CDER 2019 Complex Generic Drug Product Development Workshop

Presenter and Facilitator Biographies

Karen Bengtson

Senior Regulatory Health Project Manager
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

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

Lisa Bercu, JD

Regulatory Counsel
Office of Generic Drug Policy (OGDP)
OGD | CDER | FDA

Lisa Bercu is a regulatory counsel in the Office of Generic Drug Policy, Office of Generic Drugs (OGD). Before joining OGD in October 2016, Ms. Bercu worked at a medical society providing strategic advice on issues including pain medicine, drugs, and devices. She holds a JD degree from Georgetown University Law Center and a BA from the University of Michigan.

Denise Conti, PhD

Chemical Engineer
ORS | OGD | CDER | FDA

Dr. Denise Conti's specialization is drug products in the nasal and oral inhalation drug delivery area. In her current role, Dr. Conti is responsible for the development of product-specific guidances for generic drug development, reviewing and responding to controlled correspondences, pre-ANDA meeting requests, citizen petitions and internal consults. Dr. Conti is also the project officer on multiple regulatory science research initiatives related to nasal and oral inhalation drug products, under the GDUFA regulatory science research program. Prior to joining the FDA, Dr. Conti completed her B.Sc. in Chemical Engineering from Regional University of Blumenau (Brazil), her M.Sc. in Materials Science and Engineering from Santa Catarina State University (Brazil), and her Ph.D. in Chemical Engineering from the Wayne State University (Detroit, Michigan). Dr. Conti is the author and co-author on numerous research manuscripts in the oral inhalation drug delivery area.

Lanyan (Lucy) Fang, PhD

Associate Division Director

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Dr. Lanyan (Lucy) Fang has served as the Associate Director of the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards, since February 2019. Prior to that, she served as Team Lead of the Quantitative Clinical Pharmacology team within DQMM for 5 years. She has established herself as the FDA expert in the use of quantitative clinical pharmacology approaches in the review and regulation of generic drugs. Prior to her current position, Lucy worked as senior clinical pharmacology reviewer in the FDA's Office of Clinical Pharmacology (2009 – 2014) and senior pharmacokinetist with Merck (2007 – 2009).

CDR Andrew Fine, PharmD, BCPS

Team Lead

Office of Bioequivalence (OB)
OGD | CDER | FDA

Commander Fine is a clinical team leader in the Office of Generic Drug 's Division of Clinical Review, where he's served since 2014. As team leader, Commander Fine leads a team of physicians and provides clinical and regulatory oversight for ANDA and pre-ANDA activities. He earned his PharmD from the University of Illinois and completed a pharmacy practice residency at Northwestern University. Andrew is board certified in pharmacotherapy and earned a certificate in pharmacoepidemiology from the University of Pennsylvania. Prior to joining OGD, CDR Fine spent 4.5 years as a safety reviewer in CDER's Office of Surveillance and Epidemiology, Division of Pharmacovigilance where he led postmarketing safety efforts for Multiple Sclerosis drug products.

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.

Priyanka Ghosh, PhD

Staff Fellow

ORS | OGD | CDER | FDA

Dr. Priyanka Ghosh is a pharmacologist within the Division of Therapeutic Performance. Her specialization is drug products in the topical and transdermal drug delivery area. In her current role, Dr. Ghosh is responsible for the development of product-specific guidances for generic drug development, reviewing and responding to controlled correspondences, citizen petitions and Pre-ANDA meeting packages. Dr. Ghosh is also the project officer on multiple regulatory science research initiatives related to topical and transdermal drug products, under the GDUFA regulatory science research program. Prior to joining the FDA, Dr. Ghosh completed her B.Tech in Biotechnology from West Bengal University of Technology (India) and a Ph.D. in Pharmaceutics and Drug design from the University of Kentucky. Dr. Ghosh is the author on numerous research manuscripts and review articles in the topical and transdermal area.

Xiajing Gong, PhD

Staff Fellow

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Xiajing (Jean) Gong received her Ph.D. in Biomedical Engineering from Drexel University. She is currently a staff fellow in the Division of Quantitative Methods and Modeling, in OGD's Office of Research and Standards. Her research projects at FDA include the development and application of big data analytics tools to support drug development and regulatory decisions.

Vidula Kolhatkar, PhD

Acting Biopharmaceutics Team Lead

Office of New Drug Products (ONDP)
Office of Pharmaceutical Quality (OPQ)
CDER | FDA

Dr. Kolhatkar is currently Acting Biopharmaceutics Lead in the Division of Biopharmaceutics/Office of New Drug products (ONDP) at OPQ and is primarily involved with the review of the biopharmaceutics aspects of the new and generic drug product submissions. She joined FDA in 2014 and has experience reviewing various drug products such as solid orals (IR and MR), semisolids and other complex products such as injectable suspensions, intravaginal rings, etc. Before joining FDA, Dr. Kolhatkar received her Ph.D. in Pharmaceutical Sciences from University of Maryland and was a post-doctoral fellow at University of Illinois Chicago working in novel drug delivery systems.

Michelle Lin, MD

Medical Officer

OB | OGD | CDER | FDA

Michelle Lin, MD currently serves as a medical officer in the Division of Clinical Review in the Office of Bioequivalence. Before joining the FDA, she worked as a clinical associate at Children's National Hospital. She holds a MD degree from the University of Florida School of Medicine. She completed her residency at University of Texas Houston and her fellowship training at Emory University. She is board certified in General Pediatrics and Pediatric Endocrinology.

Robert Lionberger, PhD

Director

Office of Policy for Pharmaceutical Quality (OPPQ)
ORS | OGD | CDER | FDA

Robert Lionberger, Ph.D. serves as Director of the Office of Research and Standards within the Office of Generic Drugs. In this role, Dr. Lionberger leads OGD's implementation of the GDUFA regulatory science commitments including internal research activities and external research grants and collaborations to ensure the therapeutic equivalence of generic drug products. In his 10 years as member of the OGD Science Staff, his accomplishments include the development of bioequivalence methods for complex and locally acting drugs, mathematical modeling of drug dissolution and absorption, and incorporation of pharmaceutical development information into the ANDA review process. He received his undergraduate degree from Stanford University in Chemical Engineering, and a Ph.D. from Princeton University in Chemical Engineering, working on modeling the rheology of colloidal suspensions. After his Ph.D., he spent two years of post-doctoral research in Australia in the Department of Mathematics and Statistics at the University of Melbourne. Prior to joining the FDA, he was an Assistant Professor of Chemical Engineering at the University of Michigan.

Tian Ma, PhD

Bioequivalence Reviewer

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Dr. Tian Ma is a bioequivalence reviewer within the Division of Bioequivalence I. Prior to joining the FDA, Dr. Ma was a postdoctoral fellow in Dartmouth College. She obtained her B.Sc. in Pharmacology from the University of Toronto, Canada, and her Ph.D. in Pharmacology from Dartmouth College.

Bita Mirzai-Azarm, MSc

Branch Chief

OPQ | CDER | FDA

Bita Mirzai-Azarm is a Branch Chief in the U.S. FDA's CDER/ Office of Pharmaceutical Quality/ Office of Lifecycle Drug Products/ Division of Liquid Drug Products. Her Branch specializes in drug product quality reviews of generic injectable drug products (injection solution/suspension/emulsion; sterile powder for injections; injection combination products such as prefilled syringes, auto-injectors, IV bags). In her role as Branch Chief, Bita provides technical and managerial leadership to her review team. During her 20 years of federal service, Bita has been involved in CDER in various capacities. She has served as acting Deputy Division Director in Office of Pharmaceutical Sciences, as Lead Chemist and Senior Review Chemist in Office of Generic Drugs. Prior to joining the federal government, Bita worked as an associate scientist for 3 years at Schering-Plough Research Institute. Bita graduated with B.Sc. (honors) AND M.Sc. from University of Manitoba, Canada.

Bryan Newman, PhD

Pharmacologist

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Bryan Newman, Ph.D., is a pharmacologist in the Division of Therapeutic Performance (DTP), Office of Research and Standards (ORS), under the Office of Generic Drugs (OGD). He specializes on drug-device combination products, particularly for orally inhaled and nasal drug delivery. Dr. Newman's work at the Agency focuses on the development of product-specific guidances for generic drug development, reviewing and responding to controlled correspondences, citizen petitions, consults, and Pre-ANDA meeting requests. He also serves as a project officer and contracting officer's representative for multiple regulatory science research initiatives related to complex generics, including orally inhaled and nasal drug products. Prior to joining FDA, Dr. Newman received his B.S. degree from Louisiana State University in Biochemistry and his M.S. and Ph.D. degrees from the University of Michigan in Pharmaceutical Science. In 2012, he joined FDA as an ORISE post-doctoral fellow in the OGD Science Staff (currently ORS), and became an employee within DTP in 2014.

Suneela Prodduturi, PhD

Science and Research Staff Fellow

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Suneela Prodduturi, PhD, is a Staff Fellow in the Science Staff within the immediate office of the Office of Pharmaceutical Quality. She leads the Pre-ANDA triage efforts and is a part of the complex drug products program, coordinating the intersection between science, review, and policy. Dr. Prodduturi began her career at FDA in 2005 as a research scientist in an FDA laboratory and supported regulatory review and policy activities for four years. Dr. Prodduturi worked for 5 years in the pharmaceutical industry developing different dosage forms using novel technologies. She returned to FDA as a reviewer in Office of Life Cycle Drug Products where she was involved in quality assessment of modified-release drug products, including transdermal systems and solid orals (IR and MR) and maintains a research interest in complex drug products, especially transdermal drug delivery systems. She earned her Ph.D. in Pharmaceutics and post-doctoral fellowship from the University of Mississippi.

Bin Qin, PhD

Staff Fellow

ORS | OGD | CDER | FDA

Bin Qin is currently a Staff Fellow in the Division of Therapeutic Performance, in OGD's Office of Research and Standards. Prior to joining FDA, Bin completed a 3-year postdoctoral training in the University of Pittsburgh Medical Center. He earned his Ph.D. in Pharmaceutical Sciences from University of Missouri-Kansas City, a M.S. degree in Pharmaceutics and a B.S. degree in Pharmacy from China Pharmaceutical University.

Tannaz Ramezanli, PhD

Staff Fellow

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Tannaz Ramezanli currently serves as pharmacologist within the Division of Therapeutic Performance. She joined the FDA as an ORISE (Oak Ridge Institute for Science and Education) Fellow and currently work as a reviewer in the Topical and Transdermal Team. She is responsible for the development of product-specific bioequivalence guidances, reviewing and responding to controlled correspondences, and Pre-ANDA meetings. Dr. Ramezanli is also engaged in the development of regulatory science research initiatives related to topical and transdermal drug products through FDA-funded collaborations with research institutions around the world. She received her Ph.D. in Pharmaceutical Sciences from Rutgers University and her Pharm.D. from Tehran University of Medical Sciences.

Sam Raney, PhD

Lead for Topical and Transdermal Drug Products

ORS | OGD | CDER | FDA

Dr. Sam Raney is a thought leader in topical and transdermal drug products, with over 25 years of experience producing numerous research manuscripts, review articles, book chapters, and patents in pharmaceutical product development. Dr. Raney has been a researcher and adjunct professor within academia, a principal or sub-investigator on over 400 pharmaceutical product studies, has held senior management roles in industry, serves as an expert panel member in the U.S. Pharmacopeia, and is the Lead for Topical and Transdermal Drug Products in the FDA Office of Generic Drugs. Dr. Raney holds a Bachelors in Molecular Biophysics & Biochemistry from Yale University, and a Ph.D. in Biochemistry & Molecular Biology from the University of British Columbia in Canada.

Brock Roughton, PhD

Acting Quality Assessment Lead

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

Dr. Brock Roughton is a chemist and acting quality assessment lead within the Division of Modified Release Products. He serves as technical lead of quality assessment teams for transdermal and modified-release solid oral drug products. Prior to joining the FDA, Dr. Roughton completed his B.Sc. in Chemical and Biochemical Engineering from Colorado School of Mines and his Ph.D. in Bioengineering from the University of Kansas. Dr. Roughton also worked as a visiting research scientist at Purdue University and the Technical University of Denmark.

Satish Sharan, PhD

Pharmacologist

ORS | OGD | CDER | FDA

Satish Sharan, Ph.D. is Pharmacologist (Visiting Associate) in Quantitative Clinical Pharmacology team within the Division of Quantitative Methods and Modeling. Through his training, Dr. Sharan has acquired translational working experience in clinical pharmacology in addition to acquiring advanced modeling and simulation training using physiologically based pharmacokinetic modeling and pharmacokinetic pharmacodynamic modeling and simulation, which is routinely applied in his current role within FDA to aid in regulatory policy and decision making. Dr. Sharan graduated with Ph.D. in Pharmaceutical Sciences from Temple University, School of Pharmacy with a major in Pharmacokinetics under guidance of Dr. Swati Nagar. Thereafter Dr. Sharan pursued his post-doctoral training in modeling and simulation under guidance of Dr. Sukyung Woo at the University of Oklahoma, College of Pharmacy.

Cameron Smith, PhD

Senior Chemist

OLDP | OPQ | CDER | FDA

Cameron Smith is a Senior CMC Review Chemist in the Division of Liquid-Based Products. For the past 5 years, he has served as an assessor and technical lead on quality assessment teams for liquid-based product ANDAs with a specialty in injectable complex peptide and topical/semisolid drug products. Prior to his Agency position, he spent 15 years in the pharmaceutical industry as a medicinal chemist, primarily at Merck Research Laboratories and before that at OSI Pharmaceuticals. Dr Smith completed his Ph.D. studies in chemistry at the University of Cambridge and followed this up with postdoctoral studies at the University of Utah. He received his undergraduate degree from Monash University in Melbourne, Australia.

Brenda Stodart, PharmD, BCGP

Captain, 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.

Eleftheria Tsakalozou, PhD

Staff Fellow

ORS | OGD | CDER | FDA

Eleftheria Tsakalozou joined the FDA in 2015 as an Oak Ridge Institute for Science and Education (ORISE) Fellow. Dr. Tsakalozou began her career at the University of Athens in Athens, Greece where she trained as a pharmacist and pursued a Master of Science in Clinical Pharmacy. She obtained her Ph.D. in Pharmaceutical Sciences at the University of Kentucky in 2013 and completed a two-year Fellowship in Clinical Pharmacokinetics and Pharmacodynamics at the University of North Carolina at Chapel Hill sponsored by Quintiles. Her research interests include skin absorption physiologically-based pharmacokinetic modeling, interactions between excipients and molecular targets including gut transporters and development of quantitative modeling and simulation tools to support bioequivalence assessments.

Ross Walenga, PhD

Chemical Engineer

ORS | OGD | CDER | FDA

Dr. Ross Walenga joined the FDA in 2015 as an Oak Ridge Institute for Science and Education (ORISE) Fellow. He began his career at Virginia Polytechnic Institute and State University (Virginia Tech), where he earned a Bachelor Science in Aerospace Engineering. He later earned his Ph.D. in Engineering (mechanical track) from Virginia Commonwealth University in 2014, where he also spent 7 months as a postdoctoral fellow prior to joining the FDA. His research interests include computational fluid dynamics modeling of orally inhaled, nasal, ophthalmic, and dermal drug products to answer questions pertaining to bioequivalence.

Yan Wang, PhD

Scientific Lead

ORS | OGD | CDER | FDA

Yan Wang, Ph.D. is the Scientific Lead for long-acting drug products in the Office of in the Office of Research and Standards, Office of Generic Drugs. She is involved in developing scientific policy relating to generic drug development and review for a variety of complex formulations including microspheres, implants, in situ forming gels, and locally acting drug products via ophthalmic, otic, intrauterine, and periodontal routes. In addition, Dr. Wang is also heavily involved in GDUFA funded research projects. A major area of research focus is on the development of proper scientific tools, such as in vitro methods and modeling and simulation methods, to facilitate setting proper standards for evaluation of complex drug products. Dr. Yan Wang received her Ph.D. in Pharmaceutical Sciences from the University of Connecticut, Storrs.

Kimberly Witzmann, MD

Acting Deputy Director

OB | OGD | CDER | FDA

Dr. Kimberly Witzmann is a physician and is currently serving as the acting deputy director for the Office of Bioequivalence within the Office of Generic Drugs (CDER), at FDA. For the last 4 years, she was the team leader for the inhalation, nasal, and generic drug-device combination products team, in the Division of Therapeutic Performance (DTP), Office of Research and Standards within OGD. She is committed to making safe and effective generic drugs available to the American public. Her focus is on communications with industry for complex drug products, including communications via the controlled correspondence and pre-ANDA meetings pathways under GDUFA II. She has been a key member of teams developing guidance documents and product-specific recommendations for FDA. She has spoken nationally at multiple meetings discussing development for generic orally inhaled and nasal combination drug products. She has been with FDA-CDER for more than 9 years, involved in regulatory science and development of complex products, particularly orally inhaled drug products. Prior to joining FDA in 2009, Dr. Witzmann was an assistant Professor of pediatrics at Children's National Medical Center in Washington, DC. She has prior experience working with the pharmaceutical industry as a member of medical advisory boards and has served as a primary investigator on a number of clinical research protocols involving lung diseases. She has presented locally and nationally on premature lung disease, asthma, and sleep problems in children, and has been interviewed for local and national television. She has been co-author on several medical articles published in peer-reviewed journals, and has presented a number of abstracts at national meetings.

Xiaoming Xu, PhD

Chemist

Office of Testing and Research (OTR)
OPQ | CDER | FDA

Dr. Xiaoming Xu leads particle characterization lab in CDER/OPQ and provides hands-on trainings to reviewers on various topics, including concept of particle size and measurement. Dr. Xu is a member of the CDER Nanotechnology Working Group and is co-leading the Nanotechnology Reviewer Network at CDER. Dr. Xu is also an editorial board member of the International Journal of Pharmaceutics. His current research efforts include 1) formulation and processing design of complex drug products; 2) advancing manufacturing science of complex drug products, with focus on continuous manufacturing; 3) development of in vitro release performance tests for traditional as well as complex drug delivery systems (e.g. emulsions, liposomes, suspensions, ointments, creams, etc.); 4) evaluation of bio-equivalence of complex drug products; and 5) design and evaluation of abuse deterrent formulations for opioid analgesics.

Fang Yuan, PhD

Drug Product Quality Reviewer

OLDP | OPQ | CDER | FDA

Dr. Fang Yuan is a Drug Product Quality reviewer within the Division of Modified Release Products, specializing in pre-market submissions of complex generics including oral inhalation and nasal and long-acting injectable drug products. She is involved in reviewing pre-ANDA meeting packages and regulatory research programs to support development of complex generic products. She holds a Ph.D. degree in Pharmaceutical Science from University of Nebraska Medical Center.

Deyi Zhang, PhD

Chemist

ORS | OGD | CDER | FDA

Deyi Zhang, Ph.D. serves as a chemist in the Office of Research and Standards specializing in complex drug substances, including providing scientific support for regulatory policy and product-specific guidance development on such products and managing related research activities. He has 20 years of experience from academia, industry and regulatory agency. Prior to joining FDA in 2015, he was an Executive Director in Crown Bioscience, a biotech company focusing on oncology drug discovery and translational medicine. Before joining Crown, he worked at Eli Lilly and Company, rising from Research Scientist to Principal Research Scientist. Prior to his career at Eli Lilly, he was a NIH Postdoctoral Fellow at University of Pennsylvania. He received his Ph.D. in Organic Chemistry from University of Notre Dame. He has over 10 US patents and 40 publications and presentations.

Lei Zhang, PhD

Deputy Director

ORS | OGD | CDER | FDA

Lei Zhang, Ph.D., 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.

Liang Zhao, PhD

Division Director

ORS | OGD | CDER | FDA

Dr. Liang Zhao has been serving as Director of the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS) in Office of Generic Drugs, CDER since 2015. He initially joined FDA as a clinical pharmacology reviewer in the Office of Clinical Pharmacology in 2009 and worked as a team leader in the Division of Pharmacometrics in 2013-2015. Prior to joining FDA, he worked at Medimmune, BMS, and Pharsight for new drug R&D.

Susan Zuk, MS

Branch Chief

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

Susan holds a BS in Chemistry from Syracuse University and a MS in Biotechnology from Johns Hopkins University. During her 20 years with the FDA, she served in the Office of Generic Drugs as Chemistry Team Leader for many years, specializing in antibiotics. She joined the Office of Policy for Pharmaceutical Quality in 2015 and is currently Branch Chief in the Division of Regulations, Guidance and Standards, Branch 2. She is the lead for the FDA's Inactive Ingredient Database (IID). In this role, she is responsible for overseeing IID improvements. Susan has served on many FDA committees and working groups related to product safety and quality. She is currently a member of the FDA's Center for Drug Evaluation and Research (CDER) Excipient Working Group.