SPEAKER BIOGRAPHIES

In order of presentations (*see the Agenda*)

Janet Woodcock, MD.
Principal Deputy Commissioner - Office Of The Commissioner
U.S. Food and Drug Administration (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.

Biography Source: https://www.fda.gov/about-fda/fda-organization/janet-woodcock

Dr. Atul Gawande
Assistant Administrator for Global Health
United States Agency for International Development (USAID

Dr. Atul Gawande is the Assistant Administrator for Global Health. He is a renowned surgeon, writer, and public health leader. Prior to joining the Biden-Harris Administration, he was a practicing general and endocrine surgeon at Brigham and Women's Hospital and a professor at Harvard Medical School and the Harvard T.H. Chan School of Public Health.

He was founder and chair of Ariadne Labs, a joint center for health systems innovation, and of Lifebox, a nonprofit making surgery safer globally. He also co-founded CIC Health, a public benefit corporation supporting pandemic response operations nationally, and served as a member of the Biden transition COVID-19 Advisory Board.

From 2018-2020, he was CEO of Haven, the Amazon, Berkshire Hathaway, and JPMorgan Chase healthcare venture.

In addition, Atul was a longtime staff writer for The New Yorker magazine and has written four New York Times best-selling books: Complications, Better, The Checklist Manifesto, and Being Mortal.

He is a member of the National Academy of Medicine and the winner of two National Magazine Awards, Academy Health's Impact Award for highest research impact on healthcare, a MacArthur Fellowship, and the Lewis Thomas Award for writing about science.

Tereza Kasaeva, MD, PhD
Director
Global TB Programme
World Health Organization (WHO)

Dr. Tereza Kasaeva, MD, PhD is the Director of the World Health Organization's (WHO) Global Tuberculosis Programme. Since 2018, she has been leading WHO's work on norms, policies and standards on TB prevention and care; technical support to countries, including through the three-level WHO TB technical expert network; monitoring the global TB epidemic; promoting TB research & innovations and strengthening political and multisectoral engagement, accountability and advocacy to End TB.

Dr Kasaeva has more than 28 years of experience in public health and in leading innovative efforts for socially significant diseases, including TB.

Dr. Rogério Gaspar
Director, Regulation and Prequalification
World Health Organization (WHO)

Rogério Gaspar (Pharmacist, b. 1961) is the Director of RPQ (Department of Regulation and Prequalification) at the World Health Organization (WHO). He was for the last 36 years an academic, with extensive international regulatory experience during the last 26 years. Previously, among other positions, Vice-President of INFARMED and member of the management board of the European Medicines Agency (2000-2002), Vice-Rector of the University of Lisbon (2013-2017) and member of the Executive Committee and Vice-President of the European Federation of Pharmaceutical Sciences (EUFEPS, 2009-2013 and 2016-2020). A researcher in Nanomedicine since 1986, he was also involved in Regulatory Science and Health Systems projects in recent years.

Ronald T. Piervincenzi, PhD.
Chief Executive Officer
U.S. Pharmacopeial Convention

Ronald T. Piervincenzi, PhD., has served as Chief Executive Officer of the United States Pharmacopeia since February 2014. Dr. Piervincenzi provides strategic leadership to USP's global staff of over 1,300 across sites in the US (Rockville, Frederick, D.C.), India, China, Ghana and Switzerland, and global public health field offices including Nigeria, Indonesia, Ethiopia, and Kenya. His transformative vision has launched key USP initiatives in bringing quality across the healthcare spectrum, upholding USP's reputation as a quality leader since its founding in 1820. Under his leadership, USP has modernized its operations and launched innovative new science, including in the areas of digital medicine, cutting-edge manufacturing technologies and advanced biologics. More recently, USP has begun building a robust "capability building" services suite of offerings including quality manufacturing consulting, donor-funded work, and education. Dr. Piervincenzi served as Chair of the Council of Experts, USP's scientific

standards-setting body of 24 Expert Committees and over 750 standards-setting experts until June 2015, when he transferred this responsibility to USP's new Chief Science Officer.

Dr. Piervincenzi brings more than 20 years of industry experience across pharmaceutical sciences, research and business strategy. Before joining USP, Dr. Piervincenzi served as Vice President of Development Sciences with Biogen Idec, Inc., where he designed and launched Biogen's value-based medicine group focusing on applying tools and technologies of personalized medicine in the treatment and management of multiple sclerosis. Dr. Piervincenzi was a partner and leader in McKinsey & Company's global pharmaceutical and medical products practice for over 12 years. In this capacity, Dr. Piervincenzi launched McKinsey's global drug safety, medical and regulatory service line. With McKinsey, Dr. Piervincenzi also led the global research and information analytics team, managing staff in New Jersey, London, Brussels, and India.

Dr. Piervincenzi earned his M.S. and Ph.D. from Duke University in Biomedical Engineering, with research focused on protein engineering. He is the proud co-founder and chairman of the board for MENTOR Newark.

Jude Nwokike
Vice President & Director
Promoting the Quality of Medicines Plus (PQM+) Program
U.S. Pharmacopeial Convention

Jude Nwokike, Vice President, USP, Director of the PQM+ Program: Mr. Nwokike has more than 20 years of experience in strengthening medical products regulation and quality assurance systems. Prior to his current role, Mr. Nwokike served as director of the predecessor Promoting the Quality of Medicines (PQM) program. Before joining USP, Mr. Nwokike was the U.S. Food and Drug Administration's (FDA's) liaison working with the Center for Drug Evaluation and Research on the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) antiretroviral drugs program. Prior to the FDA, Mr. Nwokike worked with USAID-funded programs at Management Sciences for Health (MSH). He also served as principal pharmacist for the Government of Botswana.

Mr. Nwokike is a pharmacist by training with postgraduate degrees in pharmaceutical sciences and public health. He has served on international expert advisory and review committees, professional scientific associations, and international technical working groups. He is the recipient of the 2020 IPS Medal Award, which is awarded by the Industrial Pharmacy Section of the International Pharmaceutical Federation.

Deus Mubangizi
Unit Head, Prequalification Unit (PQT)
Regulation and Prequalification Department (RPQ)
Access to Medicines and Health Products Division (MHP)
World Health Organization (WHO)

Mr. Mubangizi is a senior regulator with experiences in the regulation of pharmaceutical products, Vaccines, Vector Control Products and In-Vitro Diagnostics. He is currently the Unit Head of the Prequalification Unit (PQT) within the Regulation and Prequalification Department (RPQ) of the World Health Organization (WHO), based in Geneva, Switzerland. Prior to joining WHO in 2008, Mr. Mubangizi had served as the Chief Inspector of Drugs (1996 - 2008) where he was one of the founder staff of Uganda's national medicines regulatory agency, National Drug Authority (NDA), in 1994.

In 1995, he worked with consultants appointed by WHO to establish a drug registration system for Uganda and subsequently coordinated a team that established the GMP inspection system for local and foreign manufacturing facilities marketing their products in Uganda. He headed the Inspectorate and Licensing Department of NDA Uganda from 1996 to March 2008. He participated in the initiation of medicine regulation harmonization in East Africa and Africa in General. In 2004 he joined a team of external dossier assessors for WHO Prequalification where he was shortly promoted to the level of senior assessor.

He has, on behalf of his country Uganda and for WHO Medicines Prequalification Programme, inspected sites in African, Europe, Asia, North America and South America for the manufacture of Finished Pharmaceutical Products, Active Pharmaceutical Ingredients, Vaccines and In-vitro diagnostics; national quality control laboratories; and Clinical Research Organizations where bioequivalence studies are conducted.

Hiiti B. Sillo
Unit Head, Regulation and Safety
Regulation and Prequalification Department (RPQ)
Access to Medicines and Health Products Division (MHP)
World Health Organization (WHO)

Hiiti Sillo is the current Unit Head, Regulation and Safety within the WHO department of Regulation and Prequalification. Until late 2021, he was the Team Lead, Regulatory Systems Strengthening (RSS) within the Regulation and Safety Unit. In his current capacity, he is responsible for coordinating WHO strategies for strengthening national and regional regulatory capacities, promoting regulatory networks, convergence, work-sharing and reliance as well as strengthening safety monitoring and addressing the global problem of substandard and falsified medical products.

Before joining WHO in 2018, he was the Director General of the Tanzania Food and Drugs Authority (TFDA), the position he held since 2010 after serving on several technical and managerial positions within the TFDA and its predecessor, the Pharmacy Board of Tanzania. He also championed regulatory harmonization initiatives in Africa and particularly the launch of the African Medicines Regulatory Harmonization (AMRH) for the East African Community, the AMRH showcase. Mr. Sillo is a Pharmacist and holds a Master of Science in Pharmaceutical Services and Medicines Control.

C. Michelle Limoli, PharmD
Senior International Health Science Advisor
Center for Biologics Evaluation and Research (CBER)
CBER International Affairs |

Michelle Limoli is with the International Programs Office in U.S. Food and Drug Administration's Center for Biologics Evaluation and Research (CBER). She is responsible for coordinating and collaborating on activities and strategic programs with various international organizations and governments, as well as within the CBER.

During her career at FDA, she has coordinated activities in various harmonization and multilateral initiatives such as ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use), VICH (International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products), ICCR (International Cooperation on Cosmetics Regulation), GHTF (Global Harmonization Task Force), IMDRF (International Medical Device Regulators Forum), APEC RHSC (Asia-Pacific Economic Cooperation Regulatory Harmonization Steering Committee) where she is serves as the RHSC Co-Chair, IPRF (International Pharmaceutical Regulators Forum), OECD (Organization for Economic Co-Operation and Development), and WHO (World Health Organization).

Michelle joined CBER after having worked in the Center for Drug's (CDER) international programs, and the Office of the Commissioner, where Michelle served as the Director of FDA's Europe Office. She has also worked on various cross-cutting initiatives such as international medical product anti-counterfeiting, nanotechnology, IRB and ethical issues, and exporting of pharmaceuticals for international clinical trials.

Michelle is a clinical pharmacist with both hospital and community pharmacy experience.

Gopa Raychaudhuri, PhD
Associate Director for Special Programs
CBER Liaison to WHO
Office of the Director (OC)
Center for Biologics Evaluation and Research (CBER)
U.S. Food and Drug Administration (FDA)

Gopa Raychaudhuri is the Associate Director for Special Programs in the Office of the Director in FDA's Center for Biologics Evaluation and Research (CBER). Dr. Raychaudhuri is CBER's liaison to the World Health Organization (WHO) where she oversees areas of strategic interest and CBER's scientific collaborations with the WHO. Additionally, she manages CBER's Individualized Therapeutics Program which focuses on facilitating development of bespoke gene therapies for ultra-rare diseases. Dr. Raychaudhuri received Bachelor of Science and Master of Science degrees in Biochemistry from the University of Toronto and a PhD in Microbiology from the University of Virginia. She did her post-

doctoral training at NIAID/NIH where her research was on vaccine development. Dr. Raychaudhuri joined the Office of Vaccines Research and Review in FDA/CBER as a scientific reviewer in 1999 and has been in her current position since 2010.

Margaret M. Kober, RPh., MPA
Chief, Project Management Staff
Office of Regulatory Operations (ORO)
Office of New Drugs (OND) | CDER | FDA

Ms. Kober is a Chief, Project Management Staff in the Office of Regulatory Operations within the Office of New Drugs, Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration. In this capacity, Ms. Kober provides supervisory leadership and direction to the project management staff, participates in the development and implementation of policy and strategy for the regulation of reproductive, urologic, dermatologic, and dental product classes, and participates in meetings with industry to provide information and advice on policy, law, and regulations.

Previously, Ms. Kober held the position of Regulatory Review Officer in the Division of Drug Marketing, Advertising, and Communications (DDMAC) in CDER. She was responsible for the regulation of promotional activities related to metabolic and endocrine drug products. She has also served as a Team Leader for the Drug Registration and Listing project.

Ms. Kober joined FDA with 15 years of experience in community pharmacy practice and continued to practice in this setting until 2020. Ms. Kober received her Bachelor of Science degree in Pharmacy from the University of Rhode Island and her master's degree in Public Administration with a concentration in health policy and administration from George Mason University.

John Ibrahim, PharmD, BCPS
Associate Director for Regulatory Affairs
Office of Regulatory Operations (ORO)
Office of Generic Drugs (OGD)
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

John Ibrahim is the Associate Director for Regulatory Affairs for the Office of Regulatory Operations in the Office of Generic Drugs. John received his Doctorate in Pharmacy from St. John's University in 2006 and became a Board-Certified Pharmacotherapy Specialist in 2014. Prior to joining the FDA, John practiced in community pharmacy, clinical pharmacy in the hospice setting, and clinical pharmacy in the hospital setting.

Day 2

Ramya Gopinath, MD
Medical Officer
Division of Anti-Infectives (DAI)
Office of New Drugs (OND) | CDER | FDA

Dr. Ramya Gopinath is a Medical Officer in the Division of Anti-Infectives (DAI), Center for Drug Evaluation and Research (CDER) , Food and Drug Administration, USA. She obtained her medical degree at Madras Medical College, Chennai, India and completed an internal medicine residency and infectious disease fellowship at the University of Toronto in Canada. Following a 5-year research fellowship from 1995-2000 at the Laboratory of Parasitic Diseases, NIAID, NIH where she investigated human host response to parasitic infections, Dr. Gopinath transitioned to private practice in infectious disease for several years. She has been at FDA since 2015 and has worked with many drug sponsors on antimicrobial drug applications at various stages of development, on Guidances for Industry and on regulatory science research.

Tina T. Nhu, PharmD, Mc. PM, BS. Pharm.
Commander (CDR) | United States Public Health Service
Team Leader Regulatory Project Manager
Division of Project Management (DPM)
ffice of Generic Drugs (OGD) | CDER | FDA

Commander (CDR) Tina Nhu, Pharm. D, Mc. PM, B.S. Pharm. is currently assigned to the Food and Drug Administration (FDA) as Regulatory Project Manager (RPM) Team Leader (TL) for the Division of Project Management at the Office of Generic Drugs (OGD) in the FDA's Center for Drug Evaluation and Research.

CDR Nhu graduated with a Bachelor of Pharmacy from the Massachusetts School of Pharmacy and Health Sciences in 2000 and Doctor of Pharmacy from the University of Florida College of Pharmacy in 2010. She began her career with the United States Public Health Service (USPHS) in 2009. As TL, she directs a team of Regulatory Project Managers to manage the review and approval of the Abbreviated New Drug Applications (ANDAs). She also leads and manages all PEPFAR (President's Emergency Plan for AIDS Relief) ANDAs.

Peter Capella, PhD.
Director
Division of Immediate and Modified Release Drug Products
Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Quality (OPQ) | CDER | 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. His group directly supported PEPFAR ANDA quality assessments both pre- and post-marketing.

Monica Zeballos, PharmD, RPh
Captain |United States Public Health Service
Senior Program Consultant
Division of Antivirals (DAV)
Office of Infectious Diseases (OID) | Office of New Drugs (OND) |CDER| FDA

CAPT Monica Zeballos is the subject matter expert and lead coordinator in CDER's Division of Antivirals. She manages and coordinates the regulatory review and approval activities of HIV antiretroviral (ARV) New Drug Applications for use in the PEPFAR program, a program with life-saving international impact. She received a Doctor of Pharmacy from Shenandoah University's Bernard J. Dunn School of Pharmacy in 2000. Monica is recognized as one of the primary experts and leaders in the coordination of FDA review of HIV ARV drugs for PEPFAR use internally and externally.

Mitchell Chan, PharmD, BCPS
Lieutenant Commander |United States Public Health Service
Clinical Analyst, Team Leader
Project Facilitate
Oncology Center of Excellence (OCE) | FDA

Lieutenant Commander Mitchell Chan is a Clinical Analyst and Team Lead in the U.S. Food and Drug Administration (FDA) Oncology Center of Excellence's Project Facilitate and has been a part of Project Facilitate since its launch. LCDR Chan's career started as a clinical pharmacist in the Indian Health Service in New Mexico. He started at the FDA as a Regulatory Health Project Manager, managing drug approvals for breast, gynecologic/supportive care and genitourinary indications. As a Clinical Analyst with Project Facilitate, he performs clinical reviews of expanded access applications and manages the Project Facilitate Call Center. As a USPHS commissioned officer, LCDR Chan deployed numerous times for natural and man-made disasters such as COVID-19, hurricanes, and other humanitarian missions. He has earned his Bachelor of Science in General Science from Oregon State University, his Doctor of Pharmacy degree from the University of New England College of Pharmacy, completed a PGY1 Pharmacy Practice Residency focused on critical care and emergency medicine, and is a Board Certified Pharmacotherapy Specialist.

Frank Holcombe, PhD.
Senior Advisor
Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Quality (OPQ) | CDER | FDA

Frank Holcombe is Senior Advisor to the Immediate Office in the Office of Lifecycle Products (OLDP) , Office of Pharmaceutical Quality, Center for Drug Evaluation and Research. He received a Ph.D. in Chemistry from the University of Virginia for work in total synthesis of indole alkaloids and did postdoctoral research in synthesis of antimalarials at Lehigh University. Before joining the FDA, Frank worked in the pharmaceutical industry, in quality assurance, ophthalmic product development, polymer research and manufacturing, and diagnostic device research and development. He joined the FDA Office of Generic Drugs as a reviewer in 1991, has held several positions including that of Division Director, and now serves OLDP as an advisor on policy and quality issues. During his career at FDA, he has worked in the areas of data and quality standards development, guidance development and implementation, product quality assessment development, and has been a member of several external organization guidance working groups including ICH.

Ramesh Raghavachari, PhD.
Chief, Branch I.
Division of Post Marketing Activities I (DPMA I)
Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Quality (OPQ) | CDER | FDA

Ramesh Raghavachari is the Chief of Branch I in the Division of Post Marketing Activities (DPMA) which is a part of the Office of Lifecycle Drug Products (OLDP) in the Office of Pharmaceutical Quality at FDA's Center for Drug Evaluation and Research. He received a Ph.D. in Organic Chemistry from Temple University, Philadelphia. After post-doctoral research and industry experience, he joined FDA more than nineteen years ago. Ramesh has experience in supporting drug product quality reviews across a wide range of therapeutic areas both in Pre-marketing and post-marketing of New Drugs.

DAY 3

Mrunal Atul Jaywant, Ph. D., PGDMM
Senior Director, R&D, USP (India)

Dr. Mrunal is a Senior Director - R&D at USP India. She is overseeing Compendial Development Laboratory, and Analytical Research and Development Laboratory at USP India. The main responsibilities are to develop and validate analytical methods and characterize reference materials/ impurity standards to support Development of Documentary standards (such as Monographs for Drug substance, Drug products, Excipients and Food) and Reference standards. Dr. Mrunal is also an approved instructor (faculty) for USP Education courses and delivers courses across the globe. Dr. Mrunal has 27 years of Pharmaceutical Industrial experience that includes over 6.5 years of association with USP India.
Dr. Mrunal is leading Nitrosamine Impurities Workstream globally that is responsible for formulating "Focused Nitrosamine Strategy" for USP.

Andre Raw, PhD.
Associate Director of Science and Communication
Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Quality (OPQ) | CDER | 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).

Rong Wang, PhD., PharmD.
Acting Division Associate Director
Division of Bioequivalence I (DBI)
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD) | CDER | 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 processes for ANDA assessment.

Ja Hye Myung, PhD.
Pharmacologist
Division of Bioequivalence III
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD) | CDER | FDA

Dr. Ja Hye Myung is a pharmacologist at the Division of Bioequivalence III, Office of Bioequivalence within the Office of Generic Drugs, CDER/FDA. In her role, she assesses in vivo bioequivalence studies submitted by pharmaceutical industries through abbreviated new drug applications (ANDAs) and in vitro bioequivalence studies for a variety of complex dosage forms, such as topical cream/gel, nasal spray and long-acting injection.

She involves several interdisciplinary research projects on the development of new analytical methods and bioequivalence evaluation methodologies for oral, ophthalmic, and other complex formulations.

Prior to joining the FDA, Dr. Myung was Chief Scientist for Capio Biosciences and Postdoctoral Research Fellow at the Oak Ridge Institute for Science and Education. Dr. Myung has a B.Sc. in Pharmacy and a M.Sc. in Industrial Pharmaceutics from the Chungnam National University in South Korea, and Ph.D. in Biopharmaceutical Sciences from the University of Illinois at Chicago.

CDR Yi Zhang, PhD.
Senior Advisor
Division of Therapeutic Performance II | Office of Research and Standards | Office of Generic Drugs | CDER | FDA

CDR Yi Zhang is the Senior Advisor for oral drug products in Office of Generic Drugs. She received a Ph.D. in Pharmacology from East Tennessee State University, Master of Medicines in Pharmaceutical Sciences from Beijing University, and Bachelor in Pharmaceutical Sciences from Shenyang Pharmaceutical University. As a subject matter expert in developing and establishing optimal and rigorous bioequivalence (BE) standards and approaches for various drug dosage forms to promote generic drug development and approval, she has led multiple teams in ORS, including Product Specific Guidance (PSG) Development Team, Dermatological and Topical Product Team, and Immediate Release Oral Solid Dosage Forms Drug Team.

CDR Zhang also leads the research projects to address broad regulatory scientific issues encountered throughout generic drug approvals. By publishing PSGs, responding to public inquires (including controlled correspondences and citizen petitions), managing pre-ANDA meetings, addressing internal consults, and leading research projects to establish novel BE approaches, CDR Zhang and her groups have improved FDA's generic drug approval process, provided the transparency to the generic drug industry with regard to regulatory and scientific perspectives, and facilitated the generic industry develop generic drug products more efficiently and effectively by submitting high quality applications to the FDA.

Donna A. Volpe, PhD.
Research Chemist
Division of Applied Regulatory Science
Office of Clinical Pharmacology (OCP) | CDER | FDA

Donna Volpe is a principal investigator in OCP's Division of Applied Regulatory Science. She received her M.A. and Ph.D. from the University of Buffalo. Donna has experience in in vitro assays for drug permeability, metabolism and transport. She has been involved in the revision of FDA's BCS biowaiver and in vitro drug-drug interaction guidances for industry.

Haritha Mandula, PhD.
Lead Pharmacologist
Division of Biopharmaceutics
Office of New Drugs (OND) | CDER | FDA

Haritha Mandula is a Senior Pharmaceutical Quality Assessor in the Division of Biopharmaceutics, ONDP, OPQ in the FDA's Center for Drug Evaluation and Research. She received a Ph.D. in Pharmaceutical Sciences from Texas Tech University, Health Sciences Center in 2005. Haritha has experience supporting review of the biopharmaceutical aspects of new and generic drug product review submissions across a wide range of therapeutic areas. Haritha also serves on several review committees at the FDA including the Biopharmaceutical Classification System (BCS) committee and In Vitro In Vivo Correlations (IVIVC) committee. Haritha has been the recipient of several awards at FDA including CDER Regulatory Science Excellence Awards, CDER Special Recognition Awards and FDA Commissioner's Special Citation Awards.