SPEAKER BIOGRAPHIES

In order of appearance

Day 1 Speakers

Janet Woodcock, M.D.
Principal Deputy Commissioner
Office of the Commissioner
US Food and Drug Administration (US FDA)

Janet Woodcock is the FDA's Principal Deputy Commissioner. In this role she works closely with the Commissioner of Food and Drugs to develop and implement key public health initiatives and helps oversee the agency's day-to-day functions.

She served as the Acting Commissioner of Food and Drugs from Jan. 20, 2021, until Feb. 17, 2022.

Dr. Woodcock began her FDA career in 1986 at the Center for Biologics Evaluation and Research (CBER). At CBER, she served as Director of the Division of Biological Investigational New Drugs and as Acting Deputy Director. She later became Director of CBER's Office of Therapeutics Research and Review, which oversaw 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), leading the Center's work that is the world's gold standard for drug approval and safety. There she conceived and implemented 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; launching the Safety First and Safe Use initiatives designed to improve drug safety management within and outside the FDA, respectively; developing the Sentinel Network for drug safety and spearheading CDER efforts on patient-focused drug development.

In 2004, Dr. Woodcock became the FDA's Deputy Commissioner and Chief Medical Officer. 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 be the therapeutics lead for "Operation Warp Speed" in early 2020. This entailed supporting the development, evaluation, and availability of treatments such as monoclonal antibodies and antiviral drugs for patients with COVID-19.

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: the Nathan Davis award from the American Medical Association in 1999; the Roger W. Jones Award for executive leadership from American University in 2000; the VIDA award from the Society for Hispanic Health and the first Leadership Award in Personalized Medicine from the Coalition for Personalized Medicine in 2005; the Garry Neil prize for Innovation in

Drug Development in 2009; a Lifetime Achievement Award in 2015 from the Institute for Safe Medication Practices; 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.

Sally Choe, PhD
Director
Office of Generic Drugs (OGD) | CDER | US FDA

Sally Choe, PhD, serves as the director of the Office of Generic Drugs (OGD), where she is the principal authority on all matters related to generic drug review, and scientific advisor to the Commissioner and other agency officials. Previously, Dr. Choe served as deputy director of the Office of Study Integrity and Surveillance (OSIS) in CDER's Office of translational Sciences (OTS). With more than 18 years of experience in global drug development, Dr. Choe is an accomplished leader in both government and the private sector. She is a recognized expert in drug review, clinical pharmacology, biopharmaceutics, and pharmacokinetics. Dr. Choe was senior director at PAREXEL International Corporation, overseeing the Asia-Pacific region and Japan offices, as well as managing the global Vice President Technical consultant group. From 2006 - 2011, Dr. Choe was leader of the metabolism and endocrinology team in FDA's Office of Clinical Pharmacology, OTS. She supervised scientists in clinical and pharmacology review and evaluation of New Drug Applications (NDAs), Biologics License Application (BLAs), and investigational new drug applications (INDs), including original submissions and amendments. Prior to FDA, she also was a clinical pharmacology manager at Pfizer Global Research and a research investigator at Bristol-Myers Squibb. Dr. Choe earned her master's and doctoral degrees in pharmaceutics from the University of Michigan and her bachelor's degree in electrical engineering from Virginia Polytechnic Institute and State University.

Michael Kopcha, PhD, RPh
Director
Office of Pharmaceutical Quality (OPQ) | CDER) | US FDA

Michael Kopcha, Ph.D., R.Ph. is the Director of the FDA's Office of Pharmaceutical Quality (OPQ). This office has over 1,300 staff responsible for assuring the availability of quality medicines for the American public through assessment, inspection, surveillance, research, and policy. OPQ contributes to the assessment of nearly every type of human drug marketing application including New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and Biologics License Applications (BLAs), including 351(k) applications (i.e., biosimilars). OPQ also performs the quality assessment of Investigational New Drug Applications (INDs) and establishes quality standards for over-the-counter drug products and facilities.

Prior to joining the FDA, Dr. Kopcha amassed more than 25 years of experience in major and mid-sized innovator, generic, drug/device, and over-the counter (OTC) pharmaceutical and consumer health companies. He developed expertise in areas including formulation and process development, product scale-up, process validation, technology transfer, project management, change management, and offshoring/outsourcing. Dr. Kopcha most recently served as Vice President, and global research and development franchise head, for cough, cold, and respiratory products at Novartis Consumer Health, Inc.

Dr. Kopcha earned his doctorate and master's degrees in pharmaceutical science, and a bachelor's degree in pharmacy from Rutgers University. He also served as an adjunct assistant professor in the Department of Pharmaceutics at Ernest Mario School of Pharmacy at Rutgers.

Peter Capella, PhD
Director
Division of Immediate and Modified Release Drug Products | Office of Lifecycle Drug Products
Office of Pharmaceutical Quality (OPQ) | CDER) | US FDA

Peter received a Ph.D. in analytical chemistry from the University of Kansas in 1991. He has over 15 years in pharmaceutical development experience from both the NDA and ANDA side, as well as nearly 15 years at the FDA supporting generic drug quality review across a wide range of therapeutic areas. He has been involved in important FDA initiatives like the PEPFAR program for prioritizing AIDS drugs for developing countries, as well as the current KASA initiative for structured drug product assessment.

Rakhi Shah, PhD
Associate Director
Office of Pharmaceutical Manufacturing Assessment (OPMA)
Office of Pharmaceutical Quality (OPQ) | CDER) | US FDA

Dr. Rakhi Shah is working as associate director for regulatory affairs in OPMA. She serves as the principal advisor to the office and deputy office directors and provides staff leadership and direction in the area of assessment of manufacturing and facilities for A/NDAs, supplements including inspections to support applications approval. Her prior role in FDA includes branch chief in OPMA, team leader in OGD and sr. research scientist in OTR. She is a recognized subject matter expert in the area of pharmaceutical manufacturing and has served on multiple internal and external committees and working groups. She has a Ph.D. in pharmaceutical sciences, M.S. in Bioprocess technology and B.S. in Pharmaceutical Sciences.

Kimberly Raines, PhD
Branch Chief
Division of Biopharmaceutics | Office of New Drug Products
Office of Pharmaceutical Quality (OPQ) | CDER) | US FDA

Dr. Kimberly Raines serves as a Branch Chief responsible for the coordination and management biopharmaceutics assessments conducted for the life cycle of FDA-approved PDUFA and GDUFA drug products. Dr. Raines develops CDER biopharmaceutic guidances, leads research projects within her division, and provides subject matter expertise to FDA policy initiatives. She has co-authored original research articles and presented internationally on in vivo bioequivalence, biowaivers, in vitro dissolution, and physiologically based model informed quality risk assessment. Dr. Raines received her Ph.D. in pharmaceutical sciences from the University of Maryland School of Pharmacy and a B.S. in chemistry from Duke University. Prior to joining the FDA, Dr. Raines completed post-doctoral training at the University of North Carolina Lineberger Comprehensive Cancer Center.

Mayra Pineiro Sanchez, PhD
Senior Pharmaceutical Quality Assessor
Division of Immediate and Modified Release Drug Products | Office of Lifecycle Drug Products
Office of Pharmaceutical Quality (OPQ) | CDER) | US FDA

Mayra possesses over 20 years of experience in CMC assessment of generic products in CDER and currently serves as Senior Pharmaceutical Quality Assessor (SPQA) in the Division of Immediate and Modified Release Products III/Office of Lifecycle Drug Products (OLDP)/Office of Pharmaceutical Quality (OPQ). Mayra also serves as the ANDA Application Technical Lead (ATL) in the multidisciplinary Integrated Quality Assessment (IQA) Team. She provides expert technical guidance in the pre-market quality assessment of generic drug products. In this capacity, she ensures a risk-based approach to the assessment of critical pharmaceutical quality attributes and their relevance to the drug product's safety and effectiveness. Mayra obtained her Bachelor of Science in Chemistry from the University of Puerto Rico and her Ph.D. in Pharmaceutical Chemistry from The University of Michigan. She performed her post-doctoral research at the Lombardi Cancer Center, Georgetown University.

Iilun Murphy, MD
Deputy Director
Clinical and Regulatory Affairs
Office of Generic Drugs (OGD) | CDER | US FDA

Iilun Murphy is the Deputy Director for Clinical and Regulatory Affairs in the Office of Generic Drugs since January 2020. Dr. Murphy began her FDA career in 2007, joining CDER's Office of New Drugs, Division of Gastroenterology and Inborn Errors of Metabolism Products as a medical officer. In 2011, Dr. Murphy transitioned to the newly developed Center for Tobacco Products serving in various leadership roles within the Office of Science until she returned to CDER in 2020. Dr. Murphy holds a Bachelor of Arts from Cornell University and a Doctor of Medicine from Stanford University School of Medicine. She completed the Harvard University and Boston University Combined Residency Program in Pediatrics. She is board certified in pediatric medicine. Dr. Murphy continues to be involved in clinical teaching as an Assistant Clinical Professor of Pediatrics at George Washington University School of Medicine.

Ted Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs (OGD) | CDER | US FDA

Ted Sherwood has been the Director of the Office of Regulatory Operations (ORO) within the Office of Generic Drugs (OGD) since 2014. ORO consists of three divisions: Division of Project Management, Division of Filing Review, and Division of Labeling Review. Previously, he served as the Associate Director of Immediate Office Operations, Office of Pharmaceutical Science [now the Office of Pharmaceutical Quality (OPQ)]. Prior to joining OPQ in 1999, he spent a dozen years in OGD. He held various positions including, reviewing new submissions for determination of fileability, conducting program analyses, and coordinating congressional activities. Ted received his bachelor's degree from the University of Maryland in 1992.

Russell Storms, PhD
Associate Director for Analytics
Office of Regulatory Operations
Office of Generic Drugs (OGD) | CDER | US FDA

Russell Storms is the Associate Director for Analytics in the Office of Regulatory Operations in the Office of Generic Drugs in the FDA's Center for Drug Evaluation and Research. He received a Ph.D. in Computer Science from the Naval Postgraduate School in Monterey, California in 1998. Russell is responsible for the timely and accurate management of all data calls, reporting, and analysis within the Office of Generic Drugs in support of the Generic Drug User Fee Act (GDUFA).

David Holovac, RPh
Data Analyst
Office of Regulatory Operations
Office of Generic Drugs (OGD) | CDER | US FDA

David Holovac is a pharmacist/data analyst in the Office of Regulatory Operations, Office of Generic Drugs. He received his pharmacy degree from Duquesne University. After practicing retail pharmacy, David joined the U.S. Public Health Service as a Commissioned Officer where he attained the rank of Captain prior to his later retirement from the Public Health Service.

During his expansive uniformed service and civilian career, he worked in three different areas: the U.S. PHS Supply Service Center at Perry Point, Maryland as Chief of Bulk Compounding, the Health Resources and Services Administration (HRSA), and the Food and Drug Administration (FDA). David has worked with the Office of Generic Drugs (OGD) for the majority of his career as both a commissioned officer and a civilian. He has supported a multitude of Information Technology (IT) functions and programs and established, programmed, and managed OGD's first information server. He supports IT efforts in OGD and develops and analyzes OGD metrics and reports related to the Generic Drug User Fee Amendments (GDUFA).

Robert Berger

Data Analyst
Analytics Team | Immediate Office
Office of Regulatory Operations
Office of Generic Drugs (OGD) | CDER | US FDA

Robert Berger has worked with the analytics team since 2018 developing reports and documentation and improving data quality. Bob's prior data experience includes four years on the Data Quality Management Team (DQMT) in CDER's Office of Business Informatics, where he analyzed and repaired data problems in CDER's Document Archiving, Reporting and Regulatory Tracking System (DARRTS), and documented DQMT's processes. He also has 30 years of experience intermittently teaching various database programs – both off-the-shelf and custom-built systems – and multiple spreadsheet applications. Bob received his Bachelor of Science in Mechanical Engineering from the University of Maryland, College Park, in 1987.

Andrew Coogan, PharmD
Lieutenant Commander, United States Public Health Service
Division of Legal and Regulatory Support (DLRS)
Office of Generic Drug Policy (OGDP) | CDER | US FDA

Andrew Coogan is a Lieutenant Commander in the United States Public Health Service and a member of the Patent and Exclusivity Team (PET) in the Office of Generic Drug Policy. He joined FDA in 2014 as a Regulatory Project Manager and has been a member of the PET since 2018. Before joining FDA, he was a clinical pharmacist with Indian Health Service on the Navajo Reservation in Arizona. He received his Bachelor of Science in Pharmaceutical Science and his Doctorate of Pharmacy from the University of Pittsburgh and is a Master of Public Health Candidate at the Johns Hopkins Bloomberg School of Public Health.

Derek Smith, PhD
Deputy Director
Office of Pharmaceutical Manufacturing Assessment
Office of Pharmaceutical Quality (OPQ) | CDER) | US FDA

Derek Smith joined FDA in 2010 and has served as compliance officer, CMC assessor, Quality assessment lead, Branch Chief, and Division Director prior to his current role. Derek is the Associate Director of Regulatory Affairs (Acting) for the Office of Pharmaceutical Manufacturing Assessment within OPQ. He provides leadership and oversight for the assessment of the manufacturing process and facilities for biologics and small molecule drug applications with a focus on the integration of application assessment and inspection findings and data reliability assessments. He also serves as the co-chair for the New Inspection Protocol Project (NIPP) initiative for pre-approval inspections and is a member of the Knowledge-aided Assessment and Structured Application (KASA) initiative steering committee. He holds a Ph. D in Chemical and Biochemical Engineering from University of Maryland, Baltimore County.

Geoffrey Wu, PhD, PMP, CPH
CDR, U.S. Public Health Service
Deputy Director
Office of Life Cycle Products (OLDP)
Office of Pharmaceutical Quality (OPQ) | CDER) | US FDA

Commander Geoffrey Wu, Ph.D., PMP, CPH, Deputy Office Director, OLDP, OPQ, joined FDA's OTR in 2010, has served as research scientist, science staff, chemistry reviewer, special assistant to the Office Director, staff supervisor (Division Director equivalent), Associate Director of Sciences and Communication (ADSC), acting Division Director, and Deputy Office Director. He is a scientist officer in the United States Public Health Service. Throughout his FDA tenure, he has been deeply involved, leading or co-leading regulatory review and research for Controlled Correspondence, ANDAs, and supplemental ANDAs and NDAs. Between 2013 and 2017, he served as a founding member on the OPQ Emerging Technology Team (ETT). He was a core member in multiple policy development efforts, such as emerging technology, continuous manufacturing, and comparability protocols. Dr. Wu has training and education in pharmacy, pharmaceutical science, protein chemistry, polymer chemistry, and process analytical technology. He has more than 20 peer-reviewed publications and been invited to multiple national and international conferences to present or discuss the above related topics. His Ph.D. thesis from the University of Utah focused on self-assembly of hybrid hydrogels containing coiled-coils and drug-free macromolecular therapeutics to induce apoptosis by coiled-coiled mediated crosslinking of antigens.

Nilufer Tampal, PhD
Associate Director for Scientific Quality
Immediate Office | Office of Bioequivalence (OB)
Office of Generic Drugs (OGD) | CDER | US FDA

Dr. Nilufer Tampal is the Associate Director for Scientific Quality in OB within OGD. 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 leadership and expertise in utilization of advanced analytic data tools in the assessment of bioequivalence studies submitted in ANDAs. Dr. Tampal serves as the FDA Topic Lead for the ICH Expert Working Group on M13: Bioequivalence for Immediate Release Solid Oral Dosage Forms. Dr. Tampal received her Ph.D. in Toxicology from the University of Kentucky and an M.S. in Chemistry from Bombay University, India. She started her career at the FDA in 2002, as an investigator in the Office of Study Integrity and Surveillance and has held various leadership positions in OB for the last 12 years. Prior to her FDA career, she gained years of experience in synthesis and analysis of small molecules working as chemist at a multinational pharmaceutical company in India.

Shujun Chen, PhD
Senior Pharmaceutical Quality Assessor
Division of Pharmaceutical Manufacturing II (DPM II) | Office of Pharmaceutical Manufacturing Assessment (OPMA)
Office of Pharmaceutical Quality (OPQ) | CDER) | US FDA

Shujun Chen is a Senior Pharmaceutical Quality Assessor (SPQA) in Division of Pharmaceutical Manufacturing II in the Office of Pharmaceutical Manufacturing Assessment (OPMA) in the FDA's Center for Drug Evaluation and Research. She has been serving as a process and facility reviewer in OPMA since Jan. 2015 and an SPQA in ANDA Aligned Team 18 since Aug. 2020. Dr. Chen has been an active participant in industry meetings on Continuous Manufacturing and other advanced manufacturing technologies that were submitted through FDA's Emerging Technology Program. She has represented OPMA at different conferences and working groups on topics from advanced manufacturing to OPMA review policies. Prior to joining FDA, Dr. Chen worked as a polymer consultant at Exponent, a multidisciplinary scientific and engineering consulting company. Dr. Chen holds a Ph.D. in Polymer Science and Engineering from University of Massachusetts Amherst with postdoctoral training in Chemical Engineering at Massachusetts Institute of Technology.

Minglei Cui, PhD
Commander, United States Public Health Service
Team Leader, Division of Bioequivalence II (DBII)
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD) | CDER | US FDA

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

Cynthia (Yiyue) Zhang, PhD, RAC
Senior Staff Fellow
Division of New Drug Study Integrity (DNDSI), Office of Study Integrity and Surveillance Session (OSIS)
Office of Translational Sciences (OTS)
Office of Generic Drugs (OGD) | CDER | US FDA

Dr. Yiyue (Cynthia) Zhang is currently a Senior Staff Fellow with Office of Study Integrity and Surveillance, Office of Translational Sciences, Center for Drug Evaluation and Research (CDER). Dr. Zhang has conducted, coordinated and reviewed comprehensive FDA BIMO clinical and analytical inspections covering BA/BE, PK, PD, immunogenicity and animal rule studies in support of NDA, ANDA, BLA and IND applications. Dr. Zhang has a Ph.D. in Cellular and Molecular Pharmacology and a B.S. in Pharmacy. She completed a postdoctoral fellowship at Johns Hopkins University School of Medicine prior to joining FDA.

Kara Scheibner, PhD
Pharmacologist
Division of Generic Drug Study Integrity (DGDSI)
Office of Study Integrity and Surveillance Session (OSIS)
Office of Translational Sciences (OTS) | CDER | US FDA

Kara A. Scheibner, PhD is a Pharmacologist in the Division of Generic Drug Bioequivalence Evaluation within the Office of Study Integrity and Surveillance/Office of Translational Sciences/Center for Drug Evaluation and Research at the U.S. Food and Drug Administration. Dr. Scheibner earned a B.S. in Pharmacology/Toxicology from the University of Sciences in Philadelphia, Pennsylvania and a PhD in Pharmacology and Molecular Sciences from The Johns Hopkins University School of Medicine in Baltimore, Maryland under the mentorship of Philip A. Cole, M.D, Ph.D. Following postdoctoral training in cell biology/immunology and molecular biology/cancer, she was appointed Assistant Professor at the University of Maryland, School of Medicine in the Center for Stem Cell Biology and Regenerative Medicine where she continued her work in cancer research, specifically assessing the role of microRNAs on hematopoietic and leukemia stem cells. While there, she also taught and co-directed several courses in the graduate school, was a member of the Molecular Medicine admissions committee and multiple thesis committees and mentored/trained students at the graduate and undergraduate levels. Dr. Scheibner joined the FDA as a Pharmacologist in July of 2014.

Victoria Keck, MS, VMD
Team Leader
Division of Pharmacology/Toxicology Review (DPTR)
Office of Safety and Clinical Evaluation (OSCE)
Office of Generic Drugs (OGD) | CDER | US FDA

Dr. Victoria Keck is a Lead Toxicologist and Team Leader in OGD's Division of Pharmacology/Toxicology Review. In this role, Dr. Keck leads pharmacology/toxicology reviews of Drug Master Files and Abbreviated New Drug Applications. She has worked for the Division of Clinical Review conducting pharmacology/toxicology reviews since 2015. She is a laboratory animal veterinarian with expertise in animal models and research. Dr. Keck has a master's in Biotechnology from Johns Hopkins University (Baltimore, MD), a veterinariae medicinae doctoris (VMD) from the University of Pennsylvania (Philadelphia, PA), and she completed her laboratory animal medicine residency at Vanderbilt University Medical Center (Nashville, TN).

Byeongtaek (BT) Oh, PhD
Staff Fellow
Division of Pharmaceutical Manufacturing Assessment-I |
Office of Pharmaceutical Manufacturing Assessment |
Office of Pharmaceutical Quality (OPQ) | CDER) | US FDA

Byeongtaek Oh currently serves as a CMC reviewer for FDA/CDER/OPQ/OPMA, overseeing manufacturing process and facility for ANDAs, NDAs, and IND meeting packages. Byeongtaek has been deeply involved in various data integrity cases in collaboration with other offices within the Agency, as well as data integrity impact assessment on the regulatory submissions. Byeongtaek Oh received a Ph.D. in Pharmaceutical Sciences from the University of Missouri-Kansas City (2016) and completed a postdoctoral fellowship at the Stanford University (2016-2019) prior to his FDA career, where he focused on the development of combination products (drug/device, biologic/device) and preclinical efficacy studies for cardio- and neuro-vascular device use.

Partha Roy, PhD
Director
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD) | CDER | US FDA

Dr. Roy is a recognized senior clinical / regulatory strategist and a proven business leader with 21 years of drug development experience in both US FDA and industry involving new drugs, novel biologics, generics and biosimilars. Currently leads an FDA/CDER Office that oversees the thorough assessment of bioequivalence data required to support Abbreviated New Drug Application (ANDAs). Manages a multi-disciplinary program, providing leadership and management oversight to OB Division Management and primary and secondary assessors.
Partha plans, manages, organizes, and directs all the regulatory review operations, program segment(s), functions, and activities of OB. OB establishes bioequivalence specifications for drug products and develops guidelines for bioequivalence reviews, industry protocols, and studies.
Prior to his current role, Partha was Vice President in PAREXEL's Regulatory and Access Consulting Global Business Unit, possessing a unique blend of executive management, regulatory strategy and thought leadership focused on driving corporate growth and delivery

Dave Coppersmith, JD
Regulatory Counsel
Division of Policy Development | Office of Generic Drug Policy
Office of Generic Drugs (OGD) | CDER | US FDA

Dave Coppersmith is a regulatory counsel in the Division of Policy Development, Office of Generic Drug Policy, Office of Generic Drugs (OGD) in FDA's Center for Drug Evaluation and Research. Before joining OGD in May 2019, he was a supervisory regulatory counsel in the Center for Tobacco Products' Office of Compliance and Enforcement. Mr. Coppersmith received his B.A. in Economics and Political Science from St. Mary's College of Maryland and his J.D. from the University of Baltimore School of Law.

Day 2 Speakers

Andre Raw, PhD
Senior Science and Policy Advisor
Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Quality (OPQ) | CDER) | US FDA

Andre Raw received his B.S. degree from the Massachusetts Institute of Technology and his Ph.D. in chemistry from the University of California at Berkeley. Within his tenure within FDA, he has been promoted to FDA Agency Expert and to Chemistry Division Director. Currently he is the Associate Director for Science and Communication in the Office of Life Cycle Drug Products (OLDP) in the Office of Pharmaceutical Quality (OPQ).

Dr. Raw was involved in the development of several important FDA initiatives, including the Guidance on Pharmaceutical Solid Polymorphism and Co-crystals, Regulations on Listing of Polymorph Patents, Question Based Review, QbD Example for Generic Modified Release Products. He was instrumental in FDA's recent approval of generic versions of complex active ingredients including Lovenox (enoxaparin sodium) and Copaxone (glatiramer acetate). More recently, Dr. Raw has been active in Risk Based Review and Quality Informatics Initiatives and in one of the architects of Knowledge-Aided Assessment and Structured Application (KASA).

Jinong (Jenn) Li, PhD
Chemist
Office of Pharmaceutical Manufacturing Assessment (OPMA)
Office of Pharmaceutical Quality (OPQ) | CDER) | US FDA

Dr. Jenn Li is a reviewer who joined the Office of Pharmaceutical Manufacturing Assessment (OPMA), CDER in 2019. Prior to that, she was a product specialist of in vitro diagnostic devices in CDRH, and a principal investigator and assistant professor at Johns Hopkins School of Medicine.
She received her PhD in Microbiology from Umea University, Sweden, with board certification in laboratory medicine from American Association of Clinical Chemistry.

Sarah Ibrahim, PhD, PharmD
Associate Director for Global Generic Drug Affairs
Office of Generic Drugs (OGD) | CDER | US FDA

Sarah Ibrahim is the Associate Director for OGD's Generic Drug Global Affairs. In this role, Dr. Ibrahim develops strategies to address identified and emerging regulatory challenges in relation to the international nature of the generic drug industry. In collaboration with other CDER and FDA offices, she supports stakeholder engagement concerning issues related to globalization of the generic pharmaceutical supply and harmonization of regulatory approaches for generic drugs. Dr. Ibrahim received her PhD in Biopharmaceutics/Pharmaceutics from the School of Pharmacy, University of Cincinnati and a B.S. in Pharmacy and Pharmaceutical Sciences from Cairo University, Egypt. Dr. Ibrahim started her career at the FDA in 2014 as a scientific reviewer in the Office of Pharmaceutical Quality. Prior to her FDA career, she has years of experience in the US pharmaceutical industry in pharmaceutical development. She is also a coinventor in several patent applications. As an assistant professor, along with the founding faculty, Dr. Ibrahim established the pharmaceutical sciences department for the second school of pharmacy in the state of New Jersey.

Karen Bengtson
Lead Regulatory Health Project Manager
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD) | CDER | US FDA

Karen Bengtson is a Lead Regulatory Health Project Manager in the Office of Research and Standards (ORS), Office of Generic Drugs (OGD), CDER, FDA. She joined ORS in 2018 and is involved in process development and implementation of the pre-ANDA Program under GDUFA II. Prior to joining ORS, Karen worked as a regulatory project manager in the Office of New Drugs and the Office of Surveillance and Epidemiology of CDER. She was in private industry for 14 years and worked for several small biotech companies during that time, before joining the FDA. She received her Bachelor of Arts degree in biological sciences from the University of Baltimore, Baltimore County.

Xiaoming Xu
Branch Chief
Office of Testing and Research (OTR)
Office of Pharmaceutical Quality (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.

Darby Kozak PhD
Deputy Director
Division of Therapeutic Performance I (DTP I)
Office of Research and Standards (ORS)
Office of Generic Drugs (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).

Michael Spagnola, MD
Clinical Team Leader
Division of Clinical Safety and Surveillance (DCSS)
Office of Safety and Clinical Evaluation (OSCE)
Office of Generic Drugs (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.

Lei Zhang, PhD
Deputy Director
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD) | CDER | US FDA

Dr. Lei Zhang is the Deputy Director of ORS within OGD. 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 science-based regulatory decision making. Before joining FDA in 2002, she worked at Bristol Meyers Squibb as a Research Investigator and Preclinical Candidate Optimization Team Leader. Dr. Zhang is an Adjunct Professor in the Department of Bioengineering and Therapeutic Sciences, University of California at San Francisco (UCSF), Schools of Pharmacy and Medicine. Dr. Zhang received her Ph.D. in Biopharmaceutical Sciences from UCSF. She is the Rapporteur for the ICH M13 Expert Working Group that is developing an 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. She has published more than 120 peer-reviewed papers and book chapters.

Susan Hakeem, PharmD
Regulatory Health Project Manager
Office of Research and Standards | Immediate Office
Office of Generic Drugs (OGD) | CDER | US FDA

Susan Hakeem is a Regulatory Health Project Manager in the Office of Research and Standards in the FDA's Center for Drug Evaluation and Research. She received a Doctorate in Pharmacy from Howard University College of Pharmacy in 2018 and a Bachelor of Science in Public Health from the University of Maryland, College Park. Susan completed a post-doc ORISE fellowship in ORS and has experience in research and supporting drug review teams across a wide range of therapeutic areas. She represents CDER on several committees and working groups, including efforts related to the Complex Product Database, Generic Combination Drug Products, Diversity Equity & Inclusion, as well as scientific and policy issues.

Robert Gaines
Deputy Director
Office of Program and Regulatory Operations (OPRO)
Office of Pharmaceutical Quality (OPQ) | CDER) | US FDA

CAPT Robert "Bob" Gaines is the Deputy Director for the Office of Program and Regulatory Operations (OPRO) within the Office of Pharmaceutical Quality (OPQ). He earned his PharmD from Howard University in Washington, DC. His pharmacy career includes serving as an ambulatory care pharmacist at the Alaska Native Medical Center in Anchorage, AK and serving as the Deputy Chief of Pharmacy Operations at St. Elizabeth's psychiatric hospital in Washington, DC. Bob joined the FDA in 2010 and has served in various roles including Chemistry Project Manager (OGD), Regulatory Project Manager (OGD), Regulatory Reviewer (OM), Division Director (OPQ/OPRO), and as a Team Leader (OND Policy) prior to becoming OPRO's Deputy Director. He has served for 16+ years in the USPHS. His time in service includes serving in various roles including Pharmacist, Chief of Pharmacy Operations, Ancillary Services Branch Chief and the Operations Section Chief on Rapid Deployment Force-5. He has deployed to numerous disaster and events, including multiple deployments for COVID-19 where he served in critical leadership roles.

Warren Simmons, PharmD
LT, U.S. Public Health Service
Regulatory Project Manager
ORP | Office of Generic Drugs (OGD) | CDER | US FDA

Lieutenant (LT) Warren Simmons II, Pharm.D. comes from Lorton, VA. He Graduated from Hampton University School of Pharmacy in 2012 with a Doctor of Pharmacy degree and a minor in Leadership Studies. LT Simmons began his career in 2012 as a community pharmacist for CVS. In 2014, he was given the opportunity to expand his scope by joining the U.S. Food and Drug Administration as a Regulatory Project Manager in the Office of Generic Drugs, where he oversees the safe and timely approval of generic medication for the American public. In 2017, LT Simmons took his passion for pharmacy and public health one step further by becoming a Commissioned Officer in the U.S. Public Health Service. One of the most important aspects of LT Simmons' life is family. When he is not busy carrying out the mission of the Public Health Service, he enjoys coming together to spending time with his loved ones. He is a member of the American Pharmacists Association and Commissioned Officers Association.

Peter Enos, PharmD, MBA
Filing Primary Reviewer
Division of Filing Review
Office of Generic Drugs (OGD) | CDER | US FDA

Peter Enos is a Filing Primary Reviewer for the Division of Filing Review in the Office of Generic Drugs in the FDA's Center for Drug Evaluation and Research. He earned his Doctor of Pharmacy in 2017 and his Master of Business Administration in 2020. Currently, he is pursuing his Master of Health Administration concurrent to his duties at the FDA. Peter has previous experiences in retail operations management, private consulting, and inpatient clinical practice. He leverages his diversified skillset to support DFR in the drug review process involving Abbreviated New Drug Applications, Controlled Correspondences, and Prior Approval Supplements.

Elizabeth Kim, APRN, FNP-BC
Lieutenant Commander, U.S. Public Health Service
Controls Coordinator, Division of Filing Review (DFR)
Office of Regulatory Operations (ORO)
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LCDR Elizabeth Kim is a Controlled Correspondence Coordinator for the Division of Filing Review (DFR) in OGD's Office of Regulatory Operations (ORO). In this role, LCDR Kim reviews and responds to inquiries submitted by generic drug manufacturers or associated industry related to generic drug development. Prior to joining the FDA in 2015, LCDR Kim worked as a family nurse practitioner providing primary care to populations across the lifespan in various clinical settings. LCDR Kim obtained a Master of Science in Nursing degree from the University of Maryland School of Nursing. She is a board-certified family nurse practitioner.

Tu-Van Lambert, MS RAC
Senior Regulatory Health Project Manager
Division of Clinical Safety and Surveillance | Office of Safety and Clinical Evaluation
Office of Generic Drugs (OGD) | CDER | US FDA

Tu-Van Lambert is a Senior Regulatory Health Project Manager in OGD's Division of Clinical Safety and Surveillance, where she provides regulatory affairs and project management oversight and coordination for multidisciplinary teams of scientists, clinicians, and specialists on broad premarket and postmarket generic drug safety and surveillance activities for OGD. She received a Master of Science in Biochemistry from the University of Maryland, College Park.

Andrew Fine, PharmD, BCPS
Senior Advisor
CDR, USPHS
Division of Clinical Review (DCR)
Office of Safety & Clinical Evaluation (OSCE)
Office of Generic Drugs (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.

Alexander Gontcharov, PhD
Staff Fellow
Division of Pharmaceutical Manufacturing III | Office of Pharmaceutical Manufacturing Assessment (OPMA)
Office of Pharmaceutical Quality (OPQ) | CDER) | US FDA

Alexander Gontcharov is a Staff Fellow in the Office of Pharmaceutical Quality in the FDA's Center for Drug Evaluation and Research. He received a Ph.D. in organic chemistry from Case Western Reserve University in 1997 and spent large part of his professional career doing drug development at major pharmaceutical companies. At FDA, Alex is involved in assessment of manufacturing process and facilities for NDAs and ANDAs across multiple therapeutic areas and dosage forms.

Haitao Li, PhD
Branch Chief
Division of Pharmaceutical Manufacturing III | Office of Pharmaceutical Manufacturing Assessment
Office of Pharmaceutical Quality (OPQ) | CDER) | US FDA

Haitao Li is the Branch chief of Branch 7, Division of Pharmaceutical Manufacturing III. She received her Ph.D. in organic chemistry from the University of California at San Diego. Dr. Li oversees quality assessment of manufacturing processes and facilities submitted in various types of regulatory submissions to the FDA.

Alex Viehmann
Division Director
Division of Quality Intelligence II, Office of Quality Surveillance (OQS)
Office of Pharmaceutical Quality (OPQ) | CDER) | US FDA

Alex Viehmann is currently the Director for the Division of Quality Intelligence II within the Office of Pharmaceutical Quality/Office of Quality Surveillance. The Division performs post-market quality-based assessments of drug sites and products, enhanced by data integration and analytics tools developed in support of monitoring and improving drug quality, to inform congressional inquiries and data calls, future GMP inspections, enforcement decisions, and application assessment. Alex joined the FDA in May 2008 as an Operations Research Analyst in the Policy and Standards Development staff within the Office of Pharmaceutical Sciences where he collaborated with stakeholders on developing policy and standards on sampling, test method evaluation, and statistical quality control. He then transitioned to the Science and Research staff where he provided statistical support for CMC review, GMP inspections, and enforcement actions. Since joining OQS in 2015, Alex has guided the development of OPQ's Quality Metrics program, CDER/ORA's New Inspection Protocol Project (NIPP), and OQS's analytics and modeling program. He is also actively engaged in implementing Pharmaceutical Quality System (PQS) assessments in support of Established Conditions and the Site Engagement Program (SEP). He currently serves as the Regulatory Chair for ICH Q9 and as a member of the PIC/S Expert Circle Working Group on Quality Risk Management.

Alex received his Bachelor's degree in economics from the University of Maryland at College Park.

Ashley Boam, MSBE
Director
Office of Policy for Pharmaceutical Quality (OPPQ)
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Ashley Boam currently serves as Director of the Office of Policy for Pharmaceutical Quality (OPPQ) in the Office of Pharmaceutical Quality (OPQ) in the Center for Drug Evaluation and Research (CDER). OPPQ is responsible for developing and clearly communicating science- and risk-based policies and standards related to drug product quality, including application review and inspection. OPPQ also coordinates OPQ's work with international regulatory authorities on quality issues, leads CDER's compendial operations, coordinates CDER's involvement in quality standard-setting organizations, and addresses policy issues related to drug-device combination products.

Prior to joining CDER in 2013, Ashley spent nearly 20 years in the Office of Device Evaluation (ODE) in FDA's Center for Devices and Radiological Health (CDRH), serving as a scientific reviewer, a Branch Chief in the Division of Cardiology Devices, and finally as Associate Director for Regulations and Guidance for ODE. Ashley received her MSBE from the University of Alabama at Birmingham and her BSE from Tulane University, both in Biomedical Engineering.