
# Speaker Biographies

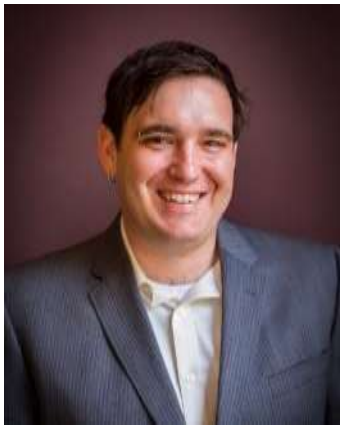
*In order of appearance:*

*Introduction*

**Robert Lionberger, Ph.D.**
Director of the Office of Research and Standards
Office of Generic Drugs

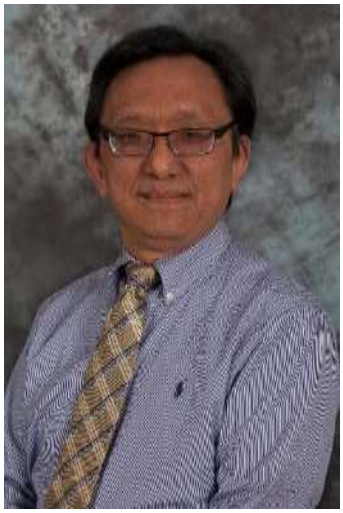
Dr. Robert Lionberger serves as Director of the Office of Research and Standards within the Office of Generic Drugs. In this role, Dr. Lionberger leads OGD's implementation of the GDUFA regulatory science commitments including internal research activities and external research grants and collaborations 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 2 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.

*Day 1 Session 1 Leads*



**Darby Kozak, Ph. D.**
Deputy Division Director in the Office of Research and Standards
Office of Generic Drugs

Dr. Darby Kozak is the Deputy Division Director for the Division of Therapeutic Performance. In this role, Dr. Kozak leads a group of interdisciplinary scientists and oversees research projects on the development of new analytical methods and equivalence evaluation methodologies for complex drug products and formulations. He specializes in complex drug substances, products that incorporate nanotechnology, and complex parenteral, ophthalmic, and otic formulations. 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).



**Bing Cai, Ph.D.**
Division Director in the Office of Lifecycle Drug Products
Office of Pharmaceutical Quality

Dr. Bing Cai is Director of the Division of Liquid-based Drug Products in the Office of Pharmaceutical Quality. In his 20-year tenure within the FDA, he has been promoted to CDER Senior Reviewer, Team Lead, Chemistry Division Deputy Director and Division Director. He has been involved in the development of several important Agency's initiatives, including the current ANDA Integrated Quality Assessment process. He has coordinated the implementation of the comprehensive review assessment using the Quality by Design and Risk-based Review concepts for various drug dosage forms to ensure a uniform drug quality program across generic and new drug products.

*Day 1 Session 1 Topic 1 Presentation 1*

**Mindy Ehrenfried, J.D.**
Regulatory Counsel in the Office of Generic Drug Policy
Office of Generic Drugs

Mindy Ehrenfried is a regulatory counsel in the Office of Generic Drug Policy. Before joining OGD in May 2019, Ms. Ehrenfried worked as a patent litigator for over 9 years, specializing in patent disputes arising under the Hatch-Waxman Amendments and the Biologics Price Competition and Innovation Act of 2009. She received her JD, MS, and BS from the University of Maryland.

*Day 1 Session 1 Topic 1 Presentation 2*

**Manivannan Ethirajan, Ph.D.**
Chemist in the Office of New Drug Products
Office of Pharmaceutical Quality

Dr. Mani Ethirajan is a chemist in the Division of Life Cycle API (active pharmaceutical ingredient). For the past 6 years, he has been reviewing Drug Master Files specifically dealing with complex APIs. Prior to FDA, he spent 13 years as a medicinal chemist in academia and a pharmaceutical company. He has co-authored several synthetic/medicinal chemistry articles published in peer-reviewed journals and books. Mani holds a Ph.D. degree in synthetic chemistry from Indian Institute of Technology-Bombay, India.

*Day 1 Session 1 Topic 1 Presentation 3*

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

Dr. Eric Pang serves as a chemist in the Office of Generic Drugs. His specialization is in the analysis of peptide and large molecule drugs. In his current role, he is actively involved with the development of product-specific guidances of complex drug products, reviewing and responding to controlled correspondences, pre-ANDA meeting requests, citizen petitions, and internal consults. He is also managing several regulatory science projects related to generic complex drug substances and products. Dr. Pang has over 8 years of experience in the Agency as a research chemist, a CMC reviewer, and a policy lead. Dr. Pang received his Ph.D. in Biochemistry from UCLA, and undergraduate degrees in Molecular Cell Biology and Legal Studies from UC Berkeley.

*Non-Speaker Panelist, Day 1 Session 1 Topic 1:*

**Daniela Verthelyi, M.D., Ph.D.**
Principal Investigator in the Office of Biotechnology Products
Office of Pharmaceutical Quality

Daniela Verthelyi, Ph.D., currently heads the Laboratory of Innate Immunity and chairs CDER's newly formed 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 including potential impurities in therapeutic products that may foster unwanted immune responses therapeutic proteins reducing their life-saving potential. Dr. Verthelyi received her M.D. from the University of Buenos Aires and a Ph.D. from Virginia Tech in the United States, and then completed a fellowship training in Immunology at the Section in Retroviral Immunology in the Center for Biologics Evaluation and Research at FDA before joining the Office of Biotechnology Products in CDER as a principal investigator.

*Day 1 Session 1 Topic 2 Presentation 1*

**Changning Guo, Ph.D.**
Chemist in the Office of Testing and Research
Office of Pharmaceutical Quality

Dr. Guo is a research chemist in the Office of Testing and Research in the Office of Pharmaceutical Quality (OPQ). He has been with FDA for 16 years and currently works in the Division of Complex Drug Analysis at Saint Louis, MO. His research at FDA focuses on inhalation drug product characterization, particle sizing, X-ray powder diffraction, and spectroscopy. He has been a principal and co-principal investigator on multiple FDA research projects, serving as a member in several FDA working groups, guidance teams, subject-matter expert panels, and grants review committees.

*Day 1 Session 1 Topic 2 Presentation 2*

**Xiaoming Xu, Ph. D.**
Senior Chemist in the Office of Testing and Research
Office of Pharmaceutical Quality

Dr. Xiaoming Xu is a Senior Chemist in the Office of Pharmaceutical Quality lab. In his role as a Principal Investigator, he leads multiple research areas such as complex ophthalmics, nanomaterials, and evaluation of abuse deterrent opioids. He also leads a particle characterization lab in CDER and provides hands-on trainings to reviewers on various topics, including concept of particle size and measurement. Dr. Xu is a member of the CDER Nanotechnology Working Group and is co-leading the Nanotechnology Reviewer Network. Dr. Xu is also an editorial board member of the *International Journal of Pharmaceutics*.

*Day 1 Session 1 Topic 2 Presentation 3*

**Meng Hu, Ph. D.**
Scientific Lead in the Office of Research and Standards
Office of Generic Drugs

Meng Hu, Ph.D., is currently a scientific lead in the Division of Quantitative Methods and Modeling under the Office of Research and Standards. His main research interests include the data analytics methodology development for in-vitro bioequivalence study, and application/development of advanced data tools to serve the OGD's needs in data management, big data analysis, and generating real world evidence from real world data. Dr. Meng Hu received his B.Eng. in Biomedical Engineering and Ph.D. in Physics from the Zhejiang University, China.

*Day 1 Session 1 Topic 3 Presentation1*

**Asif Rasheed, Ph.D.**
Chemist/Pharmaceutical Quality Assessor in the Office of Lifecyle Drug Product
Office of Pharmaceutical Quality

Dr. Asif Rasheed is a Chemist/Pharmaceutical Quality Assessor in the Office of Lifecyle Drug Product within the Office of Pharmaceutical Quality. In OPQ, he has been involved in assessment of liquid based dosage forms for oral, topical, parenteral, and ophthalmic routes and serves as application technical lead for a number of applications. He received a Ph.D. in Chemistry from the University of Tennessee, Knoxville and pursued postdoctoral fellowship at Georgia Institute of Technology, Atlanta. Dr. Rasheed joined FDA in 2008. Prior to joining FDA, he held a teaching position at the University of Wisconsin.

*Day 1 Session 1 Topic 3 Presentation 2*

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

Dr. Yan Wang is the acting team lead for Complex Drug Substances & Formulation Team in the Division of Therapeutic Performance, Office of Research and Standards. In her current role, Dr. Wang works with 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 her Ph.D. in Pharmaceutical Sciences from the University of Connecticut.

*Day 1 Session 1 Topic 3 Presentation3*

**Hiren Patel, Ph.D.**
Bioequivalence Reviewer in the Office of Bioequivalence
Office of Generic Drugs (OGD)

Hiren Patel is a bioequivalence reviewer in the Division of Bioequivalence II within Office of Generic Drugs. He is responsible for assessing the bioequivalence of the various dosage forms of generic drugs. He is the lead for reviewing the applications of topical and transdermal drug products along with the advanced techniques for demonstrating bioequivalence of such complex drug products. He has also actively served as a consultant in the research initiatives which are the collaborative efforts of FDA and global research institutions pertaining to the topical and transdermal drug products funded through FDA. He is also actively involved in the review panel for the Product-Specific Guidances for the generic topical drug products. Prior to joining FDA, Dr. Patel earned his M.S. and Ph.D. with specialization in Pharmacokinetics at Long Island University, Brooklyn, New York.

*Day 1 Session 2 Session Leads*

**Wenlei Jiang, Ph.D.**
Senior Science Advisor in the Office of Research and Standards
Office of Generic Drugs

Dr. Wenlei Jiang currently serves as a Senior Science Advisor in the Office of Research and Standards. She has been championing regulatory research in the areas of generic nanomaterials, narrow therapeutic index drugs, and modified release products to support review standards development and ensure post-market safety and efficacy of these drug products. Currently she is leading complex drug product classification and research, as well as promoting global bioequivalence harmonization. She is actively involved in multiple center-level and FDA-level working groups including CDER excipient working group, CDER nanotechnology working group, ICH M13 FDA internal experts working group, and others. She also serves as Vice Chair at Product Quality Research Institute Steering Committee and Chair at Biopharmaceutical Technical Committee. Prior to joining FDA, she worked in the pharmaceutical industry where her responsibilities included formulation development of conventional liquid and solid dosage forms and advanced parenteral drug delivery systems. She received her Ph.D. in Pharmaceutics and Pharmaceutical Chemistry from Ohio State University.

**Ethan M. Stier, Ph.D., R.Ph.**
Acting Associate Director in the Office of Bioequivalence
Office of Generic Drugs

Dr. Ethan M. Stier currently serves as the Acting Associate Director for Science in the Office of Bioequivalence. He is active in a variety of complex clinical pharmacology, bioequivalence, and regulatory areas, including pAUC, narrow therapeutic index, BCS waivers, and product specific guidance development. He is a past co-chair of the FDA BCS Committee and member of the ICH M9 Expert Working group. He received his Ph.D. in Pharmaceutical Sciences from the University of Michigan and B.S. in Pharmacy from the University of Connecticut.

*Day 1 Session 2 Presentation 1*

**Darby Kozak, Ph. D.**
Deputy Division Director in the Office of Research and Standards
Office of Generic Drugs

*See above for bio and picture*

*Day 1 Session 2 Presentation 2*

**Amanda Jones, Ph.D.**
Lead Pharmacologist in the Office of Bioequivalence
Office of Generic Drugs

Dr. Amanda Jones is a Lead Pharmacologist in the Division of Bioequivalence I. In this role, she leads a team of pharmacologists assessing the *in vivo* and *in vitro* bioequivalence of various dosage forms of generic products. She is also involved in addressing controlled correspondences and pre-ANDA meeting packages, and revision of general guidances. Prior to joining FDA in 2015, Dr. Jones was the Toxicologist Leader at GTx, Inc. where she coordinated and monitored non-clinical safety pharmacology and toxicology studies and supervised phase I clinical trials. Dr. Jones received her Ph.D. in Pharmaceutics from Ohio State University.

*Day 1 Session 2 Presentation 3*

**Susan Zuk**
Branch Chief in the Office of Policy for Pharmaceutical Quality
Office of Pharmaceutical Quality

Susan Zuk is a branch chief in the Office of Policy for Pharmaceutical Quality (OPPQ). She is also the lead for the FDA's Inactive Ingredient Database (IID). In this role, she is responsible for overseeing IID improvements. Susan has served on many FDA committees and working groups related to product safety and quality. Before joining OPPQ, she served in the Office of Generic Drugs as a chemistry team leader. Susan holds a B.S. in Chemistry from Syracuse University and an M.S. in Biotechnology from Johns Hopkins University.

*Day 1 Session 2 Presentation 4*

**Yongcheng Huang, Ph.D.**
Pharmacology/Toxicology Reviewer in the Office of Bioequivalence
Office of Generic Drugs

Dr. Yongcheng Huang is a Pharmacology/Toxicology reviewer in the Division of Clinical Review (DCR). In DCR, he has been involved in safety assessment of drug substance impurities, drug product impurities, residual solvents, elemental impurities, extractables and leachables, and excipients. Prior to joining FDA, Dr. Huang worked at Merck as a Senior Biologist leading projects in the area of cardiometabolic diseases. Dr. Huang received his Ph.D. in Pharmacology from Ohio State University and completed his postdoctoral training in the Howard Hughes Medical Institute.

*Day 2 Session 3 Session Leads:*

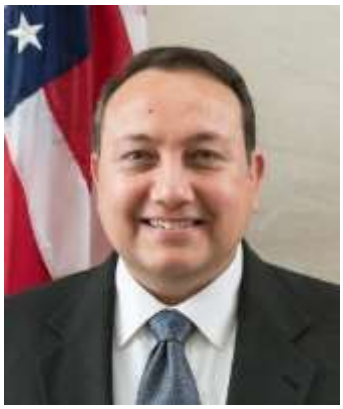
**Andrew Babiskin, Ph.D.**
Team Lead in the Office of Research and Standards
Office of Generic Drugs

Dr. Andrew Babiskin currently holds the position of Team Leader for the locally acting Physiologically Based Pharmacokinetic modeling team in the Division of Quantitative Methods and Modeling. 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. He joined FDA in 2012 as an ORISE postdoctoral fellow in the OGD Science Staff (now ORS) and became an employee within DQMM in 2014.

**Bryan Newman, Ph.D.**
Acting Team Lead in the Office of Research and Standards
Office of Generic Drugs

Bryan Newman, Ph.D., is a pharmacologist and acting 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.

**Sam Raney, Ph.D.**
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's Office of Generic Drugs. Dr. Raney's regulatory responsibilities involve overseeing the development of FDA guidances, pre-ANDA meetings, controlled correspondences, and citizen petitions, as well as the development of regulatory science research initiatives related to topical and transdermal generic drug products. 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.

*Day 2 Session 3 Topic 1 Presentation 1*

**Elizabeth Bielski, M.S., Ph.D.**
Chemist in the Office of Research and Standards
Office of Generic Drugs

Elizabeth Bielski, M.S., Ph.D. is a Chemist working at Division of Therapeutic Performance. Her areas of expertise involve orally inhaled and nasal drug products (OINDP) and drug-device combination products (DDCPs). She is actively involved in developing general and product-specific guidances, addressing controlled correspondences, pre-ANDA meeting requests, citizen petitions, internal consults, and actively collaborating on current research projects to promote generic drug development of OINDPs and DDCPs. Prior to joining the FDA, she served as an ORISE Fellow at FDA within DTP from August 2018-December 2019. Elizabeth completed her Ph.D. in Chemical Engineering from Wayne State University in July 2018 encompassing work also conducted at Department of Chemistry at the University of São Paulo (Brazil) and Department of Pharmaceutics at Virginia Commonwealth University. Prior to receiving her doctorate, she received her Bachelor of Science in Biomedical Physics Honors with University Honors in 2011, and her Master of Science in Biomedical Engineering in 2012 from Wayne State University.

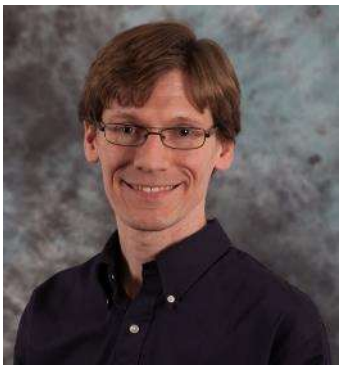
*Day 2 Topic 1 Presentation 2*

**Liangfeng Han, M.D., Ph.D.**
Clinical Analyst in the Office of Research and Standards
Office of Generic Drugs

Liangfeng Han is currently a clinical analyst in the Division of Therapeutic Performance. He has been working on the development of product-specific guidances of orally inhaled and nasal complex drug products, reviewing and responding to controlled correspondences, and analyzing clinical data related to generic product development program. Prior to FDA, he did his residency training in Shanghai, China and was a research scientist in academia. He received his M.D. from Shanghai Second Medical University and Ph.D. from Johns Hopkins University School of Medicine.

*Day 2 Session 3 Topic 1 Presentation 3*

**Ross Walenga, Ph.D.**
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 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 7 months as a postdoctoral fellow prior to joining FDA. His research interests include computational fluid dynamics modeling of orally inhaled, nasal, ophthalmic, and dermal drug products to answer questions pertaining to bioequivalence.

*Non-Speaker Panelists, Day 2 Session 3 Topic 1:*

**Denise Conti, Ph.D.**
Senior Staff Fellow 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 as well as other types of drug-device combination products. 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 and device substitutability focusing on user interface considerations, under the GDUFA regulatory science research program. Prior to joining the FDA in 2013, 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. Dr. Conti is the author and co-author on numerous research manuscripts in the oral inhalation drug delivery area.

**Liang Zhao, Ph.D.**
Division Director in the Office of Research and Standards
Office of Generic Drugs

Dr. Liang Zhao serves as the Director of Division of Quantitative Methods and Modeling. Dr. Zhao has a broad spectrum of scientific and management experience from industry and the regulatory agency. Through his 16-year professional career, he has established himself as an expert in industrial R&D, quantitative methods and modeling, and model based strategic decision makings in regulatory and industrial settings for generic and new drugs.

*Day 2 Session 3 Topic 2 Presentation 1*

**Sam Raney, Ph.D.**
Lead for Topical and Transdermal Drug Products in the Office of Research and Standards
Office of Generic Drugs

*See above for bio and picture*

*Day 2 Session 3 Topic 2 Presentation 2*

**Tannaz Ramezanli, Pharm.D., Ph.D.**
Pharmacologist in the Office of Research and Standards
Office of Generic Drugs

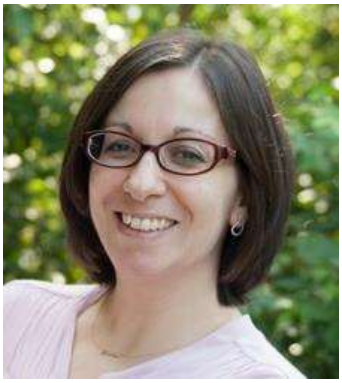
Tannaz Ramezanli is a pharmacologist within the Office of Research and Standards. She specializes in topical and transdermal products. She is responsible for the development of product-specific bioequivalence guidances, reviewing and responding to controlled correspondences, citizen petitions, and Pre-ANDA meeting packages. She also serves as Project Officer for multiple regulatory science research initiatives related to development of bioequivalence standards for complex topical 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.

*Day 2 Session 3 Topic 2 Presentation 3*

**Priyanka Ghosh, Ph.D.**
Senior Pharmacologist in the Office of Research and Standards
Office of Generic Drugs

Dr. Priyanka Ghosh is a senior pharmacologist within the Division of Therapeutic Performance. Her areas of expertise include products in the topical and transdermal drug delivery area. In her current role, Dr. Ghosh is responsible for multiple regulatory science research initiatives related to topical and transdermal drug products, including projects related to development of noninvasive imaging techniques for evaluation of cutaneous pharmacokinetics, under the GDUFA regulatory science program. She is actively involved in development of general and product-specific guidances, addressing controlled correspondences, pre-ANDA meeting requests, and citizen petitions in her area of expertise. 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.

*Day 2 Session 3 Topic 3 Presentation 1*



**Eleftheria Tsakalozou, Ph.D.**
Staff Fellow in the Office of Research and Standards
Office of Generic Drugs

Dr. Eleftheria Tsakalozou joined FDA in 2015 as an Oak Ridge Institute for Science and Education Fellow. She is currently a Staff Fellow at the Division of Quantitative Methods and Modeling. Dr. Tsakalozou obtained her Ph.D. in Pharmaceutical Sciences at the University of Kentucky in 2013 and completed a 2-year Fellowship in Clinical Pharmacokinetics and Pharmacodynamics at the University of North Carolina at Chapel Hill. Her research interests include dermal 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.

*Day 2 Session 3 Topic 3 Presentation 2*

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

Dr. Satish Sharan is a reviewer in 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 at the Division of Quantitative Methods and Modeling at FDA to aid in regulatory policy and decision making. In his current role, Dr. Sharan conducts review of controlled correspondence, pre-ANDA product development meetings, ANDA consults, citizen petitions, participates in center-wide working groups, and manages contracts and grants funded by CDER for development of novel quantitative methods for advancement of generic drug development.

*Non-Speaker Panelist, Day 2 Session 3 Topic 3:*

**Lanyan (Lucy) Fang, Ph.D.**
Associate Director in the Office of Research and Standards
Office of Generic Drugs

Dr. Lanyan (Lucy) Fang is the Associate Director of the Division of Quantitative Methods and Modeling (DQMM). She previously served as 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. Dr. Fang worked as 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).

*Day 2 Session 4 Session Leads*

**Andrew Babiskin, Ph.D.**
Team Lead in the Office of Research and Standards
Office of Generic Drugs

*See above for bio and picture*

**Ping Ren, Ph.D.**
Senior Pharmacologist in the Office of Research and Standards
Office of Generic Drugs

Dr, Ren is a senior pharmacologist in the Office of Research and Standards. He conducts the in-depth reviews for product-specific recommendation for generic drug development and responds industry control correspondences, citizen petitions, and internal consults. In addition, he has participated in several scientific research projects, such as impact of excipients on BCS Class III drug, adverse event profile analysis, and in vitro nasogastric tube study.

**Pahala Simamora, Ph.D.**
Division Director in the Office of Lifecyle Drug Product
Office of Pharmaceutical Quality

Dr. Pahala Simamora is the Division Director for the Division of Liquid Based Products II. His division is responsible for collaborative evaluation and assessment of Abbreviated New Drug Applications (ANDAs) for liquid-based drug products for parenteral, ophthalmic, topical and oral routes, and making risk-informed recommendations on their approvability. Dr. Simamora joined FDA in 2010 as a Chemistry Reviewer. Since that time, he has held additional positions with increasing responsibilities including acting Team Leader and Branch Chief in OLDP/OPQ. Prior to joining FDA, he spent 14 years in pharmaceutical industry conducting work on formulation, process development, and scale up for brand, generic and OTC drugs of various dosage forms including injectables, solid orals, powders, liquids, and semisolids. He received his Ph.D. in Pharmaceutical Sciences from the University of Arizona, his M.S. in Chemistry from Pittsburg State University, and his Chemistry Diploma from the Academy for Chemical Analyses, Bogor, Indonesia.

*Day 2 Session 4 Topic 1 Presentation 1*

**CDR Yi Zhang, M.M., Ph.D.**
Team Lead in the Office of Research and Standards
Office of Generic Drugs (OGD)

CDR Yi Zhang has led multiple teams in ORS, including the Product-Specific Guidance (PSG) Development Team, Dermatological and Topical Product Team, and Immediate Release Oral Solid Dosage Forms Drug Team. She is a subject matter expert in developing and establishing optimal and rigorous bioequivalence (BE) standards and approaches for various drug dosage forms to promote generic drug development. CDR Zhang also leads the research projects to address broad regulatory scientific issues encountered throughout generic drug approvals. By publishing PSGs, responding to public inquires (including controlled correspondences and citizen petitions), managing pre-ANDA meetings, addressing internal consults, and leading research projects to establish novel BE approach, CDR Zhang and her teams have improved FDA's generic drug approval process, provided the transparency to the generic drug industry with regard to regulatory and scientific perspectives, and facilitated the generic industry develop generic drug products more efficiently and effectively by submitting high quality applications to FDA.

*Day 2 Session 4 Topic 1 Presentation 2*

**Fang Wu, Ph.D.**
Senior Pharmacologist in the Office of Research and Standards
Office of Generic Drugs

Dr. Fang Wu is a senior pharmacologist reviewer and scientific lead for oral Physiologically-based Pharmacokinetic modeling in Division of Quantitative Methods and Modeling. Dr. Wu has been with FDA for more than 8 years. She is responsible for using quantitative clinical pharmacology and 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 new drug applications and ANDA biopharmaceutics 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.

**Xiajing Gong, Ph.D.**
Staff Fellow in the Office of Research and Standards
Office of Generic Drugs

Xiajing (Jean) Gong is currently a staff fellow in the Division of Quantitative Methods and Modeling, in OGD's Office of Research and Standards. Her research projects at FDA include the development and application of big data analytics tools to support drug development and regulatory decisions.

*Non-Speaker Panelist, Day 2 Session 4 Topic 1:*

**Liang Zhao, Ph.D.**
Division Director in the Office of Research and Standards
Office of Generic Drugs

*See above for bio and picture*

*Day 2 Session 4 Topic 2 Presentation 1*

**Katherine Tyner, Ph.D.**
Acting Associate Director in the Immediate Office
Office of Pharmaceutical Quality

Dr. Katherine Tyner is the Associate Director of Science (acting) in the Immediate Office of the Office of Pharmaceutical Quality. She received her Ph.D. in Chemistry from Cornell University and joined FDA in 2007. While at FDA, Dr. Tyner has investigated the quality, safety, and efficacy of complex drug products including drug products containing nanomaterials, and she currently leads the CDER nanotechnology working group and is active in other CDER and FDA nanotechnology initiatives. Dr. Tyner has also led efforts to streamline in vitro testing for drug products administered via enteral feeding tubes. Dr. Tyner is the author of multiple book chapters and journal articles concerning the appropriate characterization and biological impact of complex products.

*Day 2 Session 4 Topic 2 Presentation 2*

**Mamta Kapoor, Ph.D.**
Staff Fellow, Office of Lifecyle Drug Product
Office of Pharmaceutical Quality

Dr. Mamta Kapoor has several years of experience in multidisciplinary scientific areas such as formulation development, drug (small molecule, nucleic acid) delivery, nanotechnology and cell culture. For the past 6 years, she has worked at FDA, assessing data on Chemistry Manufacturing and Controls (CMC) in applications for generic drug products including the products intended for enteral feeding tube (e.g., nasogastric) administration. Dr. Kapoor is also deeply involved in Agency's efforts in streamlining industry submissions on in vitro enteral feeding tube study, with an end goal to reduce back and forth between industry and the Agency. Prior to joining the Agency, she received her Ph.D. in Pharmaceutics from University of Connecticut, and Post-doctorate from University of Minnesota, after gaining industrial experience in pre-formulation.

*Day 2 Session 4 Topic 2 Presentation 3*

**CDR Minglei Cui, Ph.D.**
Team Lead in the Office of Bioequivalence
Office of Generic Drugs

CDR Minglei Cui is a Team Leader in the Division of Bioequivalence II and Commander (O-5) in the U.S. Public Health Service Commissioned Corps. Her current responsibilities are to review drug products submitted in Abbreviated New Drug Applications to determine the adequacy of the data from bioequivalence studies based on study design, analytical methodology, and statistical analysis. CDR Cui has led and represented the Division on several inter-office and inter-center Working Groups. CDR Cui has contributed her diverse expertise in generating important Agency guidance for locally acting GI products and oral drug products with Nasogastric tube administration. Prior to joining the FDA, CDR Cui worked in the pharmaceutical industry with extensive experience in areas of pain and neuroscience. She led multiple projects in both new drug discovery and new applications of existing drugs for the treatment of chronic pain. As a nationally-recognized expert in pain research, she has authored numerous landmark patents, publications, and research presentations. CDR Cui received her Ph.D from Indiana University School of Medicine and joined the Division of Bioequivalence in December 2007 as a Pharmacologist.

*Closing Remarks*

**Lei Zhang, Ph.D.**
Deputy Director in the Office of Research and Standards (ORS)
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ORS implements the Generic Drug User Fee Amendments (GDUFA) science and research commitments to ensure the therapeutic equivalence of generic drug products. Dr. Zhang is an accomplished professional with more than 22 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 the science-based regulatory decision-making. Before joining FDA in 2002, she worked at Bristol-Meyers Squibb Company 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, Schools of Pharmacy and Medicine. Dr. Zhang received her Ph.D. in Biopharmaceutical Sciences from UCSF. She is a member of the ICH Generic Drug Discussion Group (GDG), serving as the U.S. FDA Topic Leader. Additionally, she is the Rapporteur for ICH M13 Informal Working Group that is developing M13 guideline to harmonize bioequivalence (BE) study design for immediate-release oral dosage form drugs. Dr. Zhang was named American Association of Pharmaceutical Scientists (AAPS) Fellow in 2013.