Complex Generic Drug Product Development Workshop

September 12-13, 2018

Speaker Biographies

Kris André
Associate Director for Regulatory Affairs in the Office of Research and Standards
Office of Generic Drugs

Kris Andre is an Associate Director of Regulatory Affairs and works in the Office of Research and Standards. Before joining the FDA, Kris was in private industry in the biotech field for 17 years and worked for several small companies during that time. At the FDA, Kris is involved in implementing the pre-ANDA complex generic drug program under GDUFA II. She received her Master of Science from Virginia Polytechnic Institute and State University.

Andrew Babiskin, Ph.D.
Chemical Engineer in the Office of Research and Standards
Office of Generic Drugs

Andrew Babiskin, PhD manages the Locally-Acting Physiologically Based Pharmacokinetic Modeling Team in the Division of Quantitative Methods. He joined the FDA in 2012 as an ORISE (Oak Ridge Institute for Science and Education) postdoctoral fellow in the OGD Science Staff and became an employee within DQMM in 2014.His current work focuses on advancing mechanistic-based absorption modeling of local-acting complex products to develop/support novel in vitro and in vivo pharmacokinetic-based methods to establish bioequivalence in lieu of a bioequivalence study with clinical endpoints. Dr. Babiskin received his B.S. degree from the University of Maryland (College Park) in Chemical Engineering and his M.S. and Ph.D. degrees from the California Institute of Technology in Chemical Engineering.

Robert T. Berendt, PhD
Branch Chief, Branch I in the Division of Modified Release Products
Office of Pharmaceutical Quality

Dr. Robert Berendt is a branch chief in the Office of Lifecycle Drug Products, where he specializes in the quality assessment of modified-release drug products, including transdermal systems and topical delivery systems. Previous work in CDER has included primary quality assessment of ANDAs for injectables, solid orals (IR and MR), and transdermal systems; and he supported regulatory review and policy activities for three years as a pharmaceutical scientist in the FDA laboratories at White Oak. He earned his doctorate in pharmaceutical chemistry from the University of Kansas. His dissertation research focused on solid-state characterization of pharmaceutically relevant systems, and he specialized in the application of solid-state NMR spectroscopy to understand the crystallization of small-molecule drug substances. He is a member of the CDER Transdermal Working Group and the CDER Excipients Working Group, and he maintains a research interest in the solid-state chemistry of drugs.

Kelley Burridge, PhD
Chemistry Reviewer in the Office of Lifecycle Drug Products

Office of Pharmaceutical Quality

Dr. Kelley Burridge assesses the quality of liquid-based drug products including topical semisolids, injectables, and peptides. Previously, Dr. Burridge served as a lead reviewer of plastic and reconstructive surgery devices in the Office of Device Evaluation in the Center for Devices and Radiological Health. Device review experience includes tissue adhesives, tissue markers, wound dressings, hemostatic agents, sutures, surgical meshes, and negative pressure wound therapies. Prior to joining the FDA, she obtained postdoctoral training experience and worked as an industrial process engineer. Dr. Burridge received a B.S. in Chemical Engineering from Cornell University and a Ph.D. in Biomedical Engineering from Boston University with special training in Biomolecular Pharmacology.

Jane Chang, PhD
Branch Chief in the Office of Process and Facilities
Office of Pharmaceutical Quality

Jane Chang, PhD works at the Office of Process and Facilities as a Branch Chief responsible for evaluation of complex drug substances submitted for ANDAs and drug product manufacturing process. Dr. Chang joined the FDA in 2005 as a CMC reviewer in Office of New Drug Quality Assessment, where she evaluated IND and NDA submissions and provided guidance to sponsors/applicants. In 2014, she was promoted to Master Reviewer. Before joining FDA, she was a Group Leader at Abbott Laboratories and led a team to conduct drug substance process research and development. Jane received a B.S. in Chemistry from National Taiwan University and a PhD in Organic Chemistry from the University of Illinois at Urbana-Champaign, Illinois, under the direction of Dr. Robert Coates. After graduation, she was a postdoctoral research associate with Professor George Barany from University of Minnesota.

Dale Conner, Pharm.D.
Director
Office of Bioequivalence

Denise Conti, PhD
Chemical Engineer in the Office of Research and Standards
Office of Generic Drugs

Dr. Denise Conti's specialization is drug products in the nasal and oral inhalation drug delivery area. In her current role, Dr. Conti is responsible for the development of product-specific guidances for generic drug development, reviewing and responding to controlled correspondences, pre-ANDA meeting requests, citizen petitions and internal consults. Dr. Conti is also the project officer on multiple regulatory science research initiatives related to nasal and oral inhalation drug products, under the GDUFA regulatory science research program. Prior to joining the FDA, Dr. Conti completed her B.Sc. in Chemical Engineering from Regional University of Blumenau (Brazil), her M.Sc. in Materials Science and Engineering from Santa Catarina State University (Brazil), and her Ph.D. in Chemical Engineering from the Wayne State University (Detroit, Michigan). Dr. Conti is the author and co-author on numerous research manuscripts in the oral inhalation drug delivery area.

Ying Fan, PhD

Team Leader, ANDA Team in the Office of Bioequivalence
Office of Generic Drugs

Dr. Fan specializes in reviewing drug products submitted in Abbreviated New Drug Applications (ANDAs) to determine the adequacy of the data from clinical endpoint bioequivalence studies and skin irritation, sensitization and adhesion studies based on study design, methodology, and statistical analysis. Before joining OGD, she worked in the Office Clinical Pharmacology in the Office of Translational Sciences supporting Office of New Drug, Division of Pulmonary, Allergy, and Rheumatology Products, Division of Anesthesia, Analgesia, and Rheumatology, and Office of Non-prescription Drugs. She obtained her Ph.D. in Pharmaceutical Sciences and minor of Statistics from Oregon State University, and a Master degree in Traditional Chinese Herb in Zhejiang Medical University, China.

Dhaval K. Gaglani, MS
Branch Chief, Branch III for the Division of Modified Release Products
Office of Pharmaceutical Quality

Dhaval Gaglani is responsible for the evaluation and product quality assessment of ANDAs for modified release drug products including Inhalation & Nasal products. He previously served as Team Lead and Chemistry reviewer in the Office of Generic Drugs, focusing on ANDAs for injectables, solid orals, transdermal and inhalation products. Prior to joining the FDA, Dhaval spent several years in the pharmaceutical industry with industrial experience in product development, support of manufacturing process development, scale-up and validation. Dhaval has an undergraduate degree in Pharmacy and M.S. in Pharmaceutics from Long Island University.

Priyanka Ghosh, PhD
Staff Fellow in the Office of Research and Standards
Office of Generic Drugs

Dr. Priyanka Ghosh is a pharmacologist within the Division of Therapeutic Performance. Her specialization is drug products in the topical and transdermal drug delivery area. In her current role, Dr. Ghosh is responsible for the development of product-specific guidances for generic drug development, reviewing and responding to controlled correspondences, citizen petitions and Pre-ANDA meeting packages. Dr. Ghosh is also the project officer on multiple regulatory science research initiatives related to topical and transdermal drug products, under the GDUFA regulatory science research program. Prior to joining the FDA, Dr. Ghosh completed her B.Tech in Biotechnology from West Bengal University of Technology (India) and a Ph.D. in Pharmaceutics and Drug design from the University of Kentucky. Dr. Ghosh is the author on numerous research manuscripts and review articles in the topical and transdermal area.

Stella Grosser, PhD
Division Director in the Office of Biostatistics
Office of Translational Sciences

Stella Grosser is Director of the Division of Biometrics VIII, in CDER's Office of Biostatistics. She supervises a staff of 20 statisticians supporting the Office of Generic Drugs' review and research activities. She has been at CDER since 1999, as a statistical reviewer and team leader working with the Office of New Drugs as well as the Office of Generic Drugs. Prior to joining the FDA, she was an adjunct

assistant professor of biostatistics at UCLA. She received her Ph.D. in biostatistics from UCLA and a B.A. in mathematics from Yale University.

Meng Hu, Ph.D.
Staff Fellow in the Office of Research and Standards
Office of Generic Drugs

Dr. Meng Hu is a staff fellow in the Division of Quantitative Methods and Modeling. His main research interests include the methodology development for in-vitro bioequivalence study (e.g., multivariate analysis for demonstrating equivalence between complex particle size distributions) and application and development of big data analytics to facilitate business intelligence in OGD (e.g., Prediction of ANDA submission by machine learning methodologies). He received his Ph.D. in physics from the Zhejiang University, China.

Usha Katragadda, PhD
Bioequivalence Reviewer in the Division of Bioequivalence III
Office of Generic Drugs

Usha Katragadda serves as a Bioequivalence Reviewer in the Office of Generic Drugs located in the Center for Drug Evaluation and Research. She is responsible for the review of clinical pharmacology, bioequivalence, dissolution, and drug manufacturing data submitted by pharmaceutical firms. Dr. Katragadda began her service with the FDA in 2014. Prior to joining OGD, she conducted one year of post-doctoral training at the Division of Product Quality Research at the FDA. Dr. Katragadda has earned a Doctor of Philosophy degree in Pharmaceutical Sciences from Mercer University, Atlanta, GA. She earned a Master of Science degree in Chemistry from University of Dayton, Dayton, OH.

Darby Kozak, Ph.D.
Chemist and Team Lead in the Office of Research and Standards
Office of Generic Drugs

Dr. Darby Kozak is Chemist and Team Lead for the Complex Drug Substances and Formulations team in the Division of Therapeutic Performance. In this role, Dr. Kozak leads a team of interdisciplinary scientists and oversees research projects on the development of new analytical methods and equivalence evaluation methodologies for complex parenteral, ophthalmic, and otic drug products and formulations that incorporate nanotechnology. Prior to joining the FDA in 2015, Dr. Kozak was the Chief Scientist for Izon Science, a Research Fellow at the Australian Institute for Bioengineering and Nanotechnology, Lecturer at the University of Queensland, and Visiting Fellow at the Fred Hutchinson Cancer Research Center. Dr. Kozak has a B.Sc. in Chemical Engineering from the University of Washington (Seattle, WA) and Ph.D. in Physical Chemical from the University of Bristol (United Kingdom).

Andrew A. LeBoeuf, MS, JD
Regulatory Counsel in the Office of Generic Drug Policy
Office of Generic Drugs

Andrew LeBoeuf represents OGD in multiple Center- and Agency-level working groups that are responsible for developing new and analyzing current policies impacting the review and approval of generic drug products, including generic drug-device combination products. Prior to joining CDER, Andrew held positions in FDA's Center for Devices and Radiological Health and its Office of Regulatory Affairs focusing on investigations and enforcement of the Quality System Regulations as well as the associated regulatory provisions on advertising and promotion issues. Andrew received his B.S. in Biology from Loyola University Chicago, his M.S. in Applied Physiology from Rosalind Franklin University of Medicine and Science, and his J.D. from The John Marshall Law School.

Yiwei Li, PhD
Chemist in the Office of Pharmaceutical Quality
Office of Pharmaceutical Quality

Yiwei Li, PhD is a chemist in the Office of Life-Cycle Drug Products. Dr. Li has been with the FDA since 2014. Prior to joining the FDA, he worked as a senior research scientist in the pharmaceutical industry including Merck Research Laboratories and Inception Sciences. Yiwei Li received his Ph. D. in Organic Chemistry from The Scripps Research Institute where he studied natural product total synthesis.

Zhichuan (Matt) Li, PhD
Staff Fellow in the Office of Research and Standards
Office of Generic Drugs

Dr. Zhichuan (Matt) Li received his Ph.D. in Pharmacology from the Medical University of Ohio. As a staff fellow in the Division of Quantitative Methods and Modeling, his main research interests include the application of quantitative clinical pharmacology in product specific guidance development and ANDA assessment.

Robert Lionberger, PhD
Director of the Office of Research and Standards
Office of Generic Drugs

Robert Lionberger, Ph.D. serves as Director of the Office of Research and Standards within the Office of Generic Drugs. In this role, Dr. Lionberger leads OGD's implementation of the GDUFA regulatory science commitments including internal research activities and external research grants and collaborations to ensure the therapeutic equivalence of generic drug products. In his 10 years as member of the OGD Science Staff, his accomplishments include the development of bioequivalence methods for complex and locally acting drugs, mathematical modeling of drug dissolution and absorption, and incorporation of pharmaceutical development information into the ANDA review process. He received his undergraduate degree from Stanford University in Chemical Engineering, and a Ph.D. from Princeton University in Chemical Engineering, working on modeling the rheology of colloidal suspensions. After his Ph.D., he spent two years of post-doctoral research in Australia in the Department of Mathematics and Statistics at the University of Melbourne. Prior to joining the FDA, he was an Assistant Professor of Chemical Engineering at the University of Michigan.

Tian Ma, PhD
Bioequivalence Reviewer in the Office of Bioequivalence
Office of Generic Drugs

Dr. Tian Ma is a bioequivalence reviewer within the Division of Bioequivalence I. Prior to joining the FDA, Dr. Ma was a postdoctoral fellow in Dartmouth College. She obtained her B.Sc. in Pharmacology from the University of Toronto, Canada, and her Ph.D. in Pharmacology from Dartmouth College.

Soumyarwit Manna, Ph.D.
ORISE Fellow in the Office of Research and Standards
Office of Generic Drugs

Soumyarwit Mann, PhD currently works an ORISE (Oak Ridge Institute for Science and Education) Fellow at Division of Therapeutic Performance. His present research includes physicochemical characterization of complex drug formulations to facilitate preparation of product specific draft guidances for ensuring generic drug products demonstrate bioequivalence to their brand counterparts. Dr. Manna received his Ph.D. in Materials Science and Engineering from University of Cincinnati.

Patricia Onyimba, M.S.
Branch Chief in the Office of Lifecycle Drug Products
Office of Pharmaceutical Quality

Patricia Onyimba is a Branch Chief with the Division of Liquid-Based Products and oversees review of Chemistry, Manufacturing and Controls (CMC) sections of generic drug applications for ophthalmic products and oral liquid products. Patricia joined the FDA in 2010 and has served in various capacities (including Review Chemist, Assistant to the Director of Chemistry Division 1 and Chemistry Team Leader in the Office of Generic Drugs). Prior to joining the FDA, Patricia spent over 16 years working for various pharmaceutical companies and contract research organization where she managed quality control and analytical development teams that were responsible for method validations and transfers, stability program design, drug substance and drug product specifications development, and providing analytical support to formulation development teams. Patricia holds a Bachelor of Science degree in Chemistry from the University of Nigeria, Nsukka and a Master of Science degree from the Johns Hopkins University, Baltimore, MD.

Eric Pang, Ph.D.
Chemist in the Office of Research and Standards
Office of Generic Drugs

Eric Pang, PhD serves as a chemist in the Office of Generic Drugs. Dr. Pang is actively involved with the development of product specific guidances of generic complex drug products. He is also managing several regulatory science projects related to generic complex drug substances and products. Eric has over seven years of experience in the Agency as a research chemist, a CMC reviewer, and a policy analyst. he has worked on several highly visible research topics involving the safety and efficacy of the pending and approved drug products. He has served as CMC technical lead on reviewing and approving many drug applications with various dosage forms, such as tablets, capsules, topical, injectable, modified-release, and device-drug combination products. Eric earned his Ph.D. from UCLA and B.S. from UC Berkeley.

Suneela Prodduturi, PhD
Science and Research Staff Fellow
Office of Pharmaceutical Quality

Suneela Prodduturi, PhD is a Staff Fellow in the Science Staff within the immediate office of the Office of Pharmaceutical Quality. She leads the Pre-ANDA triage efforts and is a part of the complex drug products program, coordinating the intersection between science, review, and policy. Dr. Prodduturi began her career at FDA in 2005 as a research scientist in an FDA laboratory and supported regulatory review and policy activities for four years. Dr. Prodduturi worked for 5 years in the pharmaceutical industry developing different dosage forms using novel technologies. She returned to FDA as a reviewer in Office of Life Cycle Drug Products where she was involved in quality assessment of modified-release drug products, including transdermal systems and solid orals (IR and MR) and maintains a research interest in complex drug products, especially transdermal drug delivery systems. She earned her Ph.D. in Pharmaceutics and post-doctoral fellowship from the University of Mississippi.

Bin Qin, Ph.D.
Staff Fellow in the Office of Research and Standards
Office of Generic Drugs

Bin Qin is currently a Staff Fellow in the Division of Therapeutic Performance, in OGD's Office of Research and Standards. Prior to joining FDA, Bin completed a three-year postdoctoral training in the University of Pittsburgh Medical Center. He earned his Ph.D. in Pharmaceutical Sciences from University of Missouri-Kansas City, a M.S. degree in Pharmaceutics and a B.S. degree in Pharmacy from China Pharmaceutical University.

Tannaz Ramezanli, PhD
Staff Fellow in the Office of Research and Standards
Office of Generic Drugs

Tannaz Ramezanli currently serves as pharmacologist within the Division of Therapeutic Performance. She joined the FDA as an ORISE (Oak Ridge Institute for Science and Education) Fellow and currently work as a reviewer in the Topical and Transdermal Team. She is responsible for the development of product-specific bioequivalence guidances, reviewing and responding to controlled correspondences, and Pre-ANDA meetings. Dr. Ramezanli is also engaged in the development of regulatory science research initiatives related to topical and transdermal drug products through FDA-funded collaborations with research institutions around the world. She received her Ph.D. in Pharmaceutical Sciences from Rutgers University and her Pharm.D. from Tehran University of Medical Sciences.

Sam Raney, PhD
Lead for Topical and Transdermal Drug Products in the Office of Research and Standards
Office of Generic Drugs

Dr. Sam Raney is a thought leader in topical and transdermal drug products, with over 25 years of experience 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, serves as an expert panel member in the U.S. Pharmacopeia., and is the Lead for Topical and Transdermal Drug Products in the FDA Office of Generic Drugs. Dr. Raney holds a Bachelors in Molecular Biophysics & Biochemistry from Yale University, and a Ph.D. in Biochemistry & Molecular Biology from the University of British Columbia in Canada.

Satish Sharan, Ph.D.
Pharmacologist in the Office of Research and Standards
Office of Generic Drugs

Satish Sharan, PhD is Pharmacologist (Visiting Associate) in Quantitative Clinical Pharmacology team within the Division of Quantitative Methods and Modeling. Through his training, Dr. Sharan has acquired translational working experience in clinical pharmacology in addition to acquiring advanced modeling and simulation training using physiologically based pharmacokinetic modeling and pharmacokinetic pharmacodynamic modeling and simulation, which is routinely applied in his current role within FDA to aid in regulatory policy and decision making. Dr. Sharan graduated with Ph.D. in Pharmaceutical Sciences from Temple University, School of Pharmacy with major in Pharmacokinetics under guidance of Dr. Swati Nagar. Thereafter Dr. Sharan pursued his post-doctoral training in modeling and simulation under guidance of Dr. Sukyung Woo at University of Oklahoma, College of Pharmacy.

Kamal N. Tiwari, PhD
Quality Assessment Lead (acting) in the Division of Process Assessment III
Office of Pharmaceutical Quality

Kamal Tiwari, Ph.D. is a Medicinal Chemist with experience in Drug Discovery/Product Development/Manufacturing /Operation/Business Management. Kamal joined the FDA in 2010 as a CMC reviewer, after a successful career in the pharmaceutical industry. Kamal is currently acting Quality Assessment Lead in CDER OPQ's Office of Process and Facilities for Pharmaceutical Quality. He has extensive knowledge of PET Drugs, Botanical Drugs, Complex Drug Substances, GMP, and Quality Systems Regulations.

Eleftheria Tsakalozou, PhD
Staff Fellow in the Office of Research and Standards
Office of Generic Drugs

Eleftheria Tsakalozou joined the FDA in 2015 as an Oak Ridge Institute for Science and Education (ORISE) Fellow. Dr. Tsakalozou began her career at the University of Athens in Athens, Greece where she trained as a pharmacist and pursued a Master in Science on Clinical Pharmacy. She obtained her Ph.D. 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 sponsored by Quintiles. Her research interests include skin absorption physiologically-based pharmacokinetic modeling, interactions between excipients and molecular targets including gut transporters and development of quantitative modeling and simulation tools to support bioequivalence assessments.

Katherine Tyner, PhD
Associate Director for Science (Acting)
Office of Pharmaceutical Quality

Dr. Katherine Tyner leads the OPQ Science Staff in coordinating the intersection between science, review, and policy in OPQ as well as facilitating interactions between other CDER offices and FDA Centers. Dr. Tyner's group leads the OPQ effort for the Pre-ANDA program. She received her Ph.D. in Chemistry from Cornell University and joined the FDA in 2007 as a chemist specializing in nanotechnology. While at the FDA, Dr. Tyner has investigated the quality, safety, and efficacy of complex drug products, and she currently leads the CDER nanotechnology working group and is active in other CDER and FDA complex drug product initiatives. Dr. Tyner is the author of multiple book chapters and journal articles concerning the appropriate characterization and biological impact of complex drug products.

Ross Walenga, PhD
Chemical Engineer in the Office of Research and Standards
Office of Generic Drugs

Dr. Ross Walenga joined the FDA in 2015 as an Oak Ridge Institute for Science and Education (ORISE) Fellow. 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.

Yan Wang, Ph.D.
Scientific Lead in the Office of Research and Standards
Office of Generic Drugs

Yan Wang, PhD is the Scientific Lead for long acting drug products in the Office of in the Office of Research and Standards, Office of Generic Drugs. She is involved in developing scientific policy relating to generic drug development and review for a variety of complex formulations including microspheres, implants, in situ forming gels, and locally acting drug products via ophthalmic, otic, intrauterine, and periodontal routes. In addition, Dr. Wang is also heavily involved in GDUFA funded research projects. A major area of research focus is on the development of proper scientific tools, such as in vitro methods and modeling and simulation methods, to facilitate setting proper standards for evaluation of complex drug products. Dr. Yan Wang received her PhD in Pharmaceutical Sciences from the University of Connecticut, Storrs.

Xiaoming Xu, PhD
Senior Staff Fellow in the Office of Pharmaceutical Quality
Office of Testing and Research

Dr. Xiaoming Xu received his B.S. and M.S. degree in Pharmaceutics from China Pharmaceutical University, and his Ph.D. in Pharmaceutical Sciences from the University of Connecticut. Dr. Xu is a

member of the FDA/CDER Nanotechnology Working Group and is co-leading the Nanotechnology Reviewer Network at CDER. He served as the government liaison to the USP Expert Committee on excipients. Dr. Xu is an editorial board member of the International Journal of Pharmaceutics. Dr. Xu has made significant contributions in implementing quality by design in the formulation and process design of liposomal drug delivery system, for which he was selected as the inaugural recipient of American Association of Pharmaceutical Scientists Quality by Design and Product Performance Graduate Student Award (2011). His current research efforts focus on: 1) formulation and processing design of complex drug products; 2) advancing manufacturing science of complex drug products, with focus on continuous manufacturing; 3) development of in vitro release performance tests for traditional (e.g. tablets, capsules) as well as complex drug delivery systems (e.g. emulsions, liposomes, nano-suspensions, ointments, creams, etc.); 4) evaluation of bio-equivalence of complex drug products; and 5) design and evaluation of abuse deterrent formulations for opioid analgesics.

Deyi Zhang, PhD
Chemist in the Office of Research and Standards
Office of Generic Drugs

Deyi Zhang, PhD serves as a chemist in the Office of Research and Standards specializing in complex drug substances, including providing scientific support for regulatory policy and product-specific guidance development on such products and managing related research activities. He has 20 years of experience from academia, industry and regulatory agency. Prior to joining FDA in 2015, he was an Executive Director in Crown Bioscience, a biotech company focusing on oncology drug discovery and translational medicine. Before joining Crown, he worked at Eli Lilly and Company, rising from Research Scientist to Principal Research Scientist. Prior to his career at Eli Lilly, he was a NIH Postdoctoral Fellow at University of Pennsylvania. He received his Ph.D. in Organic Chemistry from University of Notre Dame. He has over 10 US patents and 40 publications and presentations.

Lei Zhang, Ph.D.
Deputy Director of the Office of Research and Standards
Office of Generic Drugs

Lei Zhang, Ph.D., serves as the Deputy Director of the Office of Research and Standards, Office of Generic Drugs. She is an accomplished professional with 20 years of combined experiences in the areas of drug research, development and regulatory review and approval. Before joining FDA in 2002, Dr. Zhang worked at Bristol-Meyers Squibb Company as a Research Investigator and Preclinical Candidate Optimization Team Leader. She has contributed to numerous regulatory guidance development and revision including guidances on drug interaction and regulatory research focuses on the science-based regulatory decision-making. Dr. Zhang is a member of the International Transporter Consortium. Prior to her role as the deputy director of ORS, Dr. Zhang was previously Senior Advisor for Regulatory Programs and Policy in FDA's Office of Clinical Pharmacology, Office of Translational Sciences. She is an Adjunct Professor in the Department of Bioengineering and Therapeutic Sciences, UCSF Schools of Pharmacy and Medicine and has authored and co-authored numerous papers, book chapters, abstracts, and invited presentations. Dr. Zhang received her Ph.D. in Biopharmaceutical Sciences from the University of California, San Francisco.
