Small Business and Industry Assistance
Knowledge Management and Modernization of Regulatory Quality Assessment and Submissions at FDA

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SPEAKER BIOGRAPHIES

Brenda Stodart, PharmD, BCGP, RAC-US
Captain, United States Public Health Service | *Director*, Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER) |Food and Drug Administration (FDA)

CAPT Brenda Stodart is currently the Director for the Center for Drug Evaluation and Research (CDER's) Small Business and Industry Assistance (SBIA) Program. 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 nine years. CAPT Stodart received her MS in Regulatory Science from University of Maryland, PharmD from the University of Arkansas Medical Sciences and BS in Pharmacy from Howard University. She is also a Board-Certified Geriatric Pharmacist (BCGP). CAPT Stodart has had experience in hospital and retail pharmacy before joining the FDA.

Lawrence X. Yu, PhD
Director, Office of Product Quality Assessment II (OPQA II) | FDA

Lawrence X. Yu, Ph.D., is the Director, Office of Product Quality Assessment II, Food and Drug Administration and Rapporteur, ICH M4Q(R2) Expert Working Group. Dr. Yu is also an adjunct Professor at the University of Michigan and is an Associate Editor of the AAPS Journal. He led and established the modern US FDA pharmaceutical quality oversight, including people, organization, process, and technology. 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."

Andre Raw, PhD
Associate Director, Office of Pharmaceutical Quality Assessment I (OPQA I)
Office of Pharmaceutical Quality (OPQ) | Center for Drug Evaluation and Research (CDER) | FDA

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 Pharmaceutical Quality Assessment I (OPQA I) in the Office of Pharmaceutical Quality (OPQ).

Dr. Raw was involved in the development of several important FDA initiatives, including Guidances on Pharmaceutical Solid Polymorphism and Co-crystals, Regulations on Listing of Polymorph Patents, and on matters related to Nitrosamine Impurities. He was instrumental in FDA's approval of generic versions of complex active ingredients, including Lovenox (enoxaparin sodium) and Copaxone (glatiramer acetate). Currently, he is involved in Risk and Quality Informatics Initiatives and is a principal architect of Knowledge-Aided Assessment and Structured Application (KASA).

Larisa Wu, PhD
Associate Director for Science and Communication
Office of Product Quality Assessment II (OPQA II) | Office of Pharmaceutical Quality (OPQ)
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Dr. Larisa Wu is the Associate Director for Science and Communication in the Office of Product Quality Assessment II (OPQA II) 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 including integrated team-based quality assessment (IQA), Knowledge-aided Assessment and Structured Application (KASA), and Concept of Operations (ConOps) for Inspection of Human Drugs. Recently, Larisa has been serving as the Rapporteur Supporter and Content Manager of the ICH M4Q(R2) Expert Working Group. 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 Medical Bioengineering.

Elvira Argus, PhD
Biological Reviewer
Division of Gene Therapy 2 | Office of Gene Therapy (OGT)
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Elvira Argus joined the Office of Gene Therapy at CBER FDA in 2022 as a biological reviewer, specializing in evaluation of CMC data for ex vivo gene-modified products at all stages of development, from INTERACT meetings to BLA supplements. She currently serves as the FDA Deputy Topic Leader for the ICH M4Q(R2) Expert Working Group. Before joining the FDA, Elvira worked in the biotechnology industry, advancing gene-modified immunotherapy programs to the IND stage. She holds a Ph.D. in Molecular Biology and a B.S. in Bioengineering.

Rakhi Shah, PhD
Associate Director, Office of Pharmaceutical Manufacturing Assessment (OPMA)
Office of Pharmaceutical Quality (OPQ) | Center for Drug Evaluation and Research (CDER) | FDA

Dr. Rakhi Shah has been with the FDA since 2004, serving as a research scientist, senior reviewer, team lead, branch chief, associate director for regulatory affairs prior to her current role as associate director for science and communication in OPMA. She provides staff leadership and direction in assessment of manufacturing and facilities for A/NDAs and BLAs, and supplements including inspections to support applications action.

She is a recognized subject matter expert in pharmaceutical manufacturing and has served on multiple internal and external committees and working groups, notably, ICHM4Q(R2), KASA, NIPP, etc. She has a Ph.D. in pharmaceutical sciences, M.S. in Bioprocess technology and B.S. in Pharmaceutical Sciences.

Geoffrey Wu, PhD, PMP, CPH
Commander, U.S. Public Health Service
Office Director (acting), Office of Pharmaceutical Quality Assessment I (OPQA I)
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Commander Geoffrey Wu, Ph.D., PMP, CPH, joined the FDA's Office of Testing and Research (OTR) in 2010, has served in multiple capacities, including research scientist, science staff, chemistry reviewer, staff supervisor, Associate Director of Sciences and Communication (ADSC), acting Division Director, acting Office Director, and Deputy Office Director. He is a scientist officer in the United States Public Health Service. Throughout his FDA tenure, he has been deeply involved, leading or co-leading regulatory review and research for PDUFA and GDUFA programs. Between 2013 and 2017, he served as a founding member on the OPQ Emerging Technology Team (ETT).

In the recent years, he has been a core and/or leading member in multiple policy and/or scientific development efforts, such as emerging technology, continuous manufacturing, comparability protocols, knowledge-aided assessment and standard submissions (KASA), pharmaceutical quality chemistry manufacturing and controls (PQ/CMC, aka Structured Pharmaceutical Quality Submissions (SPQA)), novel complex generic drugs, and advanced analytics. He has training and education in pharmacy, pharmaceutical science, protein chemistry, polymer chemistry, process analytical technology, and data science.

Zhouxi (Josie) Wang, PhD
Senior Biologist, Office of Pharmaceutical Manufacturing Assessment (OPMA)
Office of Pharmaceutical Quality (OPQ) | Center for Drug Evaluation and Research (CDER) | FDA

Zhouxi Wang is a quality assessor in OPMA/OPQ at CDER, FDA. She has conducted quality assessments for a broad range of applications, including original and supplemental ANDAs and NDAs, as well as inspections. She actively participates in multiple working groups and initiatives, such as Knowledge-Aided Assessment and Structured Application (KASA), Pharmaceutical Quality/Chemistry, Manufacturing & Controls (PQ/CMC), and guidance development. She leverages her expertise and training in quantitative analysis and software/database development to support various projects.

Zhouxi holds a Ph.D. in Chemistry, an M.E. in Material Science, and a B.E. in Polymer Science and Engineering**.**