CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE

DRUG MASTER FILE (DMF) AND DRUG SUBSTANCE WORKSHOP

VIA WEBCAST
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MARCH 3-4, 2021

Speaker Biographies

In Order of Workshop Presentations

Day 1

Lawrence Yu, PhD
Director
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Lawrence X. Yu, Ph.D., is the Director, Office of New Drug Products, Food and Drug Administration. Dr. Yu created the Question-based Review, defined the Pharmaceutical Quality by Design (QbD), inaugurated the FDA modern review system - Integrated Quality Assessment (IQA), developed the FDA historic concept of operations agreement to integrate review and inspection, and originated the Knowledge-aided Assessment and Structured Applications (KASA) initiative. Dr. Yu is also an adjunct Professor at the University of Michigan. His compartmental absorption and transit (CAT) model has laid the foundation for the commercial software, GastroPLUSTM and Simcyp®, which are being widely used in the pharmaceutical industry. Dr. Yu is a fellow and the past section Chair of the American Association of Pharmaceutical Scientists and an Associate Editor of the AAPS Journal. Dr. Yu has authored/co-authored over 150 papers and given over 300 invited presentations. He is a co-editor of the books entitled "Biopharmaceutics Applications in Drug Development", "FDA Bioequivalence Standards", and "Developing Solid Oral Dosage Forms: Pharmaceutical Theory and Practice, 2nd Ed."

Erin Skoda, PhD
Branch Chief (Acting)
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Erin Skoda is currently an Acting Branch Chief in the Division of Lifecycle API in the Office of New Drug Products within OPQ. She has worked on CMC quality assessment, division initiatives and policies, and collaborations with several divisions and offices within the Agency. She holds a Ph.D. in organic chemistry from the University of Pennsylvania. Prior to joining the FDA in 2014, Erin worked as a medicinal chemist.

Vathsala Selvam

Technical Information Specialist
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Vathsala Selvam is a Technical Information Specialist in the Division of Life cycle API (DLAPI), where she manages administrative aspects of DMF submissions. Vathsala is an essential member of the DLAPI staff and has taken the lead on various projects and assignments. She acts as a liaison between DMF data entry staff, FDA reviewers, and industry on inquiries related to administrative portion of DMF submissions. She performs administrative review on various submissions, drafts correspondence letters to DMF holders and their responsible agents, as well as verifies that DMF submissions are administratively complete prior to quality review. Prior to her position in DLAPI, she was a Conflict-of-Interest Specialist in the division that cleared special government employees for their participation in advisory committee meetings.

Before joining FDA in 2004, Vathsala worked as a Computer Programmer/Analyst for a reputed company. Vathsala is married to Mouna Selvam, who is a chemist in the FDA for over 30 years and they are blessed with two children. Vathsala enjoys her work and to be a part of public health service.

Jonathan Resnick

Project Management Officer
Cloud Collaboration Capability Team
Division of Data Management Services & Solutions
Office of Business Informatics (OBI)
CDER | US FDA

Jonathan Resnick is a member of CDER's Division of Data Management Services and Solutions. His focus is on electronic submissions and has been with FDA since 2011. Prior to joining FDA, Jonathan spent 18 years working in IT project management supporting federal and private sector clients.

Hanah Pham

Commander, USPHS
Division of User Fee Management and Budget Formulation (DUFMBF)
Office of Management (OM)
CDER | US FDA

CDR Hanah Pham currently serves as a Facilities Team Lead in the Generics Branch, Division of User Fee Management and Budget Formulation, Office of Management at FDA's Center of Drug Evaluation and Research. Her primary responsibility is to lead her team to timely and accurately execute GDUFA user fee requirements on generic drug manufacturers. She joined her Division in the early phase of GDUFA I implementation in 2012. She received a Doctor of Pharmacy degree from Hampton University and a Master of Science degree from University of Florida.

Evelyn Hong, MS, PharmD

Lieutenant Commander, USPHS
Division of User Fee Management and Budget Formulation (DUFMBF)
Office of Management (OM)
CDER | US FDA

LCDR Evelyn Hong currently serves as a Senior Program Manager, Team Lead in the Applications team of the Generics Branch, Division of User Fee Management and Budget Formulation, Office of Management in FDA's Center for Drug Evaluation and Research. In her position, she is responsible for designing and implementing the Office's policies and business processes necessary in assessing and collecting generic user fees; assessing and evaluating the user fee obligations for all submitted generic drug submissions. She joined the Division in the early phase of GDUFA implementation in 2012. She received a Doctor of Pharmacy degree from University of Nebraska – Medical Center and a Master of Science degree from University of Florida.

Jayani Perera, PhD

Review Chemist
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality (OPQ)
CDER | US FDA

Jayani Perera joined the FDA in 2014 as a review chemist in the Office of Pharmaceutical Science. With the stand of Office of Pharmaceutical Quality in 2015, she remained with the Division of Life Cycle API. She has assisted in the design, optimization, and management of the GDUFA Completeness Assessment (CA) process and the Timely Consult and Early Information Request (TCIR) Process for Drug Master Files. In addition to her role as a primary reviewer in the chemistry, manufacturing and controls (CMC) of generic API, Jayani also serves as the secondary reviewer for CAs. Jayani holds a Ph.D. degree in Inorganic/Organometallic Chemistry from Wayne State University in Detroit, Michigan.

David Skanchy (CDR), PhD
Director
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

CDR David Skanchy has been at the FDA for 18 years as a review chemist and manager in the generic drug program. He is currently the director of the Division of Lifecycle API in the Office of Pharmaceutical Quality and has served in this position for the last 8 years.

Benjamin Y. Danso, PharmD
Regulatory Business Process Manager
Office of Program & Regulatory Operations (OPRO)
Office of Pharmaceutical Quality (OPQ)
CDER | US FDA

Benjamin Danso joined the FDA in 2004 as a Regulatory Project Manager with the Office of Generic Drugs. During the reorganization in 2012, he was assigned to the transitional team in the Office of Pharmaceutical Science. With the standup of Office of Pharmaceutical Quality, he remained with the Office of Program and Regulatory Operations. He assisted in multiple roles in regulatory and business processes to aid in the standup of the Office of Pharmaceutical Quality. He served as the Post-Marketing Branch Chief, leading the design, optimization, and management of post-approval submissions for New and Generic drug applications. In 2019, he was transferred to serve as the program manager with the Division of Life Cycle API. Benjamin holds a Doctor of Pharmacy Degree from Temple University in Philadelphia, Pennsylvania.

Wei Liu, PhD
Senior Pharmaceutical Quality Assessor
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Wei Liu joined the FDA in 2012 and currently is a senior pharmaceutical quality assessor in the Division of Life Cycle API, Office of New Drug Products within the Office of Pharmaceutical Quality (OPQ). She focuses on the assessment of chemistry, manufacturing and controls (CMC) information for drug substances. She has a M.S. from Chinese Academy of Sciences and Ph.D. from University of Florida.

Cassandra Abellard

Quality Assessor/Consumer Safety Officer
Division of Pharmaceutical Manufacturing
Office of Pharmaceutical Manufacturing Assessment (OPMA)
Office of Pharmaceutical Quality
CDER | US FDA

Cassandra Abellard is currently a reviewer in DPM IV Branch 11, Office of Pharmaceutical Manufacturing Assessment (OPMA). She started her career with the Agency in 2014 as a Consumer Safety Officer (Investigator) in ORA and moved to OPMA as a Process/Facility Assessor in 2015.

Prior to her experience at the FDA, she worked in the Pharmaceutical and Food Industries for over 17 years in various roles from Production Management to Quality Management. Within OPMA, she serves as a process and facility reviewer for generic and new drug applications.
She has an AAS in Veterinary Science and a B.Sc. in Cellular Biochemistry from Plattsburgh State University.

Anita Tiwari, PhD

Senior Pharmaceutical Quality Assessor
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Anita obtained her Ph.D. in Organic Chemistry from Lucknow University, India. She worked as a research scientist at Southern Research Institute for 23 years in the area of drug discovery and development of anticancer and antiviral drugs. She joined FDA, Office of Generic Drugs in 2013 as a CMC review chemist, focusing on quality assessment of drug master files (DMFs) in the DMF team. She became an Acting Quality Assessment Lead in 2017 in the Division of Lifecycle API (DLAPI) in the Office of New Drug Products (ONDP). Currently she is Senior Pharmaceutical Quality Assessor.

Xinghua Wu, PhD

Chemist
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Xinghua is currently working with Division of Lifecycle API as a chemist reviewing Drug Master Files submissions. He received his M.S. in Quality Assurance and Regulatory Affairs from Temple University, Philadelphia, and Ph.D. in Medicinal Chemistry from Rutgers University, New Brunswick. Prior to joining the FDA in 2014, he worked for Idenix and Celgene, and gained his expertise in process chemistry and analytical chemistry.

David Amspacher, MBA
Chemist
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

David Amspacher is a Drug master file reviewer in the Division of Lifecycle API at the FDA and has 25 years of experience in API manufacturing and IND, NDA, and ANDA regulatory activities. Dave started his journey in the Marine Corps and afterward received his bachelor's degree in chemistry at York College of Pennsylvania. He did his graduate work at Louisiana State University under Rob Strongin and worked as a process chemist at Pfizer for over a decade where he earned his MBA at the University of Rhode Island. Dave joined the FDA in 2014 and lives with his lovely wife Nicole in southern Pennsylvania where they used to enjoy international travel and scuba diving before the world came to a screeching halt.

Bapu R. Gaddam, PhD
Chemist
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Bapu R. Gaddam is a quality reviewer in the division of lifecycle API and joined FDA about seven years ago. He has review experience of several complex drug substances and participated in facility inspections. Before joining FDA, Dr. Gaddam has worked as project leader for small molecule drug discovery programs for thirteen years in several therapeutic areas. As a project leader, Dr. Gaddam was responsible for moving the program forward and involved in selecting the candidates for the advancement based on their profile generated from *in vitro* and *in vivo* studies. Bapu R. Gaddam was also responsible for the initial formulations for the toxicology studies and cGMP manufacturing of drug substance for phase-I and Phase-II studies.

Day 2

Ramnarayan (Ram) Randad, PhD

Branch Chief
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Ramnarayan (Ram) Randad Ph.D. is a Branch chief in the Division of Lifecycle API. He joined FDA in 2002 as a review chemist. He has served on a number of working groups such as Post approval drug substance guidance, Complex Drug Substance, Risk-Based Review, QbR, DMF Completeness assessment team, and US Pharmacopeia monograph development committees. He has frequently represented Agency on CMC and regulatory science issues at various conferences. He has published 28 research papers and has 14 patents and has authored chapter on "FDA Drug Review and Regulation" in the "Burger's Medicinal Chemistry, Drug Discovery and Development". Prior to joining FDA he worked in a various research positions for National Cancer Institute, Tibotec, and Neogenesis.

Hongbiao Liao

Chemist
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Hongbiao Liao graduated from State University of New York at Albany and received MS in organic chemistry in 1999. Prior to joining FDA, he has worked as a senior chemist in Merck & Co 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.

Barbara Scott

Chemist
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Ms. Barbara O. Scott is a chemist and CMC Senior Assessor in the Division of Life Cycle API, Office of New Drug Product, Office of Pharmaceutical Quality at the FDA Center for Drug Evaluation and Research. Ms. Scott has been with the Agency for over 17 years and came to the Agency with over ten years of pharmaceutical and biotechnology experience. Ms. Scott received her M.S. in Chemistry from the University of California at Berkeley, and a B.S. in Chemistry from Ithaca College in Ithaca, New York.

Ms. Scott joined the FDA in 2004, as a generic drug chemistry reviewer in the Center for Drug Evaluation and Research. In her current position as CMC Senior Assessor with the FDA's Office of Pharmaceutical Quality, she focuses on the chemistry, manufacturing and controls (CMC) of active pharmaceutical ingredients. Her current professional interests include the scientific and regulatory aspects of drug substance manufacture and quality control.

Naomi L. Kruhlak, PhD

Scientific Lead
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Dr. Naomi Kruhlak has worked for US FDA's Center for Drug Evaluation and Research (CDER) as a computational toxicologist for 19 years, developing and applying (quantitative) structure-activity relationship ((Q)SAR) models to support the regulatory review of pharmaceuticals. She is the Scientific Lead for CDER's Computational Toxicology Consultation Service and is the Principal Investigator on three FDA/CDER Research Collaboration Agreements with commercial (Q)SAR software developers, as well as an Inter-Agency Agreement with NIH generating in silico-based drug safety predictions. Dr. Kruhlak has published 43 peer-reviewed articles describing data standardization, transformation, and classification for modeling purposes, and the creation and regulatory application of (Q)SAR models with chemical interpretability. Dr. Kruhlak holds B.Sc. and Ph.D. degrees in chemistry from the University of Salford, England, and the University of Calgary, Canada, respectively.

Chanchal Gupta

Pharmacology/Toxicology Reviewer
Division of Clinical Review (DCR)
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD)
CDER | US FDA

Chanchal Gupta is a Pharmacology/Toxicology reviewer in the Division of Clinical Review (DCR) within the Office of Generic Drugs (OGD) at the Food and Drug Administration (FDA). Chanchal joined DCR in 2017 where she conducts safety assessment of impurities, residual solvents, excipients, and extractables/leachables in generic drug products.

Chanchal completed Bachelor of Science in Pharmacy from the University of Delhi, India. She earned Master of Science and Doctor of Philosophy in Pharmacology and Toxicology from the National Institute of Pharmaceutical Education and Research, Mohali, India. Her doctoral research focused on the role of high glucose and insulin-induced epigenetic changes in breast cancer using in vitro models. Prior to joining the FDA, she worked as a Research Scientist in private sector for two years.

Deborah F. Johnson, PhD
Branch Chief
Division of Lifecycle API ONDP | OPQ | CDER

Deborah has a Ph.D. in Organic Chemistry from Brigham Young University. She worked as a pre-formulation chemist for Wyeth Pharmaceuticals for 4 years and then joined the US FDA in Aug 2010 as an CMC assessor for Abbreviated New Drug Applications (ANDAs). In 2012 she joined the newly formed Drug Masterfile Review team. After the Office of Pharmaceutical reorganization this group became known as the Division of Lifecycle API (DLAPI) and is now located in the Office of New Drug Products. In 2014 Deborah became a branch chief and is still serving in that position.

Sruthi King, PhD
Associate Director of Pharmacology/Toxicology
Division of Clinical Review (DCR)
Office of Bioequivalence (OB)
Office of Pharmaceutical Quality
CDER | US FDA

Sruthi King earned her Ph.D. in pharmacology from Georgetown University and completed postdoctoral training at Stanford University in the Department of Dermatology. Sruthi joined FDA in 2008 as a Pharmacologist in the Division of Gastroenterology and Inborn Error Products within the Office of New Drugs and later moved to the Office of Generic Drugs as team leader in 2015. Sruthi now serves as an Associate Director of Pharmacology and Toxicology in Division of Clinical Review within the Office of Generic Drugs (OGD) at the Food and Drug Administration (FDA). Sruthi has been a member of the CDER nitrosamine task force for the past 2. 5 years and also serves on several working groups with international regulators to harmonize approaches related to nitrosamine safety assessments.

Jay Jariwala
Team Leader
Division of Drug Quality
Office of Manufacturing Quality
Office of Compliance
CDER | US FDA

Jay Jariwala is a Team Leader with the Office of Manufacturing Quality (OMQ), Office of Compliance, CDER, where he provides leadership and operational oversight of compliance officers assessing violative establishment inspections and resulting regulatory actions. During his tenure he spearheaded numerous regulatory actions such as warning letters, regulatory meetings, and import alerts. He also participates in inspections as a Subject Matter Expert. He was instrumental in developing various risk-based assessment processes including Warning Letter review procedure currently being utilized. He also represented CDER in Mutual Reliance Agreement Initiative in assessing various EU drug inspectorates' capabilities.

He also served as an Assistant Country Director with FDA's India Office from 2017 to 2019. His primary role is to advise FDA leadership on drug policy issues as it concerns India and collaborate with various governmental, internal, and industry stakeholders to advance FDA's strategic priorities in India. He also acted as Supervisory Consumer Safety Officer managing all inspections conducted by the India Office.

He began his FDA career in CDRH, where he spent 7 years in CDRH Office of Compliance and held positions of increasing responsibilities starting as a compliance officer to a quality system specialist. While at CDRH, he was part of Medical Device Single Audit Program (MDSAP) team which is a collaborative inspection effort between US FDA, Health Canada, Therapeutic Goods Administration of Australia, and ANVISA Brazil. Due to his multi-commodity and multi-center background, he was member of a core group instrumental in developing CGMPs for Combination Products, resulting FDA guidance, and investigator training. He was selected and successfully completed CDER's Emerging Leader Program (ELP.) He has regularly spoken at various conferences and taught various CGMP related courses on behalf of the Agency.

Brian Connell, PhD
Senior Pharmaceutical Quality Assessor
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Brian Connell holds a Ph.D. in organic chemistry and has been involved in the review of Drug Master Files and drug substances at the FDA since 2013. As a member of the Division of Lifecycle API, Brian has interests in strategies for impurity control, including mutagenic and elemental impurity control, to ensure the safety and quality of APIs available in the U.S. market.

Larisa Wu, PhD

Senior Pharmaceutical Quality Assessor
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Larisa Wu, Ph.D., is the ONDP Associate Director for Science and Communication (acting). Prior to ONDP, she was in OPQ Immediate Office where she served as Special Assistant to OPQ Deputy Director since OPQ stood up in 2015. Since she joined FDA in 2011, Larisa contributed significantly to various initiatives that became pivotal to the launch of OPQ, including integrated team-based quality assessment, risk-based review, and ANDA backlog review and management. In her most recent roles, Larisa worked extensively on several FDA, CDER, and OPQ initiatives including: Knowledge-aided Assessment and Structured Application (KASA), Concept of Operations (ConOps) for Inspection of Human Drugs, Process and Facility Integration, OPQ Secondary Assessment, and BARDA-FDA Drug Shortage Program. Her contributions have been recognized in award ceremonies at the agency, center, and office level. Larisa received her Ph.D. degree in Bioengineering from University of Utah, followed by a postdoctoral fellowship in Pharmaceutical Sciences at University of Maryland, School of Pharmacy. She also holds an M.S. degree in Chemistry and a B.S. degree in Biomedical Engineering.

Poster Presenter Biographies

In order of poster presentation.

Wei Song, Ph.D.
Review Chemist
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality (OPQ)
CDER | US FDA

Wei Song currently is Quality Assessor of Division of Life Cycle API (DLAPI) in FDA Office of Pharmaceutical quality (OPQ). She has more than 15 years of combined experiences in the areas of drug development and regulatory review and approval. Before joining the FDA, Wei was an analytical scientist working at a contract research organization (CRO). She has been with the Center for drug evaluation and research (CDER) since 2012. As Drug Substance Quality Assessor, she is responsible for the evaluation of drug substance chemistry development, manufacturing, specifications, analytical methods, container closure systems, stability.

Yingzi Wang, Ph.D.
Chemist
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Dr. Wang is a Chemist working in the Division of Lifecycle API, Office of New Drug Products, Office of Pharmaceutical Quality in FDA's Center for Drug Evaluation and Research. Her primary job function is to support GDUFA by reviewing drug master files (DMFs) for drug substances (DSs)/active pharmaceutical ingredients (APIs). She also contributes to several related regulatory/consulting workflows, such as providing controlled correspondences to sponsors' questions to FDA during the drug product development stage and reviewing new USP PF monograph proposals. Before she joined FDA in 2017, Dr. Wang worked as a research investigator in the pharmaceutical research and development field. She received her PhD in Physical Chemistry from Clark University.

Steve Kinsley, Ph.D.

Chemist
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Steve Kinsley completed a BS in Chemistry at Saint Louis University. After completing a Ph.D. in Organic Chemistry under Andrew Streitwieser at University of California, Berkeley, and a Post-Doctorate under Tobin Marks at Northwestern, Steve worked for seven years, attaining the rank of Senior Scientist at Rohm and Haas in Philadelphia. After a few years helping his father in a family business, Steve taught Organic and Inorganic Chemistry at Washington University in St. Louis from 2003 to 2016, where he received multiple Teaching Awards and was often selected to speak to incoming freshmen regarding majoring in Chemistry. Steve joined the FDA in 2016 as a Regulatory Business Process Manager and transferred to the Division of Lifecycle API in 2018 as an Assessor.

Weiqin Jiang, MS, Ph.D.

Chemist
Division of Lifecycle API
Office of Pharmaceutical Quality
Office of New Drug Product
OPQ | CDER | US FDA

Dr. Weiqin Jiang finished her PhD at the University of Chicago's Organo-metallic Chemistry program. Her dissertation focused on the synthetic studies of Taxol and asymmetric Diels-Alder reaction using Chromium Fischer carbene complexes. Weiqin then joined Dr. Dale Boger group in The Scripps Research Institute, CA as a postdoctoral fellow and worked on the higher order iminodiacetic acid libraries for probing protein-protein interactions in order to discover small peptide mimic targeting Erythropoietin protein. Weiqin worked in drug discovery group in Pharmaceutical Research Institute in Johnson & Johnson at Raritan, NJ for a decade, where she published patents on pyrroloquinoline as novel phosphodiesterase type 5 inhibitor for male erectile dysfunction and pyridine-imidazoles and aza-indoles as selective progesterone receptor modulators. In J&J she also worked on liver-selective glucocorticoid antagonist for the treatment of Type II diabetes and PET (positron emission tomography) Tracer Design & Synthesis of TRPV1 Antagonist using [^{3}H]-Ligand. In 2008, she started in OGD (Office of Generic Drug) as Drug Product Quality Assessor, evaluating drug substance chemistry, drug product composition, development, specifications, analytical methods, container closure systems, stability, quality aspects of labeling and environmental impact in abbreviated new drug applications (ANDAs). In 2013, she joined the Division of Lifecycle API as drug substance reviewer. During her tenure in FDA, she regularly reviewed USP-PF monographs. Weiqin earned her BS degree in Fudan University in polymer chemistry and MS degree in Rutgers University in medicinal chemistry.

Manivannan Ethirajan, Ph.D.
Chemist
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Mani Ethirajan is currently a chemist in the Division of Life Cycle API (DLAPI).
For the past 7 years, he has been reviewing Drug Master Files specifically dealing with complex APIs. Prior to FDA, he spent 13 years as a Medicinal chemist in academia and pharmaceutical company and received NIH-STTR grant. He has co-authored several synthetic/medicinal chemistry articles published in peer-reviewed journals and books. Mani holds a PhD degree in synthetic chemistry from Indian Institute of Technology-Bombay, India.

Keduo Qian, Ph.D.
Chemist
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Keduo Qian joined DLAPI/ONDP in 2013 as a drug master file (DMF) reviewer. Previously, she was Research Assistant Professor of Medicinal Chemistry and Natural Products at the University of North Carolina at Chapel Hill. She received her Ph.D. in Pharmaceutical Sciences from UNC-Chapel Hill. In addition to the assessment of chemistry, manufacturing process, controls and stability of drug substances associated with DMFs, Keduo specializes in the quality assessment of complex active pharmaceutical ingredients (APIs), such as low molecular weight heparins (LMWHs), polymers, peptides, etc. Keduo was detailed to the Office of Pharmaceutical Manufacturing Assessment (OPMA) during 2018-2019, with emphasis on the assessment of complex API manufacturing as well as compliance of manufacturing facilities.

Thomas O'Connor, Ph.D.

Director
Division of Product Quality Research
Office of Testing Research
Office of Pharmaceutical Quality
CDER | US FDA

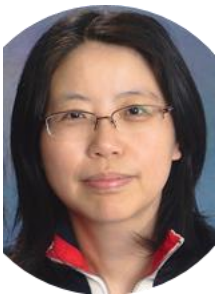
Dr. O'Connor is the director of the Division of Product Quality Research in the Office of Testing and Research in the Office of Pharmaceutical Quality and is a member of CDER's Emerging Technology Team. His responsibilities include managing regulatory science projects to support the implementation of emerging technologies in pharmaceutical manufacturing such as continuous manufacturing, 3D printing, and the utilization of modeling and simulation for quality assurance. Tom is a co-author of several papers and book chapters on continuous manufacturing and emerging pharmaceutical technology. He has participated in the review of several regulatory applications utilizing continuous manufacturing. 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.
Prior to joining the FDA, Tom worked at ExxonMobil Research and Engineering where he held job functions in both process analytical technology and process control. Dr. O'Connor earned a B.S. in chemical engineering from the Cooper Union and a Ph.D. in chemical engineering from Princeton University.

Madhusudhan Gowravaram, Ph.D.

Chemist
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Madhusudhan Gowravaram is a Senior Pharmaceutical Quality Assessor and Team Leader in the Division of Lifecycle API, Office of New Drug Products/OPQ/CDER/FDA. He has been at the FDA since 2014. During his career at the FDA, he has been involved in the quality assessment of Active Pharmaceutical Ingredients (APIs) in support of ANDA and NDA applications. Prior to joining the FDA, he worked as a Medicinal Chemist in Pharmaceutical R&D for 20 years, where he contributed to several R&D programs in infectious, cancer, and inflammatory disease areas. His educational background is as a synthetic chemist with a Ph.D. in Organic Chemistry and M.Sc. in Chemistry.

Yun (Jenny) Wang, Ph.D.



Chemist
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Jenny has been a CMC assessor in the Office of New Drug Product's Division of Lifecycle API since 2013. Prior to joining the FDA, Jenny worked as an analytical chemist for about 13 years in both branded and generic pharmaceutical companies. Jenny graduated from University of Miami with a PhD in Chemistry.

Yan Ma, Ph.D.

Chemist
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Yan Ma, Ph.D. is a chemist in the Division of Lifecycle API / ONDP/OPQ/CDER at the U.S. Food and Drug Administration (FDA). In her role at FDA, Dr. Ma performs critical scientific or technical reviews of Drug Master Files, amendments, or other FDA submissions which pertain to chemistry, manufacturing processes, controls, and stability. She prepares a comprehensive summary of the data reviewed and submits substantive recommendations and conclusions showing the result of these reviews. She also served as a technical or project lead for cluster reviews of DMF submission. Prior to working in government, she was a Senior Research Investigator in Analytical Research and Development at Bristol-Myers Squibb. Dr. Ma received her doctorate from Rutgers University at New Brunswick in Organic Chemistry, her M.S. in Physical Chemistry and B.S. in Applied Chemistry from Fudan University, Shanghai, China.

Donglei Yu, Ph.D.

Chemist
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Donglei Yu obtained her Ph.D. in Pharmaceutical Sciences from the University of North Carolina at Chapel Hill. She was a research faculty in Eshelmen School of Pharmacy in UNC-Chapel Hill before she joined FDA in 2008. She began her FDA career in the Center for Veterinary Medicine (CVM) as a Chemist doing method development of veterinary medicine including Arsenic speciation. She joined the Division of Life Cycle API in 2013 as a review Chemist.

David Green

Senior Pharmaceutical Quality Assessor
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Mr. David Green is a chemist and Senior Pharmaceutical Quality Assessor in the Division of Life Cycle API, Office of New Drug Product, Office of Pharmaceutical Quality at the FDA Center for Drug Evaluation and Research. Mr. Green has been with the Agency for more than twelve years and came to the Agency with over ten years of pharmaceutical and biotechnology experience. Mr. Green received his M.S. in Chemistry from Syracuse University, and a B.S. in Chemistry from the University of Maryland, College Park.
Mr. Green joined the FDA in 2008, as a generic drug chemistry reviewer in the Center for Drug Evaluation and Research. In his current position as Senior Pharmaceutical Quality Assessor with the FDA's Office of Pharmaceutical Quality, he focuses on the chemistry, manufacturing and controls (CMC) of generic active pharmaceutical ingredients. His current professional interests include the scientific and regulatory aspects of drug substance manufacture and quality control.

Yongjun Gao, Ph.D.

Chemist
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Dr. Yongjun Gao holds a Ph.D. degree in Medicinal Chemistry. He completed his postdoctoral training and subsequently worked as a full-time research faculty at Johns Hopkins University. His drug discovery and development research activities include work in the areas of organic synthesis, medicinal chemistry, carbohydrate chemistry, heterocyclic chemistry, radiochemistry, neuroscience and PET imaging. Yongjun's research work at Hopkins not only produced 22 peer-reviewed publications and one US patent as the primary contributor, but also led to the successful developments of three radiotracers for PET imaging of neuroreceptors and translating them into clinical development through three FDA IND approvals. Yongjun's research achievements also won him two NARSAD Young Investigator Awards from the Brain & Behavior Research Foundation.
In December 2013, Yongjun joined the US FDA as a CMC assessor for Drug Master Files. He currently is a Senior Chemist in the Division of Lifecycle API (DLAPI).

Fatima Sequeira, Ph.D.
Chemist
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Fatima Sequeira is a Chemist in the Division of Lifecycle API (DLAPI) where, with a team of fellow scientists, she evaluates DMFs for generic drugs. Fatima has taken the lead on numerous projects within DLAPI and has worked on various assignments with other divisions including review of INDs, drafting controlled correspondence letters, and she recently completed a successful detail with the Biopharm Division. Before joining the FDA in 2014, Fatima was awarded a nationally competitive post-doctoral fellowship at the National Institute of Standards and Technology (NIST) to conduct research in the field of cellular and molecular biology. Fatima earned her Ph.D. in synthetic-organic chemistry at SUNY Buffalo.

Mahmut Levent
Chemist
Division of Lifecycle API
Office of New Drug Products
Office of Pharmaceutical Quality
CDER | US FDA

Mahmut Levent joined the FDA in 2015 as a chemist where he currently reviews generic drug applications. Prior to joining the FDA, Mahmut worked as a senior research scientist or bench chemist at Wyeth, Pfizer and Teva. Overall, he worked for more than 25 years for several companies in the chemical and pharmaceutical industry. Mahmut holds a bachelor's degree in chemical engineering. Additionally, he holds his master's degree in chemistry from the City College of New York City and another master's degree in management from the NJIT.

Sad Ahamed, Ph.D.
Chemist
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Dr. Sad Ahamed is currently chemistry assessor in the Division of Lifecycle API (DLAPI). He has been with the center for drug evaluation and research (CDER) since 2017. As a chemistry assessor, he is responsible for the evaluation of drug master file (DMF) applications relating to the chemistry manufacturing and controls (CMC) of drug substance to ensure data are in compliance with regulatory guidelines. Prior to joining the agency, Sad had over 10 years of experience within the pharmaceutical industry in research and development. He earned his Ph.D. in chemistry from Jadavpur University, India. After graduation, Sad joined the Department of Chemistry at George Mason University, VA, USA as postdoctoral research fellow. He also taught chemistry as an Adjunct Professor in the Department of Chemistry, George Mason University.