SPEAKER BIOGRAPHIES

In order of presentations (see the Agenda)

Day 1

Keynote

Janet Woodcock, MD
Acting Commissioner
US Food and Drug Administration (US FDA)

Janet Woodcock was named Acting Commissioner of Food and Drugs on January 20, 2021.

As Acting Commissioner, Dr. Woodcock oversees the full breadth of the FDA portfolio and execution of the Federal Food, Drug, and Cosmetic Act and other applicable laws. This includes assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices; the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation; and the regulation of tobacco products.

Dr. Woodcock began her FDA career in 1986, joining the agency's Center for Biologics Evaluation and Research (CBER) as Director of the Division of Biological Investigational New Drugs, as well as serving as CBER's Acting Deputy Director for a period of time. She later became Director of the Office of Therapeutics Research and Review in CBER, which included the approval of the first biotechnology-based treatments for multiple sclerosis and cystic fibrosis during her tenure.

In 1994, Dr. Woodcock was named Director of the FDA's Center for Drug Evaluation and Research (CDER), overseeing the center's work that is the world's gold standard for drug approval and safety. There she led many of the FDA's drug initiatives, including introducing the concept of risk management as a new approach to drug safety; modernizing drug manufacturing and regulation through the Pharmaceutical Quality for the 21st Century Initiative; advancing medical discoveries from the laboratory to consumers more efficiently under the Critical Path Initiative; and launching the Safety First and Safe Use initiatives designed to improve drug safety management within and outside the FDA, respectively.

In 2004, Dr. Woodcock became Deputy Commissioner and Chief Medical Officer in the Office of the Commissioner. Later she took on other executive leadership positions in the Commissioner's Office, including Deputy Commissioner for Operations and Chief Operating Officer.

In 2007, Dr. Woodcock returned as Director of CDER until she was asked to lend her expertise to "Operation Warp Speed" for developing therapeutics during the COVID-19 pandemic, such as evaluating the potential benefits of monoclonal antibody treatments for certain COVID-19 patients. From late 2020, she split her time advising "Operation Warp Speed" on advancing COVID-19 therapeutics while also serving as the Principal Medical Advisor to the Commissioner on key priorities on behalf of the Office of the Commissioner.

Dr. Woodcock holds a Bachelor of Science in chemistry from Bucknell University (Lewisburg, PA), and a Doctor of Medicine from the Feinberg School of Medicine at Northwestern University Medical School (Chicago). She also completed further training and a fellowship in rheumatology, as well as held teaching appointments at the Pennsylvania State University and the University of California in San Francisco. She is board certified in internal medicine.

Dr. Woodcock has been bestowed numerous honors over her distinguished public health career, most notably: A Lifetime Achievement Award in 2015 from the Institute for Safe Medication Practices; the Ellen V. Sigal Advocacy Leadership Award in 2016 from Friends of Cancer Research; the Florence Kelley Consumer Leadership Award in 2017 from the National Consumers League; and the 2019 Biotechnology Heritage Award from the Biotechnology Innovation Organization and Science History Institute.

Session 1

Session Leads

Liang Zhao, PhD *Director* Division of Quantitative Methods and Modeling (DQMM) Office of Research and Standards (ORS) OGD | CDER | US FDA	**Bing Li, PhD** *Acting Associate Director for Scientific Innovation* Office of Bioequivalence (OB) OGD | CDER | US FDA

Liang Zhao, PhD
Director
Division of Quantitative Methods and Modeling (DQMM)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD) | Center for Drug Evaluation and Research (CDER) | U.S. 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 makings in regulatory and industrial settings for generic and new drugs. He initially joined the FDA as a clinical pharmacology reviewer in the Office of Clinical Pharmacology in 2009 and worked as a team leader in the Division of Pharmacometrics in 2013-2015. Prior to joining FDA, he worked at Medimmune for biotech products, BMS for small molecule drug development, and Pharsight as an associate consultant for new drug R&D. Dr. Zhao has a diversified educational backgrounds in Pharmaceutical Sciences, Applied Statistics, and Business Administration.

Bing Li, PhD
Acting Associate Director for Scientific Innovation
Office of Bioequivalence (OB)
OGD | CDER | US FDA

Dr. Bing V. Li serves as Acting Associate Director for Scientific Innovation for Office of Bioequivalence within the Office of Generic Drugs. 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 Office of Bioequivalence. Dr. Li is an Expert Pharmacologist at the FDA in the area of 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

Mitchell Frost, MD
Acting Deputy Director
Division of Therapeutic Performance II (DTP II)
ORS | OGD | CDER | US FDA
Dr. Mitchell Frost serves as Acting Deputy Director of the Division of Therapeutic Performance II, Office of Research and Standards, Office of Generic Drugs, CDER/FDA. Since his joining the Office of Research and Standards in 2016, Dr. Frost has been helping to oversee GDUFA-funded clinical research and to manage clinical issues related to product-specific guidance development and pre-application support. One of Dr. Frost's main focuses is on the protection of the human subject participants of clinical studies. He has served on FDA's Institutional Review Board (IRB) and currently serves as a Human Subject Protection Liaison to the FDA IRB and the Office of the Chief Scientist.

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

Dr. Yuqing Gong is currently a Visiting Associate at Division of Quantitative Methods & Modeling (DQMM), Office of Research and Standards (ORS), Office of Generic Drugs (OGD) at FDA. Dr. Gong received her Ph.D. in Pharmaceutical Science from the University of Tennessee Health Science Center. She joined FDA after her graduation in March 2020. Her current research interests include population pharmacokinetics (PPK), modeling and simulations, and clinical pharmacology-related bioequivalence (BE) evaluations.

Gloria Huang, PhD
Lead Chemist
Division of Liquid-Based Products II (DLBP II)
Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Quality (OPQ) | CDER | US FDA

Gloria Huang joined the FDA in 2010 and has served as a Chemist, Lead Chemist, and acting Quality Assessment Lead in the Liquid-Based Drug Product Division of the Office of Lifecycle Drug Products. She has extensive experience in reviewing a wide variety of complex dosage forms for different routes of administrations including NTI drugs, drug-device combination products, antibiotics, and peptides. She is a member of the CDER's various working groups drafting MOUs, MaPPs, and Guidance documents. She has also served as the FDA Liaison for the USP Chemical Medicine 5 Expert Committee. Prior to joining the FDA, Gloria worked at USP and served in various leadership roles in which she managed a group of scientists in reference standards development and evaluation. Gloria has also worked in the pharmaceutical industry on drug product research and development. Gloria Huang has a Ph.D. and B.S in Chemistry and a Master's in Environmental Engineering.

Kairui (Kevin) Feng, PhD
Staff Fellow
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.

Q&A Panel

Mitchell Frost, MD *Acting Deputy Director* DTP II | ORS | OGD | CDER US FDA (see biography above)	**Yuqing Gong, PhD** *Pharmacologist* DQMM | ORS | OGD | CDER US FDA (see biography above)	**Gloria Huang, PhD** *Lead Chemist* DLBP II | OLDP | OPQ | CDER US FDA (see biography above)
Kairui (Kevin) Feng, PhD *Staff Fellow* DQMM | ORS OGD | CDER | US FDA (see biography above)	**Kimberly Witzmann, MD** *Deputy Director,* OSCE & *Acting Director* Division of Clinical Review (DCR) OSCE | OGD | CDER | US FDA	**Stella C. Grosser, PhD** *Director* Division of Biometrics VIII (DB VIII) OB | OTS | CDER | US FDA *(see biography below)*

Kimberly Witzmann, MD
Deputy Director
Office of Safety and Clinical Evaluation (OSCE)
OGD | CDER | US FDA
And *Acting Director*
Division of Clinical Review (DCR)
OSCE | OGD | CDER | US FDA

Dr. Kimberly Witzmann is a physician, and the Deputy Director for the newly created Office of Safety and Clinical Evaluation within the Office of Generic Drugs (CDER), at FDA. The Office of Safety and Clinical Evaluation was formed as part of a recent reorganization within OGD and was able to consolidate the groups within OGD that address issues related to clinical safety, substitutability, and therapeutic equivalence, throughout the generic product's lifecycle. As the Deputy Office Director, she is responsible for concentrating on complex, long-range and emerging problems, and issues in the area of clinical evaluation of generic drug products in ANDAs, and she serves as the authority on clinical review issues, and complex combination products. She is committed to making safe and effective generic drugs available to the American public. Dr. Witzmann has been with OGD for more than 6 years; prior to the reorganization, Dr Witzmann served as the acting Deputy Director in the Office of Bioequivalence (OB), and before that role, she was team leader for the inhalation, nasal, and generic drug-device combination products team, in the Division of Therapeutic Performance (DTP), Office of Research and Standards. During her time in OGD, she has focused on communications with industry for complex drug products. She has spoken at national meetings discussing development for generic orally inhaled and nasal combination drug products, as well as user interface considerations for complex generic combination products; she has been a co-author on several medical articles published in peer-reviewed journals. She has been with FDA-CDER for almost 12 years, having spent her first 5 years in CDER's Office of New Drugs. Prior to joining FDA in 2009, Dr. Witzmann was an assistant Professor of pediatrics at Children's National Medical Center in Washington, DC. She has prior experience working with the pharmaceutical industry as a member of medical advisory boards and has served as a primary investigator on a number of clinical research protocols involving lung diseases.

Stella C. Grosser, PhD
Director
Division of Biometrics VIII (DB VIII)
Office of Biostatistics (OB)
Office of Translational Sciences (OTS) | CDER | US FDA

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.

Session 2

Session Leads

Wei-Jhe Sun, PhD *Visiting Associate* *Division of Bioequivalence* ORS | OGD | CDER | US FDA	**Fang Wu, PhD** *Scientific Lead* DQMM ORS | OGD | CDER | US FDA	**Rong Wang, PhD** *Acting Associate Director* Division of Biometrics I (DB I) OB | OGD | CDER | US FDA

Wei-Jhe Sun, PhD
Visiting Associate
Division of Bioequivalence
ORS | OGD | CDER | US FDA

Dr. Wei-Jhe Sun joined the FDA in 2018 and is currently a visiting associate in Office of Research and Standards at the Office of Generic Drugs. He has been working and collaborating on several projects to provide new standards for FDA to evaluate generic drug equivalence. Prior to joining FDA, he worked in the pharmaceutical industry as a formulator. Dr. Sun received his Ph.D. in Pharmaceutics from the University of Minnesota. He has a variety of research interests, including the formulation design, drug delivery, manufacturing sciences and solid-state pharmaceutics. Throughout his time working in the field, he has published 13 peer-reviewed journal articles.

Fang Wu, PhD
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 Division of Quantitative Methods and Modeling. Dr. Wu has been with FDA for more than 9 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.

Rong Wang, PhD
Acting Associate Director
Division of Biometrics I (DB I)
OB | OGD | CDER | US FDA

Dr. Rong Wang is currently the acting associate director in the Division of Bioequivalence I (DBI), Office of Bioequivalence (OB), Office of Generic Drugs (OGD). Dr. Wang has worked as a pharmacologist in OB for over ten years and accrued extensive knowledge and experiences in generic drug bioequivalence evaluation. She supervises DBI scientists in conducting bioequivalence assessment of abbreviated new drug applications (ANDAs) and addressing inquiries submitted by applicants through control correspondences and meetings such as post complete response meetings and mid-cycle meetings. Dr. Wang also actively participates in various working groups within the Agency where she has contributed her expertise and experiences in revising or developing general guidance for ANDA submission and establishing work process for ANDA assessment. Dr. Wang received her undergraduate degree in pharmacy from Shanghai Medical University and her Ph.D. in Microbial and Biochemical Pharmaceutical Science from Institute of Medicinal Biotechnology, Chinese Academy of Medical Science & Peking Union Medical College in China. Dr. Wang also earned her Pharm.D. from University of Florida. Prior to joining FDA, she had worked as a clinical pharmacist at University of California San Francisco Medical Center.

Speakers

Saeid Raofi, MS
Pharmacologist
DTP II | ORS | OPQ | CDER | US FDA

Saeid Raofi earned a Bachelor of Arts degree in Economics in 1990 and a Master of Science degree in pharmacology in 1999 from the University of Texas at Austin. He has several years of experience conducting health care and drug related research and regulatory work for a variety of government agencies at state and federal level. He has been with the U.S. Food and Drug Administration, Office of Generic drugs since 2008 conducting abbreviated new drug applications assessments and regulatory research.

Manar Al-Ghabeish, PhD
Staff Fellow
Division of Product Quality Research (DPQR)
OTR | OPQ | CDER | US FDA

Manar Al-Ghabeish received her B.S. in Pharmacy and M.S. in Pharmaceutical Sciences from University of Jordan and she earned her Ph.D. in Pharmaceutics from University of Iowa. She is a pharmacologist in OTR. The area of research she has been involved in includes: Complex drugs and dosage forms, nasal drug delivery, gastrointestinal local acting drugs and abuse deterrent formulations (ADFs). She is also a trained CMC assessor for NDA/ANDA. She is the assigned primary assessor for several ADF ANDAs including the recent approved ANDA (ANDA 208269

Fang Wu, PhD
Scientific Lead
DQMM | ORS | OGD | CDER | US FDA
(see biography above)

Melanie Mueller, PharmD, PhD
Team Lead, Lead Toxicologist
Division of Pharmacology / Toxicology Review (DPTR)
OSCE | OGD | CDER | US FDA

Dr. Melanie Mueller is a Lead Toxicologist for the Division of Clinical Review in OGD's Office of Bioequivalence. In this role Dr. Mueller guides and mentors Pharmacology and Toxicology assessors to conduct comprehensive, data-driven safety reviews, that are aligned with CDER Pharmacology/Toxicology principles. Dr. Mueller is an active member of several CDER-wide working groups and Pharm/Tox subcommittees with efforts ranging from standardizing internal technical review processes to outreach to industry with the goal of increasing quality submissions of generic application packages. Prior to joining FDA in 2014, Dr. Mueller was a postdoctoral fellow at the Johns Hopkins School of Medicine, a doctoral fellow at the Johns Hopkins School of Medicine, a visiting research scholar at the National Institute on Drug Abuse, and an adjunct faculty member at Stevenson University (Maryland, US). Dr. Mueller has a PharmD from the University of Saarland (Germany) and a PhD in Pharmaceutical Sciences from the University of Saarland (Germany).

Q&A Panel

Saeid Raofi, MS	**Manar Al-Ghabeish, PhD**	**Fang Wu, PhD**	**Melanie Mueller, PharmD, PhD**	**Xiaoming Xu, PhD**	**Heather Boyce, PhD**
Pharmacologist DTP II | ORS | OPQ CDER | US FDA *(see biography above)*	*Staff Fellow* Division of Product Quality Research (DPQR) OTR | OPQ | CDER | US FDA *(see biography above)*	*Scientific Lead* DQMM | ORS | OGD CDER | US FDA *(see biography above)*	*Team Lead, Lead Toxicologist* Division of Pharmacology / Toxicology Review (DPTR) OSCE | OGD | CDER | US FDA *(see biography above)*	*Lab Chief, Branch III* DPQR | OTR | OPQ | CDER | US FDA	*Acting Team Lead* DTP II | ORS | OGD | CDER | US FDA

Xiaoming Xu, PhD
Lab Chief, Branch III
DPQR | OTR | OPQ | CDER | US FDA

Dr. Xiaoming Xu serves as the Lab Chief of the Branch 3 in Division of Product Quality Research in Office of Testing and Research, where he leads multiple research areas including complex formulations, abuse-deterrent formulations, and advanced manufacturing. Dr. Xu is a member of the FDA Nanotechnology Task Force and CDER Nanotechnology Working Group. As the FDA representative, Dr. Xu also participates in various international collaborations in areas relating to nanotechnologies, including standard development and International Pharmaceutical Regulator's Program.

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 immediate release oral drug products. Heather's current topics of interest and research are focused on clinical study design, clinical pharmacology, and generic equivalency of abuse deterrent formulations. 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.

Session 3

Session Leads

Pahala Simamora, PhD *Director* DLBP II |OLDP OPQ | CDER | US FDA	**Darby Kozak, PhD** *Deputy Director* Division of Therapeutic Performance I (DTP I) ORS | OGD | CDER | US FDA

Pahala Simamora, PhD
Director
DLBP II |OLDP

OPQ | CDER | US FDA

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 for liquid-based drug products such as injectables, topical liquids/semisolids, ophthalmic, otic, nasal, inhalation and oral liquid products and making risk-informed recommendations on their approvability. Dr. Simamora joined the FDA in 2010 as a Chemistry Reviewer in OGD. Prior to joining the FDA, he spent 14 years in pharmaceutical industry with industrial experience in product development, process development, scale-up and validation. 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.

Darby Kozak, PhD
Deputy Director
Division of Therapeutic Performance I (DTP I)
ORS | OGD | 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).

Speakers

Wenlei Jiang, PhD
Senior Science Advisor
Immediate Office (IO)
ORS | OGD | CDER | US FDA

Dr. Wenlei Jiang currently serves as Senior Science Advisor at the Office of Research and Standards (ORS)/Office of Generic Drugs (OGD)/Center for Drug Evaluation and Research (CDER)/U.S. FDA. She is leading complex drug product classification and research, promoting global harmonization of bioequivalence criteria, developing opportunities for scientific outreach, and coordinating post-market generic drug safety investigation. She is current Co-chair of International Pharmaceutical Regulator Program (IPRP) Nanomedicine Working Group, Chair at Product Quality Research Institute (PQRI) Steering Committee and serves at National Cancer Institute (NCI) Nanotechnology Characterization Laboratory (NCL) Scientific Oversight Committee. Prior to joining FDA, she was at Novartis Pharmaceutical Corporation where her responsibilities included formulation development of conventional liquid and solid dosage forms, as well as advanced parenteral drug delivery systems. She received her PhD in Pharmaceutics and Pharmaceutical Chemistry from The Ohio State University.

Yiwei Li, PhD
Branch Chief
Division of Pharmaceutical Manufacturing IV (DPMA IV)
Office of Pharmaceutical Manufacturing Assessment (OPMA)
OPQ | CDER | US FDA

Yiwei Li is currently serving as a Branch Chief in the Office of Pharmaceutical Manufacturing Assessment (OPMA) within the Office of Pharmaceutical Quality (OPQ) at the FDA. He supports the assessment of drug product quality and manufacturing processes and facilities for liquid-based dosage forms intended for oral, topical, parenteral, and ophthalmic routes. Prior to joining the FDA in 2014, Dr. Li was a research fellow at Merck Research Laboratories and Inception Science. He received his B.Sc. in Chemistry from Peking University (Beijing, China), M. Sc. in Chemistry from University of Guelph (Guelph, Canada), and Ph.D. in Organic Chemistry from The Scripps Research Institute (California, USA). Outside of work, Dr. Li enjoys spending time with family, hiking, and traveling.

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

Dr. Bin Qin is currently 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 GUDFA 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.

Q&A Panel

Wenlei Jiang, PhD *Senior Science Advisor* IO | ORS | OGD CDER | US FDA *(see biography above)*	**Yiwei Li, PhD** *Branch Chief* DPMA IV | OPMA OPQ | CDER |US FDA *(see biography above)*	**Bin Qin, PhD** *Staff Fellow* DTP I | OGD CDER | US FDA *(see biography above)*	**Bruce Lerman, PhD** *Lead Pharmacologist* DB I | OB | OGD CDER | US FDA	**Darby Kozak, PhD** *Deputy Director* DTP I ORS | OGD CDER | US FDA *(see biography above)*

Bruce Lerman, PhD
Lead Pharmacologist
DB I | OB | OGD | CDER | US FDA

Dr. Bruce Lerman, Ph.D., is currently a Lead Pharmacologist in the Division of Bioequivalence I in the Office of Bioequivalence. Dr. Lerman leads a team of pharmacologists assessing bioequivalence of a wide array of generic drug products. One area of focus for Dr. Lerman is the assessment of iron colloidal products including being part of a multi-disciplinary team involved in developing the product specific guidance for generic drugs referencing Venofer Injection. Dr. Lerman also serves on the Narrow Therapeutic Index Working Group within the Office of Generic Drugs. Dr. Lerman received his Ph.D. in Pharmacology from George Washington University.

Session 3-2

Session Leads

Pahala Simamora, PhD *Director* Division of Liquid Based Products II (DLBP II) OLDP | OPQ | CDER | US FDA *(see biography above)*	**Darby Kozak, PhD** *Deputy Director* Division of Therapeutic Performance I (DTP I) ORS | OGD | CDER | US FDA *(see biography above)*

Speakers

Chunsheng Zhao, PhD
Bioequivalence Reviewer
Division of Bioequivalence III (DB III)
OB \|OGD \| CDER \| US FDA

Dr. Chunsheng Zhao serves as a Bioequivalence reviewer in the Division of Bioequivalence III, Office of Bioequivalence (OB), Office of Generic Drugs (OGD). She received her Ph.D. in Medicinal Chemistry from School of Pharmacy, University of Washington. She obtained her M.S in Organic Chemistry from Shanghai Institute of Materia Medica, Chinese Academy of Sciences, and B.S. in Pharmacy from Tongji Medical University, School of Pharmacy, China.

Poonam Chopra, PhD
Review Chemist
DLBPII \| OPQ \| CDER \| US FDA

Dr. Poonam Chopra is currently working as a Chemist in the Office of Pharmaceutical Quality (OPQ) at the US Food and Drug Administration (US FDA). Prior to joining the Agency, Dr. Chopra received her B.S. and M.S degrees in Biological Sciences from Panjab University, Chandigarh, India. She earned her Ph.D. in Pharmaceutics from the University of Cincinnati, Ohio in Pharmaceutics in Ocular Iontophoresis of Nanocarriers for Sustained Drug Delivery to the Eye. She worked as a Research Scientist in Cincinnati Children's Hospital Medical Center prior to joining FDA. Dr. Chopra has several publications in the field of Formulation and Ocular Drug Delivery. Since past 7 years she has been working at the FDA assessing Chemistry Manufacturing and Controls (CMC) aspects in applications for generic drug products such as Ophthalmic, Otic, Oral, Parenteral, Topical including Drug-Device Combination Products. She has received multiple awards in recognition to her contributions towards regulatory science within US FDA.

Mingliang Tan, PhD
Staff Fellow
DQMM \| OGD \| CDER \| US FDA

Dr. Ming-Liang Tan is a Staff Fellow in the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS), Office of Generic Drugs (OGD). In his current role, Dr. Tan's responsibilities include managing research projects to support bioequivalence studies, addressing controlled correspondences and citizen petitions, providing response to pre-ANDA meeting requests and internal consults, and developing product specific guidance. His main research interests include the physiologically-based pharmacokinetics (PBPK) modeling and simulations, with a focus on the area of locally-acting complex products such as ophthalmic drug products.

Q&A Panel

Chunsheng Zhao, PhD *Bioequivalence Reviewer* DB III | OB OGD | CDER | US FDA *(see biography above)*	**Poonam Chopra, PhD** *Review Chemist* DLBPII OPQ | CDER | US FDA *(see biography above)*	**Mingliang Tan, PhD** *Staff Fellow* DQMM | OGD CDER | US FDA (*See biography above)*	**Asif Rasheed, PhD** *Senior Chemist* DLBP I | OLDP |OPQ CDER | US FDA	**Kai Kwok, PhD** *Senior Pharmaceutical Quality Assessor* DLBP II | OLDP |OPQ CDER | US FDA

Asif Rasheed, PhD
Senior Chemist
DLBP I | OLDP |OPQ | CDER | US FDA

Dr. Asif Rasheed is a Senior 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 has served 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.

Kai Kwok, PhD
Senior Pharmaceutical Quality Assessor
DLBP II | OLDP |OPQ | CDER | US FDA

Kai Kwok is a Senior Pharmaceutical Quality Assessor in the Division of Liquid-based Drug Products. In this role, he acts as the application technical lead for integrated quality assessment of generic parenteral, ophthalmic, topical, oral and inhalation solution drug products. For the past 7 years, he has been reviewing ANDA, Bio-IND, and Pre-ANDA meeting packages involving with complex drug products. Also, he served as a FDA liaison in the USP Packaging and Distribution Expert Committee for developing USP packaging chapters and standards and as a member for development of FDA guidance for drug delivery performance of drug-device combination products. Prior to FDA, he spent over 10 years as a formulation scientist for drug product and manufacturing process development in pharmaceutical companies. He received his B.S. in Pharmacy from Temple University and Ph.D. in Pharmaceutical Sciences from University of Michigan.

Closing

Lei Zhang, Ph.D.
Deputy Director
ORS | OGD | CDER | U.S. FDA

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 23 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 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 Leads

Lei Zhang, Ph.D. *Deputy Director* ORS | OGD | CDER | U.S. FDA *(see biography above)*	**Lanyan (Lucy) Fang, Ph.D.** *Acting Deputy Director* DQMM | ORS | OGD | CDER | US FDA

Lanyan (Lucy) Fang, Ph.D.
Acting Deputy Director
DQMM | ORS | OGD | CDER | US FDA

Dr. Lanyan (Lucy) Fang currently serves as acting Deputy Director and has served as Associate Director of the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards, since February 2019. Prior to that, she served as Team Lead of the Quantitative Clinical Pharmacology team within DQMM for 5 years. She has established herself as the FDA expert in the use of quantitative clinical pharmacology approaches in the review and regulation of generic drugs. She co-leads CDER work group tasked with the use of partial area under the curve for the bioequivalence assessment. Dr. Fang also served as the co-chair of Generic Drug Science Committee in 2018 and moderated the 2018 Generic Drug Science Day. Prior to her current position, 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 PhD in Pharmaceutical Sciences from The Ohio State University and is a graduate of the Excellence in Government Fellows program (2014-2015).

Speakers

Meng Hu, Ph. D.
Acting Team Lead
DQMM | ORS | OGD | CDER | US FDA

Dr. Meng Hu received both his Bachelor of Engineering in Biomedical Engineering and Ph.D. in Physics from the Zhejiang University, China. He conducted his post-doctoral training at Drexel University, Philadelphia. He joined the FDA's Center for Drug Evaluation & Research as a staff fellow in 2015 and currently serves as a scientific lead in the Division of Quantitative Methods and Modeling under the Office of Research and Standards in the Office of Generic Drugs. His main research interests include the development and application of advanced data analytics tools to promote business intelligence in government, big data management, generation of real-world evidence, and quantitative methods to facilitate assessment for in-vitro bioequivalence study. His published works include machine learning (ML) based time-to-event analysis, predictive analysis of first abbreviated new drug application (ANDA) submission for new chemical entities based on ML methodologies, equivalence assessment of complex particle size distribution, quantitative method to facilitate active pharmaceutical ingredient (API) sameness assessment for complex peptide products, and analysis of dissolution failure of solid oral drug products in field alert reports.

Miyoung Yoon, PhD
Acting Team Lead
DQMM | ORS | OGD | CDER | US FDA

Dr. Miyoung Yoon currently serves as the acting Team Lead for the quantitative clinical pharmacology team in the Division of Quantitative Methods and Modeling, Office of Research and Standards, Office of Generic Drugs, CDER/FDA. Since her joining the team in 2019, Miyoung has been leading the team's efforts to conduct regulatory and research activities leveraging clinical pharmacology tools and expertise and actively developing collaborations with multiple stakeholders. Miyoung received her Ph.D. degree in pharmacology/toxicology from the School of Pharmacy at Seoul National University in South Korea and completed her post-doctoral training at the U.S. Environmental Protection

Agency through the National Research Council of the National Academies of Sciences, Engineering, and Medicine's Research Associateship program.

Huzeyfe Yilmaz, PhD
Staff Fellow
Division of Complex Drug Analysis (DCDA)
OTR | OPQ | CDER | US FDA

I am an experienced researcher with background in applied physics (optics and photonics). I have worked on developing novel optical devices and synthesizing new optical materials during my doctoral studies. I have also developed Raman spectroscopy methods for signal enhancement and single nanoparticle sensing. As a materials scientist, I have experience in electron microscopy, spectroscopy and micro/nano fabrication and synthesis by training. During my postdoctoral studies at Washington University, I have developed a chemical sensor based on plasmonic nanoparticles while utilizing chemometric detection algorithms. My experience in combining machine learning approaches in spectroscopy was furthered during my ORISE fellow appointment at FDA. I have developed chemical imaging methods for transdermal drug delivery systems using Raman spectroscopy. I have also developed several methods for cryofixation and electron microscopy imaging of nanomaterial containing drug products. Currently, I am a staff fellow at the Division of Complex Drug Analysis in Office of Testing and Research at CDER/FDA. I am the recipient of two intramural nanotechnology grants as PI and co-PI and I lead several research projects on characterization of complex drugs based on spectroscopy and microscopy methods.

Yan Wang, PhD
Acting Team Lead
DTP I | ORS | OGD | CDER | U.S. FDA

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.

Q&A Panel

Meng Hu, Ph. D. *Acting Team Lead* DQMM | ORS | OGD CDER | US FDA (*See biography above)*	**Miyoung Yoon, PhD** *Acting Team Lead* DQMM | ORS | OGD CDER | US FDA *(See biography above)*	**Huzeyfe Yilmaz, PhD** *Staff Fellow* Division of Complex Drug Analysis (DCDA) OTR | OPQ | CDER | US FDA (*See biography above)*
Yan Wang, PhD *Acting Team Lead* DTP I | ORS | OGD | CDER | U.S. FDA (*See biography above)*	**Robert Lionberger, PhD** *Director* ORS | OGD | CDER | US FDA	**Daniel Willett, PhD** *Chemist* DCDA | OTR | OPQ | CDER | US FDA

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.

Daniel Willett, PhD
Chemist
DCDA | OTR | OPQ | CDER | US FDA

Dr. Daniel Willett is a Chemist in the Division of Complex Drug Analysis withing the Office of Pharmaceutical Quality. Daniel started his FDA career in 2016 as an ORISE Research Fellow before becoming a Chemist in 2017. While at the FDA, he has worked on developing a wide variety of spectroscopic and imaging-based approaches in combination with multivariate data analysis techniques for physicochemical analysis of pharmaceutical products on both the nano and macro scales.

Session 2

Session Leads

Changning Guo, PhD *Supervisory Chemist* DCDA OTR | OPQ | CDER | US FDA	**Michael Spagnola, MD** *Lead Physician* Division of Clinical Safety and Surveillance (DCSS) OSCE | OGD | CDER | US FDA	**Sneha Dhapare, PhD** *Visiting Associate – Pharmacologist* DTP I ORS | OGD | CDER | US FDA

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 focus 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.

Michael Spagnola, MD
Lead Physician
Division of Clinical Safety and Surveillance (DCSS)
OSCE | OGD | CDER | US FDA

Dr. Michael Spagnola is an internal medicine and hospital medicine physician. He currently serves as a lead physician in the Division of Clinical Safety and Surveillance in the Office of Safety and Clinical Evaluation in the Office of Generic Drugs. Dr. Spagnola's focus includes the clinical review of orally inhaled generic products, evaluation of the user interface of complex drug-device generic combination products, and retention of reserve samples for bioequivalence studies. Dr. Spagnola received his M.D. from the George Washington University School of Medicine and Health Sciences.

Sneha Dhapare, PhD
Visiting Associate – Pharmacologist
DTP I | ORS | OGD | CDER | US FDA

Dr. Sneha Dhapare currently serves as Visiting Associate-Pharmacologist in the Division of Therapeutic Performance (DTP), Office of Research and Standards (ORS), Office of Generic Drugs (OGD), Center of Drug Evaluation and Research (CDER) at the FDA. She holds degrees in Bachelor of Pharmacy (2011) from the University of Mumbai, India, Master of Science degree (2013) in Pharmaceutical Sciences from Creighton University, Omaha, NE, and Ph.D. in Pharmaceutical Sciences from Virginia Commonwealth University (2017). She has also worked as is a Postdoctoral Fellow in the Virginia Commonwealth University (2017-2018). In her current role, Sneha is involved in the assessment of proposed generic inhaled and nasal drug products, with respect to the formulation, device, and use-related factors that affect product performance and subsequently the efficacy of these products in patients. Her work includes making recommendations for approach to establishing bioequivalence for generic inhaled and nasal products in the product-specific guidances (PSGs). To inform the PSG development, Sneha is actively involved in the GDUFA-funded research to explore potential tools and methods to establish bioequivalence for complex generic products, including inhalation products. In the past, Sneha has worked in research supported by the National Institutes of Health (NIH) focused on development of inhaled drug products and their in vitro as well as in vivo evaluation with an emphasis on lung delivery. Sneha has published several peer-reviewed manuscripts and abstracts related to aerosol formulation and lung delivery. Sneha has served as an editorial board member and scientific reviewer for high impact factor journals in the areas of aerosol science and pharmaceutics.

Speakers

Susan Boc, PhD
Scientific Researcher
DTPI | 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.

Vipra Kundoor, PhD
Pharmacologist
DB I | OB | OGD | CDER | US FDA

Dr. Vipra Kundoor is a Pharmacologist in the Division of Bioequivalence I within Office of Generic Drugs. She is responsible for assessing the bioequivalence of the various dosage forms of generic drugs. She is also involved in addressing controlled correspondences and pre-ANDA meeting packages. She is the focal point expert for nasal and inhalation drug products within the division and conducts secondary reviews for these complex dosage forms. She is also actively involved in the review panel for the Product-Specific Guidances for nasal and inhalation drug products. Prior to joining FDA in 2010, Dr. Kundoor earned her Ph.D. with specialization in Pharmaceutics at University of Maryland and M.S. with specialization in Pharmacology at South Dakota State University.

Sneha Dhapare, PhD
Visiting Associate – Pharmacologist
DTP I | ORS | OGD | CDER | US FDA
(*See biography above)*

Michael Spagnola, MD
Lead Physician
Division of Clinical Safety and Surveillance (DCSS)

OSCE | OGD | CDER | US FDA
(*See biography above)*

Q&A Panel

Susan Boc, PhD *Scientific Researcher* DTPI | ORS | OGD | CDER US FDA (*See biography above)*	**Vipra Kundoor, PhD** *Pharmacologist* DB I | OB | OGD | CDER | US FDA (*See biography above)*	**Sneha Dhapare, PhD** *Visiting Associate – Pharmacologist* DTP I | ORS | OGD | CDER | US FDA (*See biography above)*	**Michael Spagnola, MD** *Lead Physician* DCSS OSCE | OGD | CDER US FDA (*See biography above)*

Bryan Newman, PhD *Acting Team Lead* DTP I | ORS | OGD CDER | US FDA	**Changning Guo, PhD** *Supervisory Chemist* DCDA | OTR | OPQ | CDER | US FDA (*See biography above)*	**Bing Cai, PhD** *Director* DLBP I | OLDP | OPQ CDER | US FDA

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

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.

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.

Session 3 - 1

Session Leads

Ying Fan, PhD *Team Lead* DCR | OSCE | OGD | CDER | US FDA	**Tannaz Ramezanli, PhD, PharmD** *Staff Fellow* DTP I | ORS | OGD | CDER | US FDA

Ying Fan, PhD
Team Lead
DCR | OSCE | OGD | CDER | US FDA

Dr. Ying Fan is currently a Lead Pharmacologist in the Division of Clinical Review (DCR), Office of Safety and Clinical Evaluation (OSCE), Office of Generic Drug (OGD). In this role, she leads a clinical team of medical officers and pharmacologists responsible for the review of comparative clinical endpoint bioequivalence studies, skin irritation/sensitization/adhesion studies, comparative analysis, submitted to support approval of ANDAs. Her team is also involved in addressing controlled correspondences, pre-ANDA meeting packages, REMs protocols, and citizen petitions. Dr. Ying Fan received her Ph.D. in major of Pharmaceutical Sciences and minor of Statistics from Oregon State University. She joined FDA as a primary reviewer in Office of Clinical Pharmacology, Office of Translational Sciences, supporting new drug approval. During her tenure in the FDA, Dr. Fan made significant contributions to the approval and regulation of local acting drug products and complex generic drug products. She has been an active member on various committees and working groups within FDA. She initiates, leads, or participates in multiple research projects, general guidances and product specific guidances development or revision including topical and transdermal drug products. Over the past 13 years in FDA, she has received numerous awards from CDER/FDA for her dedication and accomplishment as a scientist, reviewer, and leader.

Tannaz Ramezanli, PhD, PharmD
Staff Fellow
DTP I | ORS | OGD | CDER | US FDA

Dr. Tannaz Ramezanli is a pharmacologist within the Office of Research and Standard (ORS) at Office of Generic Drugs (OGD) at the U.S. FDA. 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 leading Pre-ANDA meetings with industry. 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.

Speakers

Megan Kelchen, PhD
Pharmacologist
DTP I | ORS | OGD | CDER | US FDA

Megan Kelchen, Ph.D., is a pharmacologist in the Division of Therapeutic Performance I. Her specialization is drug products for topical, transdermal, and mucosal drug delivery. Dr. Kelchen is responsible for the development of product-specific guidances for generic drug development, reviewing and responding to controlled correspondences, citizens petitions, and pre-ANDA meeting requests. Dr. Kelchen is also engaged in regulatory science research initiatives related to complex generics under the GDUFA regulatory science research program. Prior to joining FDA, Dr. Kelchen received her B.A. degree from Wartburg College in Biology and her Ph.D. in Clinical Pharmaceutical Sciences from the University of Iowa. She joined the FDA as an ORISE (Oak Ridge Institute for Science and Education) post-doctoral fellow in 2018 before moving into her current role.

Sam Raney, PhD
Associate Director for Science
IO | ORS | OGD | CDER | US FDA

Dr. Sam Raney is a thought leader in topical and transdermal drug products, with over 30 years of experience in skin research, producing numerous research manuscripts, review articles, book chapters and patents in pharmaceutical product development. Dr. Raney has been a researcher and adjunct professor within academia, a principal or sub investigator on over 400 pharmaceutical product studies, has held senior management roles in industry, and serves on multiple expert committees and panels for the U.S. Pharmacopeia. He is the Associate Director for Science in the FDA's

Office of Research and Standards and serves as the Chief Scientific Advisor for topical product bioequivalence issues in FDA's Office of Generic Drugs. Dr. Raney holds a bachelor's degree in Molecular Biophysics & Biochemistry from Yale University, and a Ph.D. in Biochemistry & Molecular Biology from the University of British Columbia in Canada.

Ahmed Zidan, PhD
Senior Pharmacologist
DPQR | OTR | OPQ | CDER | US FDA

Dr. Ahmed Zidan is a senior pharmacologist staff in the Division of Product Quality Research of Office of Testing and Research of CDER. Ahmed leads the topical and transdermal drug products laboratories of DPQR and provides hands-on trainings to reviewers on various topics including transdermal delivery systems, in vitro release, and permeation testing of pharmaceuticals, and preformulation consideration for development of topical and oral drug products. In his current role, Dr. Zidan leads the regulatory science research related to topical and transdermal drug products of OPQ. Ahmed leads the research projects of CDER related to the development of in vitro characterization methods for demonstration of bioequivalence of topical products. Dr. Zidan also leads OTR research efforts supporting the development of general and product-specific guidance documents, review strategies for pre-ANDAs and ANDAs and citizen petitions for topical drug products. Ahmed is also an FDA-USP liaison of complex excipients Expert Committee. Ahmed coordinated various workshops and symposia in various national and international events on the regulatory aspects of various dosage forms. His research activities and collaborations produced over 90 publications and 3 book chapter. Prior joining FDA, Dr. Zidan was a professor of Pharmaceutics at Zagazig University and King Abdulaziz University. Ahmed completed his bachelor's degree in pharmacy and master's degree in Zagazig University, and his doctoral degree in Drug Delivery in Zagazig University through a joint supervision program with Howard University, Washington D.C.

Khondoker Alam, PhD
Staff Fellow
DQMM | ORS | OGD | CDER | US FDA

Dr. Khondoker Alam obtained his PhD in Pharmaceutical Sciences at the University of Oklahoma Health Sciences Center in 2017 and completed one year Fellowship in Office of Clinical Pharmacology. Dr. Alam is currently a 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.

Eleftheria Tsakalozuo, PhD
Staff Fellow
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.

Q&A Panel

Megan Kelchen, PhD *Pharmacologist* DTP I | ORS | OGD | CDER | US FDA (*see biography above*)	**Ahmed Zidan, PhD** *Senior Pharmacologist* DPQR | OTR | OPQ | CDER | US FDA (*See biography above)*	**Sam Raney, PhD** *Associate Director for Science* IO | ORS | OGD | CDER | US FDA (*See biography above)*
Khondoker Alam, PhD *Staff Fellow* DQMM | ORS | OGD | CDER | US FDA (*See biography above)*	**Eleftheria Tsakalozuo, PhD** *Staff Fellow* DQMM | ORS | OGD | CDER | US FDA (*See biography above)*	**Markham Luke, MD, PhD** *Director* DTP I | ORS | OGD | CDER | US FDA

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

Markham C. Luke, MD, PhD serves as FDA Supervisory Physician (Dermatology) and Director of the Division of Therapeutic Performance (DTP1) in the Office of Research and Standards, Office of Generic Drugs at FDA. DTP1 is responsible for facilitating pre-application development of complex generic drugs by conducting and promoting regulatory science research to establish standards to ensure therapeutic equivalence of new complex 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 MD degree and a PhD 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.

Session 3 - 2

Session Leads

Ying Fan, PhD *Team Lead* DCR | OSCE | OGD | CDER | US FDA (*See biography above)*	**Tannaz Ramezanli, PhD, PharmD** *Staff Fellow* DTP I | ORS | OGD | CDER | US FDA (*See biography above)*

Speakers

Josephine Aimiuwu, PhD
Pharmacologist
DB II | OB | OGD | CDER | US FDA

Dr. Josephine Aimiuwu is a Pharmacologist/Assessor in the Division of Bioequivalence II (DBII), Office of Bioequivalence (OB), Office of Generic Drugs (OGD). In this role, she assesses the bioequivalence portion of abbreviated new drug applications (ANDA) and post-approval supplements. She joined the FDA in 2010 and has experience evaluating bioequivalence studies for various dosage forms of generic products such as narrow therapeutic drugs, topical non-

corticosteroids and corticosteroids, ophthalmic products and abuse deterrent formulations. She is also involved in addressing pre-ANDA meeting packages and controlled correspondences. Dr. Aimiuwu stepped away from the FDA for four years to work in Bangladesh and Nigeria, where she gained further experience in global regulatory framework as a Senior Technical Advisor with USAID-funded NGOs. In that role, she provided technical assistance and facilitated the leveraging of resources with consortia of global partners to strengthen the countries' Generic Drug Regulatory Program. Dr. Aimiuwu obtained her Ph.D. in Pharmaceutics from The Ohio State University, Columbus, Ohio.

Tannaz Ramezanli, PhD, PharmD
Staff Fellow
DTP I | ORS | OGD | CDER | US FDA
(*See biography above)*

Priyanka Gosh, PhD
Acting Team Lead
DTP I | ORS | OGD | CDER | US FDA

Dr. Priyanka Ghosh is a senior pharmacologist within the Division of Therapeutic Performance. Her areas of expertise include products in the topical and transdermal drug delivery area. In her current role, Dr. Ghosh leads regulatory science research initiatives related to topical and transdermal drug products, including projects related to development of noninvasive imaging techniques for evaluation of cutaneous pharmacokinetics, under the GDUFA regulatory science program. Dr. Ghosh also leads the development of general and product-specific guidances, review strategies for pre-ANDA meeting requests and citizen petitions and is the co-chair of the Bioequivalence Standards for Topicals Committee within OGD. Prior to joining FDA, Dr. Ghosh completed her bachelor's degree in Biotechnology from West Bengal University of Technology (India) and a Ph.D. in Pharmaceutics and Drug Design from the University of Kentucky.

Q&A Panel

Josephine Aimiuwu, PhD	**Tannaz Ramezanli, PhD, PharmD**	**Priyanka Gosh, PhD**	**Markham Luke, MD, PhD**	**Sam Raney, PhD**
Pharmacologist DB II | OB | OGD | CDER | US FDA (*See biography above)*	*Staff Fellow* DTP I | ORS | OGD | CDER | US FDA (*See biography above)*	*Acting Team Lead* DTP I | ORS | OGD | CDER | US FDA (*See biography above)*	*Director* DTP I | ORS | OGD CDER | US FDA (*See biography above)*	*Associate Director for Science* IO | ORS | OGD CDER | US FDA (*See biography above)*

Closing

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