Fiscal Year (FY) 2022 Generic Drug Science and Research Initiatives Public Workshop
SPEAKER, PANELIST, and COORDINATOR BIOGRAPHIES

Ahmed Zidan, Ph.D.
Senior Pharmacologist Staff, Office of Testing and Research/Office of Pharmaceutical Quality

Dr. Ahmed Zidan is a senior pharmacologist staff in the CDER/OPQ. Ahmed joined FDA in 2005 and has a Ph.D. in pharmaceutical sciences in Zagazig University in collaboration with Howard University. Dr. Zidan leads the topical and transdermal drug products laboratories of DPQR in OPQ and provides hands-on trainings to reviewers on various topics, including 3D printing, preformulation consideration for development of oral drug products, transdermal delivery systems and in vitro release and permeation testing of pharmaceuticals. Dr. Zidan is a member of the Transdermal Working Groups of CDER and additive manufacturing and chaired several scientific lab events at CDER. Dr. Zidan is also an editorial board member of several pharmaceutical journals and published over 100 peer-reviewed articles and book chapters.

Aloka Srinivasan, PhD
Principal and Managing Partner, RAAHA, LLC

Aloka Srinivasan, Ph.D., the Principal and Managing Partner of RAAHA LLC has more than two decades of experience in the pharmaceutical industry, including nine years of progressive experience with the U.S. FDA in the Office of Generic Drugs, Lupin Pharmaceuticals, Lachman Consultants and PAREXEL International. Prior to starting her own consulting, Dr. Srinivasan was the VP and Head of Regulatory at Lachman, VP-Regulatory at Lupin and Principal at Parexel. Dr. Srinivasan spent more than nine years in Office of Generic Drugs, FDA as a reviewer and Team Leader. Dr. Srinivasan is one of the world class experts on nitrosamine based on her research background and has been supporting the industry in addressing these carcinogenic impurities in the drugs. Dr. Srinivasan received her Ph.D. from University of Missouri, Columbia under Dr. Richard N. Loeppky of nitrosamine fame. Her thesis was titled, “Putative Intermediates in Activation of Beta Hydroxy Nitrosamines”. Dr. Srinivasan also spent seven years as a scientist at National Cancer Institute, working for Dr. Larry K. Keefer, researching on nitrosamines in potential nitric oxide donor drugs.

Amin Rostami, Ph.D.
Professor of Systems Pharmacology, University of Manchester
Chief Scientific Officer, Certara

The scientific work of Professor Rostami covers wide areas of drug development over last 30 years, ranging from pharmaceutics (e.g., bioequivalence) to clinical pharmacology (e.g., mixture pharmacology of drug/metabolites) and beyond (e.g., provision of systems parameters for human tissue for in vitro to in vivo (IVIVE) scaling). As a leader in the field of physiologically based pharmacokinetics (PBPK) and quantitative systems pharmacology (QSP), Amin is internationally recognized for his expertise in the use of IVIVE to predict the behavior of drugs in human body and understanding the associated inter-individual variabilities under the so called "bottom up" modelling. Amin is a Professor of Systems Pharmacology and the Director of CAPKR (Centre for Applied Pharmacokinetic Research) at the University of Manchester. In addition, he is the Senior Vice President of Research & Development and Chief Scientific Officer at Certara. He facilitates the incorporation of the latest advances in translational modelling to biosimulation platforms offered by Certara to its pharmaceutical clients to accelerate regulatory approvals and bring safer drug products to the patients faster. He was a founding editor of Pharmacometrics and System Pharmacology and serves on the Editorial Boards of several other journals.

Andre Raw, Ph.D.
Associate Director for Science and Communication, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality, Office of Generic Drugs

Andre Raw received his B.S. degree from the Massachusetts Institute of Technology and his Ph.D. in chemistry from the University of California at Berkeley. Within his tenure at FDA, he has been promoted to FDA Agency Expert and to Chemistry Division Director. Currently, he is the Associate Director for Science and Communication in the Office of Life Cycle Drug Products in the Office of Pharmaceutical Quality. Dr. Raw was involved in the development of several important FDA initiatives, including the Guidance on Pharmaceutical Solid Polymorphism and Co-crystals, Regulations on Listing of Polymorph Patents, Question Based Review, QbD Example for Generic Modified Release Products. He was instrumental in FDA's recent approval of generic versions of complex active ingredients including Lovenox (enoxaparin sodium) and Copaxone (glatiramer acetate). More recently, Dr. Raw has been active in Risk Based Review and Quality Informatics Initiatives and in one of the architects of Knowledge-Aided Assessment and Structured Application (KASA).

Andrew Hooker, PhD
Professor of Pharmacometrics, Uppsala University

Andrew Hooker is a Professor of Pharmacometrics at Uppsala University, Sweden. Andrew received a BS in Physics with a Mathematics Minor at the University of Colorado and received a Masters and then a PhD in Bioengineering from the University of Washington, Seattle. Andrew joined the faculty at Uppsala University in 2006. His research ranges between methodological and applied pharmacometrics, including: optimal (adaptive) experimental design, methodological problems associated with building and evaluating

pharmacometric models (including using models for bioequivalence evaluation) and the development and use of PKPD models in a range of therapeutic areas and drug classes. Andrew is a co-developer of a number of software programs including Xpose, PsN and the optimal design program PopED. Andrew has published over 75 papers in peer reviewed journals, supervised 12 students to their PhD degree and mentored 11 post-docs.

Anna Schwendeman, Ph.D.
Co-Director, Center for Research on Complex Generics

Anna Schwendeman is the Willian I Higuchi Collegiate Professor of Pharmacy and a member of Biointerfaces Institute at the University of Michigan. Dr. Schwendeman is a co-director of the FDA funded Center for Research on Complex Generics. Prior to starting her academic career in 2012, Dr. Schwendeman spent 12 years in pharmaceutical industry at Cerenis Therapeutics, Pfizer, and Esperion Therapeutics on clinical development of lipid nanoparticle products. Her current research focus is on optimization lipoprotein nanoparticles for drug delivery purposes as well as analytical characterization of complex parenteral products including liposomes, microspheres, LAI suspensions, recombinant proteins and their biosimilars.

Betsy Ballard, MD
Medical Officer, Office of Research and Standards, Office of Generic Drugs

Dr. Betsy Ballard is a board-certified surgeon with twenty-five years in private practice before joining the FDA. She has worked at FDA for 12 years with time spent in CDRH, OND and OGD as a medical officer reviewing applications for devices, drugs, and combination products.

Bill Brashier, M.D.
Group Head, Respiratory Clinical Development, Novartis Healthcare Pvt, Ltd.

Bill Brashier, M.D., is a pulmonologist by training and a European Respiratory Society Fellow. Currently, he heads Sandoz's respiratory clinical development. He has extensive experience in respiratory research, including drug development, disease mechanisms, clinical trials, and molecular biology, spanning more than two decades. He has also published several publications in high-impact peer-reviewed journals. Over the last 10 years, he has been involved in the development of generic orally inhaled drug products. He is also a reviewer for Journals such as Chest, ARJCCM, and Thorax. He has also authored eight book chapters, focusing on disease pathogenesis pathways in chronic inflammatory disorders of the lungs. He has also received several research awards and funding from organizations such as the Medical Research Council of the United Kingdom, John Hopkins School of Medicine U.S., and the European Respiratory Society. At the European Respiratory Congress in Stockholm in 2008, he received the best research COPD award for demonstrating the link between lung function and cardiac morbidity. His current work includes phenotyping and endotyping non-smoking COPD.

Bing Li, Ph.D.
Associate Director for Science, Office of Bioequivalence, Office of Generic Drugs

Dr. Bing V. Li serves as the Associate Director for Science for Office of Bioequivalence within OGD. 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 the Office of Bioequivalence. Dr. Li is an Expert Pharmacologist at FDA in 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.

Brandon Wood, B.Sc.
Associate Director, Regulatory Affairs, Generic Steriles, Teva Pharmaceuticals

Brandon Wood, B.Sc. is an Associate 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. Prior to joining Teva in 2018, he served in 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.

Brendan Muldoon, Ph.D.
Senior Director, Research and Development, Teva Pharmaceuticals

Brendan Muldoon is a Senior Director in TEVA Pharmaceuticals and has 20 years of industrial experience. Brendan is the Site Head for TEVA NI Limited. In this role, Brendan leads a group of interdisciplinary scientists that are responsible for developing generic products for markets worldwide. The group has developed a wide range of products from immediate/delayed release solid oral dosage forms to complex combination products. The group develops investigational medicinal products for early pharmacokinetic studies and subsequent ANDA submission. The team transfers projects globally for manufacture of exhibit batches and collaborates with technical operations for commercial launch. Brendan has been responsible for multiple ANDA approvals and launches. Prior to entering into generic development, Brendan developed branded products for NDA applications. Brendan holds an undergraduate degree in Chemistry and a Ph.D. in pharmaceutics from the Queens University of Belfast. Brendan has worked closely with the university and has guest lectured to undergraduate students in industrial pharmacy.

Carl Peck, MD
Adjunct Professor, Schools of Pharmacy & Medicine, University of California, San Francisco
Consultant, NDA Partners

Carl Peck MD is Adjunct Professor, UCSF, and is Cofounder and Expert Consultant of NDA Partners/a ProPharma Company. His career long interest in quantitative clinical pharmacology is expressed in more than 175 published peer-reviewed papers and chapters. As former Director of the FDA Center for Drug Evaluation and Research (CDER), he championed incorporation of advanced quantitative clinical pharmacology approaches in regulatory science and medical product development. His contributions have been recognized via an Honorary degree from Sweden's Uppsala University, the 1999 FDA Distinguished Alumnus Award, 2012 ASCPT Gary Neal Prize for Innovation in Drug Development, 2017 ASCPT Sheiner-Beal Pharmacometrics Award and the 2018 Gary Levy Memorial Lectureship.

Chirag Walawalkar, B. Eng.
Associate Director, Combination Products & Device Research and Development, Teva Pharmaceuticals

Chirag Walawalkar has extensive experience in designing and launching medical devices and combination products, implementing new automation, process and equipment validation, continuous improvement, engineering, and manufacturing management. Chirag joined Teva's Combination Products and Device R&D team in 2019 where he currently manages device development for specialty biologics, biosimilar, and generics programs. He started his career at a privately held medical device company, specializing in development of catheter care products to reduce catheter related blood stream infections (CRBSI). Later, he transitioned to leadership roles in manufacturing and engineering management where he led deployment of lean Six Sigma and continuous process improvement. Chirag holds a bachelor's degree in Biomedical Engineering from Rutgers University.

Dama Venugopala Rao, Ph.D.
Analytical Expert, Dr. Reddy's Laboratories Ltd.

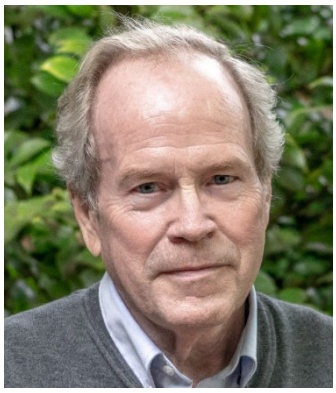
Dr, Dama (Dama Venugopal Rao) over 20 years of experience in Analytical Research and Development and has been associated with Dr Reddy's Laboratories Ltd since 2001. He is currently working as the lead structural characterization and analytical expert for complex injectables in Analytical Research and development for the last 2½ years. His expertise includes characterization of natural products, peptides, glycosaminoglycans, cross linked polymers as drug substances, random poly peptides, PLGA-based depot formulations, Liposomes, and ophthalmic emulsions using various advanced integrated analytical technologies. He has worked on 300+ drug products for ANDAs and dossiers catering to various geographies, such as North America, South America, Europe, Russia, China, Japan, and India. He is an author or co-author of more than 20 scientific papers. He is currently serving as a USP-Expert committee member (BIO3 - Complex Biologics & Vaccines) 2020-2025 cycle. He received a master's in Organic chemistry from Sri Krishnadevaraya University, Ananthapur, Anadhrapradesh and Doctorate in analytical chemistry from Sri Krishnadevaraya University, Ananthapur. He received

his MBA degree from Narsee Monjee Institute of Management Studies (NMIMS), Mumbai. He is a certified six sigma black belt from the American Society for Quality (ASQ).

Darby Kozak, Ph.D.
Deputy Director, Division of Therapeutic Performance I, Office of Research and Standards, Office of Generic Drugs

Dr. Darby Kozak is the Deputy Division Director for the Division of Therapeutic Performance I in OGD. Dr. Kozak leads a group of interdisciplinary scientists on the development of new analytical methods and equivalence evaluation methodologies for complex drug substances and parenteral, ophthalmic, and otic formulations. Prior to joining FDA, Dr. Kozak was Chief Scientist for Izon Science and Research Fellow at the 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).

David Feigal, JR, MD, MPH
Partner, NDA Partners



Dr. Feigal is a Partner in NDA Partners LLC and Adjunct Faculty at the O'Connor School of Law, Arizona State University where he teaches Food and Drug Law and policy. He has previous served as Vice President for Global Regulatory Affairs at Amgen Inc and Senior Vice President for Global Regulatory and Safety at Élan Pharmaceuticals. His career in the development of medical therapeutics began with training as a physician epidemiologist with an M.D. degree from Stanford University and an M.P.H. from the University of California Berkeley. After his training in Internal Medicine, he was a member of the full-time faculty in the Schools of Medicine at the University of California at San Francisco and San Diego. He later spent twelve years at the US FDA's heading the Antiviral Drug Division, the Anti-Infective Drug Division and ODE IV in the Center for Drug Evaluation and Research, the Medical Deputy Director in the Center for Biologics Research and Evaluation and serving as the Director of the Center for Devices and Radiological Health from 1999 to 2004. His consulting activities focus on early-stage medical product developers, particularly combination products, Apps and software, and regulatory strategy.

David Kellehan, Ph.D.
Senior Manager, Global Technical Services, Vlatris

David Kellehan has 6 years' experience working in the pharmaceutical industry. He obtained his Ph.D degree in organic chemistry from NUI, Galway in 2012. After working as a postdoctoral researcher in UCC, Ireland for 3 years he moved into industry as a process chemist in Pfizer before moving into a global function in Viatris in 2019. He has experience working on API process manufacture, continuous improvement projects and product technical transfers. For the last 3 years he has been leading the GTI & nitrosamine approach and control strategies for the branded generic portfolio of Viatris.

Géraldine Cellière, Ph.D.
Vice President, Application, Simulations Plus, Lixoft Division

Dr Géraldine Ayral joined Lixoft in 2016 as VP Application. She leads the team in of all pre- and post-sales activities (demonstrations, trainings, technical charge support), research activities (improvement and development of new methods, application to case studies, publications), as well as the MonolixSuite development (product specification and testing). She also leads the consulting services, focused on technical aspects of population PK/PD modeling and simulation. Dr. Geraldine holds an engineering degree from Ecole Polytechnique (Paris, France) and a Master's in computational biology from ETH Zürich (Switzerland), obtained in 2012. After an experience as assistant project manager at SoBios, a start-up developing software for modeling and in silico simulation, she started a Ph.D. in systems biology and multi-scale modeling at INRIA Paris. She received her doctoral degree in 2016.

Grace Kocks, B.Sc. (Hons)
Principal Application Scientist, Lhasa Ltd.

Grace Kocks is a Principal Application Scientist in Lhasa Limited's Applied Sciences Team. She joined Lhasa in 2013 as a scientist, after achieving her B.Sc. at the University of Leeds in Biomedical Science. Now, she utilises her existing knowledge to engage and collaborate closely with Lhasa's members. She has continued to build on Lhasa's strong reputation for facilitating data sharing over the years and is proud to co-chair two industry data sharing consortiums. The Nitrites in Excipients database was established in 2020, and Grace collaborates with numerous organisations, to increase the knowledge and data available to support the assessment of risk excipients may pose to nitrosamine formulation.

Hailey Fehrenbach, M.S.
Industrial and Human Factors Engineer, Batelle Memorial Institute

Hailey Fehrenbach is an Industrial and Human Factors Engineer for Medical Device Solutions at Battelle Memorial Institute. In this role Hailey Fehrenbach conducts research on the development of new medical devices ranging from neurotechnology to combination drug delivery devices. She specializes in human factors research and user interface design. Prior to joining Battelle in 2021, Hailey completed her Master's degree in Industrial and Human Factors Engineering and conducted human factors research on surgical devices at Ethicon. Hailey Fehrenbach has a B.Sc. in Design from the University of Cincinnati (Cincinnati, OH) and a M.S. in Industrial and Human Factors Engineering from Wright State University (Dayton,OH).

Irene Chan, Ph.D.
Deputy Director, Division of Medication Error Prevention and Analysis, Office of Medication Error Prevention and Risk Management, Office of Surveillance and Epidemiology

CAPT Irene Z. Chan currently serves as Director in the Division of Medication Error Prevention and Analysis 1 (DMEPA 1) at CDER/FDA. She is responsible for leveraging her knowledge of regulatory principles, human factors, and risk management to provide oversight of safety recommendations regarding drug nomenclature, labels, labeling, packaging, and product design. CAPT Chan also represents CDER/FDA on the AAMI Human Factors Committee. Over the last ten years, CAPT Chan has been responsible for expanding the CDER human factors evaluation program, and DMEPA serves as the scientific lead for human factors submissions for drug and therapeutic biologic products, including combination products. CAPT Chan received a B.S. in Pharmacy and her Doctor of Pharmacy from Rutgers University.

Janet Vaughn, B.S.
Vice President, North America Generic Regulatory Affairs, Teva Pharmaceuticals

Janet Vaughn is the Vice President North America Generics Regulatory Affairs, Teva Pharmaceuticals USA. In this role, Janet provides regulatory guidance, manages and leads teams in strategic decision making, ensuring quality submissions to the FDA. She is intimately involved with R&D formulation development, clinical, quality, and other functions that have resulted in securing FDA approvals for various products. Janet has held positions in quality control/analytical research, quality assurance and regulatory affairs at various companies with a combined experience of more than 30 years in the pharmaceutical industry. Janet has a B.Sc. in Pure and Applied Chemistry from the University of the West Indies.

Jason Rodriguez, Ph.D.
Director, Division of Complex Drug Analysis, Office of Testing and Research, Office of Pharmaceutical Quality

Jason Rodriguez is the Director for the FDA Division of Complex Drug Analysis in St. Louis, MO. He has a Ph.D. in Chemistry from the University of Illinois Urbana-Champaign and B.S. in chemistry from the University of Texas-Pan American. Prior to serving in management roles, Dr. Rodriguez established a program in spectroscopic screening techniques using portable Raman and near infrared technologies with an emphasis on using these tools to enhance raw material screening and developing new methods to test finished drugs. Dr. Rodriguez leads a team of scientists that spans a broad cross-section of pharmaceutical research and testing projects including dissolution, chromatography, inhalation, transdermal and mass spectrometry. Dr. Rodriguez is also currently serving as the regulatory chair of the ICH expert working group (Q3E) on development of a technical guideline on extractables and leachables.

Jingyue (Jan) Yang, Ph.D.
Senior Research Scientist, Division of Pharmaceutical Analysis, Office of Testing and Research, Office of Pharmaceutical Quality

Jingyue (Jan) Yang is a Sr. Research Scientist in the Division of Pharmaceutical Analysis in the Office of Testing and Research, Office of Pharmaceutical Quality. In her various roles, Jan develops and applies analytical methods to assess the quality of pharmaceutical products and to investigate adverse events associated with medical product use. She also performs research to improve the characterization and understanding of complex drug substances and products to support generic drug assessment and approval. Jan has been a key team member to provide analytical support to FDA's task force for the investigation of nitrosamine contamination in the past few years. She has developed important analytical methods to detect and quantitate various nitrosamines in pharmaceutical products and is currently conducting research to study the prevalence of nitrosamine contamination in pharmaceuticals and to investigate risk mitigation strategies. Jan earned her B.Sc. in chemistry from Beijing University in China and received her Ph.D. in chemistry from Washington University, Saint Louis, MO. She was a postdoctoral researcher in biomedical research and worked as an analytical chemist at a pharmaceutical company prior to joining FDA in 2014.

Joga Gobburu, Ph.D.
Professor & Director, Center for Translational Medicine, University of Maryland

Dr. Gobburu is a Professor with the School of Pharmacy and the School of Medicine, University of Maryland, Baltimore, MD. He held various positions at the FDA between 1998 and 2011. He has experience with overseeing the review of Investigational New Drug Applications (INDs), New Drug and Biological Licensing Applications, numerous FDA Guidances, and policies pertaining to drug approval and labeling. At the FDA, he was part of the committee responsible for 21st Review Process and provided input into PDUFA planning. He received numerous FDA awards such as the Outstanding Achievement Award and recognized with the Senior Biomedical Research Scientist appointment. He also received the Outstanding Leadership Award from the American Conference on Pharmacometrics (2008), the Tanabe's Young Investigator Award from the American College of Clinical Pharmacology (2008) and Sheiner-Beal Pharmacometrics Award from the American Society of Clinical Pharmacology and Therapeutics (2019). He is also a Fellow of AAPS and ACCP. Dr. Gobburu is on the Editorial Boards of several journals. He has published over 100 papers and book chapters.

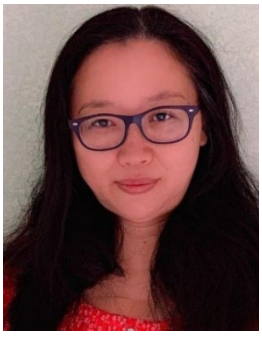
Karen Feibus, Ph.D.
Team Lead, Division of Therapeutic Performance I, Office of Research and Standards, Office of Generic Drugs

Dr. Feibus is the lead medical officer for the Drug-Device Combination Products Team in OGD's Office of Research and Standards (ORS). Prior to joining ORS, Dr. Feibus was the team leader for OGD's Clinical Safety Team and worked as a medical officer in the Division of Clinical Review. Dr. Feibus received her medical degree from the Georgetown University School of Medicine and completed her obstetrics and gynecology residency training at the University of Maryland Medical System. At FDA, she completed a Certificate in Public Health through the Georgetown University School of Continuing Education and a Certificate in Pharmacoepidemiology through the University of Pennsylvania School of Medicine. Following almost 9 years of clinical practice as an obstetrician/gynecologist, Dr. Feibus joined CDER's Office of New Drugs (OND) in December 2003 where she worked as a medical officer in OND's Office of Nonprescription Products and then as the team leader for the Maternal Health Team. From 2012 through 2014, Dr. Feibus addressed gaps in the reproductive health needs of women Veterans across the adult life span as the Deputy Director of Reproductive Health for the Veterans Health Administration's Office of Women's Health Services. In late 2014, Dr. Feibus returned to FDA and joined OGD.

Kausik Nanda, Ph.D.
Associate Principal Scientist, Merck & Co.

Kausik Nanda has more than 21 years of experience in the pharmaceutical industry. His expertise spans organic, organometallic, coordination, and analytical chemistry. In his early career as a medicinal chemist, Kausik had worked on discovery programs in the neuroscience, cardiovascular, and infectious disease areas, where his team successfully developed lead identification, lead optimization and pre-clinical candidates. In his later career, Kausik's work focused on solving multitude of problems in the development area, arising from chemical interaction in the drug product. The range of activities encompasses early development through commercial launch. His current research interest is in the field of novel drug degradation mechanism operating on drug product.

Ke Ren, Ph.D.
Acting Deputy Director, Division of Bioequivalence III, Office of Bioequivalence, Office of Generic Drugs



Ke Ren is the currently an acting Deputy Director in the Division of Bioequivalence III (DBIII) in the Office of Bioequivalence of OGD. In this role, she leads a team of scientists responsible for the assessment of the bioequivalence section of Abbreviated New Drug Applications. During her time in DBIII, Dr. Ke Ren has a variety of technical and administrative roles and has participated in the drafting of numerous Agency guidances pertaining to bioequivalence. Dr. Ren received her Ph.D. in Pharmaceutical Science from the University of Florida in 2005 and then undertook post-doctoral training at the University of Florida before joining OGD in 2008.

Kevin Blake, M.D., Ph.D.
Translational Sciences Senior Specialist, Scientific Evidence Generation Department, European Medicines Agency

Kevin Blake is the Senior Specialist in Clinical Pharmacology in the Translational Science Office at EMA and has been Scientific Secretariat for the Pharmacokinetics Working Party (PKWP) since 2015. He is also an EMA Scientific Coordinator in the Scientific Advice Office with a focus on procedures relating to generics/hybrids. Prior to joining EMA in 2010 he was a Clinical Assessor at the then Irish Medicines Board (now HPRA) since 2006. Dr. Blake received his primary medical degree (MB. BCh. BAO) at University College Dublin in 1989 and a Ph.D. in Epidemiology at the University of Western Australia in 2003 on the topic of fetal growth and cardiovascular disease risk in later life (the 'fetal origins' hypothesis). While at EMA he has been involved in a number of guidelines including those on post-authorization efficacy studies (2016), first-in-human clinical trials (2017) and on the reporting of physiologically based pharmacokinetic (PBPK) modelling and simulation (2018). He is also EMA lead in the development of product-specific bioequivalence guidelines with the PKWP. He has over 30 scientific publications including recent overviews of the EMA experience with PBPK models, product specific guidelines. and biowaivers. His interests include the regulatory approval of generics, including complex generics; sharing regulator's experience with submitted applications; and the use of modelling and simulation/extrapolation in drug approval.

Khondoker Alam, Ph.D.
Senior Staff Fellow, Division of Quantitative Methods and Modeling, Office of Research and Standards, Office of Generic Drugs

Dr. Khondoker Alam obtained his Ph.D. in Pharmaceutical Sciences at the University of Oklahoma Health Sciences Center in 2017 and completed a one-year Fellowship in the Office of Clinical Pharmacology. Dr. Alam is currently working as a Sr. Staff Fellow at the Division of Quantitative Methods and Modeling at the Office of Research and Standards. His role in the division is to utilize translational tools such as physiologically based pharmacokinetic (PBPK) modeling to address specific questions pertinent to drug development process and/or regulatory decision making. His research interests include PBPK modeling, development of computational tools for virtual bioequivalence, studying the role of transporter proteins and metabolizing enzymes in drug disposition and drug-drug interaction.

Kiran Krishnan, Ph.D.
Senior Vice President, Global Regulatory Affairs, Apotex Inc.

Kiran joined Apotex in 2006, holding roles of increasing responsibility within Global Regulatory Affairs. Today, he is responsible for overseeing the global regulatory function for Apotex. In addition to creating and executing the company's global regulatory strategy, he also manages a worldwide team of regulatory professionals. Dr. Krishnan has more than 18 years of regulatory experience in the generic pharmaceutical industry, integrating regulatory strategy into drug development. He was part of the American Association for Accessible Medicines (AAM) team that actively engaged with the FDA to develop the commitment letter to support the second authorization of the Generic Drug User Fee Act. Dr. Krishnan has a master's degree in pharmacy with a specialization in Industrial Pharmacy and a Ph.D. in Pharmacy.

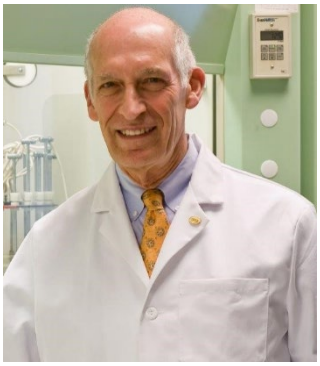
Lanyan Fang, Ph.D.
Deputy Director, Division of Quantitative Methods and Modeling, Office of Research and Standards, Office of Generic Drugs

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).

Laura Kleiman, Ph.D.
Founder and Chief Executive Officer, Reboot Rx

Laura Kleiman is the Founder and CEO of Reboot Rx, the nonprofit health tech startup dedicated to fast-tracking the development of affordable cancer treatments using repurposed generic drugs, AI technology, and innovative funding models. Laura's career has focused on building collaborations across disciplines and sectors to expand treatment options for cancer patients. She holds a Ph.D. in Computational and Systems Biology from MIT, was an American Cancer Society Postdoctoral Fellow at the Massachusetts General Hospital and Harvard Medical School, and most recently served as Scientific Research Director in the Department of Data Sciences at the Dana-Farber Cancer Institute. Laura has been featured in Forbes and the Boston Business Journal, named a CHM Patrick J. McGovern Tech for Humanity Prize Changemaker finalist, and recognized with awards from The Commonwealth Institute's Extraordinary Women Advancing Healthcare, 40 Under 40 in Cancer, the Massachusetts Life Sciences Center's MassNextGen Initiative, and the Dana-Farber Cancer Institute.

Leslie Z. Benet, Ph.D.
Professor of Bioengineering & Theoretical Science, Schools of Pharmacy and Medicine, University of California, San Francisco



Dr. Benet, Professor and former Chairman (1978-1998), Department of Bioengineering and Therapeutic Sciences, University of California, San Francisco, received his A.B. (English), B.S. (Pharmacy), M.S. from the University of Michigan and Ph.D. from the University of California. He has received nine honorary doctorates, five from European universities and four U.S. His research interests, more than 610 publications, and 12 patents are in the areas of pharmacokinetics, biopharmaceutics, drug delivery and pharmacodynamics. He is listed among the most highly cited pharmacologists world-wide with more than 31,000 citations according to Clarivate Analytics. During 1986, Dr. Benet was a Founder and first President of the American Association of Pharmaceutical Scientists (AAPS). In 1987, Dr. Benet was elected to membership in the National Academy of Medicine of the US National Academy of

Sciences. He has received the highest scientific awards of AAPS, Rho Chi, American Association of Colleges of Pharmacy, American Society for Clinical Pharmacology and Therapeutics, American College of Clinical Pharmacology, American Pharmacists Association, International Pharmaceutical Federation, International Society for the Study of Xenobiotics and the Controlled Release Society. Dr. Benet formerly served as Chair of the FDA Center for Biologics Peer Review Committee and the FDA Expert Panel on Individual Bioequivalence and as a member of the initial FDA Science Board and the initial Generic Drugs Advisory Committee.

Liang Zhao, PhD
Director, Division of Quantitative Methods and Modelling,
Office of Research and Standards, Office of Generic Drugs

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. Dr. Zhao has a broad spectrum of scientific and management experience from industry and the regulatory agency. Through his 16-year professional career, he has established his leadership in industrial R&D, quantitative methods and modeling, and model based strategic decision makings in regulatory and industrial settings for generic and new drugs. He initially joined the FDA as a clinical pharmacology reviewer in the Office of Clinical Pharmacology in 2009 and worked as a team leader in the Division of Pharmacometrics in 2013-2015. Prior to joining FDA, he worked at Medimmune for biotech products, BMS for small molecule drug development, and Pharsight as an associate consultant for new drug R&D. Dr. Zhao has a diversified educational background in Pharmaceutical Sciences, Applied Statistics, and Business Administration.

Mark Sale, M.D.
Executive Vice President, Pharmacometrics, Certara

Dr. Sale is currently Vice President in the Integrated Drug Development group at Certara. He works directly with clients on pharmacometrics models as well as supervises teams of scientists. He also is involved with the software development group at Certara focusing on the incorporation of machine learning methods. Prior to joining Certara, Dr. Sale was Executive Vice President of Pharmacometrics at Nuventra Pharma Sciences, and before that was Global head of Research Modeling and Simulation at GlaxoSmithKline. Prior to GlaxoSmithKline, Dr. Sale was a member of the faculty at Georgetown University. Dr. Sale has a research record that includes work in machine learning methods for pharmacometrics model selection. In 2006, he was inventor on a U.S. patent “Unsupervised machine learning-based mathematical model selection” and is principle investigator on a grant from FDA for model selection algorithm development (“Development of a model selection method for population pharmacokinetics analysis by deep-learning based reinforcement learning”). Dr. Sale received his M.D from the Ohio State University before completing a residency in Internal Medicine at Indiana University and a fellowship in Clinical Pharmacology at Stanford University. He is currently also adjunct faculty at State University of New York at Buffalo.

Markham Luke, M.D., Ph.D.
Director, Division of therapeutic Performance I, Office of Research and Standards, Office of Generic Drugs

Markham C. Luke, M.D., Ph.D. serves as FDA Supervisory Physician (Dermatology) and Director of the Division of Therapeutic Performance 1 (DTP1) in the Office of Research and Standards at OGD. DTP1 is responsible for facilitating pre-application development of generic drugs by conducting and promoting regulatory science research to establish standards to ensure therapeutic equivalence of new generic drug products. Markham has been at FDA since 1998 serving various roles, including as the Lead Medical Officer for dermatology drugs in the Office of New Drugs at CDER, Chief Medical Officer and Deputy Director for the Office of Device Evaluation in CDRH, and as Acting Director for Cosmetics in CFSAN. Markham has an M.D. degree and a Ph.D. in Pharmacology from Johns Hopkins University, internal medicine training at Johns Hopkins Bayview Medical Center, and dermatology residency and fellowship at Washington University, St. Louis, MO and at NCI/NIH, Bethesda, MD. Markham is an Associate Professor in Dermatology at the Uniformed Services University of the Health Sciences, Bethesda, MD. Markham has research interests in dermato-pharmacology, clinical pharmacology, product innovation and design – especially for combination drug-device products, clinical study design and endpoints assessment (including patient-reported outcomes) for medical, surgical, and aesthetic products and serves as consultant dermatologist to various parts of FDA.

Martin Ehlert, Ph.D.
Vice President, Global API Research and Development, Apotex Inc.

Martin Ehlert obtained a B.Sc. in Applied Chemistry at McMaster University in 1987. He subsequently obtained a Ph.D. in Chemistry at the University of British Columbia in 1992. In 1994, Dr. Ehlert commenced his career in the pharmaceutical industry as an industrial postdoctoral fellow at Phytogen Life Sciences and continued with the company for the next four years 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.

Mary Beth Privitera, M.Design, Ph.D., FIDSA
Principal, Human Factors & Research, HS Design

Dr. Mary Beth Privitera, M.Design, FIDSA, is internationally known as an expert in medical product design, specifically in the area of applied human factors. She is a principal at HS Design, responsible for human factors and research. Additionally, she serves as faculty and co-chair of the Association for the Advancement of Medical Instrumentation's Human Engineering Committee. Dr. Privitera also holds an appointment as Professor at the University of Cincinnati's Department of Biomedical Engineering and works collaboratively among the Colleges of Medicine, Engineering and Design. She is currently the Co-Founder and Director of the Medical Device Innovation and Entrepreneurship Program. Her previous academic appointments include industrial design and several years in the

Department of Emergency Medicine. She has worked on devices which are intended for use across the practice of medicine and in home health situations. Her current research focuses on applied ergonomics and design interpretation. She has authored several peer reviewed articles and a book titled “Contextual Inquiry for Medical Device Design,” promoting best practices for phase zero medical device development. Her second book, edited and written in collaboration with AAMI Human Factors faculty, is titled “Applied Human Factors in Medical Device Design.” This book aims at bringing all references and best practices together in one resource compendium.

Meenakshi Jain, MPharm
Director and Head, Development Regulatory Center, Sandoz Inc. (India)

Meenakshi Jain is the Director and Head of Development Regulatory Center in Sandoz Development Center, Hyderabad, India. In this role, Meenakshi is part of global regulatory affairs team responsible for global submissions for Sandoz Development Center (SDC), Hyderabad, India. She acts as a competent and strong business partner on new product development matters within regulatory affairs and with all of the respective R&D formulation, analytical development, clinical, quality and other functions of SDC in strategic decision making and ensuring quality submissions globally. Prior to joining Sandoz in July 2020, Meenakshi worked with Mankind Pharma and Sun Pharma in India. She has a combined experience of 18 years in the Pharmaceutical Regulatory Industry. She has worked in pre and post approval regulatory submissions for Solid Oral dosage forms, Complex Injectables and Ophthalmic products and has successful history of filings, approvals and launches and has also provided regulatory support to manufacturing facilities during Inspections. Meenakshi Jain has Master’s in Pharmacy from Panjab University, University Institute of Pharmaceutical Sciences, Chandigarh, India.

Melissa Lemke, Ph.D.
Founder, Human Ability Designs

Melissa R. Lemke is a biomedical engineer with mastery in regulatory medical device Human Factors Engineering (HFE) gained through over 18 years of experience as a researcher and consultant in the industry. She is the founder and principal of Human Ability Designs, LLC as well as an expert consultant, innovator, researcher, and educator. Melissa leads Human Ability Designs' mission to help individuals, teams, and organizations develop and apply rigorous HFE regulatory strategies and processes to launch successful medical products in the worldwide market that are safe and effective, accessible, and usable for intended end users and overall market needs. Melissa's passion for good design and love of HFE initiated when her brother Matt sustained a spinal cord injury in 1999 while serving in the U.S. Army. Once Matt was discharged from rehabilitation and started working towards living independently, Melissa saw first-hand the challenges her brother faced using medical devices and products designed for mainstream users. She also experienced various usability challenges as a lay caregiver for Matt. Melissa teaches Principles of Human Factors and Usability at the University of Wisconsin at Milwaukee, is an AAMI human factors faculty member, is a participating committee member and contributing author of AAMI human factors standards, and is an expert who has helped hundreds of clients successfully meet FDA human factors requirements for combination product and medical device submissions.

Meng Hu, Ph.D.
Team Lead, Division of Quantitative Methods and Modeling, Office of Research and Standards, Office of Generic Drugs

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 inOGD. His main research interests include the development and application of advanced data analytics tools to promote business intelligence in government, big data management, generation of real-world evidence, and quantitative methods to facilitate assessment for in-vitro bioequivalence study. His published works include: machine learning (ML) based time-to-event analysis, predictive analysis of first abbreviated new drug application (ANDA) submission for new chemical entities based on ML methodologies, equivalence assessment of complex particle size distribution, quantitative method to facilitate active pharmaceutical ingredient (API) sameness assessment for complex peptide products, and analysis of dissolution failure of solid oral drug products in field alert reports.

Michael Banks, M.Sc.
Senior Vice President, Global Head Regulatory Affairs, Teva Pharmaceuticals

Michael is Senior Vice President Regulatory Affairs Research and Development for Teva Pharmaceuticals. Michael is globally responsible for all Regulatory Affairs activities for Teva. He has over 30 years of Industry Experience having previously worked in different Regulatory and Medical Affairs roles for IVAX, Sandoz and Astra Pharmaceuticals. He has been Chair or Deputy-Chair of Medicines for Europe (MFE) Regulatory and Scientific Affairs Committee; Chair of the MFE working group with the European Medicines Agency (EMA) on Centralised Procedures (CP) for Generics and is a member of the International Generic and Biosimilars Association's Scientific Committee and a Member of IFPMA RA Committee. Michael is a Fellow of the Royal Society of Medicine and a Fellow of the Organisation for Professionals in Regulatory Affairs.

Partha Roy, Ph.D.
Director, Office of Bioequivalence, Office of Generic Drugs

Dr. Partha Roy is a recognized senior clinical / regulatory strategist and a proven business leader with 21 years of drug development experience in both FDA and industry involving new drugs, novel biologics, generics and biosimilars. He currently leads the Office of Bioequivalence (OB) that oversees the thorough assessment of bioequivalence data required to support Abbreviated New Drug Application (ANDAs). He manages a multi-disciplinary program, providing leadership and management oversight to OB Division Management and primary and secondary assessors. Prior to his current role, Partha was Vice President in PAREXEL's

Regulatory and Access Consulting Global Business Unit, providing executive management, regulatory strategy, and thought leadership focused on driving corporate growth and delivery. Dr. Roy completed his Postdoctoral Fellowship in Drug Metabolism and PK from Boston University, Boston, MA. He obtained his Ph.D. in Biochemical Toxicology from University of South Florida, Tampa Florida and B.S. in Pharmacy from Jadavpur University, Kolkata, India.

Patrick Vallano, Ph.D.
Head of Innovative Programs, Research and Development, Viatris

Dr. Vallano has over 25 years' experience in the pharma industry developing generic, novel, and biosimilar products. He earned a Ph.D. in Chemistry from Oregon State University and over the last 20 years has served in various roles of increasing responsibility in pharmaceutical R&D. Among his team's accomplishments was developing the analytical characterization tools employed for Mylan's (now Viatris) glatiramer acetate products, which include the first FDA approved generic of the three times a week Copaxone® product. More recently, Dr. Vallano led biosimilars R&D at Mylan before moving into his current role as Head of Innovative Programs R&D at Viatris. Dr. Vallano has presented at numerous scientific meetings and has authored 17 original papers, review articles, and book chapters in the areas of analytical separations, bioanalysis, and complex drug product characterization.

Priyanka Ghosh, Ph.D.
Team Lead, Division of Therapeutic Performance I, Office of Research and Standards, Office of Generic Drugs

Dr. Priyanka Ghosh is a senior pharmacologist within the Division of Therapeutic Performance. Her areas of expertise include products in the topical and transdermal drug delivery area. In her current role, Dr. Ghosh leads regulatory science research initiatives related to topical and transdermal drug products, including projects related to development of noninvasive imaging techniques for evaluation of cutaneous pharmacokinetics, under the GDUFA regulatory science program. Dr. Ghosh also leads the development of general and product-specific guidances, review strategies for pre-ANDA 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.

Rachel Dunn, Ph.D.
Director, Division of Pharmaceutical Analysis, Office of Testing & Research, Office of Pharmaceutical Quality

Rachel Dunn joined FDA in 2020 as the Director of the Division of Pharmaceutical Analysis. Dr. Dunn earned a Ph.D. in Chemistry from the University of Illinois at Urbana-Champaign. She held positions in the lab and in management at Chemir Analytical Services (now EAG Laboratories), including Associate Scientist and Director of Technical Services. Prior to joining FDA, Dr. Dunn oversaw the operations and staff of the Chemistry Department at Washington University in St. Louis.

Raghuram Pannala, PhD
Senior Vice President, Corporate Quality Compliance, Pharmacovigilance & Regulatory Affairs, ScieGen Pharmaceuticals Inc.

Dr. Raghu Ram Pannala heads the Corporate Quality Compliance, Pharmacovigilance & Regulatory Affairs at ScieGen Pharmaceuticals Inc. He has over 28 years of experience in the Pharmaceutical Industry, in the areas of Analytical Development, Quality Control, Quality Assurance, Regulatory Affairs, Compliance and Pharmacovigilance. Dr. Raghu Ram Pannala has published 24 research publications till now. He is a contributing author for PDA FDA Technical Report – 80, 'Data Integrity Management System for Pharmaceutical Laboratories, and sub team lead in the PDA Remote Audits & Inspections Team, and PDA COVID-19 PtC Task Force. He served as a member in IPC [Indian Pharmacopeial Commission] and USP [United States Pharmacopeia] 2005-2010 monographs acquisition committee. Dr. Raghu Ram Pannala holds a Ph.D in Analytical Chemistry from Sri Krishnadevaraya University, India. He holds certifications from ASQ [American Society for Quality], and Indian Statistical Institute.

Raja Velagapudi, Ph.D.
Executive Director, Pharmaceutical Development and Clinical Development, Sandoz Inc.

Raja Velagapudi is currently Executive Director, Clinical Development, Sandoz Inc., U.S. Raja received his Master of Pharmacy (1976) from Andhra University (India), Masters in Pharmaceutics (1978) from Duquesne University, and his doctorate in Biopharmaceutics (1983) from the University of Texas at Austin. He worked at the FDA as a reviewer for 9 years in the Division of Biopharmaceutics (Office of Clinical Pharmacology). He worked in the brand pharmaceuticals (Ciba-Geigy/Knoll Pharmaceuticals/Abbott) for 13 years in clinical pharmacology and pharmacokinetics. At Barr Laboratories/Teva, he worked on the clinical development of generics drugs and biosimilars for 7 years. At Sandoz, he works in clinical development of small molecules through business development and in licensing for the last 10 years.He has been an active participant of the FDA GDUFA Generic Drug Sciences and Research Workshops over the years and served as a panelist and a speaker for the Modeling and Simulation sessions.

Ravi Iyer, Ph.D.
Senior Director, Head Real World Evidence Strategy, Global HEOR, Teva Pharmaceuticals

Dr. Ravi Iyer is a Health Economics and Outcomes research professional with over 15 years of experience. He applies his Master of Business Administration and doctorate degrees to develop sound scientific evidence for therapies across all phases of product life cycle. Ravi's years of experience supporting product launches globally provides him with thorough knowledge of evolving regulatory and market access trends in the U.S. and across the globe. He has led the development and execution of several outcomes research projects and currently heads the real-world evidence strategy function at Teva. Dr. Iyer is well published, having authored over 30 peer reviewed publications and over 100 peer reviewed abstracts presented at major scientific congresses.

Rebeka Jereb, Ph.D.
Clinical Scientist, Sandoz Inc.

Rebeka Jereb is a Scientist at Clinical Development department, Sandoz Development Center Ljubljana, Slovenia. In this role, Rebeka performs various modeling activities during the development of generic drug products. She has expertise in physiologically based pharmacokinetic modeling and IVIVC/IVIVR and has developed various PBPK models for regulatory purposes, e.g., to set drug product specification criteria. Prior to joining Sandoz in 2020, Rebeka was a Researcher at the Pharmacy Institute (University of Ljubljana, Faculty of Pharmacy). She has received her master's degree and Ph.D. in pharmaceutics from the University of Ljubljana, Faculty of Pharmacy (Ljubljana, Slovenia).

Robert (Bob) Dorsam, Ph.D.
Director, Division of Pharmacology/Toxicology Review, Office of Safety and Clinical Evaluation, Office of Generic Drugs

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. In 2014, he joined 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.

Robert (Bob) Iser, M.S.
Senior Vice President, Global Quality Management, Amneal Pharmaceuticals

Bob Iser is the Senior Vice President responsible for global quality management at Amneal (including site quality and global quality systems oversight) and has more than 20 years of U.S. FDA and Biopharmaceutical industry experience in product development, manufacturing, quality systems, policy and procedure development and validation of analytical methods. Prior to joining Amneal, Bob served as Vice President, Regulatory Consulting Services for Parexel International, where he led the Strategic Compliance Team advising clients on developing global regulatory strategies. He is also a former 14-year veteran of the FDA where he served various leadership roles across several offices at CDER, including the Office of Pharmaceutical Quality, Office of Pharmaceutical Science, and OGD. He holds an M.S. in Chemistry from Wright State University and a B.S. in Chemistry from Muskingum College.

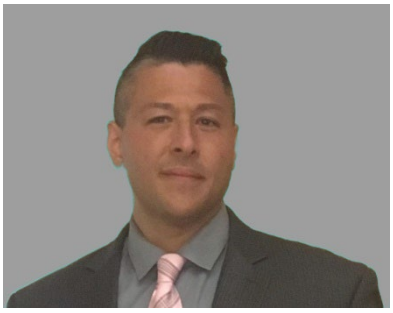
Robert Lionberger, Ph.D.
Director, Office of Research and Standards (ORS), Office of Generic Drugs (OGD), Center for Drug Evaluation and Research (CDER), Food and Drud Administration (FDA)

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 18 years ago, he was an Assistant Professor of Chemical Engineering at the University of Michigan.

Róisín Wallace, Bsc., MRSC
Head of Global Device Development, Viatris

Róisín Wallace is the Head of Global Device Development at Viatris. In this role Róisín leads the design, development, technical regulatory strategy, commercialisation and lifecycle management of device & drug-delivery technology and combination product development for Viatris's growing branded, biosimilar and generic portfolio. Her focus is on developing products that enable access to high quality, safe, robust and effective device and combination products to meet the worlds' evolving patient healthcare needs. Róisín graduated with a BSc. in Analytical Science (Chemistry) from Dublin City University, Ireland and subsequently joined Pfizer Global Research & Development in the UK. Róisín held various roles within Analytical Research & Development with responsibility for analytical development of products from Phase I to commercialization covering API, solid oral and injectable products, before taking a leading role in the establishment of a new Pharmaceutical Sciences organization in India. She subsequently joined Pfizer's Devices Centre of Emphasis where she was accountable for multiple device programs in Pfizer's injector device portfolio from device concept through development, industrialization, and global registration. Róisín joined Mylan's newly established Global Respiratory Group in the UK late in 2011 to lead its Device Development Group. She relished the opportunity to move home to Dublin, Ireland during 2012 to establish and lead a new purpose-built R&D Pilot Plant and expand the Device Development Group to support Mylan's growing respiratory portfolio. In January 2016 Róisín took on a new role within Mylan as Head of Global Device Development, leading a group responsible for the design, development, commercialization and lifecycle management of device and drug-delivery technology and combination product development for Mylan's branded, biosimilar and generic products.

Rosario Lobrutto, Ph.D.
Executive Director, Head of Scientific Affairs, Sandoz Inc.



Rosario has 25+ years' experience as an inspiring, patient-centric leader in the industry driving R&D with a strong focus on regulatory strategy, commercial, and operational excellence in development, scale-up, and launch preparation of generic/branded products at Merck, Novartis, TEVA and Sandoz. This includes development of APIs/drug products containing small molecules, synthetic polypeptides and proteins and drug-device combination products. Currently at Sandoz, he is Head of Scientific Affairs responsible for M&A evaluations and external partnership product development and oversees due diligence evaluating partner capabilities and CMC aspects of new product opportunities amenable to co-development, in-licensing or acquisition. He also oversees the development and implementation of effective regulatory and development strategies leading to timely ANDA and NDA (505b2) submissions, approvals, and launches.

Sally Choe, Ph.D.
Director, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration

From 2006 to 2011, Dr. Choe was leader of the metabolism and endocrinology team in CDER's Office of Clinical Pharmacology, Office of Translational Sciences (OTS). Between 2011 and 2016, she served as senior director at PAREXEL International Corporation, overseeing the Asia-Pacific region and Japan offices, as well as managing the global Vice President Technical consultant group. Dr. Choe returned to FDA in January 2017 and served as deputy director of the Office of Study Integrity and Surveillance in OTS. With more than 20 years of experience in global drug development, Sally is a recognized expert in drug review, clinical pharmacology, biopharmaceutics, and pharmacokinetics. She received her undergraduate degree in electrical engineering from Virginia Polytechnic and State University and her master's and doctoral degrees in pharmaceutics from the University of Michigan.

Sam Raney, Ph.D.
Associate Director for Science, Office of Research and Standards, Office of Generic Drugs

Sam Raney is a thought leader in topical and transdermal drug products, with over 30 years of experience in skin research, producing numerous research manuscripts, review articles, book chapters and patents in pharmaceutical product development. Dr. Raney 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, and serves on multiple expert committees and panels for the U.S. Pharmacopeia. He is the Associate Director for Science in the FDA's Office of Research and Standards and serves as the Chief Scientific Advisor for topical product bioequivalence issues in OGD. 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.

Sarah Ibrahim, PhD
Associate Director for Global Generic Drug Affairs, Office of Generic Drugs, FDA

Sarah Ibrahim is the Associate Director for Generic Drug Global Affairs in the Office of Generic Drugs (OGD)/ Center of Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). In this role, Dr. Ibrahim develops OGD strategies to address identified and emerging regulatory challenges in relation to the international nature of the generic drug industry. In collaboration with other CDER and FDA offices, she supports stakeholder engagement concerning issues related to globalization of the generic pharmaceutical supply and harmonization of regulatory approaches for generic drugs. Dr. Ibrahim received her PhD in Biopharmaceutics/Pharmaceutics from the School of Pharmacy, University of Cincinnati and a B.S. in Pharmacy and Pharmaceutical Sciences from Cairo University, Egypt. Dr. Ibrahim started her career at the FDA in 2014 as a scientific reviewer in the Office of Pharmaceutical Quality. Prior to her FDA career, she has years of experience in the US pharmaceutical industry in the area of pharmaceutical development. As an assistant professor, along with the founding faculty, Dr. Ibrahim established the pharmaceutical sciences department for the second school of pharmacy in the state of New Jersey.

Sarah Rogstad, PhD
Senior Scientific Advisor, Office of Testing and Research, Office of Pharmaceutical Quality, Office of Generic Drugs

Dr. Sarah Rogstad is the Senior Scientific Advisor in the Office of Testing and Research (OTR) 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, and she is the lead for FDA's multi-attribute method (MAM) research.

Siddharth Chachad, M.B.B.S.
Executive Vice President & Head, Global Clinical Management, Dr. Reddy's Laboratories Ltd.

Dr. Chachad is a clinical pharmacologist with 20 years of experience in medical affairs and global clinical development for registration of new drugs, complex generics, biosimilars, and vaccines. He has experience in medical safety leadership with comprehensive theoretical and practical knowledge of the legal and regulatory requirements surrounding global pharmacovigilance and Preclinical and Clinical regulatory consultancy and expert representation at the Scientific Advice Meetings with the heath authorities including EMA, MHRA, USFDA, TGA and WHO. He further has experience in Preclinical and Clinical Strategy Design for registration of conventional vaccines, multivalent "universal" vaccine and Covid products. Dr. Chachad is an internationally acclaimed speaker at various seminars and conferences on clinical research and pharmacovigilance and an expert faculty in the functional areas of clinical development and pharmacovigilance at the teaching and training

institutes, India, Czech Republic, and Netherlands. Dr. Chachad has audit experience of over 100 audits including Clinical, BE and Pharmacovigilance audits. He is the author of over 25 publications in scientific journals and congress presentations, and expert signatory for 1000+ clinical and nonclinical dossier modules

Sridevi Challa, M. Tech, Chemical Engineering
Team Lead, Formulation Development, Sandoz, a Novartis Division

Sridevi Challa is the Team Lead-Formulation Development at Sandoz Development Center, Hyderabad (India). In this role, she leads a group of interdisciplinary scientists including Formulation experts and QbD, Data Science experts by providing scientific guidance and strategic planning during the development of formulated products including preformulation, formulation, scale up and packaging activities, and supports the filing of products in various markets. She specializes in complex drug products including parenterals, ophthalmic suspensions, liposomes and digital approaches for smart formulation development. Prior to joining the Sandoz Development Center in 2018, Sridevi Challa worked with Dr. Reddy's Laboratories Ltd. She has a Master's in Chemical Engineering and is currently pursuing a Ph.D. from IIT Bombay. Sridevi Challa is a certified Master Black Belt and a design thinking coach. She is recognized as a Digital Ambassador in her organization and drives several six sigma projects as a Lean coach.

Sruthi King, Ph.D,
Deputy Director, Division of Pharmacology/Toxicology Review, Office of Safety and Clinical Evaluation, Office of Generic Drugs

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 FDA in 2008 as a Pharmacologist in the Division of Gastroenterology and Inborn Error Products within the Office of New Drugs and later moved to OGD as team leader in 2015. Sruthi now serves as Deputy Director in the Division of Pharmacology/Toxicology Review in the Office of Safety and Clinical Evaluation within OGD at FDA. Sruthi has been a member of the CDER nitrosamine task force for the past 3 years and serves on several working groups with international regulators to harmonize approaches related to nitrosamine safety assessments.

Sunny Chapel, Ph.D.
Chief Scientific Officer, Amador Bioscience
Chief Executive Officer, Ann Arbor Pharmacometics Group

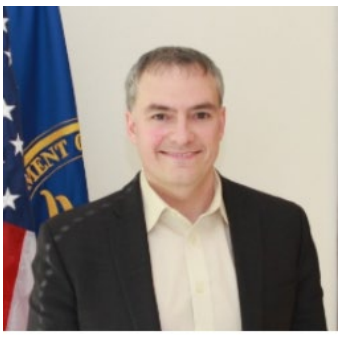
Dr. Sunny Chapel is the CEO and founder of Ann Arbor Pharmacometrics Group, a premier pharmacometrics consulting firm. She has specialized in quantitative drug development (model-informed drug development nowadays) contributing to hundreds of BLA/NDA submissions. In 2021, she joined forces with her former Amgen colleague at Amador Bioscience, a CRO specializing in clinical pharmacology centered drug development with research centers across the US, EU, and CN. As Amador's CSO, Dr. Chapel has overseen the expansion of A2PG's mentorship program and cross-functional team-science approach to scientists across three

continents and spanning the entire development pipeline. Dr. Chapel's specialties include strategic application of pharmacometrics for regulatory success, clinical trial simulation, clinical study design evaluation using modeling and simulation, and global regulatory strategy and support. Before cofounding A2PG, Dr. Chapel held positions at Pfizer, Amgen, and Sanofi-Aventis. She holds a Ph.D. in Pharmacokinetics and a MS in Statistics from the University of Iowa and a B.S. in Pharmacy from Seoul National University.

Susana Almeida, Ph.D.
Clinical Development & Safety Director, Medicines for Europe

Dr. Susana Almeida is Clinical Development and Safety Director at Medicines for Europe (formerly EGA). Before joining Medicines for Europe, Susana was the Chair of the Association's Bioequivalence Working Group for almost 15 years. She has worked in clinical trials and pharmacovigilance in Europe and in North America, and her experience includes the pharmaceutical industry and clinical research organizations. She has overseen the conduction of dozens of clinical trials carried out in Europe, North and South America, and Asia. At Medicines for Europe, Susana is responsible for the coordination of multiple working groups, working on different aspects involving policy and regulatory science: Susana coordinates the activities related to clinical development, pharmacovigilance/drug safety, and medical devices (single integral products, Medical Device Regulation article 117). She has represented the International Generic and Biosimilar Medicines Association (IGBA) in multiple Expert Working Groups at the International Council for Harmonisation (ICH): M13, Generic Discussion Group and M9. She is also involved in the Therapeutics Pillar of the Access to COVID-19 Tools (ACT) Accelerator partnership, launched by WHO and partners. She holds a PhD in Clinical Pharmacology from the Faculty of Medicine, Universidad Autònoma de Barcelona (UAB), Spain and has authored several scientific papers and patents.

Thomas O'Connor, Ph.D.
Deputy Director, Office of Testing and Research, Office of Pharmaceutical Quality, Office of Generic Drugs



Thomas O'Connor, Ph.D. is the deputy director of the Office of Testing and Research in the Office of Pharmaceutical Quality and is a member of CDER's Emerging Technology Team (ETT). His responsibilities include managing research and testing projects that answer and anticipate pharmaceutical quality-related regulatory challenges through scientific approaches. Tom is a co-author of several papers on emerging pharmaceutical technology such as continuous manufacturing, 3D printing, and the utilization of modeling and simulation for quality assurance. Through the ETT, he has contributed to the review of several regulatory applications utilizing novel technologies. He is the co-chair of the OPQ Manufacturing Science and Innovation Center of Excellence and is a member of the advanced manufacturing working groups within the FDA. Tom has been at the FDA since 2013 serving in various roles including as a chemistry reviewer in the Office Generic Drugs and a team leader in the immediate office of the Office of Pharmaceutical Quality. Prior to joining the FDA, Tom worked at ExxonMobil Research and Engineering where he held job functions in both process analytical technology and process control. Tom earned a B.S. in chemical engineering from the Cooper Union and a Ph.D. in chemical engineering from Princeton University.

Tracy VonBriesen, RN, M.S.
Director, Clinical Development, Fresenius Kabi

Tracy VonBriesen RN, M.S., is the Director of Clinical Development at Fresenius Kabi focusing on new product development of combination drug-device products. Most recently, Tracy is building a new Medical Information Team specifically for Infusion Devices. Tracy has led teams to provide clinical and human factors support during development activities required for product life cycle management of serialized and non-serialized infusion devices and combination products. Tracy is a nurse with over 20 years of experience and holds a master's degree in Patient Safety Leadership from the University of Illinois School of Medicine. Prior to her corporate nursing career, Tracy's clinical background includes a variety of hospital-based assignments including neonatal intensive care, and liver transplant.

Utpal Munshi, Ph.D.
Acting Director, Division of Bioequivalence I, Office of Bioequivalence, Office of Generic Drugs

Utpal M. Munshi, Ph.D., is the Division Director (Acting) of the Division of Bioequivalence I (DBI) in the Office of Bioequivalence, in OGD. He leads a team of scientists responsible for the assessment of the bioequivalence section of Abbreviated New Drug Applications and other stakeholder submissions. During his time in DBI, Dr. Munshi has had a variety of technical and administrative roles and has participated in the drafting of numerous Agency guidances pertaining to bioequivalence. 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 in 2007.

Valerie Niddam-Hildesheim, Ph.D.
Senior Director, Global Nitrosamines Project Lead, Global Medical Affairs & PV, Teva Pharmaceuticals

Valerie Niddam-Hildesheim is Senior Director in Medical Affairs Research and Development for Teva. Since 2019, she is globally responsible for the Nitrosamine project and leads a group of interdisciplinary scientists. Valerie Niddam-Hildesheim has more than 20 years of industry experience having previously led the chemical department for Teva API division in Israel for development of generic drugs. Valerie Niddam-Hildesheim was then in charge of the global development strategy for Finish Products Development in Israel for oral, nasal, and sterile drugs. She obtained a Ph.D. in Organic Chemistry at the University of Aix-Marseille in France followed by two postdoctoral positions in chemistry at Weizmann Institute and Hadassah Hospital in Israel.

Wenlei Jiang, Ph.D.
Senior Advisor for Innovation and Strategic Outreach, Office of Research and Standards, Office of Generic Drugs

Dr. Wenlei Jiang is a Senior Biomedical Research and Biomedical Product Assessment Service (SBRBPAS) Expert and currently serves as a Senior Advisor for Innovation and Strategic Outreach in the Office of Research and Standards in OGD. She is leading complex drug product classification and research, promoting global harmonization of bioequivalence criteria, developing opportunities for scientific outreach, and coordinating post-market generic drug safety investigation. She is the current Chair at Product Quality Research Institute (PQRI) Steering Committee and serves at National Cancer Institute (NCI) Nanotechnology Characterization Laboratory (NCL) Scientific Oversight Committee. She also co-chairs IPRP Nanomedicine Working Group, and supports ICH M13, generic drug cluster, and other global regulatory affairs activities. Prior to joining FDA, she was at Novartis Pharmaceutical Corporation where her responsibilities included formulation development of conventional liquid and solid dosage forms, as well as advanced parenteral drug delivery systems. She received her Ph.D. in Pharmaceutics and Pharmaceutical Chemistry from The Ohio State University.

William Chong, M.D.
Director, Office of Safety and Clinical Evaluation, Office of Generic Drugs

Dr. William (Bill) Chong is the Director of the Office of Safety and Clinical Evaluation (OSCE) in OGD. Dr. Chong started his FDA career in the Office of New Drugs reviewing applications for new drugs for diabetes mellitus prior to joining OGD in 2019 as the Associate Director for Clinical Affairs before assuming the role of Director for OSCE. In this role, Dr. Chong oversees the OGD Divisions responsible for the analysis of pharmacologic/toxicologic data for excipients and impurities, comparative clinical data such as comparative clinical bioequivalence studies and comparative analyses and monitoring generic drug products in the post-marketing space to ensure that generic drug products are safe and therapeutically equivalent. Prior to joining FDA, Dr. Chong completed his training in Internal Medicine at Thomas Jefferson University in Philadelphia, PA and a fellowship in Endocrinology and Metabolism at the National Institute of Health in Bethesda, MD.

Xioming Xu, Ph.D.
Lab Chief, Branch III, Division of Product Quality Research, Office of Testing and Research, Office of Pharmaceutical Quality, Office of Generic Drugs

Xiaoming Xu serves as Lab Chief in Division of Product Quality Research in Office of Testing and Research in FDA, where he leads multiple regulatory science research areas such as complex formulations, nanomaterials and advanced manufacturing. He also leads multiple subject-matter-expert (SME) teams to identify and address regulatory challenges and research gaps, to support the development of product specific guidances (PSGs) for complex drug products. Xiaoming is a member of FDA Nanotechnology Task Force and is responsible for developing international collaborative programs and standards in areas related to nanotechnology. Xiaoming received his B.S. and M.S. degrees in

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Yan Wang, Ph.D.
Team Lead, Division of Therapeutic Performance I, Office of Research and Standards, Office of Generic Drugs

Dr. Yan Wang is the team lead for Complex Drug Products Team in the Division of Therapeutic Performance I (DTP I), Office of Research and Standards (ORS), 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.

Yaping Zhu, Ph.D.
Executive Director, Device Development & Inhalation Development, Sandoz Inc., a Novartis Division

Yaping Zhu is an Executive Director of Device Development and Inhalation Development at Sandoz Inc. Her current responsibilities include device development for generic drug-device combination products. Dr. Zhu joined Sandoz Inc. in 2007 as Senior Director, leading Inhalation and External Product Development. In 2008, she served as interim Vice President of R&D at Sandoz Inc., leading generic product development of various dosage forms. Prior to joining Sandoz, Dr. Zhu held a director position at Kos Pharmaceutical, a subsidiary of Abbott, for inhalation product development. Dr. Zhu is a co-inventor of 17 patents. She has more than 30 peer-reviewed publications and authored a book chapter. She received a Ph.D. in Pharmaceutical Sciences from the University of Strathclyde, UK.

Yu Chung Tsang, Ph.D.
Chief Scientific Officer, Biopharmaceutics and Biostatistics, Apotex, Inc.

Dr. Yu Chung Tsang is currently working at Apotex Inc. as Chief Scientific Officer, Biopharmaceutics and Biostatistics. He obtained his bachelor's degree (1984) in Pharmacy and Ph.D. degree in Pharmacokinetics in 1990 from the University of Toronto. He has been with Apotex since then. His main responsibilities are to provide pharmacokinetic and statistical advice in preparing protocol and study report for pharmacokinetic/pharmacodynamic and clinical studies of complex drug and biosimilar products, and in the design of bioequivalence/clinical endpoint studies and the analysis of data for the development of traditional drug products in the Apotex group of companies. Dr. Tsang is currently the Chair of the Bioequivalence Committee in the Canadian Generic Pharmaceutical Association, and the Past Chair of the Generic Pharmaceuticals Focus Group of the American Association of Pharmaceutical Scientists.