
# Speaker Biographies

In order of presentations (refer to the Agenda)

**Lawrence X. Yu, Ph.D.**
Director
Office of New Drug Products (ONDP) | Center for Drug Evaluation and Research (CDER) | US FDA

Lawrence X. Yu, Ph.D., is the Director, Office of New Drug Products, Food and Drug Administration and Rapporteur, ICH M4Q(R2) Expert Working Group. Dr. Yu implemented Biopharmaceutics Classification System at the FDA, described 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 400 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."

**Benjamin Y. Danso, Pharm.D.**
Commander, United States Public Health Service
Regulatory Business Process Manager
Office of Program & Regulatory Operations (OPRO)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER) | US FDA

CDR 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.

**Jayani Perera, Ph.D.**
Senior Chemist
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (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 a secondary reviewer for CAs. Recently she served in the GDUFA III DMF implementation working group. Jayani holds a Ph.D. degree in Inorganic/Organometallic Chemistry from Wayne State University in Detroit, Michigan.

**Jennifer Nguyen, Pharm.D.**
Senior Regulatory Business Process Manager
Office of Program and Regulatory Operations (OPRO) | Office of Pharmaceutical Quality (OPQ) | Center for Drug Evaluation and Research (CDER) | US FDA

Jennifer Nguyen is currently a Senior Regulatory Business Process Manager, in the Office of Program and Regulatory Operations (OPRO) in OPQ, managing original ANDA quality assessments. She previously held other responsibilities within OPRO including acting Quality Assessment Lead and Associate Director for Regulatory Affairs. Prior to joining the FDA, Jennifer was a pharmacy manager at a health department and practiced community pharmacy with a focus on HIV/TB, vaccines, and emergency preparedness. She received her Doctor of Pharmacy from the University of North Carolina at Chapel Hill.

**David Skanchy, Ph.D.**
Commander, United States Public Health Service
Director
Division of Lifecycle API (DLAPI) | Office of New Drug Products (ONDP) Office of Pharmaceutical Quality (OPQ) | Center for Drug Evaluation and Research (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.

**Erin Skoda, Ph.D.**
Branch Chief
Division of Lifecycle API
Office of New Drug Products (ONDP) | Center for Drug Evaluation and Research (CDER) | US FDA

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

**Iain Margand, R.Ph.**
Commander, United States Public Health Service
Patent and Exclusivity Team, Division of Legal & Regulatory Support (DLRS)
Office of Generic Drug Policy (OGDP)
Office of Generic Drugs (OGD)
Center for Drug Evaluation and Research (CDER) | US FDA

CDR Iain Margand is a U.S. Public Health Service Officer with the Division of Legal and Regulatory Support (DLRS). He graduated from the University of Maryland School of Pharmacy in 1992 with a B.S. in Pharmacy. He began his career with the FDA in 2004 with the Regulatory Support Branch, now the Division of Filing Review. He transferred to the Office of Generic Drug Policy in 2013 and assisted in developing the Patent and Exclusivity Team within the DLRS. Prior to joining FDA CDR Margand worked in various pharmacy practices, including long term care, home health and hospital settings.

**Ziyang Su, Ph.D.**
Policy Lead
Division of Regulations, Guidance and Standards | Office of Policy for Pharmaceutical Quality (OPPQ) | Office of Pharmaceutical Quality (OPQ) | Center for Drug Evaluation and Research (CDER) | US FDA

Ziyang Su is a Policy Lead in the Office of Pharmaceutical Quality in the FDA's Center for Drug Evaluation and Research. In this role, she leads workgroup meetings to develop new guidance and revise existing guidance. Her responsibilities also include reviewing policy proposals, providing consult to petitions and responding to external inquiries. With 10 plus years of experience at both the FDA and innovative pharmaceutical industry, her expertise spans federal policy development, quality assessment of regulatory submissions, leading manufacturing facility inspections and formulation/process development. She holds a Ph.D. in Pharmaceutical Sciences from Purdue University.

**Andre Raw, Ph.D.**
Associate Director for Science and Communication
Office of Lifecycle Drug Products (OLDP) | Office of Pharmaceutical Quality (OPQ) | Center for Drug Evaluation and Research (CDER) | US FDA

Dr. Raw was involved in the development of several important FDA initiatives, including the Guidance on Pharmaceutical Solid Polymorphism and Co-crystals, Regulations on Listing of Polymorph Patents, Question Based Review, and QbD Example for Generic Modified Release Products. He was instrumental in FDA's approval of generic versions of complex active ingredients, including Lovenox (enoxaparin sodium) and Copaxone (glatiramer acetate). He is currently involved in Risk and Quality Informatics Initiatives and is a principal architect of Knowledge-Aided Assessment and Structured Application (KASA). More recently, Dr. Raw has been active in Nitrosamine Impurities.

Andre Raw received his B.S. degree from the Massachusetts Institute of Technology and his Ph.D. in chemistry from the University of California at Berkeley. Within his tenure at FDA, he has been promoted to FDA Agency Expert and to Chemistry Division Director. Currently, he is Associate Director for Science and Communication in the Office of Life Cycle Drug Products (OLDP) in the Office of Pharmaceutical Quality (OPQ).

**Larisa Wu, Ph.D.**
Associate Director for Science and Communication
Office of New Drug Products (ONDP) | Office of Pharmaceutical Quality (OPQ) | Center for Drug Evaluation and Research (CDER) | US FDA

Dr. Larisa Wu is the Associate Director for Science and Communication in the Office of New Drug Products (ONDP) at US FDA. Larisa has been with the Agency since 2011, starting her career as a Chemistry Reviewer. Over the years, Larisa contributed significantly to various initiatives that became pivotal to the launch of Office of Pharmaceutical Quality (OPQ), including integrated team-based quality assessment (IQA), risk-based review, and ANDA backlog review and management. After OPQ stood up in 2015, Larisa was a Special Assistant in the OPQ Immediate Office and 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. Most recently, Larisa leads the FDA KASA for NDAs initiative, and serves as the Rapporteur Supporter and Content Manager of the ICH M4Q(R2) Expert Working Group. Larisa received her Ph.D. degree in Bioengineering from the 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 Medical Bioengineering.

**Marlene Kim, Ph.D.**
Chemist (Computational Toxicologist)
Health Informatics Staff | Office of Data, Analytics, & Research (ODAR) Office of the Commissioner (OC) | US FDA

Marlene Kim is a registrar for FDA's Global Substance Registration System. She is a chemist specialized in cheminformatics and computational toxicology. Marlene has experience supporting FDA's Center for Drug Evaluation and Research drug safety reviewers and quality assessors with (quantitative) structure-activity relationship ((Q)SAR) predictions and read-across assessments that were submitted by applicants.

**Naomi L. Kruhlak, PhD**
Scientific Lead
Computational Toxicology Consultation Service (CTCS)
Division of Applied Regulatory Science (DARS)
Office of Clinical Pharmacology (OCP)
Office of Translational Sciences (OTS)
CDER| US FDA

Dr. Naomi Kruhlak has worked for US FDA's Center for Drug Evaluation and Research (CDER) as a computational toxicologist for over 20 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 vendors, as well as an Inter-Agency Agreement with NIH generating in silico-based drug safety predictions. Dr. Kruhlak has published 44 peer-reviewed articles and a book chapter describing data standardization, transformation, and classification for modeling purposes, as well as 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.

**Frank Switzer, Ph.D.**
Chemist
Health Informatics Staff | Office of Data, Analytics, And Research (ODAR) | Office of Digital Transformation (ODT) | Office of the Commissioner (OC) | US FDA

Frank Switzer is a member of the Health Informatics Staff in the Office of Data, Analytics, and Research in FDA's Office of the Commissioner. He received a Ph.D. in chemistry from Dartmouth College in 1987. Frank has been the primary data manager for FDA's Global Substance Registration System (GSRS) since joining FDA in 2008. Frank was also co-editor with FDA's Lawrence Callahan of the ISO 11238 substances standard published in 2012. Frank taught college chemistry for 20 years before joining the FDA.

**Tyler Peryea**
Health Informatics Staff
Office of Data, Analytics, And Research (ODAR) | Office of Digital Transformation (ODT) | Office of the Commissioner (OC) | US FDA

Tyler Peryea is a cheminformatician in the Health Informatics Staff, Office of Data, Analytics, & Research, Office of the Commissioner. He supports the Global Substance Registration System (GSRS) project which coordinates with all FDA centers to link common data together in a standardized open-source framework. He has over 15 years of experience in software development, scientific data management, and general data science. Before joining the FDA, Tyler spent seven years at the National Center for Advancing Translational Sciences (NIH NCATS). While at NIH NCATS, Tyler served as a mentor to six data science and software engineering students, coauthored 14 publications, and helped develop dozens of open-source scientific software applications including "InXight Drugs", "GSRS", "MolVec", "NCATSFind Resolver", "CureID" and "Pharos." Tyler served as co-chair for FDA's 2022 Scientific Computing Days event.

**Barbara O. Scott**
Review Chemist
Division of Lifecycle API
Office of New Drug Products (ONDP) | Office of Pharmaceutical Quality (OPQ) | Center for Drug Evaluation and Research (CDER) | US FDA

Ms. Barbara O. Scott is a chemist and CMC Senior Assessor in the Division of LifeCycle 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.

**David Green**
Senior Pharmaceutical Quality Assessor
Division of Life Cycle API (DLAPI) | Office of New Drug
Product (ONDP) | Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (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 fourteen 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, where 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.