopharmaceutics & Bioquivalence, GCM, Dr. Reddy's Laboratories Ltd.

Dr. Tausif Ahmed is currently working as Vice President & Head-Biopharmaceutics & Bioequivalence in the Global Clinical Management group, IPDO at Dr. Reddy's Laboratories Limited (DRL), Hyderabad. He is responsible for managing all Bioequivalence studies supporting global complex generic products at DRL. He is 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, Sai Life Sciences Limited, and Piramal Enterprises Limited in the past. He obtained MS in Pharmaceutics from NIPER and PhD in Pharmaceutical Medicine (specialization: Biopharmaceutics and PK/PD) from Hamdard University (Ranbaxy, now Sun Pharma Sponsored). He has been working in the field of drug discovery, development, phase I/II, and generic BA-BE studies for more than 23 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/II/III regulatory submissions, nationally and globally. He has co-authored two book chapters and over 50 papers and presentations. He is a reviewer for many international journals and is on the Editorial board of Int. J. Pharma Research. 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 PhD students.

Daniel Snieder, PhD
Head, Global Quality Systems IT Quality/Technical Quality, Viatris

Dan Snider received his Doctor of Philosophy degree in Chemistry from West Virginia University in 1995 and soon thereafter began his career at Mylan Pharmaceuticals in Research and Development. Dan is currently the Head of Global Quality Systems, Technical Quality and IT Quality at Viatris. Dan has worked on several initiatives with Industry and U.S. FDA such as Polymorphism in Generic Drug Products and Quality by Design as well as various other Chemistry Manufacturing Controls related topics.

Robert Dorsam, PhD
Director, DPTR/OSCE/OGD/CDER/FDA

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 then conducted postdoctoral research at the National Institutes of Health (NIH). He then 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). In 2014, he joined the Office of Generic Drugs (OGD) as a team leader where he helped to build OGD's Pharmacology/Toxicology team. He later assumed a supervisory role when he became Associate Director of Pharmacology/Toxicology in OGD's Division of Clinical Review. More recently, Bob became Director of the Division of Pharmacology/Toxicology Review in OGD. He is committed to the growth of the Pharm/Tox discipline by advancing several technical areas, promoting process-improvement, and through 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.

Naomi Kruhlak, PhD
Scientific Lead, DARS/OCP/OTS/CDER/FDA

Dr. Naomi Kruhlak has worked for US FDA's Center for Drug Evaluation and Research (CDER) as a computational toxicologist for 22 years, developing and applying (quantitative) structure-activity relationship ((Q)SAR) models to support the regulatory review of pharmaceuticals. She is the Scientific Lead for CDER's Computational Toxicology Consultation Service and is the Principal Investigator on three FDA/CDER Research Collaboration Agreements with commercial (Q)SAR software vendors, as well as an Inter-Agency Agreement with NIH generating in silico-based drug safety predictions. Dr. Kruhlak has published 46 peer-reviewed articles and book chapters describing data standardization, transformation, and classification for modeling purposes, as well as the creation and regulatory application of (Q)SAR models with chemical interpretability. Most recently, she led the development of the Carcinogenic Potency Categorization Approach for predicting the carcinogenic potency of nitrosamine impurities. Dr. Kruhlak holds B.Sc. and Ph.D. degrees in chemistry from the University of Salford, England, and the University of Calgary, Canada, respectively.

Bing V. Li, PhD
Associate Director for Science , OB/OGD/CDER/FDA

Dr. Bing V. 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.

Bhagwant Rege, PhD
Division Director, DPQA VI/OPQAI/OPQ/CDER/FDA

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. Most recently he served as a division director for CDER/OPQ/OLDP/ Division of Immediate and Modified Release Products III. Prior to joining 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.

Diaa Shakleya, PhD
Senior Research Scientist, DPQR/OPQR/OPQ/CDER/FDA

Dr. Diaa Shakleya is a Senior Research Scientist within the Office of Pharmaceutical Quality Research. 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 Food and Drug Administration (FDA) for over 9 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 58 peer-reviewed publications and more than 100 scientific podium and poster presentations.

Matthew D. Vera, PhD
Supervisory Chemist , DPQA II/OPAQI/OPQ/CDER/FDA

Matthew Vera completed his B.S. in chemistry at Lebanon Valley College, and was a Fulbright Scholar in chemistry at the University of Munich. He subsequently returned to the U.S. and earned a Ph.D. in organic chemistry from the University of Pennsylvania. After completing his degree at Penn, Matt worked as a research scientist in the pharmaceutical industry in the areas of new drug discovery and medicinal chemistry. Matt joined the FDA Office of Generic Drugs in 2010 as a CMC review chemist, focusing on the quality assessment of drug master files (DMFs) and generic drug applications (ANDAs) for immediate-release solid oral dosage forms. He has worked as a review team leader and currently serves as a supervisor in OPQ's Office of Product Quality Assessment I. Matt has extensive experience handling nitrosamine issues from the quality assessment perspective. He also serves as a co-lead in some internal nitrosamine research projects with OPQ's Office of Pharmaceutical Quality Research.

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

Dr. Lanyan (Lucy) Fang currently serves as Deputy Director of the Division of Quantitative Methods and Modeling (DQMM) in OGD's Office of Research and Standards. Prior to that, she served as Associate Director and Team Lead of the Quantitative Clinical Pharmacology team within DQMM. She has established herself as the FDA expert in the use of quantitative clinical pharmacology approaches in the review and regulation of generic drugs. She co-leads CDER work group tasked with the use of partial area under the curve for the bioequivalence assessment. Prior to her current position, Dr. Fang worked as the senior clinical pharmacology reviewer in the FDA's Office of Clinical Pharmacology (2009 – 2014) and senior pharmacokinetist in Merck (2007 – 2009). Dr. Fang obtained her Ph.D. in Pharmaceutical Sciences from Ohio State University and is a graduate of the Excellence in Government Fellows program (2014-2015).

Ahmed Zidan, PhD
Senior Staff Fellow, DQPR V/OPQR/OPQ/CDER/FDA

Dr. Ahmed Zidan is a senior pharmacologist staff at the Division of Product Quality Research of Office of Testing and Research 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 OTR 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 various publications and book chapter. Ahmed completed his bachelor's and master's degree in pharmaceutical sciences at Zagazig University, and his doctoral degree in Drug Delivery at Howard University.

Liang Zhao, PhD
Director, DQMM/ORS/OGD/CDER/FDA

Dr. Liang Zhao has been serving as the Director of Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards, Office of Generic Drugs, CDER/FDA since 2015. He has demonstrated excellence and leadership in drug development and regulatory science for new and generic drugs during his 19-year professional tenure including in Pharsight as an associate consultant, BMS as a research investigator, MedImmune as an Associate Director, and FDA as Clinical Pharmacology reviewer, Pharmacometrics Team Leader, and Division Director. Dr. Zhao and his team have introduced a broad array of innovative tools in the realm of drug deliveries, bioequivalence assessment, and big data tools including machine learning to pharmacometrics. They have also implemented the Model Integrated Evidence (MIE) Industry Meeting Pilot to support regulatory communications between generic applicants and the FDA and proposed a regulatory mechanism of using Model Master File to support regulatory submissions. Liang currently serves as the Chair of the FDA ModSim WG for the Modeling & Simulation community cross FDA centers and offices. He has published over 110 peer reviewed publications and 8 book chapters. He received the 2023 Gary Neil Prize for Innovation in Drug Development from ASCPT in recognition to his contribution to clinical pharmacology and pharmacometrics.

William Ganley, PhD
Senior Specialist, Nanopharm Ltd. (an Aptar Pharma Company)

Will is a Physical Chemist with a PhD from the University of Bristol, UK. He started his career as a postdoc in Pharmaceutical Surface Science Lab at the University of Bath, UK. His focus was on advancing physical characterisation and simulation techniques for dry powder inhaler formulations, aiming to better understand the connection between physical attributes and delivery to patients. In 2019 he joined Nanopharm as Head of Computational Pharmaceutics where he led the development of a number of statistical and mechanistic modelling methodologies, notably Nanopharm's Simhalation PBPK platform. Will is now a senior member of the Science & Technology department at Nanopharm where he supports Nanopharm's customers in product development and regulatory strategy and manages a portfolio of internal research and development projects aimed at advancing Nanopharm and Aptar Pharma's scientific excellence in the use of advanced physical characterisation and digital technologies in inhaled and nasal drug product development. Will has authored a number of peer reviewed publications on pharmaceutics, statistics and physical chemistry, has presented his work at a range of international conferences and is a Scientific Advisor for the Drug Delivery to the Lungs conference.

Jessica Spires, PhD
Principal Scientist, Simulation Plus

Dr. Jessica Spires is a principal scientist at Simulations Plus, Inc. She is focused on physiologically based pharmacokinetic (PBPK) modeling of non-oral routes of administration, including dermal, ocular, and pulmonary administration, in the GastroPlus™ and MembranePlus™ software platforms. She is currently the principal investigator on FDA grants focusing on transdermal drug products quality and performance attributes via enhanced virtual bioequivalence simulations, and on PBPK/PD modeling of ophthalmic drug products to support translation from pre-clinical species to human. She is a graduate of Case Western Reserve University with a Doctoral degree in biomedical engineering.

Jan de Backer, PhD
MBA Chief Executive Officer, Fluidda

Jan De Backer graduated from Delft University of Technology, The Netherlands as aerospace engineer. He attained an MSc degree in aerodynamics and specialized in applied biomedical computational fluid dynamics leading to a PhD from the University of Antwerp, Belgium. He is an alumnus of the MBA programs at London Business School, London and Columbia Business School, New York. Dr. De Backer has received several awards for his innovative research in the field

of airway modeling in respiratory and sleep medicine. His work has been published in international journals. Dr. De Backer founded FLUIDDA in 2005 and he has held the position of Chief Executive Officer since 2007.

Robert Bies, PhD
Professor & Associate Dean, School of Pharmacy and Pharmaceutical Sciences, University at Buffalo

Dr. Bies is currently Professor of Pharmaceutical Sciences and Associate Dean of Graduate Education at the School of Pharmacy and Pharmaceutical Sciences as well as a member of the Institute for Artificial Intelligence and Data Science at the State University of New York at Buffalo. Prior to this, Dr. Bies was Associate Professor of Medicine and Medical and Molecular Genetics at the Indiana University School of Medicine and Director of the Disease and Therapeutic Response Modeling program for the Indiana Clinical Translational Sciences Institute. He serves as: project scientist at CAMH, University of Toronto; on the editorial boards of the Journal of Pharmacokinetics and Pharmacodynamics, Clinical Pharmacology and Therapeutics:Pharmacometrics and Systems Pharmacology, Journal of Clinical Pharmacology, Biopharmaceutics and Drug Disposition; and the British Journal of Clinical Pharmacology. Dr. Bies is a member of ISoP, ACCP and ASCPT. He is also a Fellow of the International Society for Pharmacometrics. Dr. Bies received a BSc degree in Pharmacy from the University of Toronto (1991), a Pharm.D. from the UTHSCSA and the University of Texas at Austin (1994) and a Ph.D. Pharmacology from Georgetown University in 1998. This was followed by postdoctoral training at the Center for Drug Development Sciences until 2000. His research focuses on the application of pharmacometric and PBPK approaches in HIV, contraception, opiate addiction, pediatrics, psychiatry, oncology and neurology as well as on novel methods development including machine learning approaches to model selection and optimization methods for parameter optimization in dynamic systems.

Clare Butler, PhD
Principal Product Development Scientist, Teva Pharmaceuticals

Clare Butler is a principal product development scientist at Teva Pharmaceutical's global inhalation R&D department. Following completion of a Ph.D. in Pharmacology, she spent a year working at Sanofi in lyophilisation and analytics. She joined Teva in 2018 and is currently responsible for leading Teva's inhaled IVIVC initiative. Clare has a keen interest in advancing the application of IVIVC and mechanistic modelling for respiratory drug product development.

Andrew Cooper, PhD
Senior Director, Mylan Global Respiratory Group, Mylan Pharma UK (Viatris)

Dr Andrew Cooper studied at University of Bath. 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 development of inhaled products for in-vivo performance. He has particular interests in understanding the relevance of in-vitro tests to in-vivo performance and bioequivalence strategies for inhaled products.

Sivacharan Kollipara, PhD
Team Lead, Biopharmaceutics, Dr. Reddy's Laboratories Ltd.

Mr. Sivacharan Kollipara is currently working as Team Lead, Biopharmaceutics 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. Overall Mr. Kollipara has an experience of 16 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 ~25 peer-reviewed publications. 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.

Ping Zhao, PhD
Senior Program Officer, Bill & Melinda Gates Foundation

Ping graduated with a BS in Pharmacy from Beijing Medical University in China in 1994, and a PhD in Pharmaceutics from University of Washington in Seattle, WA, USA in 2002. After that, Ping worked as a DMPK scientist at Pfizer in La Jolla CA (2002-2005), a pharmacokineticist at Sonus Pharmaceuticals in Seattle (2006-2007), a clinical

pharmacologist at Amgen in Seattle (2008), and the Scientific Lead of PBPK (physiologically-based pharmacokinetic modeling) Program and Expert Pharmacologist at the Office of Clinical Pharmacology, US FDA in Silver Spring, MD (2008-2017). At FDA, Ping led reviews of PBPK submissions in IND/NDA/BLAs, research in PBPK, and policy development on PBPK, including writing the agency's first draft PBPK guidance (2016) and updated in vitro and in vivo drug-drug interaction guidances (2017). In June 2017, Ping moved to the Bill & Melinda Gates Foundation in Seattle, WA as a Senior Program Officer of Quantitative Sciences, where he applies quantitative pharmacology principles and manages Model-informed Drug development (MiDD) efforts in projects funded by the foundation. He oversees a research portfolio that uses PBPK and MIDD to improve pharmacotherapy in neglected populations, such as children, pregnant women, and breastfeeding women.

Dhaval Gaglani, PhD
Supervisory Chemist , DPQAV/OPQAI/OPQ/CDER/FDA

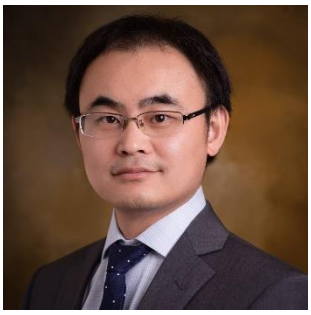
Dhaval Gaglani joined the FDA in 2010 and currently serves as the Unit Supervisor in the Office of Product Quality Assessment I (OPQA I)/Division of Product Quality Assessment V. Previously, Dhaval served in the OGD/Division of Chemistry as Team lead and review chemist. His Unit is responsible for drug product quality assessment of ANDAs for Solid, Liquid and Nasal drug products. Additionally, Dhaval and his Unit members serve as Subject Matter Experts with respect to quality assessment of Generic Inhalation products (DPIs, MDIs, and Soft mist inhalers). Prior to joining the FDA in 2010, he spent 12 years in pharmaceutical industry with industrial experience in product development, process development, scale-up and validation.

Meng Hu, PhD
Team Lead, DQMM/ORS/OGD/CDER/FDA

Dr. Hu received both his Bachelor of Engineering in Biomedical Engineering and Ph.D. in Physics from the Zhejiang University, China. He conducted his post-doctoral training at Drexel University, Philadelphia. He joined the FDA's Center for Drug Evaluation & Research as a staff fellow in 2015 and currently serves as a scientific lead in the Division of Quantitative Methods and Modeling under the Office of Research and Standards in the Office of Generic Drugs. His main research interests include the development and application of advanced data analytics tools to promote business intelligence in government, big data management, large language model, generation of real-world evidence, and quantitative methods to facilitate assessment for in-vitro bioequivalence study.

Rebecca Moody, PhD
Pharmaceutical Scientist, OPQAII/OPQ/CDER/FDA

Dr. Rebecca Moody works in the Immediate Office (IO) of the Office of Drug Product Quality II (OPQA II) at the FDA. Previously, she was a Biopharmaceutics Reviewer in the Division of Biopharmaceutics (DB). Dr. Moody received a Bachelor of Science in Biology and Chemistry from Emory University, and a Ph.D. in Chemical Biology from the University of Michigan. She has experience evaluating biopharmaceutics and quality information (e.g., in vivo biowaivers, in vitro dissolution method development, etc.) in New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and Investigational New Drug Applications (INDs). In addition, Dr. Moody serves as a scientific lead for physiologically based biopharmaceutics modeling (PBBM) in the DB Modeling and Simulation Committee.



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

Dr. Zhen Zhang is a Master Pharmacologist at FDA's Office of Generic Drugs (OGD), Office of Bioequivalence, Division of Bioequivalence I. His expertise encompasses a broad range of areas including data analysis, modeling and simulation, dissolution studies, and topical product evaluations. He co-leads the OGD's Oral PBPK Expert Committee and spearheads the efforts to modernize SAS programs, thereby enhancing the efficiency of the bioequivalence review process. With a rich background in addressing complex bioequivalence challenges, Dr. Zhang has contributed to the development of multiple FDA guidances and the Manual of Policies and Procedures (MAPP). Prior to joining the FDA in 2014, he obtained his Ph.D. in Pharmacology from the University of Wisconsin-Madison and completed his postdoctoral training at the National Institutes of Health.

Jayanti Das, PhD
Research Scientist, DQPRVI/OPQR/OPQ/CDER/FDA

Dr. Jayanti Das is working as a Research Scientist in the Office of Pharmaceutical Quality and Research (OPQR) at the U.S. Food and Drug Administration (FDA). Dr. Das has completed her Ph. D in Mechanical Engineering from the University of California, Davis. She was working as a Process Engineer at Intel Corporation prior joining to the FDA. Her work is directly related to scientific investigation and research on advanced manufacturing for pharmaceutical product quality assessment and control, product image characterization, data analysis, and data visualization.

Bryan Newman, PhD
Lead Pharmacologist, DTP I/ORS/OGD/FDA

Bryan Newman, Ph.D., 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.

Sam Raney, MS, PhD
Associate Director for Science & Chief Scientific Advisor, 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 orchestrates the development of strategic research priorities and oversees the research portfolio of FDA's generic drug science and research program. Dr. Raney is a thought leader with over 30 years of experience in pharmaceutical drug development, specializing in topical and transdermal drug products, and producing numerous research manuscripts, review articles, book chapters and patents. He has been a researcher and adjunct professor within academia, 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.

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

Dr. Anna Schwendeman is Hans W. Vahlteich Professor of Pharmacy and Professor of Pharmaceutical Sciences at the University of Michigan. Her research focuses on optimization of high-density lipoprotein (HDL) nanoparticles for treatment of atherosclerosis, sepsis, and drug delivery purposes. In 2016, she co-founded EVOQ Therapeutics (www.evoqtherapeutics.com), a company focused on the use of HDL nanodiscs for delivery of immunotherapies focused on improving the lives of individuals fighting autoimmune diseases. Dr. Schwendeman received her B.S.

from Moscow Institute of Physics and Technology and 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 discovery and translation of HDL drugs to clinical trials. She successfully submitted FDA INDs for seven different products including nanoparticles, liposome, recombinant proteins, peptides, and small molecules. Her laboratory's research in regulatory sciences is focused on analytical characterization of liposomes, polymer microspheres, peptides, and biosimilar products. Dr. Schwendeman is a co-Director of 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.

Prabkhakar Reddy, PhD
Director, Pharmaceutical Sciences, US Pharmacopeia

Dr. Prabhakar Reddy is the Director of Pharmaceutical Sciences, General Chapters, at the United States Pharmacopeia (USP) and works with Microbiology, Dosage Forms and Packaging & Distribution Expert Committee related activities. He is also the scientific lead for the Complex Generics initiatives at USP, including developing standards for Extractables & Leachables, as well as other complex products such as Complex Injectables, Ophthalmics, Topical & Transdermal, Nasal & Inhalation products. Prior to joining USP, Dr. Reddy worked in the pharmaceutical industry for more than 27 years at various small and large pharmaceutical companies in the field of analytical and bio-analytical chemistry. His expertise includes analytical and bioanalytical method development and validations, use of modern analytical technologies such as HPLC/UPLC and LC-MS/MS for characterization of both small and large molecules, use of automated instrumentation (TPW, and Sotax AT MD) for assay and dissolution testing, ICH stability testing, and preparation of regulatory documentation for IND/ANDA/NDA submissions. Dr. Reddy holds BS and MS degrees in chemistry and a PhD in bioanalytical chemistry.

Pradeep Dabhi, PhD
Co-Founder and Chief Scientific Officer, Cutyx Research

Dr. Pradeep Dabhi is a Co-Founder of Cutyx Research LLP, Ahmedabad, India, serving as a Chief Scientific Officer. Prior to his role at Cutyx, Pradeep held senior positions at reputable organizations namely Encube Ethicals and Zydus Life Sciences, where he led teams of skilled scientists focused on the analytical development of Complex dosage forms, particularly Transdermal patches, intravaginal rings (IVR) & Topical products. Pradeep also served as a Consultant to ICURE Pharmaceutical Inc., South Korea where he provided guidance on the development of Transdermal systems as per USFDA requirements. With over 14 years of experience in analytical development across the spectrum of complex dosage

forms, Pradeep has played a pivotal role in numerous research and development endeavors, including ANDAs and NDA 505 (b)(2) projects related to Topical and Transdermal Drug Delivery Systems. Pradeep has a strong background in analytical method development, qualification, validation, transfer, reverse engineering of complex formulations including advanced characterization of complex excipients; as well as in-vitro release and skin permeation testing (IVRT/IVPT) alongwith statistical evaluations, extractables and leachables (E&L) and elemental impurities. In addition, Pradeep has extensive regulatory CMC knowledge, including both early and late-stage submissions, and responses to regulatory deficiencies. Pradeep also possesses good experience of setting up of Greenfield projects as well as setting up of quality control laboratories for Transdermal patch analysis, from scratch to state-of-art labs, including instrument URS till complete IQ, OQ, PQ. Pradeep holds a Doctorate in Pharmaceutical Sciences and a Master's degree, M.S.(Pharm.) from NIPER-Ahmedabad, India.

Andrew Graves, MS
Director, Immunogenicity Assessment, Specialty Bioanalytics, Teva Pharmaceuticals

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 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.

Ripen Misri, PhD
Senior Director, Liquids & Specialty Dosage Forms, Apotex Inc

Dr. Ripen Misri obtained his PhD in pharmaceutical sciences from the University of British Columbia (Canada) and further pursued a post doctoral fellowship at BC Cancer Research Center. Dr. Misri's expertise is in development of complex dosage forms such as nanoparticulate and microparticulate drug delivery systems, inhalation and peptide therapeutics. Dr. Misri joined Apotex in 2015 and is currently Senior Director of Liquids & Specialty Dosage Forms, leading development of complex generic drug, and drug device combination products.

Thomas Tice, PhD
Senior Director, Global Strategic and Technical Marketing, Health Care, Evonik Corporation

Dr. Thomas Tice has 45 years of drug delivery experience developing bioabsorbable, long-acting injectables. His expertise includes polymeric injectable microparticles, implants and nanoparticles formulated with bioabsorbable lactide/glycolide polymers. Manufacturing process experience includes microencapsulation, nanoencapsulation and hot melt extrusion. He holds 49 US patents in the field with many foreign equivalents and has over 230 publications, presentations and invited lectures to his credit. He led the team and is one of the inventors that developed the first commercial, injectable, long-acting microparticle product and has been involved with the development of many long-acting injectables that are on the market. He has served with United States Pharmacopeia for ~20 years, presently serving on the General Chapters-Dosage Forms Expert Committee and several subcommittees including the Nanotechnology Joint Subcommittee and LG Polymer Joint Subcommittee.

Yan Wang, PhD
Acting Deputy Director, DTP I/ORS/OGD/FDA

Dr. Yan Wang is the team lead for Complex Drug Products Team and the acting deputy director in the Division of Therapeutic Performance I (DTP I), Office of Research and Standards (ORS), Office of Generic Drugs (OGD). In her current role, Dr. Wang leads a group of interdisciplinary scientists developing product specific guidances, addressing controlled correspondences, pre-ANDA meeting requests, citizen petitions and internal consults in the areas of complex drug substances and complex formulations for various routes of administration and dosage forms. She also manages research projects on 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. Dr. Wang received Ph.D. in Pharmaceutical Sciences from the University of Connecticut.

Eric Pang, PhD
Senior Chemist, DTP I/ORS/OGD/FDA

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.

Cameron Smith, PhD
Supervisory Chemist , DPQAVI/OPQAI/OPQ/CDER/FDA

Cameron 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 Silver Spring, MD. 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.

Daniela Vertheyli, PhD
Supervisory Biologist, DPQRVI/OPQR/OPQ/CDER/FDA

Dr. Daniela Verthelyi is currently the Chief of the Laboratory of Immunology in the Office of Biotechnology Products and heads the Center for Excellence in Infectious Diseases and Inflammation in CDER, FDA. She has 20 years of experience in applying bench science to regulation at FDA to facilitate the development of safe and effective therapeutics and is a key contributor to innovative policies in immunogenicity risk assessments. Her lab is focused on understanding innate immunity and inflammation and applying the information to address regulatory problems. Her group develops new methods and models to understand the role of product and process related impurities on product immunogenicity, as well as animal models to assess the safety and efficacy of innate immune response modulators and other therapeutics to respond to infectious diseases. Dr. Verthelyi has authored over 100 peer-reviewed articles, is the inventor in several patents, and has received FDA's, CBER's, and CDER's "Excellence in Laboratory Sciences" awards, among other honors. In addition to her position at FDA, she has Chaired the NIH-FDA Immunology Interest Group, the NIH-FDA Cytokine Interest Group, and served on the Advisory Boards for the NIH Human Immunology Group. Dr. Verthelyi trained in medicine at the University of Buenos Aires and then obtained a PhD in Immunology from Virginia Tech in USA.

Deyi Zhang, PhD
Senior Chemist, DTP I/ORS/OGD/FDA

Dr. Deyi Zhang is a senior chemist in the Division of Therapeutic Performance I (DTP I), Office of Research and Standards (ORS), Office of Generic Drugs (OGD) at FDA specializing in complex drug substances, including complex mixtures, peptides, oligonucleotides and polymeric APIs. In his work, he provides scientific inputs for regulatory policy and actively involves in pre-ANDA meetings, product-specific guidance development of such products, and manages related research activities. Dr. Zhang received his Ph.D. in organic chemistry from the University of Notre Dame. He had two years of NIH postdoctoral fellowship training at the University of Pennsylvania before joining Eli Lilly and Company in 2000. After 15 years in pharmaceutical industry, he joined the FDA in 2015. He has 12 US patents and over 50 publications and presentations.

Lei 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). Dr. Zhang oversees the implementation of 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 25 years of combined experiences 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 oral dosage form drugs. She was a member of the ICH Generic Drug Discussion Group (GDG), serving as the U.S. FDA Topic Lead. Dr. Zhang was named American Association of Pharmaceutical Scientists (AAPS) Fellow in 2013. She has published more than 130 peer-reviewed papers and book chapters.

William Chong, MD
Director, OSCE/OGD/CDER/FDA

Dr. William Chong is the Director of OGD's Office of Safety and Clinical Evaluation. He leads an multidisciplinary group of scientists that work to ensure that generic drug products have the same safety and efficacy profile as the reference listed drug. Dr. Chong joined FDA in 2012 in CDER's Office of New Drugs where he primarily evaluated new drug products for patients with diabetes mellitus. He subsequently joined OGD in 2019 as the Associate Director for Clinical Affairs before becoming the Director of OSCE in 2022. He is a board-certified internist and endocrinologist, and completed his Internal Medicine residency at Thomas Jefferson University Hospital in Philadelphia, PA and his Endocrinology and Metabolism fellowship at the National Institutes of Health in Bethesda, MD. Dr. Chong earned his undergraduate degree in Engineering Science at Penn State University, and his Medical Degree from Temple University School of Medicine.

Katharine Feibus, MD
Lead Physician/Team Leader, Device Evaluation Team, DTP I/ORS/OGD/FDA

Dr. Feibus is the lead physician and team leader for the Device Evaluation Team in the Office of Generic Drug's Office of Research and Standards. The Device Evaluation Team provides pre-ANDA submission device evaluations and feedback to the generic drug industry through performance and review of comparative analyses between the user interfaces of a reference listed drug that is a drug-device combination product and a proposed generic drug-device combination product. The team also oversees research contracts and grants focused on advancing the science and methods to demonstrate that a generic drug-device combination product will have the same clinical effect and safety profile as its reference listed drug when generic substitution occurs. During almost 10 years in the Office of Generic Drugs (OGD), Dr. Feibus has also served as clinical team leader for the Clinical Safety and Surveillance Team (now part of the Division of Clinical Safety and Surveillance) and a reviewer and acting team leader in the Division of Clinical Review. Dr. Feibus was a practicing obstetrician/gynecologist for nine years before joining the Federal government. Prior to her time in OGD, Dr. Feibus worked in CDER's Office of New Drugs as a medical officer and acting team leader for the Office of Nonprescription Drug Products and team leader for the Maternal Health Team in the Division of Pediatric and Maternal Health. Dr. Feibus also served as the Deputy Director of Reproductive Health in the Office of Women's Health Services at the Veterans Health Administration. Outside of work, Dr. Feibus enjoys spending time with family and friends, hiking, Nordic skiing, biking, and snuggling with her three poodles.

Brandon Wood, BS
Director of Regulatory Affairs, Generic Steriles (Teva Pharmaceuticals USA, Inc.)

Brandon Wood, B.Sc. is a Director, Regulatory Affairs, Gx Steriles, 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, iron colloids, long-acting injectables, and drug-device combination products. Brandon has been a regulatory professional for over 10 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.

Melissa Lemke, MS
Regulatory Human Factors Engineering Advisor , Human Ability Designs, LLC

Melissa Lemke is the Principal Human Factors Engineering Advisor with Human Ability Designs, a human factors firm that achieves FDA human factors regulatory success with clients seeking to optimize user interface designs. Since 2003, Melissa has achieved 100% first-time human factors regulatory clearance/approval of medical products with hundreds of clients by applying and teaching the science of human factors engineering within regulated medical product design. Melissa is talented at innovating scalable solutions to meet human factors requirements throughout the pre-market and post-market design process. She brings decades of practitioner experience and industry leadership in use-related risk management, user-centered design for products used in clinical and non-clinical environments, and training and mentorship of emerging professionals in need. Melissa is dedicated to helping teams develop and bring to market medical products that are safe, effective, and usable for people of all abilities while efficiently meeting business and market demands. Melissa is a Biomedical Engineer formally trained in human factors, ergonomics, and human research methods with expertise in within the regulatory sciences that enables FDA reviewers to swiftly approve medical technologies for patients in need. Melissa participates in standards development, teaches human factors at the University level and with AAMI, and routinely publishes her scientific contributions to our industry, including within *Applied Human Factors in Medical Device Design* (2019) and *Development of Biopharmaceutical Drug-Device Products* (2020). Her current research interests are focused on the FDA sponsored grant, *Development of a Combination Product Taxonomy*

and Comparative Human Factors Testing Method for Drug-Device Combination Products Submitted in an ANDA (2021-2024).

Vivek Viswanathan, PhD
Manager, Research & Development, Rubicon Research Canada Limited

Vivek has worked in the area of pharmaceutical product development for almost 15 years & specializes in the area of orally inhaled & Nasal drug products (OINDPs). These include dry powder inhalers (DPIs), metered dose inhalers (MDIs) & nasal products. Vivek also has considerable experience around combination product development including regulatory documentation. In addition to working on novel & specialty products for delivery via nasal & inhalation route, Vivek is also involved in development of generic products which require comparative threshold analyses & related studies. He has been involved in end-to-end combination product development from formulation development, scale up, technology transfer & design history file compilation. Additionally, Vivek's area of research also involves device development with special emphasis on risk analysis, user interface design & comparative studies. Vivek holds a PhD degree in Pharmaceutical Sciences from University of Mumbai (India). In his current position, Vivek is leading the R&D activities for Rubicon's Canada R&D center based out of Concord, ON.

Daliya Bharati, MS
Director, Regulatory Affairs & Intellectual Property , Advagen Pharma Limited

Daliya has about 20 years of rich experience in the pharmaceutical industry. Daliya leads the regulatory affairs and intellectual property activities for Advagen Pharma Limited and the Rubicon Research Group. In this role, she develops regulatory strategies for product registrations worldwide, interacts with regulatory agencies globally and manages the complete regulatory lifecycle of numerous products. Daliya has led several ANDA and NDA submissions and approvals for solid, liquid, ophthalmic, injectable and nasal products. In addition to working on generic products, she has worked extensively on drug-device combination products, specialty, and other complex generic products. She is closely associated with use-related risk analysis assessments and comparative threshold evaluations of different products. Daliya was a recipient of the Council of Scientific and Industrial Research Senior Research Fellowship and the Department of Biotechnology Junior Research Fellowship for her Master's degree at Institute of Chemical Technology, Mumbai, India which she pursued after graduating as a B.Pharm. She also holds a Diploma in Patent Law from NALSAR University, Hyderabad, India.

Amy Lukau, BA, BS
Senior Human Factors Lead, Kindeva Drug Delivery

Amy Lukau is the Senior Human Factors Lead for Kindeva Drug Delivery, supporting Global R & D and New Product Development functions for health and health security solutions. Lukau has over fourteen years working experience in research academia (biotechnology and genetic engineering) as well as the pharmaceutical and med tech industry, where her work spanned but was not limited to human factors engineering; complex combinational drug development; biologics, medical device integration for antimicrobial resistance and tuberculosis platforms; validation of facilities, equipment, and computerized systems within GMP regulated environments. She is a proud member of the Human Factors and Ergonomics Society; Parental Drug Association; AAMI and the Global Health Network, where she currently holds membership in Global Health Bioethics, Research Ethics & Review and Worldwide Antimalarial Resistance. Lukau holds a BS in Molecular Biosciences and Biotechnology and BA in Religious Studies from Arizona State University. Lukau also holds an MFA in Writing in Poetics.

Heidi Mehrzad, MS
Founder/CEO & Human Factors Expert , HFUX Research, LLC

Heidi Manijeh Mehrzad is the founder and CEO of the medical human factors and usability consultancy HFUX Research, LLC, specializing in medical device, technology, and combination product development. With a wide-ranging background as a trained pilot, emergency medical technician, software analyst, and human factors and usability expert within the (medical) product development industry, her motivation for the past 25 years has been directed towards enhancing human-product performance by optimizing user interface design, information architecture, and user and product workflow, through the application of human factors science and usability practices. Her focus has been on promoting the early integration of human factors into the medical device R&D process. She actively advocates for collaborative methodologies with the aim of advancing study designs and statistical modeling for usability evaluations, and expanding capabilities for human factors data collection in alignment with regulatory standards. Her portfolio includes medical devices spanning drug delivery and reconstitution, ophthalmic, respiratory, and endoscopy equipment, as well as various implantable and injection devices, computer-aided systems, 3D EP mapping, ultrasound-guided, and fluid management technologies, radiological diagnostic equipment, cardiac monitoring devices, and surgical systems. She holds patents in GUI design for medical imaging and surgical navigation software systems and earned a B.S. in Aeronautics and an M.S. in Human Factors and Systems from Embry–Riddle Aeronautical University (ERAU), in addition to technical degrees in Information Technology Management and Emergency Medical Services from Sacred Heart University (SHU) and Daytona State College (DSC), respectively.

Tim Briggs, MSc
Senior Principal Human Factors Engineer, Global Device Development, Viatris

Tim is a Human Factors Engineer responsible for management and application of the Human Factors/Usability Engineering process for Combination Product development within the Global Device Development group at Viatris. Tim joined the organization in 2017 and has over 12 years of experience in Medical Device Development. Tim holds a Batchelor Degree in Industrial Design and a Masters Degree in Medical Device Design from the National College of Art and Design in Dublin, Ireland. Outside of work, Tim enjoys spending time at, on and in the sea, riding mountain bikes and coaching kids soccer.

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

Megan Conrad is an Associate Professor of Mechanical Engineering at the University of 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. 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. Before joining Detroit Mercy, Dr. Conrad was a postdoctoral researcher in the Sensorimotor Performance Program at the Rehabilitation Institute of Chicago and Northwestern University where she expanded her knowledge of Hand Function and Rehabilitation Engineering. Currently, Dr. Conrad is the PI of a research project funded by the FDA's Office of Generic Drugs. The project aims to develop a user interface design taxonomy and comparative use human factors methods for use in the approval process for generic drug-device combination products. Dr. Conrad is also interested in measuring hand function in older adults and people with disabilities. She aims to identify device designs and therapeutic techniques allowing these individuals to remain independent at home and work. She has published several peer-reviewed articles relating hand function to neurological injury/rehabilitation, as well as assessing the ergonomics and human factors of products requiring manual interaction. Dr. Conrad has received extramural funding as PI or co-I on projects supported by the AHA, FDA, NIH, and NSF.

Manoj Pananchukunnath, MP
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, Injectables, Oral solid dosage forms, Peptide, Oligonucleotide, Fermentation and Synthetic APIs. 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 commercialisation. 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 centres of order of ~100 million USD annually. Manoj has held leadership positions at Mylan Inc, Jubilant Organosys Ltd, Dabur Research Foundation and Ranbaxy Pharmaceuticals. Before joining Biocon, he worked as Chief Scientific Officer at Gulf Pharmaceuticals in UAE.

Robert Berendt, PhD
Supervisory Chemist , DPQAV/OPQAI/OPQ/CDER/FDA

Dr. Robert (Bob) Berendt is a supervisory chemist 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.

Ariane O. Conrad, PharmD
Associate Director for Human Factors,
DMEPA I/OMEPRM/OSCE/CDER/FDA

Dr. Ariane O. Conrad currently serves as the Associate Director for Human Factors in DMEPA 1 at the FDA. In this role, she provides oversight for premarket and postmarket medication safety activities related to the human factors program. She joined the FDA in 2015 as a safety evaluator in DMEPA responsible for the premarket and postmarket review of medications to treat diabetes with the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) within the Office of New Drugs. Prior to joining the FDA, Dr. Conrad worked in pharmacy practice as a staff pharmacist, internal medicine clinical pharmacist, and as a clinical assistant professor of pharmacy practice at her alma mater, Xavier University of Louisiana, with a clinical appointment as an ambulatory care pharmacist. Her primary areas of clinical practice included diabetes, obesity, and hypertension. She earned her Doctor of Pharmacy degree from Xavier University of Louisiana College of Pharmacy in 2003 and she completed an ASHP accredited pharmacy practice residency with the Central Arkansas Veterans Healthcare System (2003-2004) and the FDA/ISMP Safe Medication Management fellowship (2014-2015).

Jason Flint, MBA, PMP
Deputy Director, DMEPA I/OMEPRM/OSCE/CDER/FDA

Jason Flint is the Deputy Director for the Division of Medication Error Prevention and Analysis I (DMEPA1) within the Center for Drug Evaluation and Research. He is also co-chair for the Office of Medication Error Prevention and Risk Management (OMEPRM) Research Team, is a human factors subject matter expert for research on comparative analyses by the Office of Generic Drugs (OGD) and contributes to Agency guidance and industry standards on human factors. Prior to joining the DMEPA team, Jason spent 13 years supporting the Air Force Medical Acquisition community by planning, conducting, and reporting on operational testing activities for the Air Force Medical Evaluation and Support Activity (AFMESA), including two years as their Director of Operations. He spent the previous 6 years conducting research in virology, immunology, and nanoparticle science at Cincinnati Children's Hospital and the University of Florida. Jason has a Bachelor of Science in Biology from the State University of New York at Brockport, and a Master's in Business Administration from the Warrington College of Business at the University of Florida. While in college, he also served in the United States Army Reserve as a combat medic and surgical technician.

Kyran Gibson, BS
Biomedical Engineer and Lead Reviewer, DHT IIIC/OHT III/OPEQ/CDHER/FDA

Kyran Gibson is a Biomedical Engineer and Lead Reviewer within the Division of Drug Delivery and General Hospital Devices and Human Factors, Office of Reproductive, Gastro-Renal, Urological, General Hospital Device & Human Factors at the FDA. Miss Gibson received a Bachelor of Science in Bioengineering from University of Maryland College Park. She reviews both premarket and postmarket submissions for medical devices submitted as 510(k)s, De Novos, Premarket Approvals (PMAs) as well as combination products submitted as New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and Investigational New Drug Applications (INDs). In addition, Miss Gibson serves as a focal point for Digital Health and cybersecurity for her division.

Stella Grosser, PhD
Director, DB VIII/OB/OTS/CDER/FDA

Stella Grosser is Director, Division of Biometrics 8 in the Office of Biostatistics, CDER, FDA. This division provides statistical support in review and research to the Office of Generic Drugs. She has been at the FDA for over 20 years, beginning as a statistical reviewer for new drug products and serving as a team leader before assuming her current position. Dr. Grosser received her PhD in biostatistics from UCLA and spent several years there afterwards as an assistant professor in the School of Public Health.

Edna Termilus, MD, MPH
Associate Director, DCR/OSCE/OGD/CDER/FDA

Dr. Edna Termilus is the Associate Director of the Division of Clinical Review in the Office of Safety and Clinical Evaluation within the Office of Generic Drugs at the Food and Drug Administration (FDA). In this role, she supports interdisciplinary scientists responsible for providing the clinical assessment of generic drug products and ensuring that allowable differences between a generic drug product and its reference listed drug do not alter the safety or efficacy profile. She began her FDA career in 2015 as a Medical Officer in the Center for Biologics Evaluation and Research's Office of Vaccines Research and Review primarily focused on intestinal microbiota products and vaccines for emerging infectious diseases. In 2019, she joined the Office of Science in the Center for Tobacco Products, where she supervised a team involved in clinical reviews of premarket tobacco applications, surveillance of tobacco product adverse events, and monitoring of human subjects protections in clinical trials. Edna Termilus

received her Doctor of Medicine at Morehouse School of Medicine, her Master of Public Health with a concentration in Epidemiology at The George Washington University, and her Bachelor of Science at the University of Pittsburgh. She completed her residency in pediatrics at Georgetown University Hospital and worked in a pediatric emergency room prior to joining FDA.