CDER SBIA Generic Drugs Forum 2019

Presenter and Facilitator Biographies

Om Anand, PhD

Division of Biopharmaceutics
Office of New Drug Products (ONDP)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

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.

Alicia Chen, PharmD

Acting Team Lead

Orange Book Staff
Office of Generic Drugs Policy (OGDP)
OGD | CDER | FDA

Alicia Chen is currently the acting Team Lead of the Orange Book Staff in the Office of Generic Drug Policy. Dr. Chen joined the FDA in 2014 as a bioequivalence project manager in the Office of Bioequivalence in OGD before joining the Orange Book staff as a pharmacist. Dr. Chen received her Doctorate of Pharmacy from the University of Maryland at Baltimore and received her Bachelor's degree in biochemistry from Georgetown University. Dr. Chen has had experience in hospital and retail pharmacy before joining the FDA.

Chao (Ethan) Chen, PMP, MSE, MBA

Director
Division of Data Management Services and Solutions (DDMSS)
Office of Business Informatics (OBI)
Office of Strategic Programs (OSP)
CDER | FDA

Ethan Chen provides overall leadership to CDER in streamlining electronic and traditional submissions and delivering solutions to enable rapid adoption of emerging electronic data standards. Since joining the FDA in 2012, Mr. Chen has led the several critical initiatives as the CDER Informatics Architect, including Data Management and Business Intelligence programs. Ethan has over 20-years' experience in Data Management, Enterprise Architecture, Solution Development and System Integration.

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.

Dat Doan, PharmD, PMP

Captain, United States Public Health Service
Supervisory Project Manager
Division of Project Management
Office of Regulatory Operations (ORO)
OGD | CDER | FDA

CAPT Dat Doan, PharmD, PMP, is currently a Supervisory Project Manager (SPM) in the Division of Project Management (DPM) at the Office of Generic Drugs (OGD). In this role, he is focused on several aspects of the generic drug approval process such as strategic planning, staffing, communication with industry, and process and team development to fulfill the mission of the FDA/OGD and the requirements of the Generic Drug User Fee Amendments (GDUFA II). He received his Bachelor of Science in pharmacy at the Temple University School of Pharmacy in 1996 and later received his Doctor of Pharmacy degree at Shenandoah University's Bernard J. Dunn School of Pharmacy in 2011. Prior to joining OGD in 2007, he practiced eight years as an Operations Resource Specialist with a national pharmacy retail chain.

Forest “Ray” Ford, Jr., PharmD

Commander, 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.

Elizabeth Giaquinto Friedman, JD, LLM

Regulatory Counsel

OGD | CDER | FDA

Elizabeth Giaquinto Friedman is a regulatory counsel in the Office of Generic Drug Policy, Office of Generic Drugs (OGD). Before joining OGD in October, 2013, Ms. Giaquinto was a staff member in CDER’s Office of Executive Programs since 2008. Ms. Giaquinto holds JD and LLM. degrees from Seton Hall University School of Law.

Beth (Duvall) Goldstein, BS

Science Policy Analyst

ONDP | CDER | FDA

Beth (Duvall) Goldstein co-manages the 505(b)(2) Regulatory Program in OND Policy. In that role, she is a subject matter expert and is responsible for all aspects of the program (e.g., application review, committee meetings, letter templates, tracking and data quality, liaison for review division staff, Web site publishing, Congressional reports, and internal/external training).

Beth first joined the FDA in 1996 as a Regulatory Project Manager in OND’s Division of Anti-Infective Drug Products where she worked until assuming the Postmarketing Requirement/Postmarketing Commitment (PMR/PMC) Program Manager position in OND’s Immediate Office (IO) in 2003. She later served as a Team Leader for the Regulatory Affairs team in the IO from 2006-2011, followed by the OND IO Associate Director for Regulatory Affairs (ADRA) under Dr. John Jenkins from 2011-2017, before transitioning into her current OND Policy role. Over her career, Beth has served in numerous CDER working groups and center-wide activities (e.g., Regulatory Project Management Coordinating Committee (RPMCC) Training and Certification Committee, FDA Forms, the CDER Exclusivity Board, Medicare Modernization Act (MMA) implementation, PDUFA implementation, and Inter-Center Consult Requests) and authored/edited many CDER MAPPs and guidances.

Prior to joining FDA in 1996, Beth was a Laboratory Research Technician at DuPont (Wilmington, Delaware) from 1989-1996. She has a bachelor's degree in Chemistry with a minor in mathematics from the University of Delaware. She is an Excellence in Government senior fellow (2008).

Frank Holcombe, Jr.

Chemist

Office of Lifecycle Drug Products (OLDP)
OPQ | CDER | FDA

Yaodong (Tony) Huang, PhD

Chemist/Acting Quality Assessment Lead
Office of Process and Facilities/DPAIII/BranchVIII
OPQ | CDER | FDA

Dr. Yaodong (Tony) Huang is an acting Quality Assessment Lead and Reviewer in the Division of Process Assessment, Office of Process and Facilities in CDER of FDA. He focuses on the assessment of drug product manufacturing processes employed in both Generic and New drug applications. He also performs facility review, pre-approval inspection and inspectional assessment. Prior to joining the agency in 2014, he was a Team Lead at Bayer to support formulation and process development. He received a BS degree in Chemical Engineering from Tsinghua University in Beijing, and a PhD degree in Chemical Engineering from Lehigh University.

Victoria Keck, MS, VMD

Toxicologist
Division of Clinical Review
OGD | CDER | FDA

Dr. Keck is a toxicology reviewer for the FDA's Office of Generic Drugs (OGD). She has conducted pharmacology/toxicology reviews of Drug Master Files and Abbreviated New Drug Applications for OGD since 2015. She completed her master's in Biotechnology/Bioinformatics at Johns Hopkins University, her VMD at the University of Pennsylvania, and her residency in laboratory animal medicine at Vanderbilt University Medical Center.

Andrew Kim, PharmD, PMP

Lt. Commander, United States Public Health Service
Supervisory Project Manager
Division of Project Management
ORO | OGD | CDER | FDA

Andrew Kim is a Lieutenant Commander in the United States Public Health Service and currently serves as the Supervisory Project Manager for the Division of Project Management in the Office of Generic Drugs (OGD). He has over 8 years of project management experience at OGD starting as a Regulatory Project Manager and then as the Regulatory Project Manager Team Leader for the multidiscipline supplement team. Andrew earned his bachelor's degree from the Johns Hopkins University and his PharmD from the University of Maryland.

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.

Christine Le, PharmD, PMP

Commander, United States Public Health Service
Regulatory Research Officer/Project Manager
ORS | OGD | CDER | FDA

Commander (CDR) Christine Le joined the Office of Research and Standards/OGD in January 2017 as a senior regulatory project manager. Throughout her work in the ORS, CDR Le is instrumental in policy, process development and implementation of the Pre-ANDA program under GDUFA. CDR Le also serves as the subject matter expert and provides project management support for collaboration and engagements of the CDER Offices involved in the Pre-ANDA program.

CDR Le received her Doctor of Pharmacy (PharmD) from the Bernard J. Dunn School of Pharmacy, Winchester, VA in 2001 and the Project Management Professional (PMP) certification in 2015. She has over 17 years' experience as a hospital pharmacist in Virginia.

Julia Lee, PharmD

Deputy Division Director
Division of Filing Review
ORO | OGD | CDER | 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 Doctor of Pharmacy at the University of Maryland, Baltimore, School of Pharmacy and her Bachelor of Science in Chemistry at The George Washington University.

Sau (Larry) Lee, PhD

Senior Biomedical Research Scientist
Team Leader
OPQ Botanical Review Team
CDER | FDA

Sau (Larry) Lee is a Senior Biomedical Research Scientist (SBRS) and serves as the Associate Director for Science of the Office of Pharmaceutical Quality (OPQ), the Team Leader of the OPQ Botanical Review Team, and the chair of the OPQ Emerging Technology Team. Larry and his OPQ Scientific and Research Staff are leading the effort in advancing OPQ research and in manufacturing science, complex drug substances and products containing nanomaterials, as well as in developing the regulatory policy, scientific standards as well as computational and modeling tools supporting quality review and inspection in OPQ. Larry joined the Office of Generic Drugs (OGD) in 2005 as a chemical engineer. In 2012 – 2013, Larry was the peptide team leader which specializes in CMC reviews of ANDAs for complex drug substances and products, including inhalation products. As a member of the Office of Pharmaceutical Quality (OPQ) TAG Integrated Team-based Review Pilot, Larry led a team to evaluate OPQ's vision for a team-based product and process/facility quality assessment approach. He also co-led the Risk Based Review Pilot which aimed to increase the review quality and efficiency of injectable products. In early 2013, Larry was promoted to Expert Regulatory Scientist in recognition of his expertise in evaluation of complex drug substances and products. Larry received a B.S. degree in Chemical Engineering from the University of Virginia with a minor in Materials Science and a Ph.D. in Chemical Engineering from Princeton University.

Susan Levine, JD

Deputy Director
Division of Policy Development | OGD | CDER | FDA

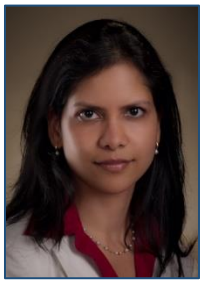
Ms. Levine currently serves as the Deputy Director of the Division of Policy Development in the Office of Generic Drug Policy where she leads development and implementation of policies for the generic drug program. Prior to this role, she was a Regulatory Counsel in the Office of Generic Drug Policy's Division of Legal and Regulatory Support where she resolved application-specific regulatory issues. She began her FDA career as a Review Chemist in the Office of Generic Drugs where she reviewed abbreviated new drug applications with a variety of dosage forms including topicals, injectables, ophthalmics, otics, and immediate release tablets. Ms. Levine received her B.S. degree in Chemical Engineering from the University of Maryland, College Park, and her J.D. from the University of Baltimore School of Law.

Hongbiao Liao, MS

Primary Reviewer
Division of Life Cycle API (DLAPI)
ONDP | OPQ | CDER | FDA

Hongbiao Liao graduated from the State University of New York at Albany and received a MS in organic chemistry in 1999. Prior to joining the FDA, he worked as a senior chemist in the pharmaceutical companies Merck and legacy Schering-Plough for fifteen years. His expertise is in process development and GMP manufacturing of active pharmaceutical ingredient. Currently he is a primary reviewer in the Division of life cycle API, ONDP/OPQ/CDER.

Nusrat Motlekar, PhD



Senior Science Policy Analyst
Office of Policy for Pharmaceutical Quality (OPPQ)
OPQ | CDER | FDA

Dr. Nusrat Motlekar has been with the agency since 2010 and has served as a CMC reviewer and currently serves as a senior science policy analyst at the Office of Policy in OPQ. Nusrat is involved with leading multi-disciplinary teams in the development of Guidances, MAPPs and other policy documents.

Prior to joining the FDA, Nusrat served as an Assistant Professor at the Division of Pharmaceutical Sciences, Butler University, Indianapolis.

Phuong (Aiden) Nguyen

Filing Reviewer
Division of Filing Review (DFR) | ORO | OGD | CDER | FDA

Phuong (Aiden) Nguyen graduated from Massachusetts College of Pharmacy and Health Sciences, located in Boston, Massachusetts in 2015. Before joining the FDA, Aiden worked as a retail pharmacist at CVS pharmacy, then as an ambulatory care pharmacist for Kaiser Permanente. He started at the FDA in 2018 and is currently a filling reviewer for the Division of Filling Review in OGD.

Vidya Pai, MS, PhD

Chemist/Acting Quality Assessment Lead
Division of Inspectional Assessment (DIA)
Office of Process and Facilities
OPQ | CDER | FDA

Vidya Pai, currently serves as a Facility Reviewer and Acting Quality Assurance Lead, in the Division of Inspectional Assessment, Office of Process and Facilities within CDER. She has over 18 years of multi-disciplinary experience supporting process and product development for the food, nutrition, vaccine and bio-based manufacturing industries. Within OPF, she has served as a process and facility reviewer for generic and new drug applications, of a variety of multiple dosage forms, supporting both review and inspectional assessment of facilities. She has a M.S. and Ph.D. in Chemical Engineering, from the University of Virginia and Bachelor's Degree in Chemical Engineering from the University of Mumbai, India.

Donal Parks MBA, MPM

Director
Division of User Fee Management and Budget Formulation
Office of Management (OM)
CDER | FDA

Donal directs the Division of User Fee Management and Budget Formulation at CDER's Office of Management. This staff is responsible for collecting user fees under the Generic Drug User Fee Amendments (GDUFA), the Prescription Drug User Fee Amendments (PDUFA), and the Biosimilars User Fee Act (BsUFA), all of which were authorized or reauthorized in the FDA Safety and Innovation Act as signed by the President on July 9, 2012. Before joining the FDA as an operations research analyst in 2008, Donal worked for the District of Columbia Office of the Chief Financial Officer, on Capitol Hill for the Chief Administrative Officer of the House of Representatives, and for a private consulting firm specializing in public health-related outsourcing work. He earned graduate degrees in finance (MBA) and in public-sector financial management (MPM) from the University of Maryland at College Park in 1995, and an undergraduate degree in Foreign Service from Georgetown University in 1988.

Bhagwant Rege, PhD

Division Director
Division of Modified Release Products
OLPD | OPQ | CDER | FDA

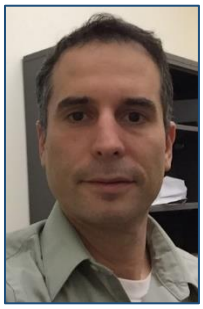
Dr. Bhagwant Rege is the Division Director for the Division of Modified Release Products in CDER/OPQ/OLDP at the FDA. Prior to joining FDA in 2010, he worked at Merck & Co. for about 9 years in oral biopharmaceutics and formulation development groups. His division at FDA is responsible for collaborative evaluation and assessment of Abbreviated New Drug Applications (ANDAs) for modified release drug products, nasal and inhalation drug products and making risk-informed recommendations on their approvability. Bhagwant has served as a team leader and review chemist in the Office of Generic Drugs where he was part of the team that developed the QbD examples for the generic industry. He is a member of the FDA Emerging Technology Team (ETT), ICH Q12 Expert Working Group (EWG), and FDA liaison on the USP expert committee on dosage forms general chapter (2015-2020).

Bhagwant received his Bachelors and Masters in pharmacy from the University of Mumbai, India and a Ph.D. in Pharmaceutical Sciences from the University of Maryland, Baltimore.

Ke Ren

Associate Director
Division of Bioequivalence III
OGD | CDER | FDA

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.

Kendra S. Stewart, RPh, PharmD

Captain, United States Public Health Service
Supervisor
Orange Book Staff
OGDP | OGD | CDER | FDA

CAPT Kendra Stewart is the Supervisor of the Orange Book Staff within the Office of Generic Drugs Policy (OGDP) at the Food and Drug Administration (FDA). She joined the FDA in 2003 as a Commissioned Officer in the US Public Health Service on the Orange Book Staff. She held that position until 2008, at which time she joined what was then known as the Labeling Review Branch within the Office of Genic Drugs (OGD). In 2013, after spending nearly five years as a labeling reviewer within that group, CAPT Stewart returned to the Orange Book staff where currently she holds the position of Senior Supervisor Regulatory Affairs. In her work with the Orange Book she is involved extensively with various policy issues, drug product listings and patent and exclusivity matters.

Brenda Stodart, PharmD, BCGP

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

CAPT Brenda Stodart is currently the Program 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.

Katherine Tyner, PhD

Chemist

Division of Applied Regulatory Science
Office of Clinical Pharmacology (OCP)
CDER | FDA

Dr. Tyner is a chemist in the Division of Applied Regulatory Science in the Center for Drug Evaluation and Research (CDER). She received her B.A. in Chemistry from Carleton College in 1999 and her PhD in Chemistry from Cornell University in 2004, where she worked under the direction of Emmanuel Giannelis. From 2004-2006 she completed a postdoctoral fellowship in a joint appointment between the Toxicology Program and the Chemistry Department at the University of Michigan under the direction of Martin Philbert and Raoul Kopelman. She joined the Food and Drug Administration in 2007 as a chemist specializing in nanotechnology. Her research involves assessing nanotechnology as it relates to the safety and efficacy of therapeutics. While at the FDA, Dr. Tyner's research group has investigated the safety and efficacy of nano-sunscreens, the effects of agglomeration and aggregation on distribution and product performance, and the effects of bioaccumulation of durable nanoparticles. Dr. Tyner is the author of multiple book chapters and journal articles concerning the appropriate characterization and biological impact of nanoparticle therapeutics.

Varun Vasudeva, PharmD

Filing Reviewer

Division of Filing Review
ORO | OGD | CDER | FDA

Varun Vasudeva joined the Office of Generic Drugs (OGD) in May of 2017 to serve as a Regulatory Filing Reviewer for the Division of Filing Review (DFR) within the Office of Regulatory Operations (ORO).

Varun graduated and received his Doctor of Pharmacy degree in 2012 from St. John's University; College of Pharmacy and Allied Health Professions, located in Queens, New York. Prior to joining FDA, he worked as a full-time Pharmacist at Giant Pharmacy in a community pharmacy setting since 2012.

Lauren Woodard, PhD

Lieutenant, United States Public Health Service
DMF Reviewer

DLAPI | ONDP | OPQ | CDER | FDA

LT Woodard, an officer in the United States Public Health Service, currently serves as a drug master file reviewer in the Division of Lifecycle API (DLAPI) within the Office of Pharmaceutical Quality (OPQ). Prior to joining the FDA in 2015, Lauren researched unique platforms for the detection and treatment of cancer in the Neuroradiology department of Johns Hopkins Medical Institute. She holds a PhD in organic chemistry from Johns Hopkins University and completed postdoctoral studies in both radiochemistry and nanotechnology.

Ankara “Nikki” Yokum, PharmD

Branch Chief

Office of Program and Regulatory Operations (OPRO)
OPQ | CDER | FDA

Nikki earned her BS in Biology with a minor in Chemistry from Davis & Elkins College in 2007 and then her Doctorate of Pharmacy from West Virginia University in 2011. Prior to joining FDA, she worked as a Pharmacy Manager for CVS Caremark in Alexandria, VA. In 2014, Nikki joined the FDA as a Product Quality Regulatory Project Manager in the former Office of Pharmaceutical Science, managing the regulatory and business process aspect of chemistry reviews. In 2015, Nikki transitioned with the reorganization into the Office of Pharmaceutical Quality’s (OPQs) Office of Program and Regulatory Operations (OPRO) as a Regulatory Business Process Manager (RBPM), leading various quality assessment teams through the Integrated Quality Assessment (IQA) process for generic drug applications. In 2016, Nikki became an (acting) Quality Assessment Lead (QAL) for RBPMs in her office and now serves as the branch chief. What she most enjoys about her career is the impact we make on public health on a daily basis and the dedicated people she works with inside and outside of the Agency.