SPEAKER BIOGRAPHIES

In order of presentations (see the Agenda)

Day 1 Presenters

Sally Choe, PhD
Director
Office of Generics 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.

Sau (Larry) Lee, PhD
Deputy Director of Science
Office of Pharmaceutical Quality (OPQ)
CDER | US FDA

Dr. Sau (Larry) Lee is the Deputy Super Office Director of Science in the Office of Pharmaceutical Quality (OPQ). He directs the activities of staff members in OPQ sub-offices responsible for the quality assessment of regulatory submissions (Office of Biotechnology Products (OBP), Office of Lifecycle Drug Products (OLDP), Office of New Drug Policy (ONDP) and Office of Pharmaceutical Manufacturing Assessment (OPMA)). He represents OPQ in programs and activities that impact quality assessments by coordinating with OPQ, CDER, and ORA. He also serves as the point person for the pharmaceutical industry and scientific/academic groups in developing programs to support science- and risk-based application assessment and approval.

Dr. Lee has been with the FDA since 2005, serving as a regulatory scientist, team lead, Associate Director for Science, Deputy Office Director, and Office Director. He has provided exemplary leadership in developing OPQ science, research and testing programs to support quality assessment, inspection, surveillance and policy. In 2016, Dr. Lee was appointed to the Senior Biomedical Research Service (SBRS) because of his extensive regulatory and scientific contributions to manufacturing science, complex drug substances and products, and emerging pharmaceutical technologies. Prior to joining the FDA, Dr. Lee received a B.S. degree in Chemical Engineering from the University of Virginia with a minor in Materials Science and a PhD in Chemical Engineering from Princeton University.

Sarah A. Ibrahim, PhD
Associate Director for Global Generic Drug Affairs
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 co-inventor 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.

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

Dr. Nilufer Tampal is the Acting Associate Director of Scientific Quality in OGD's Office of Bioequivalence. In this role, Dr. Tampal develops strategies and oversees implementation of data quality and the scientific integrity of bioequivalence data submitted in Abbreviated New Drug Applications (ANDAs). She provides expertise in utilization of advanced analytic data tools supporting ANDA reviews. Dr. Tampal received her PhD in Toxicology from University of Kentucky and a 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 (OSIS; pka OSI) and has held various leadership positions in the Office of Bioequivalence 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 in India.

Makini Cobourne-Duval, PhD
Pharmacologist
Office of Study Integrity and Surveillance (OSIS)
CDER | US FDA

Dr. Makini Cobourne-Duval earned both her Ph.D. in Pharmaceutical Sciences specializing in Pharmacology/Toxicology and her Master of Science degree in Chemistry specializing in Biochemistry from Florida A&M University. She now serves as a Pharmacologist in the Office of Study Integrity and Surveillance (OSIS) of the U.S. FDA's Center for Drug Evaluation and Research. Her work entails conducting site inspections and remote record reviews to evaluate the quality and integrity of data generated from the bioavailability and bioequivalence (BA/BE) studies in support of new drug and generic drug applications applying the principles of Good Laboratory Practices, pharmacology, pharmacokinetics, pharmacodynamics, bioanalysis, and principles of associated scientific disciplines. Additionally, she reviews other FDA investigators' inspection reports of clinical and nonclinical sites/studies to ensure compliance with FDA inspection guidelines and protocols and prepares thorough inspection reports with recommendations regarding site compliance with clinical and laboratory practices, regulations and standards.

Victoria Keck, MS, VMD
Lead Toxicologist
Division of Clinical Review
Office of Bioequivalence (OB)
OGD | CDER | US FDA

Dr. Victoria Keck is a Lead Toxicologist and Team Leader in OGD's Division of Clinical 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).

Ashley Boam, MSBE
Director
Office of Policy for Pharmaceutical Quality (OPPQ)
OPQ | CDER | US 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.

Jennifer Maguire, PhD
Deputy Director
Office of Quality Surveillance (OQS)
OPQ | CDER | US FDA

Dr. Jennifer Maguire is the Deputy Director of the Office of Quality Surveillance/OPQ/CDER/FDA. The office assesses intelligence throughout the product lifecycle to inform stakeholders about the state of pharmaceutical quality and uses data analytics to drive surveillance decisions. During her tenure at the agency, Dr. Maguire has contributed to multiple initiatives aimed at modernizing the regulation of pharmaceutical manufacturing and product quality including QbR, QbD, ICH Q12, Site Selection Model, Enterprise Risk Management, Quality Metrics and Quality Management Maturity. Dr. Maguire has a BS in Chemical Engineering from the University of Virginia and a PhD in Industrial and Physical Pharmacy from Purdue University.

Caliope Sarago, MHSA
Senior Regulatory Health Project Manager
Office of Research and Standards (ORS)
OGD | CDER | US FDA

Caliope Sarago is a Senior Regulatory Health Project Manager for the Immediate Office of OGD's Office of Research and Standards (ORS). In this role, Caliope facilitates teams of interdisciplinary scientists assigned to product specific guidance projects, responding to controlled correspondence submissions, pre-ANDA meetings and furthering research science for the development of generic drugs. Caliope began her FDA career in 2013, at the Center of Tobacco Products and joined the OGD in 2018. Prior to joining the FDA, Caliope held supervisory positions at American Type Culture Collection, in the Quality Control for Microbiology, Protistology and Mycology laboratories, and at the George Washington University Hospital (GWH), in the Transfusion (Blood Bank) Service and Ancillary Testing Program. While at GW, she also worked as a molecular biologist to develop clinical testing by PCR and immunohistochemistry for CMV, HIV and breast cancer receptors. Caliope has a B.Sc. in Applied Science and Medical Technology from Youngstown State University (Youngstown, Ohio) and a Masters in Healthcare Service Administration, with a focus in policy, from George Washington University (Washington, DC). She recently completed her Masters Certificate in Project Management from Duke University.

Fang Yuan, PhD
OPQ Pre-ANDA Triage Lead
Office of Lifecycle Drug Products (OLDP)
OPQ | CDER | US FDA

Dr. Fang Yuan received her PhD degree in Pharmaceutical Science from University of Nebraska Medical Center. She leads the pre-ANDA triage efforts and co-leads the OPQ pre-ANDA Steering Committee by providing periodic updates on pre-ANDA program in quarterly meetings. She is the main Point of Contact for OPQ, focusing on coordinating the communications amongst OPQ stakeholders and facilitating the collaboration with OGD counterparts for the pre-ANDA program. She has been a Chemistry Reviewer in Office of Lifecycle Drug Product since 2016, specialized in quality assessment of pre-market ANDA submissions and pre-ANDA submissions of complex generics including orally inhaled and nasal drug products, and long-acting injectable drug products. She serves as a government liaison in the USP Expert Committee – Aerosol Subcommittee and is a member of several FDA/CDER Working Groups (WGs) including Essential Drug Delivery Outputs (EDDOs) Guidance WG, Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) products – Quality Considerations Guidance WG, and Long-acting Drug Products WG.

Janice T. Brown, MS
Branch Chief
Office of Policy for Pharmaceutical Quality (OPPQ)
OPQ | CDER | US FDA

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

Lei Zhang, PhD
Deputy Director
Office of Research and Standards (ORS)
OGD | CDER | U.S. FDA

ORS implements the Generic Drug User Fee Amendments (GDUFA) science and research commitments to ensure the therapeutic equivalence of generic drug products. Dr. Zhang is an accomplished professional with more than 22 years of combined experiences in the areas of drug research, development and regulatory review and approval. She has contributed to numerous guidance development and research projects focused on the science-based regulatory decision-making. Before joining FDA in 2002, she worked at Bristol-Meyers Squibb Company as a Research Investigator and Preclinical Candidate Optimization Team Leader. Dr. Zhang is an Adjunct Professor in the Department of Bioengineering and Therapeutic Sciences, University of California at San Francisco, Schools of Pharmacy and Medicine. Dr. Zhang received her Ph.D. in Biopharmaceutical Sciences from UCSF. She is a member of the ICH Generic Drug Discussion Group (GDG), serving as the U.S. FDA Topic Leader. Additionally, she is the Rapporteur for ICH M13 Informal Working Group that is developing M13 guideline to harmonize bioequivalence (BE) study design for immediate-release oral dosage form drugs. Dr. Zhang was named American Association of Pharmaceutical Scientists (AAPS) Fellow in 2013.

Nnenna Nzelibe, Pharm.D., MPH, BCACP
Pharmacist
Division of Filing Review
Office of Regulatory Operations (ORO)
OGD | CDER | US FDA

Nnenna Nzelibe is a Controlled Correspondence Coordinator for the Division of Filing Review (DFR) in OGD's Office of Regulatory Operations (ORO). In this role, Dr. Nzelibe reviews and responds to inquiries submitted by generic drug manufacturers or their representatives related to generic drug development. She also coordinates various projects that arise with respect to controlled correspondences assigned to DFR. Prior to joining the FDA in 2017, Dr. Nzelibe was a pharmacy manager with Rite Aid Pharmacy in Crofton, Maryland. Dr. Nzelibe obtained her Doctor of Pharmacy (Pharm.D.) and Master of Public Health (MPH) degrees from University of Maryland (Baltimore, MD) and is also a Board-Certified Ambulatory Care Pharmacist (BCACP).

Bijal Patel, Pharm.D., BCPS
Lead Pharmacist
Division of Filing Review
Office of Regulatory Operations (ORO)
OGD | CDER | US FDA

Bijal Patel is a Team Leader in the Division of Filing Review (DFR) within the Office of Regulatory Operations. She joined the FDA in 2017. Prior to working at the FDA, she worked as a research pharmacist at the National Institute of Allergy and Infectious Diseases (NIAID), NIH. She has also worked as a clinical pharmacist and as an anticoagulation clinic pharmacist at Howard County General Hospital, Johns Hopkins Medicine. She received her Doctorate of Pharmacy from Northeastern University, Boston, Massachusetts and completed her Post-Doctoral Pharmacy Practice Residency training from VA North Texas Health Care System, Dallas, Texas. After completing the residency, Bijal obtained her Board Certification as Pharmacotherapy Specialist (BCPS).

Charlene Peterson, PharmD
Labeling Reviewer
Division of Labeling
Office of Regulatory Operations (ORO)
OGD | CDER | US FDA

Charlene Peterson is a Labeling Reviewer in the office of OGD's Office of Regulatory Operations. Dr. Peterson's primary role is to review Abbreviated New Drug Application (ANDA) submissions. She has worked in the Division of Labeling review since 2014. Prior to joining the FDA. Dr. Peterson worked at other various government facilities, DC General Hospital inpatient pharmacy and long term-care at U.S. Soldiers and Airmen's Home in Washington, DC. She worked at Ft. Meade's Kimbrough Care Center as an outpatient pharmacist, in Maryland then transferred to VA Medical Center in Washington, DC as an outpatient pharmacist and later transitioning to a Primary Care Pharmacist (Clinical Specialist) position. Dr. Peterson did a Pharmacy Residency at Howard University Hospital after graduating from the University of Connecticut with a B.S. in Pharmacy. She later received her Doctor of Pharmacy Degree from the University of Maryland School of Pharmacy.

Eunjung Esther Chuh, PharmD, BCGP
Commander, USPHS
Team Leader, Division of Labeling Review
Office of Regulatory Operations (ORO)
OGD | CDER | US FDA

CDR Eunjung Esther Chuh is a Team Leader in the Division of Labeling Review in OGD's Office of Regulatory Operations. In this role CDR Chuh leads a team of pharmacists responsible for reviewing the labeling submissions in the Abbreviated New Drug Applications. She has been with OGD since 2007 as a Regulatory Project Manager and later as a Medical Affairs Coordinator for the Division of Clinical Review in the Office of Bioequivalence. She joined the Division of Labeling Review as a primary reviewer in 2015 and has served in her current role as a team leader since 2020. CDR Chuh a has a Doctor of Pharmacy (PharmD) degree from Virginia Commonwealth University in Richmond, VA and obtained her Board Certification in Geriatric Pharmacy.

Julia Lee, PharmD
Deputy Division Director
Office of Regulatory Operations (ORO)
OGD | CDER | US FDA

Dr. Julia Lee is the Deputy Director in the Division of Filing Review. She joined the Office of Generic Drugs in 2012 as a regulatory filing reviewer. Prior to working at the Agency, she was a retail pharmacist at Walgreens. She has also worked in the Chesapeake-Atlantic node of the Pediatric Emergency Care Applied Research Network as a clinical research assistant. She received her Doctorate of Pharmacy at the University of Maryland, Baltimore, School of Pharmacy and her Bachelor of Science in Chemistry at The George Washington University.

Tao Bai, PhD
Lead Pharmacologist
Office of Bioequivalence (OB)
OGD | CDER | US FDA

Dr. Tao Bai is a Lead Pharmacologist and a Team Leader in OGD's Office of Bioequivalence (OB). In her current role she coordinates all COVID-19 related scientific inquiries submitted to OGD and provide her professional input to ensure an efficient and consistent response to these inquiries in a timely fashion. Prior to joining FDA in 2010, Dr. Bai was a postdoctoral Research Fellow at University of Maryland School of Pharmacy studying Nasal and Inhalation Drug Products. She received her Ph.D. in Pharmaceutical Sciences from University of Maryland.

Cassandra Abellard
Primary Assessor
Division of Microbiology Assessment (DMA)
Office of Pharmaceutical Manufacturing Assessment (OPMA)
OPQ | CDER | US FDA

Cassandra Abellard works for the Food and Drug Administration (OMPA) in the Center for Drug Evaluation and Research's Office of Pharmaceutical Manufacturing Assessment as a Primary Assessor. She has performed Manufacturing assessments for new and generic drug applications since 2015. She joined the FDA in early 2014 as an investigator in ORA prior to moving to CDER. In addition to performing application assessments, she routinely participates on Pre-Approval Inspections and has played crucial roles in training other assessors in these disciplines through mentoring and unique training platforms enabling easy access to up-to-date policies. She also participated in assessments for the Mutual Recognition Agreement with MRA. Prior to joining the FDA, Ms. Abellard worked the Pharmaceutical and Food Industries for over 17 years in various roles from Production Management to Quality Management. She has an AAS in Veterinary Science and a B.Sc. in Cellular Biochemistry from Plattsburgh State University. In her spare time, she enjoys gardening, sports and spending time with her family doing various activities.

Jonathan Swoboda, PhD
Senior Pharmaceutical Quality Assessor
Division of Microbiology Assessment (DMA)
Office of Pharmaceutical Manufacturing Assessment (OPMA)
OPQ | CDER | US FDA

Dr. Jonathan Swoboda works for the Food and Drug Administration in the Center for Drug Evaluation and Research's Office of Pharmaceutical Manufacturing Assessment as a Senior Pharmaceutical Quality Assessor. He performs Secondary Assessments of Process and Facility evaluations of new and generic drug applications since 2018. He joined the FDA in late 2011 and has served as a Commissioner's Fellow in the Center for Biologics Research and Evaluation in addition to a Primary Assessor in the areas of Facilities and Microbiology while performing Pre-Approval Inspections as a Microbiology Subject Matter Expert. In addition to performing application assessments, he has played crucial roles in training other assessors in these disciplines through mentoring, site visits and unique training platforms enabling easy access to up-to-date policies. Prior to joining the FDA, Dr. Swoboda completed a Post-Doctoral Fellowship in regenerative medicine at The Scripps Research Institute and the Genomics Institute of the Novartis Research Foundation in San Diego. His research focused on the development of high-throughput screening methodologies for identifying regenerative small molecules for the treatment of diabetes, cardiovascular disease, and macular degeneration. Dr. Swoboda earned his PhD and MA in Chemistry from Harvard University performing research on innovative antimicrobial therapeutics targeting drug-resistant microorganisms and his B.Sc. in Biochemistry from Brown University. In his spare time, he enjoys spending time with his wife and daughter fishing as well as car repair, woodworking, and household renovations.

Day 2 Presenters

Lakeeta Carr, MSN/MHA, BSN, RN, NHDP-BC
CAPT, USPHS
Senior Regulatory Project Manager
Office of Regulatory Operations (ORO)
OGD | CDER | US FDA

CAPT Lakeeta Carr is a Senior Regulatory Project Manager (RPM) in the Division of Project Management in OGD's Office of Regulatory Operations. In this role, CAPT Carr is responsible for coordinating and managing the lifecycle approval process for Abbreviated New Drug Applications (ANDAs). She is one of four RPMs assigned to the team that manages President's Emergency Plan for AIDS Relief (PEPFAR) ANDAs. Additionally, she serves as Chair of the Mid-Review Cycle Meeting workgroup. Prior to joining the FDA in 2015, CAPT Carr served as Associate Deputy Director of Operations Support at Federal Occupational Health, a non-appropriated agency that works with other federal organizations nationally and internationally to design and deliver comprehensive occupational health solutions exclusively to federal employees. CAPT Carr has a Bachelor of Science in Nursing (BSN) from the University of Michigan, a Master of Science in Nursing (MSN)/Master of Health Administration (MHA) from the University of Phoenix, and a Graduate Certificate in Global Health and Global Health Engagement from the Uniformed Services University.

Nicholas Daniel, PharmD, BCPS
LCDR, USPHS
Team Lead
Division of Project Management (DPM)
Office of Regulatory Operations (ORO)
OGD | CDER | US FDA

LCDR Daniel is a Team Lead for the Division of Project Management in OGD's Office of Regulatory Operations. In this role LCDR Daniel leads a group of project managers who are responsible for planning, organizing, and evaluating the review process of approximately 150 concurrent generic drug applications. Prior to joining the FDA in 2016, LCDR Daniel was a pharmacist with the Indian Health Service, in Shiprock, NM. LCDR Daniel has a B.A. with Honors in Sociology from the University of Alabama at Birmingham (Birmingham, AL) and Doctor of Pharmacy from Samford University (Birmingham, AL).

Cassandra Metu, PharmD, MS, BCPS, PMP, RAC
LCDR, USPHS
Senior Regulatory Project Manager
Office of Regulatory Operations (ORO)
OGD | CDER | US FDA

LCDR Cassandra Metu is a Senior Regulatory Project Manager (RPM) in the Division of Project Management in OGD's Office of Regulatory Operations. In this role, LCDR Metu is responsible for managing the lifecycle approval process for Abbreviated New Drug Applications (ANDAs) and operates as the liaison between the applicants and the FDA regarding the review of those ANDAs. Prior to joining the FDA in 2014, LCDR Metu served as an Advanced Practice Clinical Pharmacist providing comprehensive clinical care to the Navajo Nation at the Gallup Indian Medical Center in Gallup, NM. LCDR Metu has a Doctor of Pharmacy degree from Howard University, a Master of Science in Management with a Healthcare Administration Specialization from the University of Maryland University College, and a Graduate Certificate in Project Management from the George Washington University.

Heidi Lee, PharmD.
Branch Chief
Office of Program and Regulatory Operations (OPRO)
OPQ | CDER | US FDA

Heidi Lee is a Branch Chief with the Office of Program and Regulatory Operations, Office of Pharmaceutical Quality (OPQ). Before joining OPQ in 2019, she served in various roles such as Regulatory Project Manager, Team Leader, and Associate Director for Regulatory Affairs within the Office of Generic Drugs. She received her Doctor of Pharmacy degree from University of Maryland, Baltimore and practiced in a community setting before joining the FDA.

Thomas O'Connor, PhD
Division Director
Division of Product Quality Research (DPQR)
Office of Testing and Research (OTR)
OPQ | CDER | US FDA

Dr. O'Connor is the director of the Division of Product Quality Research in the Office of Testing and Research (DPQR) in the Office of Pharmaceutical Quality and is a member of CDER's Emerging Technology Team (ETT). His responsibilities include managing research and testing projects that answer and anticipate pharmaceutical quality-related regulatory challenges through scientific approaches. The impact of OTR research and testing is utilized to support regulatory assessment and policy development in areas such advanced manufacturing, drug quality standards, characterization of complex drug substances and drug products, and post-market product quality and public health issues. Tom is a co-author of several papers on emerging pharmaceutical technology (such as continuous manufacturing, 3D printing, and the utilization of modeling and simulation for quality assurance). Through the ETT he has contributed to the review of several regulatory applications utilizing novel technologies. He is the co-chair of the OPQ Manufacturing Science and Innovation Center of Excellence and is a member of the advanced manufacturing working groups within the FDA.

Tom originally joined the FDA as chemistry reviewer in the Office Generic Drugs. 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 PhD in chemical engineering from Princeton University.

Rachel Dunn, PhD
Division Director
Division of Pharmaceutical Analysis (DPA)
Office of Testing and Research (OTR)
OPQ | CDER | US FDA

Rachel Dunn joined the FDA in 2020 as the Director of the Division of Pharmaceutical Analysis (DPA). Dr. Dunn earned a PhD in Chemistry from the University of Illinois at Urbana-Champaign. She held positions both in the lab and in management at Chemir Analytical Services (now EAG), including Associate Scientist and Director of Technical Services. Prior to joining the FDA, Dr. Dunn supervised the operations and staff of the Chemistry Department at Washington University in St. Louis.

Patricia Onyimba, MS
Branch Chief
Division of Liquid-Based Products I (DLBPI)
Office of Lifecycle Drug Products (OLDP)
OPQ | CDER | US FDA

Patricia Onyimba is a Branch Chief with the Division of Liquid-Based Products I in Office of Lifecycle Drug Products (OLDP)/ Office of Pharmaceutical Quality (OPQ). She started her carrier as a review chemist with the FDA in 2010 and has served in different positions (Assistant to the Director, Team Leader and Branch Chief) since then. Patricia oversees review of Chemistry, Manufacturing and Controls (CMC) sections of generic drug applications for liquid-based drug products. Prior to joining the FDA, Patricia spent over 16 years in various pharmaceutical companies and contract research organization where she performed hands-on laboratory work, managed quality control and analytical development teams responsible for method validations and transfers, stability program design, drug substance and drug product specifications development, and providing analytical support to formulation development teams. Her industry experience also included managing CMC activities at contract manufacturing sites and compilation/review of CMC sections of regulatory documents. Patricia holds a Bachelor of Science (BS) degree in Chemistry from the University of Nigeria, Nsukka and a Master of Science (MS) degree from the Johns Hopkins University, Baltimore, MD.

Kshitij A. Patkar, PhD
Senior Pharmaceutical Quality Assessor
Office Pharmaceutical Manufacturing Assessment (OPMA)
OPQ | CDER | US FDA

Kshitij Patkar is a Senior Pharmaceutical Quality Assessor in the Office Pharmaceutical Manufacturing Assessment (OMPA). He oversees the review activities of drug product manufacturing processes and facilities for both generic and new drug applications. At FDA, Kshitij has almost 10 years of experience in the assessment of liquid dosage form drug product applications. Before joining FDA, Kshitij worked as a principle investigator and administrator of bioanalytical operations at Torrey Pines Institute for Molecular Studies, Florida. He received his PhD in Pharmaceutical Sciences from University of Maryland, Baltimore in 2002 with principle focus on peptide synthesis and analysis.

Melanie Mueller, PharmD, PhD
Lead Toxicologist
Office of Bioequivalence (OB)
OGD | CDER | US FDA

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

Shin (Grace) Chou, PhD
Application Technical Lead
Office of Lifecycle Drug Products (OLDP)
OPQ | CDER | US FDA

Dr. Shin (Grace) Chou is an Application Technical Lead in the OLDP of OPQ. She is responsible for conducting drug product quality review for abbreviated new drug applications (ANDA) and overseeing the technical portion of the ANDA assessment. Grace is a co-author of more than 50 peer reviewed publications on the subject of physiochemical characterization of different types of materials. While at FDA, she has conducted CMC review on more than 300 abbreviated new drug applications on liquid-based drug products. Prior to joining the FDA, Grace worked first as a senior chemist at Pfizer where she conducted formulation and process development on liquid-based drug products. Subsequently, Grace worked as a research chemist at the National institute of Standards and Technology where she developed reference standards and measurement sciences. Dr. Chou earned a B.A. in Chemistry and Physics from Bryn Mawr College and a Ph.D. in physical chemistry from Massachusetts Institute of Technology.

Changning Guo, PhD
Chemist
Division of Complex Drug Analysis
OTR
OPQ | CDER | US FDA

Dr. Guo is a research chemist at FDA/CDER/OPQ/OTR. He has been with the FDA for 16 years and currently works in the Division of Complex Drug Analysis (DCDA) at Saint Louis, MO. His research at FDA focuses on inhalation drug characterization, particle sizing, X-ray powder diffraction (XRPD), and spectroscopy. He has been a principle investigator (PI) and co-PI on multiple FDA research projects, serving as a member in several FDA working groups, guidance teams, subject-matter expert panels, and grant review committees.

Min Li, PhD
Quality Assessment Lead (Acting)
Division of Biopharmaceutics
Office of New Drug Products (ONDP)
OPQ | CDER | US FDA

Dr. Min Li is currently an acting Quality Assessment Lead in the Division of Biopharmaceutics, Office of New Drug Products (ONDP), Food and Drug Administration. Her experience focuses on the review and research in the area of in vitro dissolution method development/specification, in vitro in vivo correlation (IVIVC), mechanistic oral absorption modeling and simulation, pharmacokinetic modeling, clinically relevant specifications, risk assessment, etc. Dr. Li received her PhD in Pharmaceutical Science in 2013 from Virginia Commonwealth University. She also holds a bachelor's degree in pharmacy and master's degree in medicinal chemistry. She joined the FDA's Office of Pharmaceutical Quality (OPQ) in 2014 and has worked in the Division of Biopharmaceutics since 2015.

Vidya Pai, PhD
Branch Chief
Division of Pharmaceutical Manufacturing IV
Office Pharmaceutical Manufacturing Assessment (OPMA)
OPQ | CDER | US FDA

Dr. Vidya Pai is currently a Branch Chief in Branch 12 in the Division of Pharmaceutical Manufacturing IV, effective September 25, 2020. Vidya has most recently served as a secondary reviewer in OPQ/OPMA/DPM IV. Her prior assignments include detailing as Acting Quality Assessment Lead as well as Acting Branch Chief in DPM IV. She has extensive experience in the integrated quality assessment of many dosage forms including injection solution/powder, semi-solid, ophthalmic solution, and complex drug products. She continues to be involved in multiple cross-training efforts across OPMA and contributes to a variety of working groups across OPQ.

Vidya began her career at FDA in 2014 as a Chemical Engineer in OPS, transitioning to Office of Pharmaceutical Manufacturing Assessment (OPMA) (previously OPF) shortly thereafter. Her industry experience spans over 20 years and includes downstream Processing competency for nutritional lipids, formulation of vaccines for infectious diseases, as well as research, process innovation and technology transfer for food and bio-based materials. She received her M.S. and PhD in Chemical Engineering from the University of Virginia, Charlottesville and a B.S. in Chemical Engineering from University of Mumbai, Institute of Chemical Technology, India.

Marla Stevens-Riley, PhD
Branch Chief
Division of Microbiology Assessment (DMA)
Office Pharmaceutical Manufacturing Assessment (OPMA)
OPQ | CDER | US FDA

Dr. Stevens-Riley is a Branch Chief in the Division of Microbiology Assessment (DMA) in the Office of Pharmaceutical Manufacturing Assessment (OPMA) in the Office of Pharmaceutical Quality (OPQ). She supervises product quality microbiology primary assessors and senior pharmaceutical quality assessors (SPQAs) in the evaluation of product quality microbiology information in the chemistry, manufacturing, controls section of Abbreviated New Drug Applications (ANDAs), New Drug Applications (NDAs), supplemental applications, Drug Master Files (DMFs), Investigational Drug Applications (INDs), and meeting packages. Previously, she was a Master Microbiology Reviewer and Quality Assessment Lead (QAL) in DMA, a policy lead in the Office of Policy for Pharmaceutical Quality (OPPQ), and a Team Leader in the Division of Microbiology in the Office of Generic Drugs (OGD). During her scientific career, she has co-authored over 15 peer-reviewed scientific publications. She earned her B.S. in Biology from the College of William and Mary and her PhD in Microbiology from the University of Georgia. She completed her post-doctoral training in the Department of Microbiology and Immunology at the University of Texas Southwestern Medical Center in Dallas.

Mayra Pineiro-Sanchez, PhD
Senior Pharmaceutical Quality Assessor (SPQA)
Office of Lifecycle Drug Products (OLDP)
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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.

Howard D. Chazin, MD, MBA
Director
Clinical Safety Surveillance Staff (CSSS)
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Howard Chazin is the Director of the Clinical Safety Surveillance Staff in CDER's Office of Generic Drugs. Since 2016, he has been the lead of a multidisciplinary team of pharmacists, physicians and data analysts tasked with identifying and assessing emerging generic drug premarketing and postmarketing safety issues. From 2011-2016, Dr. Chazin was the Deputy Director/Acting Director of the Division of Hematology Clinical Review in FDA's Center for Biologic Evaluation and Research. From 2002 through 2011, he filled several roles in CDER's Office of New Drugs (OND) Division of Neurology Products and the OND Immediate Office's Guidance and Policy Team. Dr. Chazin received his medical degree from the Rutgers-Robert Wood Johnson Medical School, completed an Internal Medicine internship and Neurology residency at the George Washington University Medical Center, and obtained his MBA in Health Services Management from the Johns Hopkins University School of Medicine and Carey Business School.

Linda Forsyth, M.D.
Medical Officer
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Linda Forsyth, M.D. is a medical officer in the Clinical Safety Surveillance Staff in CDER's Office of Generic Drugs. In this role, Dr. Forsyth assesses emerging generic drug premarket and postmarket safety issues. She has been a medical officer at the FDA since 1999, working in both 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 (Washington, DC). Dr. Forsyth also has completed postgraduate studies and graduated with a Certificate in Patient and Product Safety from the University of Southern California and a Certificate in Public Health from Georgetown University.

Lauren Gilles, MPH, BSN, RN
REMS Coordinator
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Lauren Gilles is a REMS Coordinator for the Immediate Office in OGD's Office of Bioequivalence (OB). In this role, Ms. Gilles manages and facilitates timely completion of safety reviews and implementation of programs ensuring the benefits of high-risk drugs outweigh the known risks. Before her work at CDER, she was a Nurse Consultant conducting post-market surveillance of medical devices for the FDA's Center for Devices and Radiological Health (CDRH). Prior to joining the FDA in 2015, Ms. Gilles was a critical care nurse at Sibley Memorial Hospital in Washington, D.C. Ms. Gilles holds a Bachelor of Science in Nursing (BSN) from Johns Hopkins School of Nursing (Baltimore, MD) and Master of Public Health (MPH) in Community Health Education from the University of Maryland (College Park, MD). She recently completed her Masters Certificate in Project Management from Duke University.

Niles Ron, PhD
Branch Chief
Division of Post-Marketing Activities-II
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OPQ | CDER | US FDA

Dr. Niles Ron is currently a Branch Chief in the Division of Post-Marketing Activities-II, which is responsible for post-marketing activities for generic drugs, including ANDA supplement review. Dr. Ron has been at the FDA since January 2011, starting as a CMC reviewer for ANDAs. Prior to joining the FDA, Dr. Ron held several positions of increasing responsibility in scientific management in the biopharmaceutical industry spanning over a period of 12+ years, relating to CMC activities including product and process development, and manufacturing. He received his PhD from Washington University in Saint Louis in Chemical Engineering and his MBA from Clark University in Worcester, Massachusetts.

Debra M. Catterson, RPh
Lead Clinical Safety Coordinator
Clinical Safety Surveillance Staff (CSSS)
OGD | CDER | US FDA

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 12 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.