SPEAKER BIOGRAPHIES

In order of presentations (see the Agenda)

Day 1 – Keynote

Robert Califf, MD
Commissioner,
US Food and Drug Administration (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.

Day 1, Session 1A

Session Leads

Darby Kozak, PhD
Deputy Director
Division of Therapeutic Performance I (DTP I)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD) | Center for Drug Evaluation and Research (CDER) | US FDA

Dr. Darby Kozak is the Deputy Division Director for the Division of Therapeutic Performance I in the FDA's Office of Generic Drugs. Dr. Kozak leads a group of interdisciplinary scientists on the development of new analytical methods and equivalence evaluation methodologies for complex drug substances and parenteral, ophthalmic, and otic formulations. Prior to joining the FDA, Dr. Kozak was Chief Scientist for Izon Science and Research Fellow at the Australian Institute for Bioengineering and Nanotechnology. Dr. Kozak has a B.Sc. in Chemical Engineering from the University of Washington (Seattle, WA) and Ph.D. in Chemistry from the University of Bristol (United Kingdom).

Cameron Smith, PhD
Branch Chief
Liquid-Based Branch II (LBB II)
Division of Liquid-Based Products I (DLBP I)
Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Quality (OPQ) | CDER | US 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.

Speakers

Eric Pang, PhD
Senior Chemist
DTP I | ORS | OGD | CDER | US FDA

Dr. Eric Pang serves as a senior chemist in the Office of Generic Drugs. He specializes in the analysis of peptide and large molecule drugs. Currently, he serves as the SME for peptide drug products, develops product-specific guidances of complex drug products, responds to controlled correspondences, pre-ANDA meeting requests, citizen petitions, and consultations. He is also managing several regulatory science projects related to generic peptide products and topics related to immunogenicity. Dr. Pang has over 10 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.

Yili Li, PhD
C*hemist*
LBB II | DLBP I | OLDP | OPQ | CDER | US FDA
Yili Li received her B.Sc. and Ph.D. in Chemistry from Peking University, Beijing, China. She continued her career training as a Marie Curie Fellow of the European Commission in the Biochemistry Department, University of Cambridge, UK and a Post-doctoral Fogarty Visiting Fellow in the National Cancer Institute, National Institute of Health, Bethesda, MD. Her expertise is in peptide and protein chemistry, including production, purification and characterization utilizing various techniques such as HPLC/UPLC, MS, SV-AUC, amino acid sequencing analysis and bioassays. Before joining FDA, Yili was a Senior Scientist in the University of Maryland Institute for Bioscience and Biotechnology Research (IBBR), Rockville, MD. She had two decades research experience in the field of structural immunology and published two dozen of first author research papers in the world's most prestigious life science journals. Yili joined FDA in 2016 as a chemistry reviewer. She has served as a primary reviewer, secondary reviewer, and Application Technical Lead (ATL) in the Division of Liquid-Based Products I for ANDA and pre-ANDA applications. She has extensive experiences in the review of complex peptide drug products, topical products, and parenteral products.

Daniela Verthelyi, MD, PhD
Chief, Laboratory of Immunology
Division of Biotechnology Review and Research III (DBRR III)
Office of Biotechnology Products (OBP) | OPQ | CDER |
US FDA

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. in Immunology from Virginia Tech in the United States, before joining the FDA where she 1st completed a fellowship in Retroviral Immunology in the Center for Biologics Evaluation and Research and then joined the Office of Biotechnology Products in CDER as a principal investigator. She has been a driving force in risk evaluation and mitigation pertaining to the immunogenicity of therapeutic proteins, peptides, and oligonucleotides. She has Chaired the FDA-NIH Immunology Interest Group and the NIH-FDA Cytokine Interest Group and served on the Advisory Board for the NIH Human Immunology Group. She has authored over 100 scientific papers,

holds several patents, and has received FDA's, CBER's, and CDER's "Excellence in Laboratory Sciences'' awards, among other honors.

Panelists

Eric Pang, PhD
Senior Chemist
DTP I | ORS | OGD | CDER | US FDA *(See Biography above)*

Daniela Verthelyi, MD, PhD
Chief, Laboratory of Immunology
DBRR III | OBP | OPQ | CDER | US FDA *(See Biography above)*

Yili Li, PhD
Chemist
LBB II | DLBP I | OLDP | OPQ | CDER | US FDA
(See Biography above)

Cameron Smith, PhD
Branch Chief
LBB II | DLBP I | OLDP | OPQ | CDER | US FDA
(See Biography above)

Day 1, Session 1B

Session Leads

Darby Kozak, PhD
Deputy Director
DTP I | ORS | OGD | CDER | US FDA
(See Biography above)

Cynthia Sommers, MS
Branch Chief,
Division of Complex Drug Analysis (DCDA)
Office of Translational Research (OTR) | OPQ | CDER | US FDA

Cindy Sommers received her M.S. Pharmacology degree from the University of Michigan. During the past 36 years, she has worked in industry, academia and at the FDA as an accomplished and highly effective scientific leader and manager in areas of research and regulatory science. At the FDA, she served for 2 years as lab chief for DCDA B1, 5 years as Project Manager and MVP coordinator, 5 years as OTR records coordinator, 2 years as a FAC-COR and 6 years as an analytical chemist and biologist. She has demonstrated expertise in planning and tracking task force level projects, coordinating MVPs, identifying, and resolving technical issues, writing grants and manuscripts, serving on several OTR and OPQ level teams, reviewing ANDAs and applying a wide range of scientific methods.

Speakers

Deyi Zhang, PhD
Senior Chemist
DTP I | ORS | OGD | CDER | US 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 participates in pre-ANDA meetings, product-specific guidance development on such products, and manages related 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 48 publications and presentations.

Kui Yang, PhD

Senior Research Scientist
DCDA | OTR | OPQ | CDER | US FDA

Dr. Kui Yang is a Senior Research Scientist in the Division of Complex Drug Analysis in the Office of Testing and Research with the Office of Pharmaceutical Quality at FDA. She specializes in mass spectrometry-based analytical method development. Her research in regulatory science focuses on complex drug product analysis to provide scientific inputs on drug quality questions. She leads the Oligonucleotide Working Group and serves as a subject matter expert in oligonucleotide product specific guidance development at FDA. She also provides mass spectrometry training to FDA assessors. Prior to joining FDA in 2016, Dr. Yang was an Instructor in Medicine at Washington University School of Medicine where she was trained on and gained over ten years of experience in mass spectrometry-based lipidomics and biomarker research in diabetes, heart disease and Alzheimer's disease. She received a Ph.D. degree in Chemical Engineering from Tianjin University in China.

Panelists

Deyi Zhang, PhD
Senior Chemist
DTP I | ORS | OGD | CDER | US FDA
(See Biography above)

Kui Yang, PhD
Senior Research Scientist,
DCDA | OTR | OPQ | CDER | US FDA
(See Biography above)

Daniela Verthelyi, MD, PhD
Chief, Laboratory of Immunology
DBRR III | OBP | OPQ | CDER | US FDA
(See Biography above)

Likan Liang, PhD
Branch Chief
Liquid-Based Branch V (LBB V)
Division of Liquid-Based Products II (DLBP II) | OLDP | OPQ | CDER | US FDA

Dr. Liang serves as the Office of Pharmaceutical Quality Chair in multiple reviews of various generic oligonucleotide product development meeting requests and contributed to the development of the published draft Product Specific Guidance on nusinersen sodium intrathecal solution. Before joining the FDA in 2013, Dr. Liang has worked in the pharmaceutical industry for about 16 years in various capacities, in areas including API synthesis and manufacturing, formulation development for multiple dosage forms and complex drug formulations including nano-formulations, and drug product manufacturing process development, scale up, technology transfer, and commercial scale manufacturing.

Day 1, Session 2

Session Leads

Stephanie Soukup, MD
Physician
Division of Clinical Review (DCR)
Office of Safety & Clinical Evaluation (OSCE) | OGD | CDER |
US FDA

Dr. Stephanie Soukup is a pediatrician by training and completed medical school at the University of Maryland followed by residency and chief residency at Sinai Hospital of Baltimore. She practiced general pediatrics in an outpatient setting prior to joining FDA in 2018 as a primary reviewer in the Division of Clinical Review. Dr. Soukup routinely reviews comparative analyses, comparative clinical endpoint bioequivalence studies as well as clinical consults and controls.

Katharine Feibus, MD
Team Lead
DTP I | ORS | OGD |CDER| US FDA

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

Speakers

Kathryn Hartka, PharmD, PhD
Pharmacologist
DTP I | ORS | OGD |CDER| US FDA

Dr. Kathryn Hartka joined FDA in 2020 as a Pharmacologist in the Center for Tobacco Products, Office of Science. She is currently a Pharmacologist in the Division of Therapeutic Performance on the Device-Evaluation Team. In her current role, Dr. Hartka is actively involved in developing product specific guidances and addressing controlled correspondences and pre-ANDA meeting requests related to drug-device combination products. Prior to joining FDA, Kathryn conducted preclinical and clinical academic research to investigate potential treatments for substance use disorders and worked as a pharmacist in an academic medical center. She received her Bachelor of Science in Neuroscience from the University of Pittsburgh, her Pharm.D. from Virginia Commonwealth University School of Pharmacy and her Ph.D. in Pharmacology and Toxicology from Virginia Commonwealth University School of Medicine.

Stephanie Soukup, MD
Physician
DCR | OSCE | OGD | CDER| US FDA
(See Biography above)

Betsy Ballard, MD
Medical Officer
DTP I | ORS | OGD |CDER| US FDA

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

Panelists

Kathryn Hartka, PharmD, PhD
Pharmacologist
DTP I | ORS | OGD |CDER| US FDA
(See Biography above)

Stephanie Soukup, MD
Physician
DCR | OSCE | OGD | CDER| US FDA
(See Biography above)

Betsy Ballard, MD
Medical Officer
DTP I | ORS | OGD |CDER| US FDA
(See Biography above)

Lisa Bercu, JD
Regulatory Counsel
Division of Policy Development (DPD)
Office of Generic Drug Policy (OGDP) | OGD | CDER |
US FDA

Lisa Bercu is a regulatory counsel in the Office of Generic Drug Policy, Office of Generic Drugs (OGD), where she focuses on issues related to combination products. Before joining OGD in October 2016, Ms. Bercu worked at a medical society providing strategic advice on issues including pain medicine, drugs, and devices. She holds a JD degree from Georgetown University Law Center and a BA from the University of Michigan.

Markham Luke, MD, PhD
Director
DTP I | ORS | OGD |CDER| US 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.

CDR Andrew Fine, PharmD
Senior Advisor
DCR | OSCE | OGD | CDER| US FDA
Commander Fine is the Senior Advisor in the Office of Generic Drug 's, Office of Safety and Clinical Evaluation, Division of Clinical Review. As part of the division management team, Commander Fine, provides clinical, regulatory, and process oversight for ANDA and pre-ANDA activities in the division. Prior to his role as Senior Advisor, Commander Fine served as a team leader in the division for 7 years. He earned his PharmD from the University of Illinois and completed a pharmacy practice residency at Northwestern University. Andrew is board certified in pharmacotherapy and earned a certificate in pharmacoepidemiology from the University of Pennsylvania. Prior to joining OGD, CDR Fine spent 4.5 years as a safety reviewer in CDER's Office of Surveillance and Epidemiology, Division of Pharmacovigilance where he led postmarketing safety efforts for Multiple Sclerosis drug products.

Katharine Feibus, MD
Team Lead
DTP I | ORS | OGD |CDER| US FDA
(See Biography above)

Day 1, Session 3

Session Leads

Bing Cai, PhD

Director
DLBP I | OLDP | OPQ | CDER | US FDA

Dr. Bing Cai is Director of the Division of Liquid-based Drug Products in CDER/OPQ/OLDP at the FDA. In his twenty-year tenure within the FDA, he has been promoted to CDER Senior Review, 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.

Yan Wang, PhD
Team Lead
DTP I | ORS | OGD |CDER| US FDA

Dr. Yan Wang is the team lead for the 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.

Speakers

Xinran Li, PhD
Staff Fellow
Division of Bioequivalence II (DB II)
Office of Bioequivalence (OB) | OGD | CDER | US FDA

Xinran Li is the primary assessor for the in vivo and in vitro bioequivalence studies of generic drug products in the Office of Bioequivalence in the FDA's Center for Drug Evaluation and Research. She received a Ph.D. in Pharmaceutical Science from the University of Texas at Austin in 2013. Xinran has experience supporting complex drug reviews across different dosage forms as well as regulatory assessment for ANDA submission.

Bin Qin, PhD
Staff Fellow
DTP I | ORS | OGD |CDER| US FDA

Dr. Bin Qin is currently a staff fellow in the Division of Therapeutic Performance I, in OGD's Office of Research and Standards. In his current role, Dr. Qin is responsible for the development of product-specific guidance for generic drug development, reviewing and responding to controlled correspondences, pre-ANDA meeting requests and internal consults. Dr. Qin is also the project officer on multiple regulatory science research initiatives related to complex drug products, under the GDUFA regulatory science research program. Dr. Qin completed his Ph.D. in Pharmaceutical Sciences from University of Missouri-Kansas City, and pursued a postdoctoral training in University of Pittsburgh Medical Center. Dr. Qin received his B.S. in Pharmacy and M.S. in Pharmaceutics from China Pharmaceutical University.

William Smith, PhD
Research Fellow
Division of Product Quality Research (DQPR) | OTR | OPQ | CDER | US FDA

William C. Smith (Billy) is currently an ORISE Fellow with Dr. Xiaoming Xu in the Division of Product Quality Research working on complex drug formulations from emulsions to implantable polymeric devices. His research focuses on the physicochemical characterization of nano- and micro-scale materials, including the development of analytical and in vitro release test methodologies to support assessment and review, equivalence determination, and evaluation of drug product quality. Billy received his Ph.D. in 2019 from the Colorado School of Mines under Dr. Kim R. Williams, in analytical chemistry. His Ph.D. focused on the development of thermal field-flow fractionation for the characterization of hybrid colloidal nanomaterials and polymers with complex architectures.

Hongna Wang, PhD
Chemist
Division of Internal Policies and Programs (DIPAP),
Office of Policy for Pharmaceutical Quality (OPPQ) | OPQ | CDER | US FDA

Dr. Wang is an experienced Policy Lead and CMC reviewer in the Center for Drug Evaluation and Research, Office of Pharmaceutical Quality. She has led multi-disciplinary, cross-center working groups in developing internal and external policies, including the training programs for the implementation of new policies. As a Policy Lead, Dr. Wang has worked on multiple projects to establish policy and procedures for FDA staff and promote transparency on CDER current thinking to the pharmaceutical industry. She also works with colleagues in the OPQ policy group to identify areas for the improvement of existing policies/procedures, ensure product quality, and promote first cycle approval by responding to external inquiries with FDA's updated standards.

Panelists

Xinran Li, PhD
Staff Fellow
DB II | OB | OGD | CDER | US FDA
(See Biography above)

William Smith, PhD
ORISE Fellow
PQRB3 | DQPR | OTR | OPQ | CDER | US FDA
(See Biography above)

Bin Qin, PhD
Staff Fellow
DTP I | ORS | OGD |CDER| US FDA
(See Biography above)

Hongna Wang, PhD
Chemist
PDEB1 | DIPAP | OPPQ | OPQ | CDER | US FDA
(See Biography above)

Utpal Munshi, PhD
Director
Division of Bioequivalence I (DBI) | OB | OGD | CDER

Utpal M. Munshi, Ph.D., is the Division Director of the Division of Bioequivalence I (DBI) in the Office of Bioequivalence, in OGD. He leads a team of scientists responsible for the assessment of the bioequivalence section of Abbreviated New Drug Applications and other stakeholder submissions. During his time in DBI, Dr. Munshi has had a variety of technical and administrative roles and has participated in the drafting of numerous Agency guidances pertaining to bioequivalence. Dr. Munshi received his Ph.D. in Biological Chemistry from the University of Michigan and then undertook post-doctoral training at the National Cancer Institute in Frederick Maryland before joining DBI in 2007.

David Anderson, PhD
Branch Chief
Division of Microbiology Assessment II (DMA II)
Office of Pharmaceutical Manufacturing Assessment (OPMA) | OPQ | CDER | US FDA

Dr. Anderson currently serves as a Branch Chief in the Division of Microbiology II supporting the complete manufacturing assessment (facility, chemical process, and sterility control) of IND, NDA, and ANDA applications. He joined the FDA as a chemist in the Office of Process and Facilities (now the Office of Pharmaceutical Manufacturing Assessment) in 2015 providing support to a variety of activities while the office was in its infancy. Dr Anderson is recognized within the FDA as

an experienced liquid manufacturing assessor with specific expertise in the assessment of manufacturing leachable impurities and parenteral fill volume control limits. Prior to joining the FDA, Dr. Anderson spent 6 years at Eli Lilly and Company providing analytical support for small molecule synthetic route development of new drug substances across various phases of development, and two years at BASF supporting agrochemical R&D, synthetic route development, and commercial manufacturing activities. Dr. Anderson holds a Ph.D. in Pharmaceutical Sciences from Purdue University School of Pharmacy.

Janice Brown, PhD
Branch Chief
DIPAP | OPPQ | OPQ | CDER | US FDA

Janice Brown currently serves as the Branch Chief in the Policy Development and Evaluation Branch I in the Office of Policy for Pharmaceutical Quality (OPPQ), Office of Pharmaceutical Quality (OPQ) in the Center for Drug Evaluation and Research (CDER). Janice has 20 years' experience in CDER serving as a reviewer and quality assessment lead in the preapproval and postapproval review divisions evaluating product quality sections in IND's and NDA's, providing regulatory guidance to NDA applicants, and serving as an application technical lead in OPQ. Janice served 5 years in CBER as a reviewer evaluating Biologics and Establishment License Applications (BLAs/ELAs) and as an inspector leading teams for pre license/pre approval inspections of biologic and biotechnology manufacturing facilities. Before coming to the FDA, Janice spent 8 years working in the biopharmaceutical industry.

Day 1, Session 4

Session Leads

Lucy Fang, PhD
Deputy Director
DQMM | ORS | OGD | CDER | US 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 the CDER work group tasked with the use of the 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 pharmacokineticist 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).

Bing Li, PhD
Associate Director for Science
OB | OGD | CDER | US FDA

Dr. Bing V. Li serves as the Associate Director for Science for the Office of Bioequivalence in 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.

Speakers

Dapeng Cui, PhD
Pharmacologist
DB I | OB | OGD | CDER | US FDA
Dr. Dapeng Cui obtained his B.S. in Microbiology from ShanDong University (Jinan, China) and his Ph.D. in Pharmacology from Chinese Academy of Medical Sciences (Beijing, China). He also has a Master's degree in Pharmacokinetics and Pharmacodynamics from State University of New York at Buffalo, School of Pharmacy and Pharmaceutical Sciences. Dapeng has 5 years of postdoc training in Pharmacology at Georgia State University Department of Biology and Emory University School of Medicine. Before joining the FDA in 2015, Dapeng had 5 years of pharmaceutical industry experience at ICON, a global CRO focusing on clinical pharmacology support for new drug development. Dapeng is currently an Acting Team Lead in FDA/OGD/OB.

Kairui (Kevin) Feng, PhD
Senior Chemical Engineer
DQMM | ORS | OGD | CDER | US FDA

Dr. Kairui (Kevin) Feng joined the Quantitative Clinical Pharmacology team in DQMM/ORS/OGD/CDER/FDA in April 2019. Prior to joining FDA, he worked in Certara, with 13+ years' experience in quantitative clinical pharmacology in Pharsight (a Certara company in Cary, NC, USA) and in translational drug development in Simcyp (a Certara company in Sheffield, UK). He has extensive knowledge/experience in application of preclinical drug development and clinical drug development, including but not limited to drug submission, drug submission review, managing grant/contract applications and acting as grant/contract officer for communicating with internal and external stakeholders. Prior to joining Certara, he worked two years in finance modeling on a portfolio optimization project with Smith Institute in Oxford, UK. Dr. Kevin Feng received a Ph.D. in 2004 in Automatic Control and System Engineering at the University of Sheffield, UK.

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

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

Sherin Thomas, PhD
Pharmacologist
DQMM | ORS | OGD | CDER | US FDA

Dr. Sherin Thomas earned her Ph.D. in Pharmaceutical Sciences from University of Maryland Baltimore and M.S. in Pharmacology from New York Medical College. Her dissertation work focused on transdermal pharmacokinetics and in vitro in - vivo correlations. She joined the ORS/DQMM in 2020 where she contributed to research involving population pharmacokinetic modeling and physiologically based pharmacokinetic modeling focused on bioequivalence and in vitro - in vivo correlations.

Panelists

Dapeng Cui, PhD *(See Biography above)*
Pharmacologist
DB I | OB | OGD | CDER | US FDA

Kairui (Kevin) Feng, PhD

Senior Chemical Engineer
DQMM | ORS | OGD | CDER | US FDA
(See Biography above)

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

(See Biography above)

Sherin Thomas, PhD
Pharmacologist
DQMM | ORS | OGD | CDER | US FDA
(See Biography above)

Hao Zhu, PhD,
Deputy Director
Division of Pharmacometrics (DPM) | OCP | OTS | CDER | US FDA

Dr. Hao Zhu is the Acting director at the Division of Pharmacometrics, Office of Clinical Pharmacology, Center of Drug Evaluation and Research, U.S. Food and Drug Administration. Dr. Zhu received his Ph.D. in pharmaceutical sciences and Master in statistics from the University of Florida. He started his career in modeling and simulation teams in Johnson & Johnson and Bristol-Myers-Squibb. He joined FDA as a pharmacometrics reviewer more than 15 years ago. Dr. Zhu has been a clinical pharmacology team leader for more than 6 years and a QT-IRT scientific lead for 2 years. Then he became the deputy director at the Division of Pharmacometrics. His division reviews the pharmacometrics related submissions and supports pharmacometrics-related policy development.

Lucy Fang, PhD
Deputy Director
DQMM | ORS | OGD | CDER | US FDA
(See Biography above)

Bing Li, PhD
Associate Director for Science
OB | OGD | CDER | US FDA
(See Biography above)

Day 1, Closing Remarks

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

Dr. Lei Zhang is the Deputy Director in the Office of Research and Standards (ORS), OGD, CDER, U.S. FDA. 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 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-Myers 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 was 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.

Day 2, Session 5

Session Leads

Wei-Jhe Sun, PhD
Pharmacologist
Division of Therapeutic Performance II (DTP II) | ORS | OGD | CDER | US FDA

Dr. Wei-Jhe Sun joined the FDA in 2018 and is currently in the Office of Research and Standards at the Office of Generic Drugs. He has been working and collaborating on several projects to improve generic drug quality and provide 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 abuse-deterrent formulation, formulation design, drug delivery, manufacturing sciences and solid-state pharmaceutics. Throughout his time working in the field, he has published 14 peer-reviewed journal articles.

Nilufer Tampal, PhD
Acting Associate Director of Scientific Quality
OB | OGD | CDER | US FDA

Dr. Nilufer Tampal is the Acting Associate Director of Scientific Quality in OGD's Office of Bioequivalence. In this role, Dr. Tampal develops strategies and oversees implementation of data quality and the scientific integrity of bioequivalence data submitted in Abbreviated New Drug Applications (ANDAs). She provides expertise in utilization of advanced analytic data tools supporting ANDA reviews. Dr. Tampal also engages actively in multiple global efforts to support generic drug programs. She serves as the Rapporteur for ICH Generic Drug Discussion Group, FDA's Topic Lead on ICH M13 Expert Working Group and on the committee for Global Bioequivalence Harmonization Initiative. She started her career at the FDA in 2002, as an investigator in the Office of Study Integrity and Surveillance (OSIS; pka OSI) and has held various leadership positions in the Office of Bioequivalence in the last 14 years.

Speakers

Wei-Jhe Sun, PhD
Pharmacologist
DTP II | ORS | OGD | CDER | US FDA
(See Biography above)

Hongmei Li, PhD
Senior Pharmaceutical Quality Assessor
Liquid-Based Branch I (LBB I)
DLBP I | OLDP | OPQ | CDER | US FDA

Hongmei Li, PhD is currently a senior pharmaceutical quality assessor in FDA\CDER\Office of Pharmaceutical Quality\Office of Lifecycle Drug Products. She serves as application technical lead, leads interdisciplinary assessment team, and performs quality assessment on liquid-based drug product ANDA applications including many first generic or complex drug products. She has been involved in antibiotic guidance working groups and provided input in the USP expert committee as a FDA liaison. Prior to joining FDA in 2015, Hongmei worked at the Department of Process Chemistry at Merck & Co. Inc. for 8 years. She received Ph.D. in Chemistry from University of Pennsylvania.

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

Manar Al-Ghabeish 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. In 2015, Manar joined the Office of Testing and Research (OTR) at the U.S. Food and Drug Administration (FDA). She worked as a regulatory research scientist and product quality assessor. The area of research she has been involved in includes abuse deterrent formulations (ADFs), nasal drug delivery, and gastrointestinal local acting drugs. In 2021, Manar moved to the Office of Research and Standards in the Office of Generic Drugs where she continues to be involved in regulatory science related to the therapeutic performance of oral dosage forms.

Hongfei Zhou, PhD
Pharmacologist,
Division of Bioequivalence III (DB III) | OB | OGD | CDER |
US FDA

Dr. Zhou is a Senior Pharmacologist in the Division of Bioequivalence III (DBIII), Office of Bioequivalence (OB), Office of Generic Drugs (OGD), Center for Drugs Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). Dr. Zhou received his Ph.D. in Toxicology from University of Colorado and has a diversified educational background in Computer Science and Microbiology. He joined the OGD in 2014 as a bioequivalence assessor and has been actively involved in multiple scientific and regulatory working groups either as a group lead or a team member. He is experienced in assessing the in vivo and in vitro bioequivalence of various dosage forms of complex generic drug products. Prior to joining OGD, he has conducted laboratory and computational research to investigate drug induced adverse event mechanisms and provide professional support in scientific data evaluation.

Panelists

Wei-Jhe Sun, PhD
Pharmacologist
DTP II | ORS | OGD | CDER | US FDA
(See Biography above)

Manar Al-Ghabeish, PhD
Staff Fellow
DTP II | ORS | OGD | CDER | US FDA
(See Biography above)

Hongmei Li, PhD
Senior Pharmaceutical Quality Assessor
Liquid-Based Branch I (LBB I)
DLBP I | OLDP | OPQ | CDER
(See Biography above)

Hongfei Zhou, PhD
Pharmacologist
DB III | OB | OGD | CDER | US FDA
(See Biography above)

Hongling Zhang, PhD
Division Director
DB II | OB | OGD | CDER | US 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. Dr. Zhang received her Bachelor degree from Shenyang Pharmaceutical University and Ph.D. degree in Pharmacology from the University of South Florida and completed a postdoctoral training at the Moffitt Cancer Institute.

Day 2, Session 6

Session Leads

Bryan Newman, PhD
Team Lead
DTP I | ORS | OGD |CDER| US 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.

Changning Guo, PhD
Supervisory Chemist
DCDA | OTR | OPQ | CDER | US FDA

Dr. Changning Guo is a supervisory chemist at FDA. He currently serves as a lab chief in the Division of Complex Drug Analysis (DCDA) within CDER/OPQ/OTR. His research at FDA focuses on inhalation drug characterization, particle sizing, X-ray powder diffraction (XRPD), and spectroscopy. He has been a PI/co-PI on multiple FDA research projects and served as a subject matter expert for FDA working groups, guidance teams, ANDA review teams, and FDA research grant review committees. He received a BS degree in Chemistry from Tsinghua University and a PhD degree in Analytical Chemistry from Syracuse University.

Speakers

Bryan Newman, PhD
Team Lead
DTP I | ORS | OGD |CDER| US FDA
(See Biography above)

Susan Boc, PhD
Pharmacologist
DTP I | ORS | OGD |CDER| US FDA

Dr. Susan Boc is a contractor working in the Division of Therapeutic Performance 1 and specializes in oral inhalation and nasal drug products. She is responsible for the development of product-specific guidances for generic drug development, reviewing and responding to controlled correspondences, pre-ANDA meeting requests, and internal consults. Prior to joining the FDA, she spent over 8 years in the pharmaceutical industry working in the development of drug products for oral inhalation. She received her B.S. in Biochemistry from University of California, Los Angeles, and her Ph.D. in Pharmaceutical Sciences from Virginia Commonwealth University.

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

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.

Nick Holtgrewe, PhD
Chemist
DCDA | OTR | OPQ | CDER | US FDA

Dr. Nicholas Holtgrewe has been 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 degree in Chemistry from Washington University in St. Louis in 2013.

Panelists

Bryan Newman, PhD
Team Lead
DTP I | ORS | OGD |CDER| US FDA
(See Biography above)

Ross Walenga, PhD
Senior Chemical Engineer
DQMM | ORS | OGD | CDER | US FDA
(See Biography above)

Nick Holtgrewe, PhD
Chemist
DCDA | OTR | OPQ | CDER | US FDA
(See Biography above)

Ke Ren, PhD
Acting Deputy Division Director
DB III | OB | OGD | CDER | US FDA

Dr. Ke Ren is currently an acting Deputy Director in the Division of Bioequivalence III (DBIII) in the Office of Bioequivalence of Office of Generic Drugs, CDER, FDA. In this role, she leads a team of scientists responsible for the assessment of the bioequivalence section of Abbreviated New Drug Applications. During her time in DBIII, Dr. Ke Ren has developed extensive expertise in generic drug development in various therapeutic areas, including orally inhaled and nasal drug products. She has participated in the drafting of numerous Agency guidances pertaining to bioequivalence. Dr. Ren received her Ph.D. in Pharmaceutical Science from the University of Florida in 2005 and then undertook post-doctoral training at the University of Florida before joining OGD in 2008.

Day 2, Session 7

Session Leads

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

Zhen Zhang, PhD
Senior Pharmacologist
DB I | OB | OGD | CDER | US FDA

Dr. Zhen Zhang is a pharmacologist and bioequivalence reviewer at the Division of Bioequivalence I/Office of Bioequivalence/Office of Generic Drugs/CDER/FDA. He is a subject matter expert (SME) for data analysis. Besides his review work, Dr. Zhang also conducts research to address complex bioequivalence related issues and is involved in

working groups to facilitate generic drug review processes. He receives many review excellence awards and regulatory science awards both individually and as a team member. Dr. Zhang obtained his Ph.D. in Pharmacology from University of Wisconsin, Madison.

Speakers

Yuqing Gong, PhD
Pharmacologist
DQMM | ORS | OGD | CDER | US FDA

Dr. Yuqing Gong is currently a staff fellow at the Quantitative Clinical Pharmacology Team in the Division of Quantitative Methods and Modeling, Office of Research and Standards, Office of Generic Drugs, CDER/FDA. Her current role in the division is to utilize quantitative tools such as population pharmacokinetics (PPK), modeling and simulations, to address specific questions elate to generic drug development process and/or regulatory decision making. She received her Ph.D. degree in Pharmaceutical Sciences at the University of Tennessee Health Science Center in 2020.

Jing (Jenny) Wang, PhD
Research Fellow
DQMM | ORS | OGD | CDER | US FDA

Jing Wang Ph.D. received her Bachelor of Science degree in 2009 and her Master of Science degree in 2011, both in the Biomedical Engineering major, from the Xi'an Jiaotong University, China. She received her Ph.D. degree in Rehabilitation Science from the University of Pittsburgh in 2015. After her graduation, she worked in Duquesne University as a visiting assistant professor for 1 year. Then Dr. Wang worked as a post-doctoral research fellow in the Rehabilitation Engineering Research Center D.C. and the Department of Biomedical Engineering at The Catholic University of America between 2019 to 2020, after her 2 years maternity leave. Her previous research mainly focused on developing technology applications for people with neurological impairments and using kinematic and statistical analysis of biomechanical systems in clinical trials to evaluate these applications. Dr. Wang joined the Division of Quantitative Methods and Modeling of ORS OGD as an ORISE Fellow in October 2020, and she worked on multiple projects including data imputation methodology for clinical trials and incorporating machine learning algorithms to enhance product-specific guidance (PSG) review efficiency and bioequivalence (BE) assessment.

Fang Wu, PhD
Senior Pharmacologist/Scientific Lead
DQMM | ORS | OGD | CDER | US FDA

Dr. Fang Wu is a senior pharmacologist reviewer and scientific lead for oral Physiologically based Pharmacokinetic modeling in the Division of Quantitative Methods and Modeling. Dr. Wu has been with the FDA for more than 10 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 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.

Eleftheria Tsakalozou, PhD
Senior Pharmacologist
DQMM | ORS | OGD | CDER | US FDA

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.

Panelists

Yuqing Gong, PhD
Pharmacologist
DQMM | ORS | OGD | CDER | US FDA
(See Biography above)

Jing Wang, PhD
Research Fellow
DQMM | ORS | OGD | CDER | US FDA

Fang Wu, PhD
Acting Team Lead
DQMM | ORS | OGD | CDER | US FDA
(See Biography above)

Eleftheria Tsakalozou, PhD
Senior Pharmacologist
DQMM | ORS | OGD | CDER | US FDA
(See Biography above)

Zhen Zhang, PhD
Senior Pharmacologist
DB I | OB | OGD | CDER | US FDA
(See Biography above)

Stella Grosser, PhD
Director
Division of Biometrics VIII (DB VIII) | Office of Biostatistics (OB) | OTS | CDER

Stella Grosser is Director, Division of Biometrics 8 in the Office of Biostatistics, CDER. This division provides statistical support to the Office of Generic Drugs. She has been at the FDA for 21 years, beginning as a statistical reviewer for new drug products and serving as a team leader before assuming her current position. Dr. Grosser received her PhD in biostatistics from UCLA and spent several years there afterwards as an assistant professor in the School of Public Health.

Day 2, Session 8

Session Leads

Lei Zhang, PhD,
Deputy Director,
ORS | OGD | CDER | US FDA
(See Biography above)

Susan Levine, JD
Deputy Director,
DPD | OGDP | OGD | CDER | US FDA

Ms. Levine currently serves as the Deputy Director of the Division of Policy Development in the Office of Generic Drug Policy where she leads development and implementation of policies for the generic drug program. Prior to this role, she was a Regulatory Counsel in the Office of Generic Drug Policy's Division of Legal and Regulatory Support where she resolved application-specific regulatory issues. She began her FDA career as a Review Chemist in the Office of Generic Drugs where she reviewed abbreviated new drug applications with a variety of dosage forms including topicals, injectables, ophthalmics, otics, and immediate release tablets. Ms. Levine received her B.S. degree in Chemical Engineering from the University of Maryland, College Park, and her J.D. from the University of Baltimore School of Law.

Speakers

Robert Lionberger, PhD
Director
ORS | OGD | CDER | US FDA

Robert Lionberger, Ph.D. serves as Director of the Office of Research and Standards (ORS) in the Office of Generic Drugs (OGD). Dr. Lionberger 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 meetings, product specific guidance and correspondence responses. He received his undergraduate degree from Stanford University in Chemical Engineering, and a PhD from Princeton University in Chemical Engineering. After his Ph.D., he conducted post-doctoral research in Australia in the Department of Mathematics and Statistics at the University of Melbourne. Prior to joining the FDA 18 years ago, he was an Assistant Professor of Chemical Engineering at the University of Michigan.

Susan Levine, JD
Deputy Director,
DPD | OGDP | OGD | CDER | US FDA
(See Biography above)

Rosanne Pagaduan, PharmD
Supervisory Pharmacist
Division of Filing (DFR)
Office of Regulatory Operations (ORO) | OGD | CDER | US FDA

Rosanne Pagaduan is a Supervisory Pharmacist in the Division of Filing Review (DFR) within the Office of Regulatory Operations in the Office of Generic Drugs. In 2014, Rosanne began her FDA career as an Abbreviated New Drug Application (ANDA) Filing Reviewer in DFR then subsequently served as a Team Leader before entering her current role as supervisor. Prior to the FDA, Rosanne received her Bachelor of Science in Microbiology and Cell Science and her Doctorate of Pharmacy from the University of Florida. She also worked as a retail pharmacist for several years before joining the Agency.

Pamela Dorsey, PhD
Pharmacologist
DB III | OB | OGD | CDER | US FDA

Dr. Pamela Garner Dorsey is a Senior Pharmacologist in the Office of Bioequivalence, Division of Bioequivalence III within the Office of Generic Drugs. She currently serves as a primary and secondary assessor for bioequivalence review. Dr. Dorsey received a B.S. and M.S. in Chemical Engineering from North Carolina Agricultural and Technical State University, and a Ph.D. in Pharmaceutical Science from The University of Georgia. Dr. Dorsey has been with the Agency for over 8 years.

Heather Boyce, PhD
Acting Team Lead
DTP II | ORS | OGD | CDER | US FDA

Dr. Heather Boyce works for the Office of Research and Standards, Office of Generic Drugs, Center for Drug Evaluation and Research at the Food and Drug Administration in White Oak, MD. Heather has over 10 years of experience in the pharmaceutical industry including expertise in good manufacturing processes (GMP), pharmaceutical product development, bioequivalence trial design and analysis, and generic drug regulation. Heather currently leads the development of product specific guidance development for modified release oral drug products. Heather's current topics of interest and research are focused on clinical study design, clinical pharmacology, and modified release oral drug products. Heather received her PhD in Pharmaceutical Sciences at the University of Maryland, Baltimore, School of Pharmacy where her research focused on excipient properties and formulation design of abuse deterrent formulations. She received her Bachelor of Science degree in chemistry with a minor in mathematics from Temple University of Philadelphia, PA. Heather can be reached at heather.boyce@fda.hhs.gov.

Panelists

Robert Lionberger, PhD
Director
ORS | OGD | CDER | US FDA
(See Biography above)

Susan Levine, JD
Deputy Director,
DPD | OGDP | OGD | CDER | US FDA
(See Biography above)

Rosanne Pagaduan, PharmD
Supervisory Pharmacist
Division of Filing (DFR)
Office of Regulatory Operations (ORO) | OGD | CDER | US FDA
(See Biography above)

Pamela Dorsey, PhD
Pharmacologist
DB III | OB | OGD | CDER | US FDA
(See Biography above)

Heather Boyce, PhD
Acting Team Lead
DTP II | ORS | OGD | CDER | US FDA
(See Biography above)

CDR Andrew Fine, PharmD
Senior Advisor
DCR | OSCE | OGD | CDER| US FDA
(See Biography above)

Arlene Figueroa, JD
Regulatory Counsel
Division of Legal & Regulatory Support (DLRS) | OGDP | OGD | CDER | US FDA

Arlene Brens Figueroa joined the FDA in 2020 and serves as a Regulatory Counsel in the Office of Generic Drugs/Office of Generic Drug Policy within CDER. Arlene provides policy consultation on the generic drug regulatory review process within FDA, such as the implementation of the Hatch-Waxman Amendments to the FD&C Act, pertinent regulations, and FDA guidance documents. She previously worked for the Social Security Administration as an Attorney Advisor for 11 years. Arlene received her J.D. from Indiana University — Maurer School of Law in 2005 and her B.A. from Syracuse University in 2002.

Day 2, Closing Remarks

Robert Lionberger, PhD
Director
ORS | OGD | CDER | US FDA
(See Biography above)