CDER SBIA Generic Drugs Forum 2020

Presenter Biographies

Mark Abdoo

Associate Commissioner for Global Policy and Strategy
FDA

Mark Abdoo is the Associate Commissioner for Global Policy and Strategy, providing executive oversight, strategic leadership and policy direction to FDA's global operations, trade and diplomacy activities, and engagement with international stakeholders. He leads the Office of Global Policy and Strategy (OGPS), which is comprised of the Office of Diplomacy and Partnerships, the Office of Global Operations, and the Office of Trade, Mutual Recognition and International Arrangements, which are collectively dedicated to expanding the reach of FDA's global agenda in sustainable and measurable ways.

Mr. Abdoo joined FDA in 2013 as the inaugural director of the Office of Public Health and Trade (OPHT) in the Office of International Programs, where he led FDA's efforts related to the Trans-Pacific Partnership and Trans-Atlantic Trade and Investment Partnership trade agreements, and, worked with the Commissioner's Office, the Centers, the Offices of Chief Scientist and Regulatory Affairs to develop agency positions on trade issues.

Prior to joining FDA, Mr. Abdoo served in other senior positions in the Federal government including: Senior Advisor for Food Security and Agricultural Economics at the U.S. Agency for International Development (USAID); Director for Global Health and Food Security at the National Security Council staff at the White House; and, in various positions in the Office of the Secretary of Health and Human Services, including Director and Acting Deputy Director for Multilateral Affairs in the Office of Global Affairs, where he was responsible for the Department's engagement with the Agencies of the United Nations System, the Organization for Economic Cooperation and Development, and other organizations.

Mr. Abdoo received a Bachelor of Arts degree from College of the Holy Cross and conducted graduate studies at Brown University. Before joining the Federal civil service, Mark lived in East Asia for more than nine years, where he owned two consulting companies. He is fluent in Mandarin.

Kris Andre

Associate Director of Regulatory Affairs
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)
CDER | FDA

Kris Andre is an Associate Director of Regulatory Affairs and works in the Office of Research and Standards. Before joining the FDA, Kris was in private industry in the biotech field for 17 years and worked for several small companies during that time. At the FDA, Kris is involved in implementing the pre-ANDA complex generic drug program GDUFA II. She received her Master of Science from Virginia Polytechnic Institute and State University.

Ashley Boam

Director of the Office of Policy for Pharmaceutical Quality
OPQ | CDER FDA

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.

Raphael Brykman

US Food and Drug Administration
Office of Quality Surveillance
OPQ | CDER | FDA

Raphael Brykman is the Senior Scientific Advisor in the Office of Quality Surveillance, under CDER's Office of Pharmaceutical Quality. Raphael has led the creation and publication of OPQ's Report on the State of Pharmaceutical Quality, providing key insights into quality trends of the U.S. pharmaceutical drug supply. Raphael is also closely involved in the management of recent incidents, including the ever-evolving nitrosamine contamination of pharmaceutical products.

Before joining FDA, Raphael worked in the biotech and pharmaceutical private sectors for over a decade, beginning with Covance Bio and Pfizer Australia, then as a pharmaceutical consultant for Parexel Consulting, and as the Quality Assurance and Regulatory Affairs Manager at Dynex Technologies. Raphael received his Master's degree in Predictive Analytics from Northwestern University, and his Bachelor's degrees in Chemistry and Zoology from North Carolina State University.

Debra M. Catterson, RPh

Lead Clinical Safety Coordinator
Clinical Safety Surveillance Staff
Office of Generic Drugs
Center for Drug Evaluation and Research

Debra Catterson, RPh, is a pharmacist who serves as the Lead Clinical Safety Coordinator for the Clinical Safety Surveillance Staff in the Office of Generic Drugs (OGD). She has 11 years of broad experience in the coordination and management of activities regarding the safety and surveillance of generic drug products. Ms. Catterson has been at the FDA since 1995, starting as a Project Manager for the Division of Oncology Drug Products. In 1999, she joined the OGD as a Labeling Reviewer in the Division of Labeling and Program Support, and in 2005, she joined the OGD Clinical Review Team as the Medical Affairs Coordinator. She became the Lead Clinical Safety Coordinator in 2009, when the OGD established that position and subsequently developed a postmarketing surveillance program for generic drug products. Prior to joining the FDA, Ms. Catterson served as an oncology pharmacist at the National Institutes of Health.

Howard Chazin, MD

Director, Clinical Safety Surveillance Staff
OGD | CDER | FDA

Dr. Howard Chazin joined the FDA in 2002 and is the Director of CDER's Office of Generic Drugs' Clinical Safety Surveillance Staff. Dr. Chazin leads a multidisciplinary team of pharmacists, medical officers and data analysts tasked with identifying and assessing emerging complex safety issues related to potentially inferior generic drug product quality, adverse events and other generic drug safety concerns. He facilitates postmarketing safety process improvements and provides oversight on critical aspects of challenging, controversial and sensitive generic drug safety issues.

Sally Choe, PhD

Director
Office of Generic Drugs (OGD)
CDER | 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.

Pei-I Chu, MS, PhD

Branch Chief, Office of Pharmaceutical Manufacturing Assessment
DPAI | Branch
OPQ | CDER | FDA

Dr. Pei-I Chu is Branch Chief in the Office of Pharmaceutical Manufacturing Assessment within CDER. She oversees the review activities of drug product manufacturing processes and facilities for both generic and new drug applications. She joins the FDA in 2008 as a chemistry reviewer and was given increased responsibility as a Quality Assessment Lead and Branch Chief.

Prior to joining the FDA, Pei-I amassed many years of experience in major pharmaceutical companies. Her area of expertise includes formulation and process development, product scale-up, process validation, and technology transfer for solid, semi-solid and parenteral dosage forms. Pei-I earned her doctorate and master's degrees in pharmaceutical science from University of Florida, and a bachelor's degree in pharmacy from National Taiwan University in Taiwan

Dave Coppersmith

Regulatory Counsel
Office of Generic Drug Policy
OGD | CDER | FDA

Dave Coppersmith is a regulatory counsel in the Office of Generic Drug Policy, Office of Generic Drugs (OGD). 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.

Forest "Ray" Ford, Jr., PharmD

Captain, United States Public Health Service
Consumer Safety Officer
CDER Small Business and Industry Assistance (CDER SBIA)
Division of Drug Information (DDI)
Office of Communications (OCOMM)
CDER | FDA

Ray is a Consumer Safety Officer in the Office of Communication's Division of Drug Information and has been with the FDA since 2011. Prior to joining the FDA, he served in the Indian Health Service as a Clinical Pharmacist and Safety Officer for the Fort Yuma Service Unit. He graduated from the Medical University of South Carolina in 1999, and 2001.

Linda Forsyth, MD

Medical Officer
Clinical Safety Surveillance Staff
Office of Generic Drugs
Center for Drug Evaluation and Research

Linda Mary Forsyth, M.D., has worked at the FDA as a medical officer since 1999. She has 21 years of Agency experience as a medical officer, combining knowledge from two FDA centers, the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). Dr. Forsyth joined the Office of Generic Drugs as a medical officer in 2008. Previously, she worked in the Office of New Drugs, Division of Anti-Infective Products, CDER, and in the Office of Therapeutic Research and Review, Division of Clinical Trials Design and Analysis, Immunology and Infectious Diseases Branch, CBER. Prior to joining the FDA, Dr. Forsyth completed a fellowship in Allergy and Immunology at Georgetown University. Dr. Forsyth also has completed postgraduate studies and graduated with Certificates in Patient and Product Safety from the University of Southern California and in Public Health from Georgetown University.

Rachel Goehe, PhD

Director for the Division of Labeling Review
OGD | CDER | FDA

Rachel Goehe currently serves as the Director for the Division of Labeling Review (DLR) in the Office of Generic Drugs (OGD). She has over 8 years of experience at the FDA and served in various roles, which include Regulatory Fellow in OTAT/CBER, Senior Scientific Reviewer in OIR/CDRH, and Acting Staff Director in OC/CDER. She earned her Bachelor of Science in Biology at the University of Mary Washington in Fredericksburg, VA, and later received her PhD in Biochemistry & Molecular Biology at Virginia Commonwealth University in Richmond, VA. Lastly, she completed her postdoctoral training in the Department of Pharmacology & Toxicology at the Massey Cancer Center in Richmond, VA.

Steven Hertz, MS, MBA

Consumer Safety Officer
Division of Pharmaceutical Manufacturing IV
OPMA | OPQ | CDER | FDA

Mr. Hertz is an officer in FDA's Center for Drug Evaluation and Research, Office of Pharmaceutical Quality. He has been with FDA since 2008 and his work is focused on pre-approval manufacturing assessment for CDER-led and CDRH-led submissions. He has participated on both domestic and international drug product and combination product pre-approval inspections. He is an office subject matter expert for issues regarding computer validation, combination products, control systems, electronic records, bio-pharmaceutical engineering, QbD, PAT, and process validation. Mr. Hertz also has 5+ years' experience working in the biotechnology industry. His previous projects focused on process control, system administration, equipment automation, engineering, risk management, computer system validation, and process validation. He earned his B.S. in chemical engineering from the University of Virginia, his M.S. in biotechnology and his M.B.A. from Johns Hopkins University, and is a licensed Professional Engineer in the state of Maryland.

Jonathan Hughes

Regulatory Counsel
Office of Generic Drug Policy
ODG | CDER | FDA

Jonathan Hughes is a regulatory counsel in the Office of Generic Drug Policy, Office of Generic Drugs (OGD). Prior to joining the FDA, he was with the Department of Veterans Affairs. Jonathan earned his BA in Political Science from Davidson College and his JD from Washington & Lee University.

Edward K. Kim, MPA, MPH

Epidemiologist
Clinical Safety Surveillance Staff
Office of Generic Drugs
Center for Drug Evaluation & Research

Edward Kim, MPA, MPH, is a Clinical Safety Surveillance Staff epidemiologist in the Office of Generic Drugs. At FDA, he has researched and managed multifunctional programs and projects with a focus on measurable outcomes and high-impact analysis for data-driven public health improvements. Prior to his 10 years at FDA, he served as an assistant director for the New York City (NYC) Department of Health and Mental Hygiene, senior data analyst for the NYC Mayor's Office, and research investigator at Pfizer. Edward earned his master's degrees in epidemiology from Columbia University and public administration at New York University and bachelor's degree in neuroscience from Colgate University.

Myong-Jin (MJ) Kim, PharmD

Deputy Director, Division of Quantitative Methods and Modeling
Office of Research and Standards
OGD | CDER | FDA

Dr. Myong-Jin (MJ) Kim currently serves as the Deputy Director of the Division of Quantitative Methods and Modeling, Office of Research and Standards, Office of Generic Drugs, CDER/FDA. Since her joining the OGD in 2016, MJ has been leading the efforts to develop product specific guidances for solid oral dosage forms. In addition to her efforts in product specific guidance development, she serves as the FDA deputy topic lead for the International Council for Harmonisation, M13: Bioequivalence for Immediate Release Solid Oral Dosage Forms. MJ graduated from Georgia Institute of Technology in Atlanta, GA, with a Bachelor of Science degree in chemistry. Subsequently, she received a Doctor of Pharmacy degree from the Temple University School of Pharmacy in Philadelphia, PA and completed her post-doctoral training in Clinical Pharmacology at Bassett Healthcare (a major teaching affiliate of Columbia Univ. of Physicians & Surgeons) in Cooperstown, NY.

Michael Kopcha, PhD, RPh

Director
Office of Pharmaceutical Quality (OPQ)
CDER | 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 off-shoring/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.

Iilun C. Murphy, MD

Deputy Director, Clinical and Regulatory Affairs
OGD | CDER | FDA

Iilun (pronounced "ELON") C. Murphy, M.D., serves as deputy director for clinical and regulatory affairs in the Office of Generic Drugs (OGD). In this role, Iilun provides oversight of OGD activities related to the implementation and meeting of Generic Drug User Fee Amendments (GDUFA) goals and review management activities. She serves as a principal agency advisor in the development and implementation of FDA policies and long-range objectives for medical programs and activities, providing expert advice on medical program plans and legislative proposals. Iilun began her FDA career in 2007 as a medical officer in CDER's Office of New Drugs' (OND) Division of Gastroenterology Products. In 2011, Iilun joined the newly established Center for Tobacco Products (CTP) where she was actively engaged in developing and expanding the Office of Science. In addition, Iilun is a board-certified pediatrician and an assistant clinical professor of pediatrics at George Washington University School of Medicine.

Dara Nardini, Pharm.D.

Regulatory Project Manager
OGD | CDER | FDA

Dara Nardini is a registered pharmacist currently working at the Office of Generic Drugs (OGD) as a Regulatory Project Manager (RPM) and Lead New Hire Trainer for the Division of Project Management (DPM). She attended University of Maryland at College Park for her pre-pharmacy coursework and earned her Doctor of Pharmacy at the University of Maryland at Baltimore School of Pharmacy. Prior to joining OGD, she spent eighteen years in various positions including Pharmacy Manager, Regional Market Specialist and Staff Pharmacist with two national pharmacy retail chains. She joined OGD in 2015 and works toward their mission of providing regulatory oversight to expedite the availability of safe, effective, and high-quality generic drugs to patients and to the requirements of the Generic Drug User Fee Amendments (GDUFA).

Thomas O'Connor, Ph.D.

Senior Chemical Engineer
Office of Testing Research, Office of Pharmaceutical Quality
CDER | FDA

Dr. O'Connor is a senior chemical engineer in the Office of Testing and Research in the Office of Pharmaceutical Quality and is a member of CDER's Emerging Technology Team. His responsibilities include managing regulatory science projects to support the implementation of emerging technologies in pharmaceutical manufacturing such as continuous manufacturing, 3D printing, and the utilization of modeling and simulation for quality assurance. Tom is a co-author of several papers and book chapters on continuous manufacturing and emerging pharmaceutical technology. He has participated in the review of several regulatory applications utilizing continuous manufacturing and is a member of the continuous manufacturing guidance working group.

Prior to joining the FDA, Tom worked at ExxonMobil Research and Engineering where he held job functions in both process analytical technology and process control. Dr. O'Connor earned a B.S. in chemical engineering from the Cooper Union and a Ph.D. in chemical engineering from Princeton University.

Rinku Patel

LCDR, United States Public Health Service
Team Leader (Acting), Patent and Exclusivity Team
OGD | CDER | FDA

LCDR Rinku Patel is the Acting Team Leader of the Patent and Exclusivity Team within the Office of Generic Drugs Policy at the Food and Drug Administration (FDA). She joined the Office of Generic Drugs in 2012 where she has become a trusted resource with expert level knowledge of the Hatch Waxman amendments, ANDA approval timing, patent listing issues, 180-day exclusivity and other legal issue which impact our ability to approve ANDAs. In her current position, she assists with the daily management of the Patent and Exclusivity Team. LCDR Patel is also one of the primary individuals that oversees the OGDP's administration of Competitive Generic Therapy designations and exclusivity and works with other areas of the Agency in support of the 505(b)(2) program and in ensuring consistent implementation of the Medicare Modernization Act regulations.

Ashish Rastogi, PhD

Acting Quality Assessment Lead, Division of Liquid Based Products
Office of Lifecycle Drug Products
OPQ | CDER | FDA

Dr. Ashish Rastogi is an Acting Quality Assessment Lead in Division of Liquid Based Products in Office of Lifecycle Drug products in Office of Pharmaceutical Quality. Dr Rastogi joined FDA in 2014 before which he worked as a Research Scientist in US Army Institute of Surgical Research at Fort Sam Houston, Texas. Dr. Rastogi graduated from The University of Texas at Austin with PhD in Pharmacy.

Jonathan Resnick

Project Management Officer
Electronic Submissions Capability Team
Division of Data Management Services and Solutions (DDMSS)
OBI | OSP | CDER | FDA

Jonathan Resnick has been with the FDA for over 8 years, working in CDER's Office of Business Informatics. He currently focuses on process, standards, and guidance around electronic submissions. Prior to joining FDA, Jonathan spent 15 years working in IT project management supporting federal and private sector clients.

Amanda Roache, BS, MPP

ICH Coordinator
International Program
CDER | FDA

Ms. Roache is FDA's ICH Coordinator and has served as an Operations Research Analyst in the Center for Drug Evaluation and Research (CDER) at the US Food and Drug Administration since 2012. Ms. Roache works in CDER's International Program and facilitates scientific and policy exchanges with international organizations and representatives of foreign government. Ms. Roache received her B.S. in Chemistry from Saginaw Valley State University and M.P.P. from George Washington University.

Warren Simmons, PharmD

LT, United States Public Health Service
Regulatory Project Manager
Division of Project Management
Office of Regulatory Operations
OGD | CDER | 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.

Ted Sherwood

Director, Office of Regulatory Operations
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Ted Sherwood returned to the Office of Generic Drugs (OGD) to serve as the Director, Office of Regulatory Operations (ORO). ORO consists of four different divisions: the Division of Project Management, the Division of Filing Review, the Division of Labeling Review, and the Division of Quality Management Systems. 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.

Parth Soni, PharmD

Regulatory Project Manager
Division of Project Management
OGD | CDER | FDA

Parth Soni is a Regulatory Project Manager with the Division of Project Management. Within Division of Project Management, Parth is involved with the team piloting the Mid-Review-Cycle-Meetings. Parth graduated with Pharm.D. from Howard University College of Pharmacy in 2011 and is currently pursuing Healthcare MBA at George Washington University. Prior to joining the FDA, Parth practiced as a clinical/staff pharmacist at The George Washington University Hospital, where he also acted as the co-chair for the continuing education program. Parth has been with the Agency since March 2018 and enjoys his role as the Regulatory Project Manager.

Brenda Stodart, PharmD, BCGP

CAPT, United States Public Health Service
Director, CDER SBIA
SBIA | DDI | OCOMM | CDER |FDA

CAPT Brenda Stodart is currently the Director for the Center for Drug Evaluation and Research's (CDER's) Small Business and Industry Assistance (SBIA). Prior to her current position, CAPT Stodart was a Senior Regulatory Management Officer in the Office of Regulatory Policy (ORP). Before ORP, CAPT Stodart served as a Senior Health Promotion Officer in the Division of Drug Information for 9 years. CAPT Stodart received her BS in Pharmacy from Howard University and her PharmD from the University of Arkansas Medical Sciences. CAPT Stodart has had experience in hospital and retail pharmacy before joining the FDA.

Simin Tabasi

Application Team Lead
Office of Life Cycle Drug Product
OPQ | CDER | FDA

Simin Tabasi is currently Product Quality Assessor and Application Team Lead in Office of Life Cycle Drug product (OLDP) in FDA Office of Pharmaceutical quality (OPQ). She has been with Center for drug evaluation and research (CDER) since 2014. As Drug Product Quality Assessor, she is responsible for evaluation of drug substance chemistry, drug product composition, development, specifications, analytical methods, container closure systems, stability, quality aspects of labeling and environmental impact in abbreviated new drug applications (ANDAs).

Simin brings 11 years of experience in pharmaceutical drug product and manufacturing process development. She is skilled in drug product formulation development, scale up, process validation/optimization, technology transfer, commercialization and continuous post approval process improvement. As lead drug product and process development scientist, she successfully marketed numerous generic products and improved the manufacturing process of brand drug products. She was author of several original peer review papers and national presentations.

Aditi S. Thakur, MS

Quality Assessment Lead
Office of Pharmaceutical Manufacturing Assessment
OPQ | CDER | FDA

Aditi S. Thakur, M.S. joined the FDA, Office of Process and Facilities in 2015 as a chemist, where she performs pre-approval assessment of submissions and participated on Preapproval Inspections (PAIs). Currently she is working as a Quality Assessment lead in Office of Pharmaceutical Quality in the sub Office of Pharmaceutical manufacturing assessment. Prior to the FDA, she worked in two separate cGMP complaint specialty pharmaceuticals companies involving complex soft gelatin and inhalation dosage forms. Aditi earned a M.S. in Industrial Pharmacy from Long Island University, NY. Aditi is responsible for primary and secondary review of Process and Facility reviews for the submissions. Aditi has been involved in various data integrity cases in collaboration with other offices within the Agency. Aditi's interests include data Integrity evaluation of the submissions, regulatory manufacturing risk assessment, and complex manufacturing processes and dosage forms.

Tsedenia Woldehanna, MS

Office of Quality Surveillance
OPQ | CDER | FDA

Tsedenia Woldehanna has her Chemical Engineering degree from University of Virginia, and her Masters in Statistical Science from George Mason University. She joined the agency 7 years ago; first working with Office of Compliance as a case officer reviewing foreign inspections to make enforcement action and application recommendations. She is currently with OPQ Office of Quality Surveillance. She is currently the lead in designing a new and innovative surveillance analytical platform that uses facility and product information to extract useful insights and trends to help consumer officers, investigators and reviewers efficient and informed decisions. Prior to joining the agency, Tsedenia had over 10 years of experience within the pharmaceutical industry within Quality, Drug Development and Corporate Quality Systems.

Katherine Won PharmD, MBA

CMDR, United States Public Health Service
Deputy Director, Division of Labeling Review
OGD | CDER | FDA

Katherine Won is a Commander in the United States Public Health Service and currently serves as the Deputy Director for the Division of Labeling Review (DLR) in the Office of Generic Drugs (OGD). She has over 13 years of experience at the FDA and served in various roles, which include Public Health Analyst in OEP, Safety Regulatory Project Manager in OND, Labeling Reviewer, Team Leader for Labeling Project Managers as well as a Labeling Review Team in OGD. She earned her Bachelor of Science in Pharmacy at Sookmyung Women's University located in Seoul, Korea. She later received her Doctor of Pharmacy degree at University of Maryland, Baltimore.

Rose Xu

Quality Assessment Team Lead (Acting)
Office of Pharmaceutical Manufacturing Assessment
OPQ | CDER | FDA

Rose Xu got her undergraduate degree in Fudan University school of Medicine. She came to US to pursue her graduate education, first in Arizona State University, followed by Johns Hopkins University school of Medicine. She joined FDA 12 years ago after spent almost 10 years in Industry. Rose is currently an acting Quality Assessment team lead in the office of Pharmaceutical Manufacturing Assessment (OPMA)/OPQ, conducting the manufacturing process review, facility evaluation, and compliance review. In addition to the review work, she is also participating many pre-approval inspections on many domestic and international manufacturers. Rose is one of the members that drafted the guidance to Industry of "Identification of Manufacturing Establishment in Applications Submitted to CBER and CDER, Q & A". The topic she is giving today is "Facility Submission Expectations in view of the 356H Form."

Lei Zhang, PhD

Deputy Director
Office of Research and Standards
OGD | CDER | FDA

Lei Zhang serves as the Deputy Director of the Office of Research and Standards, Office of Generic Drugs. She is an accomplished professional with more than 20 years of combined experiences in the areas of drug research, development and regulatory review and approval. Before joining FDA in 2002, Dr. Zhang worked at Bristol-Meyers Squibb Company as a Research Investigator and Preclinical Candidate Optimization Team Leader. She has contributed to numerous regulatory guidance development and revision including guidances on drug interaction and regulatory research focuses on the science-based regulatory decision-making. Dr. Zhang is a member of the International Transporter Consortium. Prior to her role as the deputy director of ORS, Dr. Zhang was previously Senior Advisor for Regulatory Programs and Policy in FDA's Office of Clinical Pharmacology, Office of Translational Sciences. She is an Adjunct Professor in the Department of Bioengineering and Therapeutic Sciences, UCSF Schools of Pharmacy and Medicine and has authored and co-authored numerous papers, book chapters, abstracts, and invited presentations. Dr. Zhang received her Ph.D. in Biopharmaceutical Sciences from the University of California, San Francisco.