Fiscal Year (FY) 2023 Generic Drug Science and Research Initiatives Public Workshop
Speaker, Panelist, And Coordinator Biographies

Ajay Jaysingh Khopade, PhD
Vice President, Research and Development, Sun Pharmaceuticals Industries Ltd.

Dr. Ajay Khopade has deep scientific and senior management expertise in industrial pharmaceutical research and development (R&D), particularly including experience with sterile formulations, and encompassing both generics and innovative drug delivery systems. His research interests focus on understanding the physical chemistry of drug delivery systems and their biological implications. Dr. Khopade is a recognized expert in lifecycle management of drug products, with knowledge of end-to-end product development from concept through preclinical, CMC, clinical development, regulatory approval, and marketing. Dr. Khopade has a PhD in pharmaceutical sciences and multidisciplinary postdoctoral research experience, and is currently the Vice President of Formulation R&D at Sun Pharma.

Andre Raw, Ph.D.
Associate Director for Science and Communication, Office of Lifecycle Drug Products (OLDP), Office of Pharmaceutical Quality (OPQ), Office of Generic Drugs (OGD), Center for Drug Evaluation and research (CDER), Food and Drug Administration (FDA)

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 Associate Director for Science and Communication in the Office of Life Cycle Drug Products (OLDP) in the Office of Pharmaceutical Quality (OPQ). 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, and QbD Example for Generic Modified Release Products. He was instrumental in FDA's approval of generic versions of complex active ingredients, including Lovenox (enoxaparin sodium) and Copaxone (glatiramer acetate). He is currently involved in Risk and Quality Informatics Initiatives and is a principal architect of Knowledge-Aided Assessment and Structured Application (KASA). More recently, Dr. Raw has been active in the area of Nitrosamine Impurities.

Andrew Cooper, PhD
Senior Director, Development for In Vivo Performance, Viatris

Dr. Andrew Cooper studied at University of Bath. He began his career working in bioanalysis and drug residue analysis before spending 14 years with Pfizer Global R&D, where he gained broad experience of API and complex dosage form development. Andrew joined Mylan Global Respiratory Group (now within Viatris) in 2012, based in Sandwich (UK) and has particular interests in understanding the relevance of in-vitro tests to in-vivo performance and bioequivalence strategies for inhaled products.

Andrew Graves, MS
Director, Immunogenicity Assessment, Teva Pharmaceutical Industries Ltd.

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 on 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.

Anna Schwendeman, Ph.D.
Director, Center for Research on Complex Generics
Professor, University of Michigan

Anna Schwendeman is the Hans W. Vahlteich 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.

Ann Purrington, RPh, RAC
Regulatory Affairs Director, Kindeva Drug Delivery

Ann Purrington is a Regulatory Affairs Director at Kindeva Drug Delivery, L.P. In this role, Ann develops regulatory strategies and submissions for Kindeva and their partners' regulatory filings to ensure continued patient access to (hydrofluoroalkane) HFA oral inhalation aerosols for asthma and COPD. She received her B.S. in Pharmacy from the University of Minnesota College of Pharmacy. Her 30+ year career in industry as a pharmaceutical scientist and regulatory affairs professional has included development and registration of multiple HFA inhalation aerosols in response to the Montreal Protocol's requirements to phase out CFC inhalers. Ann is a board member of the International Pharmaceutical Aerosol Consortium for Regulation and Science (IPAC-RS) and a US subteam co-lead of the related environmental policy organization International Pharmaceutical Aerosol Consortium (IPAC). In these roles she is presently focused on initiatives and strategies to bring awareness to the regulations and need for an understanding of the submission requirements as HFA inhalers transition to lower GWP inhalation aerosols.

Annie De Groot, MD
Chief Executive Officer and Chief Scientific Officer, EpiVax, Inc.

Annie De Groot has served as Chief Executive Officer and Chief Scientific Officer of the biotech company EpiVax for the past 25 years. She is a graduate of University of Chicago and Smith College, trained in Infectious Disease at New England Medical Center and Vaccines and Immunology at the National Institutes of Health, and is the author of 210 publications and 46 patents. In addition to engaging in a wide range of research at EpiVax, Brown, URI and University of Georgia, she maintains an active role in two not-for-profits, Clinica Esperanza and GAIA Vaccine Foundation.

Bing Li, Ph.D.
Associate Director for Science, Office of Bioequivalence (OB), OGD, CDER, FDA

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.

Bryan Newman, PhD
Lead Pharmacologist, Division of Therapeutic Performance (DTP) I, Office of Research and Standards (ORS), OGD, CDER, FDA

Bryan Newman, Ph.D., is a lead pharmacologist and team lead for inhalation and nasal drug products in the Division of Therapeutic Performance. Dr. Newman's work focuses on developing product-specific guidances and 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.

Brian Sadler, PhD
Senior Scientific Director, Quantitative Pharmacology & Pharmacometrics, ICON plc

Brian M. Sadler, PhD, brings over 42 years of experience as a PKDM scientist at RTI International, a project pharmacokineticist at GlaxoSmithKline, an instructor and domain expert at Pharsight, the principal and owner of his own pharmacometric consulting compa ny, and, most recently, as Senior Scientific Director of Quantitative Pharmacology & Pharmacometrics at ICON plc. He began performing pharmacometric analyses in 1985 and has been actively involved in the population-based PK modeling of long-acting injectable formulations of aripiprazole since 2013. Dr. Sadler earned his PhD in Pharmacology (1981) and BA in Biology (1975) from the University of Missouri - Columbia.

Cameron Smith, PhD
Branch Chief, Division of Liquid Based Products (DLBP) I, Office of Lifecycle Drug Products (OLDP), Office of Pharmaceutical Quality (OPQ), CDER, FDA

Cameron is a Branch Chief in the Office of Lifecycle Drug Products/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.

Clare Butler, PhD
Principal Product Development Scientist, Teva Pharmaceuticals

Dr. Clare Butler obtained her PhD in Bimolecular and Biomedical Science at the Conway Institute, University College Dublin in 2017. Dr. Butler is currently a principal product development scientist at Teva's global respiratory R&D division in Waterford, Ireland. Her role in the division is to develop and validate physiologically based pharmacokinetic (PBPK) models to address questions that are important during the development of complex locally acting respiratory drug products. Her interests include PBPK modeling, CFD, alternate bioequivalence approaches and physiologically relevant (realistic) in vitro analytical methods.

Craig Bertha, PhD
Chemist, Division of New Drug Products (DNDP) II, Office of New Drug Products (ONDP) OPQ, CDER, FDA

Craig received his B.A. degree in Chemistry from the University of Maryland, Baltimore County in 1986, and M.S. and Ph.D. degrees in Organic Chemistry from the University of Maryland Graduate School at Baltimore in 1989 and 1992, respectively. He was a postdoctoral fellow in the Laboratory of Medicinal Chemistry at the National Institutes of Health under the direction of Kenner Rice, Ph.D. from 1992-1995. Craig then joined the FDA as a reviewer co-located in the Division of Pulmonary and Allergy Drug Products (DPADP) in 1995 and currently serves as a CMC reviewer in ONDP/DNDPII in Branch 4 under Nina Ni, supporting both the Division of Pulmonology, Allergy, and Critical Care (DPACC) and the Division of Rheumatology and Transplant Medicine (DRTM). Craig currently serves on the working group revising the 2018 draft quality guidance for MDIs and DPIs, the internal Agency working group for ICH Q3E guidance for extractables/leachables, and several Agency working groups involved in regulatory aspects related to the changing of propellants for MDIs to reduce global warming.

Daniel Robins, MBA
Chief Executive Officer, Capstone Development Services

Daniel S. Robins, Ph.D., has nearly 30 years of pharmaceutical industry experience. Dan held R&D leadership positions at Barr Laboratories, Abraxis Bioscience, Bioniche Pharma, and Mylan. Since 2013, Dan has lead Capstone Development Services., which is an innovative shared services development company focused exclusively on complex generic pharmaceuticals and medical devices. Dan earned his BA from La Salle University in chemistry, his MS and PhD in analytical chemistry from The Ohio State University, and his MBA from the Stern School of Business at NYU.

Daniel Snider, PhD
Head, Global Quality Systems/Quality Assurance IT 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.

Daniela Verthelyi, MD, PhD
Laboratory Chief, Office of Biotechnology Products (OBP), OPQ, CDER, FDA

Daniela Verthelyi, Ph.D., currently heads the Laboratory of Innate Immunity and chairs OPQ's Center for Excellence in Infectious Diseases and Inflammation. She directs a lab focused on developing tools to monitor and control innate immune and inflammatory responses. The tools developed by her lab helps to control and mitigate the impact of potential immunomodulatory impurities in therapeutic products which reduce the risk of unwanted immune responses. Dr. Verthelyi received her M.D. from the University of Buenos Aires and a Ph.D. in Immunology from Virginia Tech. She has been a driving force in risk evaluation and mitigation pertaining to the immunogenicity of therapeutic proteins, pe ptides and oligonucleotides. She has chaired the FDA-NIH Immunology Interest Group, the NIH-FDA Cytokine Interest Group, and served on the Advisory Boards for the NIH Human Immunology Group. She has contributed to multiple FDA Guidance for Industry and MAPPs, authored over 100 scientific papers, holds multiple patents, and has received FDA's, CBER's, and CDER's "Excellence in Laboratory Sciences" awards, among other honors.

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

Dr. Deyi Zhang is a senior chemist in the Office of Research and Standards, 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 on such products, and manages r elated research activities. Deyi is an organic chemist by training. After two years of NIH postdoctoral fellowship training at UPenn, he joined Eli Lilly and Company. He had 15 years pharmaceutical industry experience prior to joining FDA in 2015. He has 12 US patents and 49 publications and presentations.

Diaa Shakleya, PhD
Senior Research Scientist (Pharmacologist), Division of Product Quality Research (DPQR), Office of Testing and Research (OTR), OPQ, CDER, FDA

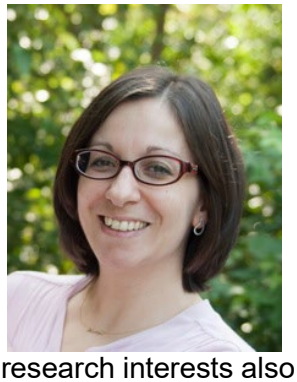
Dr. Diaa Shakleya is a Senior Research Scientist within the Division of Product Quality Research. His areas of expertise include drug products quality, opioids, and regulated bioanalysis and pharmaceutical analysis. In his current role, Dr. Shakleya leads regulatory science research work related to nitrosamine impurities, including projects related to Mitigation strategies to reduce the risk of the nitrosamine impurities in pharmaceutical drug products and effect of excipients on the formation of nitrosamines in drugs. 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

Dongyuan Wang, PhD
Program Manager, Synthon B.V.

Dongyuan Wang is a program manager in Synthon B.V and has more than 15 years' experience in the (bio)pharmaceutical industry developing generic, biosimilar and novel products. She earned a Ph.D. in Analytical Chemistry and started her career as team leader at Synthon Biopharmaceuticals B.V in the areas of analytical method development for biosimilar and complex generic API. Over the last years, she has served in various roles of increasing responsibility in (bio)pharmaceutical R&D. In her current role as a program manager, she is responsible for the development of complex generic API, focusing on generic oligonucleotide drug development.

Eleftheria Tsakalozou, PhD
Senior Pharmacologist/Acting Team Lead, Division of Quantitative Methods and Modeling (DQMM), ORS, OGD, CDER, FDA



Eleftheria Tsakalozou joined the FDA in 2015 as an Oak Ridge Institute for Science and Education (ORISE) Fellow. She is currently a Senior Pharmacologist at the Division of Quantitative Methods and Modeling at the Office of Research and Standards with expertise on physiologically-based pharmacokinetic modeling and simulation approaches for topical and transdermal drug products. Dr. Tsakalozou obtained her PhD in Pharmaceutical Sciences at the University of Kentucky in 2013 and completed a two-year Fellowship in Clinical Pharmacokinetics and Pharmacodynamics at the University of North Carolina at Chapel Hill. Her research interests also include the development of quantitative modeling and simulation tools to support bioequivalence assessments and the interactions between inactive ingredients and molecular targets including gut transporters.

Ethan Stier, PhD
Associate Director, Office of Clinical Pharmacology (OCP), Office of Translational Science (OTS), CDER, FDA

Dr. Ethan Stier is the Associate Director of Lifecycle Management in the Office of Clinical Pharmacology, OTS/FDA. Prior to that, he served as Division Director of Bioequivalence, Associate Director for Science, and Acting Deputy Office Director in the Office of Bioequivalence OGD/FDA. He is an expert in the design and interpretation of in vitro, in vivo, and in silico bioequivalence and comparative bioavailability studies used generic and new drug applications. He is a recognized leader in guidance and policy in the generic and new drug spaces having overseen the development of numerous FDA and ICH

Guidances, as well as Product Specific Guidance Development. Currently he is the lead in the Office of Clinical Pharmacology for Citizen Petition, 505B2 policy development and knowledge management, ICH Guidance development on BE/BA topics and coordination of lifecycle activities with partners across CDER. He earned in PhD in Pharmaceutical Sciences from the University of Michigan and Bachelor in Pharmacy from the University of Connecticut.

Fang Wu, PhD
Senior Pharmacologist and Scientific Lead, 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 11 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.

Feng Zhang, PhD
Associate Professor of Molecular Pharmaceutics, University of Texas at Austin

Feng Zhang is an associate professor at the Division of Molecular Pharmaceutics and Drug Delivery at College of Pharmacy at The University of Texas at Austin. He received his Ph.D. in pharmaceutics from the University of Texas at Austin. He worked in the industry for 14 years prior to joining the department of pharmaceutics at the University of Texas at Austin in 2014. He was the Director of Product Development at PharmaForm from 2007 to 2010 and Senior Scientist in the Formulation and Process development department at Gilead from 2011 to 2013. His principal research interest at UT Austin includes formulation and process design of implants for long-term drug delivery and amorphous solid dispersions for bioavailability enhancement. His research also focuses on continuous granulation and powder blending enabled by twin-screw extrusion. He is the editor of 2nd edition of “Pharmaceutical Extrusion Technology”, published in 2018. He has authored four book chapters on twin-screw extrusion process. He has published 80 peer-reviewed papers articles. He is also inventor on 12 issued patents covering a wide range of drug delivery systems. He serves on the editorial board of AAPS PharmSci Tech and North American editor for Journal of Drug Delivery Science and Technology.

Hongling Zhang, PhD
Division Director, Division of Bioequivalence (DB) II, OB, OGD, CDER, FDA

Dr. Hongling Zhang is the director of the Division of Bioequivalence II in the Office of Bioequivalence of OGD, FDA. Since joining OGD in 2008, she has been involved in evaluating bioequivalence (BE) submissions in ANDAs for many complex drug products and BE studies with complex scientific and/or regulatory issues. In her current role, she provides leadership and expertise for the assessment of BE studies submitted ANDAs. Dr. Zhang received her bachelor's degree from Shenyang Pharmaceutical University and Ph.D. degree in Pharmacology from the University of South Florida and completed a post-doctoral training at the Moffitt Cancer Institute.

Ilan Zalit, PhD
Senior Director of Gx R&D, Teva Pharmaceuticals

Dr. Ilan Zalit is the Director of a development unit at Teva Pharmaceutical Industries. Dr. Zalit has about 20 years of experience in developing models for in vivo and in vitro correlations. He has a bachelor's degree in chemistry and a master's degree in biochemistry from Tel Aviv University in Israel. Director of a development unit at Teva Pharmaceutical Industries. Has about 20 years of experience in developing models for in vivo and in vitro correlations.

James F. Clarke. PhD
Associate Principal Scientist, Simcyp Division, Certara UK

James Clarke completed his BSc at Newcastle University in Pharmacology followed by a PhD at the University of Bath focussing on dermal absorption. Since then, he has been working in the dermal modelling team at Simcyp, focused on developing novel models describing the skin and complex topical formulations. He currently leads scientific development of the dermal absorption module within the Simcyp simulator. James is currently project lead for two FDA grant awards relating to dermal absorption and virtual bioequivalence. The first is investigating PBPK model parameters affected by various skin diseases, where skin disease populations have been developed and clinical studies are currently ongoing to fill gaps in the physiological data. The second is focused on enhancing and verifying in vitro – in vivo extrapolation in the dermal absorption area in the context of utilizing in vitro characterisation data to inform PBPK models for virtual bioequivalence assessment. James also has extensive consultancy experience in the generic's industry, which has involved developing alternative PBPK model-based BE approaches. He is currently working in the areas of dermal, long-acting injectables, rectal and vaginal absorption in this context.

Jan De Backer, PhD
Chief Executive Officer, Fluidda NV

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 Busine ss 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.

Jaya Abraham, PhD
Senior Vice President, Global Pharmaceutical Development, Glenmark Pharma Ltd, India

Dr. Jaya Abraham is currently working as Senior Vice President in Glenmark R&D. She has more than three decades of experience in Pharmaceutical industry. She has developed formulations for NCEs, NDDS and Generics from Lab to Commercial scale. She has created R&D portfolio with over 50 patents, 350+ dossier fillings for different markets, led a team of over 200 scientists with multi –site glob al footprints. She has led R&Ds team in Harman Finochem/ Alvogen / Torrent/ Zydus in the past. She also has an experience in setting up green and brown field projects with operations team and led implementation of PAT tools, continuous manufacturing development of IVIVC / PKPD. She has been a part of the core team for international audits representing R&D. She has done PhD in drug delivery from BITS Pilani, PG Diploma in Patent Laws from NALSAR Hyderabad. She has been recognized by Gattefosse foundation for her scientific work and by Express Pharma in June 2017 for Outstanding Leadership.

Jessica Spires, PhD
Principal Scientist, Simulations Plus, Inc.

Dr. Jessica Spires is a principal scientist at Simulations Plus, Inc. Since 2013, she has focused on 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 two 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 PhD in biomedical engineering.

Keith Gallicano, Ph.D
President, SAAMnow

Keith Gallicano, Ph.D. (Chemistry) is a consultant in clinical pharmacology and biopharmaceutics with expertise in the areas of bioequivalence, drug-drug interactions, and pharmacokinetic, pharmacodynamic and clinical endpoint trial design and data analysis/interpretation. He has 35 years of diverse experience working in the pharmaceutical field, including various positions in government (Senior Research Scientist, Health Canada), academia (Assistant Professor of Medicine, University of Ottawa; Adjunct Professor of Pharmacology and Therapeutics, University of British Columbia), the pharmaceutical manufacturing industry (Head, Clinical and Regulatory Affairs, Axar Laboratories, Inc.; Director, Biopharmaceutics, Watson Laboratories, Inc.) and the CRO service industry (Chief Scientific Officer, Novum Pharmaceutical Research Services; Vice President, Research and Development, Axelson Biopharma Research, Inc.; Scientific Director, CroMedica Prime and Prime Trials). Dr. Gallicano has co-authored 78 publications, including research papers, reviews, and book chapters. He was a member of the Editorial Board of the Journal of Chromatography and the British Journal of Clinical Pharmacology. Dr. Gallicano has given numerous invited lectures on bioanalytical, pharmacokinetic, clinical and pharmacostatistical aspects of drug interaction and bioequivalence studies, as well as chaired or co-chaired international meetings on these topics. He is a Founder and President of Scientists Advancing Affordable Medicines (SAAMnow), which is a non-profit organization founded in 2018 that provides a dedicated platform for scientists to share cutting-edge research that facilitates the development of high-quality affordable medicines.

Khondoker Alam, PhD
Senior Pharmacologist, DQMM, ORS, OGD, CDER, FDA

Dr. Khondoker Alam is currently working as a senior staff fellow in the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS), Office of Generic Drugs (OGD) in FDA. Dr. Alam is serving as scientific lead for complex injectables such as long-acting injectables, liposomal injections etc. His role in the division is to utilize physiologically-based pharmacokinetic (PBPK) modeling and other quantitative tools to address specific questions pertinent to drug development process and/or regulatory decision making. He is responsible for reviewing pre-abbreviated new drug applications (pre-ANDA) meeting packages, ANDA post complete response letter (post-CRL) scientific meeting packages, ANDA consults and controlled correspondences on complex injectables and topical dermatological drug products where model based alternative bioequivalence approach is proposed by ANDA applicant. He is serving as project lead and key technical member for multiple FDA research projects on complex injectables, topical dermatological drug products, buccal/sublingual drug products as well as projects related to mitigation strategy for N-nitrosamine impurities. 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 interactions.

Kimberly Raines, PhD
Branch Chief, Division of Biopharmaceutics, ONDP, OPQ, CDER, FDA

Dr. Kimberly Raines is a Supervisory Pharmacologist at the FDA. Dr. Raines and her team lead efforts in establishing in vitro dissolution/release specifications and assessing biopharmaceutics topics (e.g., biowaiver, bridging, IVIVC, etc.) in regulatory submissions. Additionally, Dr. Raines develops CDER biopharmaceutic guidances, leads research projects within her division, and provides subject matter expertise to FDA policy initiatives. She has co-authored original research articles and presented on bioequivalence, biowaivers, in vitro dissolution, and physiologically based model informed quality risk assessment. Her tenure at the Agency began in the Office of Generic Drugs 15 years ago as a bioequivalence reviewer and controlled correspondence team lead. Prior to joining the FDA, Dr. Raines received post-doctoral training at the University of North Carolina Lineberger Comprehensive Cancer Center where she was an UNCF-Merck Fellow. In 2006 she received her Ph.D. in pharmaceutical sciences from the University of Maryland School of Pharmacy and a B.S. in chemistry with a concentration in pharmacology from Duke University.

Kinam Park, PhD
President, Akina, Inc.,
Professor, Pharmaceutics & Biomedical Engineering, Purdue University

Professor Kinam Park is the Showalter Distinguished Professor of Biomedical Engineering at Purdue University. He also serves as the president of Akina, Inc., specializing in specialty PLGA polymers and new fully biodegradable plastics called Nuplons. Professor Park has studied controlled drug delivery systems for four decades, with a recent focus on understanding PLGA polymers' properties and the mechanisms of drug release from long-acting injectable formulations. He is currently developing 3~6-month long-acting buprenorphine injectable formulations for treating opioid use disorder.

Kurt Brumbaugh, MS
Director, Biostatistics, Viatris

Kurt has more than 20 years' experience as a biostatistician with over 10 years in the pharmaceutical industry. He has assisted R&D in the development of generic drugs including oral, transdermal, and biosimilar products. Kurt is currently Director, Biostatistics at Viatris (formerly Mylan) where his role is to provide statistical support for in-vitro and Phase I bioequivalence studies. In this role, Kurt has assisted scientists in the development of an innovative design and statistical analysis for in-vitro skin flux studies which have led to more successful clinical studies. Kurt earned a Master's in Biostatistics after a Bachelor's in Mathematics at the University of Nebraska.

Lakshmi Raghavan, PhD
Founder & CEO, Healios Ventures

Dr. Lakshmi Raghavan is a successful, serial entrepreneur with more than 25 years of technical and business development expertise. Lakshmi Raghavan is currently the Founder and Managing Partner of Healios Ventures, leading its overall corporate strategy and Business Development. Prior to Healios Ventures, Dr. Raghavan founded Solaris Pharma Corporation in 2015, a company dedicated to developing generic and branded pharmaceutical products, from concept to commercialization. Dr. Raghavan also founded DermPathe Pharmaceuticals in 2010, a contract research organization providing contract research & development services in development of non-solid oral dosage forms, taking products from concept to clinical. Prior to DermPathe Pharmaceuticals, Dr Raghavan led the R&D at Vyteris Corporation for 6 years, where he was responsible leading all its R&D programs based on its iontophoretic transdermal technology. Dr Raghavan holds a Master of Science in Physics from the University of Madras, Chennai, India and a Doctor of Philosophy degree in Physics from Indian Institute of Technology, Chennai, India. He has more than 40 research publications and several book chapters.

Lanyan (Lucy) Fang
Deputy 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).

Lei Zhang, PhD
Deputy Director, ORS, OGD, CDER, FDA

Dr. Lei Zhang serves as the Deputy Director of ORS within OGD. Dr. Zhang oversees the implementation of the Generic Drug User Fee Amendments (GDUFA) science and research commitments 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 24 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.

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 in regulatory and industrial settings for new and generic drugs during his 18+ professional tenue including in Pharsight as an associate consultant, BMS as a research investigator, MedImmune as an Associate Director, FDA as Clinical Pharmacology reviewer and Pharmacometrics team leader. Dr. Zhao has introduced a broad array of innovative tools in the realm of drug deliveries and bioequivalence assessment, as well as big data tools including machine learning to pharmacometrics. He received the 2023 Gary Neil Prize for Innovation in Drug Development from ASCPT as a recognition to his contribution to clinical pharmacology and pharmacometrics.

Makarand Avachat, PhD
Executive Vice President, Pharmaceutical Research & Development, Lupin Ltd., India

Makarand Avachat, in his current position as Executive Vice President, Pharmaceutical R&D, leads the R&D activities for Oral, Ophthalmic, Injectable and Topical formulation development and analytical development for specialized dosage forms, for US, Europe, Asia Pacific, Latin America & India region. Makarand joined Lupin in 2002 and has since held positions of increasing responsibilities in Pharma R&D. He completed his B Pharm from Pune University & M Pharm from Kakatia University and was awarded Gold Medal for being the University topper. He has close to 35 years of experience in pharmaceutical formulation development of which last 20 years have been in leading R&D organization. His broad area of expertise is in the development of solid and liquid orals, ophthalmics, complex injectables and topical products. As a formulation scientist he had worked his way up the value chain ladder from development of products for domestic India market to complex generics and 505 b(2) NDA products for advanced markets. He has been instrumental in filing of over 150 ANDA/ generic products in US, Europe & Japan and more than 180 products for other markets. He would have overseen design, execution and review of over 600 BE studies during the course of development and regulatory filling of these products

Manar Al-Ghabeish, PhD
Staff Fellow, DTP II, ORS, OGD, CDER, FDA

Manar Al-Ghabeish is a staff fellow in the Division of Therapeutic Performance II of the Office of Research and Standards (ORS) in Office of Generic Drugs (OGD). As part of the modified release oral team in ORS/OGD, Manar is involved in developing and revising product specific guidance for modified oral drug products and reviewing and responding to internal consults, pre-ANDA meeting requests and controlled correspondences related to demonstrating bioequivalence of generics. She is also the project officer on several regulatory science research initiatives related to oral solid drug products. Before joining OGD, Manar served as a regulatory research scientist and product quality assessor in the Office of Testing and Research (OTR) in the Office of Pharmaceutical Quality (OPQ) . During her seven years in OTR/OPQ, she assessed complex generic products including topical, ocular, and modified release products. Her research focused on abuse deterrent formulations, locally acting gastrointestinal drugs, and characterization of complex drug products. She received her B.S. in Pharmacy and M.S. in Pharmaceutical Sciences from the University of Jordan, and she earned her Ph.D. in Pharmaceutics from the University of Iowa.

Markham Luke, M.D., Ph.D.
Director, DTP I, ORS, OGD, CDER, FDA

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 Lee, MD
Senior Physician, Division of Clinical Review (DCR), Office of Safety and Clinical Evaluation (OSCE), OGD, CDER, FDA

Dr. Mary Lee is a Senior Physician in Division of Clinical Review in the Office of Generic Drugs. Dr. Lee joined the FDA in 2016, and has been i nvolved with reviews for ANDAs, Bio-INDs, Product Specific Guidance documents, controlled correspondences with the generic pharmaceutical companies, and consults with clinical issues in the development of generic drugs. Prior to coming to the FDA, Dr. Lee worked as a Geriatric Medicine physician for the Mid-Atlantic Permanente Medical Group and Inova Fairfax Hospital. Dr. Lee received her Bachelor of Science degree from Massachusetts Institute of Technology, and her medical degree from Albert Einstein College of Medicine in New York.

Michael Kopcha, PhD, R.Ph
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.

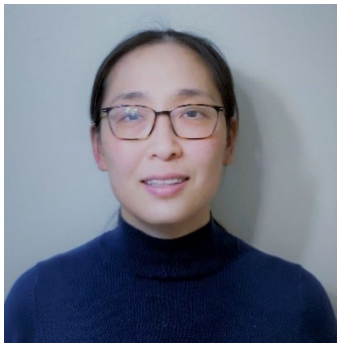
Nicholas Holtgrewe, PhD
Chemist, Division of Complex Drug Analysis (DCDA), OTR, OPQ, CDER, FDA

Dr. Nicholas Holtgrewe has bee n a Chemist at the FDA Division of Complex Drug Analysis (DCDA) within CDER/OPQ/OTR since April 2019. His research at FDA focuses on inhalation drug characterization, particle sizing, X-ray powder diffraction (XRPD), and spectroscopy and his expertise is in optics, X-ray diffraction, and Raman spectroscopy. He received a BS degree in Chemistry from Truman State University in 2008 and a PhD in Chemistry from Washington University in St. Louis in 2013.

Priyanka Ghosh, Ph.D.
Lead Pharmacologist, DTP I, ORS, OGD, CDER, FDA

Dr. Priyanka Ghosh is a lead pharmacologist within the Division of Therapeutic Performance, ORS, OGD. Her areas of expertise include products in the topical and transdermal drug delivery area. In her current role, Dr. Ghosh leads regulatory science research initiatives related to topical, transdermal and transmucosal drug products, under the GDUFA regulatory science program. Dr. Ghosh also leads the development of general and product-specific guidances, review strategies for industry meeting requests and citizen petitions 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.

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



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

Rachel Dunn, Ph.D.
Director, Division of Pharmaceutical Analysis (DPA), OTR, OPQ, CDER, FDA

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.

Raphael Nudelman, PhD
Sr. Director Impurity Expert, Research and Development, Teva Pharmaceuticals

Raphael (Raphy) is a medicinal chemist by training (PhD) with over 20 years of pharmaceutical industry experience primarily in the chemistry and toxicology interface. In Teva Pharmaceuticals he filled several roles including in the medicinal chemistry department, in the patent department, and in the non-clinical safety department, and currently he is the Impurity Expert of the company. Raphy's main topics of expertise are impurity and excipient qualification in drug substances and drug products. Over the past few years he has specialized in risk assessment of nitrosamine impurities in pharmaceuticals.

Rebeka Jereb, PhD
Senior Scientist, Clinical Development, Sandoz Pharmaceuticals

Rebeka Jereb is a Senior Scientist in Clinical Development, Sandoz Development Center Ljubljana, Slovenia. She has received her master's degree and PhD in pharmaceutics at the University of Ljubljana, Faculty of Pharmacy. Rebeka has expertise in pharmacokinetic modeling, physiologically based pharmacokinetic modeling and IVIVC/IVIVR and has developed various PBPK models for regulatory purposes, e.g., to set drug product specification criteria. She has published several research articles with focus on using PBPK modeling in generic drug development.

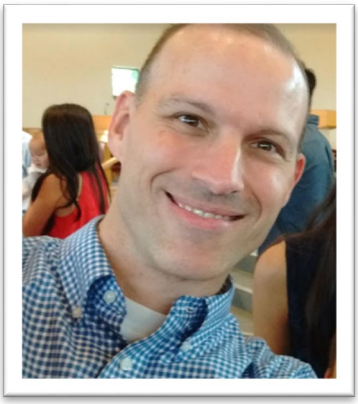
Ripen Misra, PhD
Director Co-Development, Apotex

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, and peptide therapeutics. Dr. Misri joined Apotex in 2015 and is currently Director of the Co-Development R&D, leading development of complex generic drug, and drug device combination products.

Robert Califf, MD
Commissioner, FDA

Dr. Robert M. Califf was confirmed earlier this year as the 25th Commissioner of Food and Drugs. He also served in 2016 as the 22nd Commissioner, and immediately prior to that as the FDA's Deputy Commissioner for Medical Products and Tobacco. He has spent a good portion of his career affiliated with Duke University, where he served as a professor of medicine and vice chancellor for clinical and translational research, director of the Duke Translational Medicine Institute, and was the founding director of the Duke Clinical Research Institute. He has had a long and distinguished career as a physician, researcher, and leader in the fields of science and medicine. He is a nationally recognized expert in cardiovascular medicine, health outcomes research, health care quality, and clinical research, and a leader in the growing field of translational research, which is key to ensuring that advances in science translate into medical care.

Robert (Bob) Dorsam, Ph.D.
Director, Division of Pharmacology/Toxicology Review (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.

Robert Lionberger, Ph.D.
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.

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

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

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

Dr. Rackley is Global Head, Clinical Pharmacology, Viatris Inc. He has a demonstrated history of working in the pharmaceuticals industry and an understanding of global health authority expectations. He holds a BS in Pharmacy and a PhD in Pharmaceutics from the University of Tennessee, Memphis and has over 34 years of Industry experience in pharmaceutical development, including: 7 years as a research scientist at Ciba-Geigy Corporation in the departments of Biopharmaceutics and Clinical Pharmacokinetics; 5 years as Director of Biopharmaceutics at Purepac Pharmaceutical Co.; and the last 22 years at Viatris (formerly Mylan Pharmaceuticals Inc.). Areas of expertise include assisting in formulation development with respect to in vitro screening and relevance to in vivo performance, as well as design and reporting of clinical pharmacokinetic and bioequivalence studies. Experience includes supporting development of small to complex molecules, in simple to complex formulations, for oral, topical, transdermal and injectable routes of delivery. Responsibilities include serving as a global resource for the development of products to be registered world-wide. More recent appointments include representative to the International Council for Harmonisation (ICH), on behalf of the International Generic and Biosimilar Medicines Association (IGBA), in the Generic Discussion Group, to support development of bioequivalence guidance for solid oral dosage forms, assist in identification of future bioequivalence topics for ICH consideration, and continuing as Topic Lead for IGBA as in the ICH M13 Expert Working Group.

Sajeev Chandran, PhD, MBA
Director, Pharmaceutical Research & Development, Lupin Ltd, India

Sajeev Chandran in his current role at Pharmaceutical R & D of Lupin, as Director- ADDS Research, Generics, Packaging & IVIVC/ Biopharmaceutics, is involved in leading a diverse research group of formulators, analysts, packaging development, biopharmaceutics & IVIVC experts in design, development & regulatory submission of advanced drug delivery technologies-based brand & difficult to do generic products. Prior to joining Lupin, he served as Assistant Professor and Assistant Dean, at Birla Institute of Technology & Science, Pilani, India. In his research career, he holds 10 granted patents, 50 research publications in peer-reviewed international journals and over 60 research presentations in national & international conferences/ symposia. He has delivered more than 35 invited talks and supervised three Ph D thesis work in Novel Drug Delivery System Design & Development. Dr. Sajeev Chandran obtained his Bachelor of Pharmacy degree with honors from Institute of Technology (BHU), Varanasi and Master's in Pharmacy & Ph.D. degree from Birla Institute of Technology & Science, Pilani. He earned his MBA in Operations Management from Indira Gandhi National Open University, New Delhi. He is recipient of FDD Leadership Awards 2019 under the Rising Stars Category, (Jun 2019) at 3rd Formulation Development & Drug Delivery (FDD) Conclave, Hyderabad by Express Pharma, Indian Express Group; Young Pharmacy Teacher Award- 2008 instituted by Association of Pharmaceutical Teachers of India and Young Scientist Grant Award in 2005 by Dept. of Science & Technology, Govt. of India, New Delhi.

Sam Raney, Ph.D.
Associate Director for Science, ORS, OGD, CDER, FDA

Dr. 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 FDA's Office of Generic Drugs. 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 Rogstad, PhD
Senior Scientific Advisor, OTR, OPQ, OGD, CDER, FDA

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.

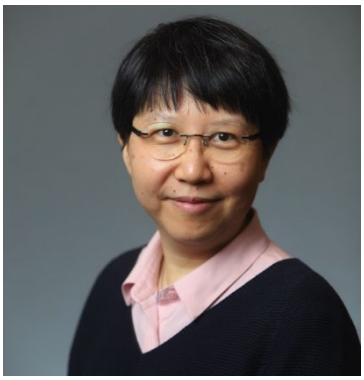
Shawn Zhang, Ph.D.
Managing Director, DigiM Solution LLC

Shawn is a co-founder and managing partner of DigiM. Shawn graduated from Rutgers University with a Ph.D. in Computational Physics and a minor in Computer Engineering. Before starting Boston-based DigiM, Shawn held senior positions at leading CAE software company Fluent (now Ansys) and leading electron microscopy company FEI (now ThermoFisher). Shawn is passionate about the combined power of imaging, AI, and computational physics. With over hundreds of publications, patents, and software products, Shawn leads DigiM to becoming a trusted partner in microstructure science across multiple industries.

Shitalkumar Pathak, M. Pharma
Senior Vice President and Head Analytical Research & Development and In-Vitro Bio Study Lab, Glenmark Pharma Ltd, India

Shital Pathak has over 26 years of experience in pharmaceutical industry. He worked with major generic companies including Sun Pharma, Sandoz (fougera), and Apotex. He has got international exposure in various analytical laboratories. He worked in USA, India, Canada, Brazil and Ireland to oversee/execute analytical development and related activities. Shital has got extensive experience in analytical method development, method validation and method transfer for characterization of API's and solid/liquid oral dosage forms, topical products and injectable products. In his current role at Glenmrak, Shital leads teams for characterization of complex injection products including peptides, Q3 characterization, reverse engineering, IVRT, in-vitro biostudy, population bioequivalence and API sameness studies. In addition, he leads activities related to specification setting, identification and characterization of impurities, preparation of reference standards, nitrosamines risk assessment, development & validation of methods for confirmatory testing of products to evaluate nitrosamine impurities.

Sook Wah Yee, PhD, M. Pharm
Assistant Adjunct Professor, University of California San Francisco



Dr. Sook Wah Yee is a researcher at the Department of Bioengineering and Therapeutics Sciences at University of California San Francisco (UCSF). Prior to joining UCSF, she earned her master's in pharmacy and Ph.D. at Cardiff University in Wales, United Kingdom. At UCSF, her project focuses on genetic determinants of anti-diabetic response through genomewide association studies. In addition, her research also focuses on determining endogenous roles of membrane transporters through data from genomewide association studies and functional studies in cells. She is actively involved in Pharmacogenomics Global Research Network (PGRN) to enhance scientific exchange and to expand the boundaries of understanding drug response within the context of precision medicine, both within the PGRN and between the PGRN and the scientific community at large.

Stephan Schmidt, PhD, FCP
Professor, University of Florida College of Pharmacy,
Director, Center for Pharmacometrics & Systems Pharmacology

Step han Schmidt is an endowed Professor in the Department of Pharmaceutics at the University of Florida, where he also serves as the Director for the Center for Pharmacometrics and Systems Pharmacology. He received his B.S. in Pharmacy from the Friedrich-Alexander University in Erlangen, Germany, and his PhD in Pharmacy from the University of Florida in Gainesville, USA. Following a post-doctoral fellowship at the Leiden-Amsterdam Center for Drug Research, he rejoined the University of Florida as faculty in 2012. Dr. Schmidt's research focuses on the development and application of mechanism/physiologically-based drug-disease trial models to address clinically relevant questions in the area of antimicrobial chemotherapy, chronic progressive diseases, special patient populations, and drug-drug interactions. He published more than 140 peer-reviewed scientific manuscripts, 8 book chapters, and 2 textbooks, including the fifth edition of Rowland and Tozer's Clinical Pharmacokinetics and Pharmacodynamics textbook, one of the world-wide leading textbooks in the quantitative clinical pharmacology arena. He received numerous awards including the University of Florida Excellence Award for Assistant Professors in 2013, the Tanabe Young Investigator Award from the American College of Clinical Pharmacology (ACCP) in 2016, the Outstanding Doctoral Thesis Mentoring Award from UF's College of Pharmacy in 2018, and the Excellence in Academia, MIDD+ Scientific Conference Award in 2021. Dr. Schmidt serves as clinical pharmacology section editor of the European Journal of Pharmaceutical Sciences as well as editorial board member of the Journal of Clinical Pharmacology and the European Journal of Pharmaceutical Sciences, and Scientific Advisor to the Editors of the Journal of Pharmaceutical Sciences.

Susan Rosencrance, PhD
Acting Director, OGD, CDER, FDA

Susan Rosencrance, Ph.D., serves as the Acting Director of the Office of Generic Drugs (OGD) in the Center for Drug Evaluation and Research (CDER). This office is responsible for the review and approval of abbrevi ated new drug applications. OGD's mission is to ensure, through a scientific and regulatory process, that generic drugs are safe and effective for the American public. From 2015 to 2022, Dr. Rosencrance served as the Director of the Office of Lifecycle Drug Products within CDER's Office of Pharmaceutical Quality (OPQ). She joined FDA in 1991, where she served in various roles within the Office of Generic Drugs and as the Deputy Director for Generic Drug Chemistry in CDER's former Office of Pharmaceutical Science, prior to the formation of OPQ. Before joining FDA, Dr. Rosencrance worked in research and development at Merck and Company. She holds a Ph.D. in chemistry from American University in Washington, D.C., and completed her dissertation research at the NIH Laboratory of Biophysical Chemistry. She received her bachelor's degree in biochemistry from Hood College and completed studies at the IIEP - University of Louis-Pasteur in the University of Strasbourg, France.

Tausif Ahmed, PhD

Vice President & Head, Biopharmaceutics & Bioequivalence, Global Clinical Management, Dr. Reddy's Laboratories Ltd.

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/Modeling 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. He 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 past. He obtained MS in Pharmaceutics from NIPER and Ph.D. 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 21 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 India and outside. Dr. Tausif has contributed to > 15 IND filings, ~400 ANDAs and multiple Phase I/II/III regulatory submissions, nationally and globally. He has co-authored 2 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. He is a guest faculty at Hamdard University, NMIMS (Mumbai), NIPER and various other universities in India. He has also supervised many Master's and Ph.D. students.

Tom Tice, PhD

Senior Director for Global Strategic & Technology Market, Evonik Nutrition & Care GmbH

Dr. Thomas Tice has 44 years' experience developing bioabsorbable injectables for long-acting drug delivery. His primary expertise includes long-acting, injectable microparticle, implant and nanoparticle formulations, bioabsorbable lactide/glycolide polymers, and microencapsulation/nanoencapsulation manufacturing processes. 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. He has served with United States Pharmacopeia for 18 years, presently serving on the General Chapters-Dosage Forms Expert Committee and several subcommittees including the Nanotechnology Joint Subcommittee and LG Polymer Joint Subcommittee.

Viral Jogani, PhD
General Manager, Research and Development, Sun Pharmaceutical Industries, Ltd

Dr. Viral Jogani holds M. Pharm. in Pharmaceutical Technology (Gold Medalist) from L M College of Pharmacy, Ahmedabad, India. He has completed his Ph.D. in P harmacy on “Nasal Drug Delivery for CNS Disorders” from Maharaja Sayajirao University of Baroda, Vadodara, India. He is responsible for formulation development of drug device combination products at Sun Pharmaceutical Industries Limited. He is leading formulation development of peptide based complex drug device combination injectable products, nasal sprays, and biosimilars. He has experience in developing NCE and generic products. He has hands on experience with peptide sameness characterization, immunogenicity evaluation, and population bioequivalence of in-vitro BE studies. He comes with 22+ years of experience in the field of pharmacy including approx. 6.5 years of experience in academics and 16 years of experience in pharmaceutical industry.

Wei-Jhe Sun, PhD
Senior Pharmacologist, DTP II, ORS, OGD, CDER, FDA

Dr. Wei-Jhe Sun is a senior pharmacologist in Office of Research and Standards at the Office of Generic Drugs. He has been working on projects to improve generic drug quality and provides new standards for FDA. Prior to joining FDA, he worked in the pharmaceutical industry as a formulator. Dr. Sun received his Ph.D. in Pharmaceutics from the University of Minnesota. He has a variety of research interests, including the abuse-deterrent formulation, formulation design, drug delivery, manufacturing sciences and solid-state pharmaceutics.

Xiaojian Jiang, PhD
Deputy Director, DB II, OB, OGD, CDER, FDA

Dr. Xiaojian Jiang is currently the Deputy Director for the Division of Bioequivalence II, Office of Bioequivalence. The Division of Bioequivalence is responsible for the review of bioequivalence studies (with pharmacokinetic endpoint) submitted to support approved of ANDAs. Dr. Xiaojian Jiang received her Ph.D. in Pharmaceutical Sciences from the University of Maryland, Baltimore. As a Divisional management and tertiary reviewer of complex BE issues, Dr. Jiang has successfully addressed numerous key scientific/regulatory issues of complex topical dosage forms, locally acting GI products, long acting injectables as well as nasal and inhalation products. She was the key speakers at various FDA, national and international venues. She has presented and published on a range of complex regulatory, scientific issues including Adaptive design approach for BE studies, deficiencies associated with IVRT, IVIVC issue and case studies, BE approaches for locally acting drug products, highly variable drug products, in vitro dissolution testing, and in vitro BE approaches for nasal spray products.

Yan Wang, Ph.D.
Team Lead, DTP I, ORS, OGD, CDER, FDA

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.

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 degree (1984) in Pharmacy and Ph.D. degree in the area of Pharmacokinetics in 1990 from the University of Toronto. He has been with Apotex since then. His main responsibilities are to provide pharmacokinetic and statistical advices 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. To date, he has been involved with the design and data analysis of over a thousand bioequivalence/clinical studies for the registration of complex drug and biosimilar products and over 300 traditional drugs in Canada, US, EU and many other international marketplaces. Dr. Tsang is the Past 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. Aside from his industrial experience, he also holds an appointment (status only) at the Leslie Dan Faculty of Pharmacy, University of Toronto.