5TH PQRI/FDA CONFERENCE ON ADVANCING PRODUCT QUALITY

Biographies - Day 3 – December 3, 2021

Product Quality Track

Innovation in Quality & Technology Beyond the Pandemic

SESSION 1: Knowledge-Aided and Structured Application (KASA) and Pharmaceutical Quality/CMC (PQ/CMC) Update

Moderator:

Nina S. Cauchon, Ph.D.
Director Regulatory Affairs
Amgen Inc.
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Nina S. Cauchon, PhD is Director Regulatory Affairs CMC at Amgen Inc in Thousand Oaks, CA, and leads RA-CMC Advocacy and External Engagement. She has experience leading both early phase & commercial programs, including small molecules and biologics. Her areas of interest are regulatory challenges for innovative modalities and emerging technologies, CMC aspects of expedited review pathways, regulatory harmonization, and science and risk-based approaches to regulations. Nina is active in several external organizations which provide a strong network and knowledge base, including being a speaker/committee member for ISPE, CASSS, PQRI, AAPS, IQ, and DIA. She is a member of the ISPE International Board of Directors, the PhRMA Global Quality and Manufacturing group, and the ICH Q2(R2)/Q14 Expert Working Group. She has a PhD from Purdue University School of Pharmacy and has over 25 years of industry experience.

Speakers:

Susan M. Rosencrance, Ph.D.
Director, Office of Lifecycle Drug Products (OLDP)
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Dr. Susan Rosencrance is the Director for the Office of Lifecycle Drug Products (OLDP) in the Office of Pharmaceutical Quality (OPQ) at the Food and Drug Administration. In this capacity, she provides executive leadership by overseeing and directing scientific review programs and activities related to evaluating and assessing drug product quality during the lifecycle of both brand name and generic drug products. Prior to joining the FDA, Susan worked in research and development at Merck & Co. in Rahway, New Jersey. Susan holds a Ph.D. in Chemistry from American University and completed her dissertation research at the NIH Laboratory of Biophysical Chemistry conducting a molecular dynamics study on hydrophobic interactions in alpha-helical coiled coils found in proteins. She received her bachelor's degree in Biochemistry from Hood College and completed studies at the University of Strasbourg in Strasbourg, France in the Institute Internationale D'Etudes Française – Université Louis-Pasteur.

Steven Kozlowski, M.D.
Director, Office of Biotechnology Products
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Steven Kozlowski is the Director of the Office of Biotechnology Products, Office of Pharmaceutical Quality, at the Center for Drugs Evaluation and Research (CDER), FDA. OBP is responsible for the quality assessment of monoclonal antibodies and most therapeutic proteins at CDER. OBP also provides expertise on immunologic responses to therapeutic proteins and performs mission related research. Dr. Kozlowski received his medical degree from Northwestern University and trained in Pediatrics at the University of Illinois. Prior to joining the FDA, Dr. Kozlowski worked as a staff fellow in the Molecular Biology Section of the Laboratory of Immunology, NIAID, NIH. Dr. Kozlowski joined the FDA in 1993 and he has been involved in all phases of the regulatory process, from pre-IND product development through inspections, licensing and post approval supplements. He is involved in ongoing policy development for biosimilars and advanced approaches for the manufacture of biopharmaceutical products.

Geoffrey Wu, Ph.D.
Deputy Office Director, Office of Lifecycle Drug Products
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Commander Geoffrey Wu, Ph.D., PMP, CPH, Deputy Office Director, Office of Lifecycle Drug Products (OLDP), OPQ, joined FDA's OTR in 2010, has served as research scientist, science staff, chemistry reviewer, special assistant to the Office Director, staff supervisor (Division Director equivalent), Associate Director of Sciences and Communication (ADSC), acting Division 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 Controlled Correspondence, ANDAs, and supplemental ANDAs and NDAs. Between 2013 and 2017, he served as a founding member on the OPQ Emerging Technology Team (ETT). He was a core member in multiple policy development efforts, such as emerging technology, continuous manufacturing, and comparability protocols. Dr. Wu has training and education in pharmacy, pharmaceutical science, protein chemistry, polymer chemistry, and process analytical technology. He has more than 20 peer-reviewed publications, and has been invited to multiple national and international conferences to present or discuss the above related topics. His Ph.D. thesis from the University of Utah focused on self-assembly of hybrid hydrogels containing coiled-coils and drug-free macromolecular therapeutics to induce apoptosis by coiled-coiled mediated crosslinking of antigens.

Michael Abernathy, MS, RAC
Data Exchange Product Owner
Accumulus Synergy

Executive Director, Global Regulatory Affairs CMC
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Michael Abernathy is currently the Accumulus Synergy CMC Product Owner responsible for leading a team in the creation, design and implementation of a Cloud-based CMC Exchange Platform. Michael is also an Executive Director at Amgen leading the company's Global RA CMC function where he is accountable for more than 65 staff globally, and a product portfolio of over 85 programs. The extent of Michael's product oversight and responsibilities traverse molecular discovery, early and late-stage clinical development and approved life-cycle programs. He also founded Amgen's RA CMC External Engagement function targeting activities that comprise a CMC focus, promoting company and industry initiatives, engaging with Health Authorities around the world. Michael has made significant contributions to several paper publication on novel modalities, emerging technologies and CMC acceleration. In 2020, Michael was selected to the non profit Accumulus Synergy Executive Leadership Team as the CMC Use Case Lead, focused on transforming the filing and review of CMC content into an automated and cloud-based eco-system.

Prior to his current post, Michael has held roles of increasing leadership at Amgen, including active contributions to several of Amgen's commercialized therapeutics, as well as spearheading the company's Analytics Optimization initiative. Michael has been an active contributor to innovation during his 20+ years as a Regulatory Affairs professional. Mr. Abernathy holds degrees from University of the Pacific, California State University and Colorado State University.

Lawrence X. Yu, Ph.D.
Director, Office of New Drug Products
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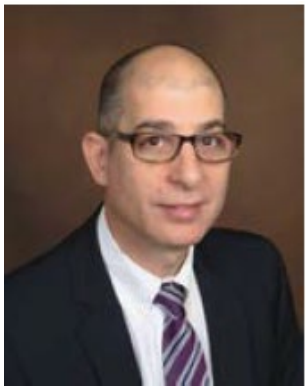
Lawrence X. Yu, Ph.D., is the Director, Office of New Drug Products, Food and Drug Administration. Dr. Yu implemented Biopharmaceutics Classification System at the FDA, created the Question-based Review, described the Pharmaceutical Quality by Design (QbD), inaugurated the FDA modern review system - 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.*"

HOT TOPIC: Remote Interactive Evaulations (RIEs)	
Moderator: **Cat Vicente**, Johnson & Johnson CVicent3@its.jnj.com	
Speakers: **Stelios C. Tsinontides, Ph.D.** Director Office of Pharmaceutical Manufacturing Assessment (OPMA)/OPQ/CDER/FDA stelios.tsinontides@fda.hhs.gov 	**Dr. Stelios Tsinontides** is Director of the Office of Pharmaceutical Manufacturing Assessment (OPMA) under the Office of Pharmaceutical Quality (OPQ) in CDER. Dr. Tsinontides has over 25 years of experience in the pharmaceutical industry. OPMA evaluates facilities, process design, and control strategies to assess capabilities of manufacturers to produce quality pharmaceutical and biotechnology products at commercial scale and provides leadership and technical expertise to Agency components internal and external to the Office of Pharmaceutical Quality regarding manufacturing quality issues. Prior to joining the FDA, Dr. Tsinontides served in senior-level positions in the pharmaceutical industry - most recently as Shire's Head of Small Molecule (SM) Drug Product Technical Services. His group was responsible for providing scientific and technical expertise for SM Drug Product scale-up and commercial manufacturing activities worldwide, to ensure establishment of commercial robust manufacturing processes and a continuous supply of product to patients. Dr. Tsinontides holds a B.E. in Chemical Engineering from City College of CUNY and an M.A. and Ph.D. in Chemical Engineering from Princeton University. He's also studied in the Wharton Management Program at the University of Pennsylvania. Dr. Tsinontides is also a Fellow at the American Institute of Chemical Engineering (AIChE).

Lane Christensen, Ph.D.
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Dr. Lane Christensen has been with the US Food and Drug Administration for over 12 years. He is currently a Branch Chief in the Office of Pharmaceutical Manufacturing Assessment (OPMA), Office of Pharmaceutical Quality, CDER. He recently completed a multi-year assignment with the FDA Office of Global Policy and Strategy located in Beijing, China and New Delhi, India being actively involved in the FDA's drug program abroad. Lane received his PhD in Pharmaceutics and Pharmaceutical Chemistry from the University of Utah.

SESSION 2: Advanced Manufacturing Concepts Beyond Continuous Manufacturing

Moderator:

Robert Meyer, Ph.D.
Principal Scientist
Merck & Co. Inc.

Robert Meyer received his BS and PhD degrees in Chemical Engineering from the University of Akron and the University of Pennsylvania, respectively. Since joining Merck in 2002, he has worked in many areas of drug product development, with a focus on emerging manufacturing platforms such as hot melt extrusion and continuous manufacturing of oral solid doses, and smaller innovations such as process modeling and PAT. As a principal scientist at Merck, he currently leads innovation and new technology development in the area of small molecule pharmaceutical commercialization.

Rajan Jog, Ph.D.
Scientific Reviewer
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Dr. Rajan Jog received his M.S. Pharm in Pharmaceutical Sciences from National Institute of Pharmaceutical Education and Research, (NIPER, Mohali) India (2010) and his Ph.D. in Pharmaceutics and Drug Design from the University of Connecticut, USA (2018). He was an ORISE (Postdoctoral) fellow at Office of Research and Standards, US FDA (2018-19). Dr. Jog is an active member of AAPS (American Association of Pharmaceutical Scientists), CRS (Controlled Release Society), and PQRI (Product Quality Research Institute). He is on the editorial board of Journal of Bioequivalence and Bioavailability, Current Nanomedicine, and Journal of Targeted Drug Delivery.

Among many awards and honors Dr. Jog has received the 2016 IPEC (International Pharmaceutical Excipients Council) Foundation award; 2017 Richardson-Vicks/A. Francis Summa Memorial Award, for outstanding research and scholarly accomplishment in the area of excipients, solid-state and nanoparticle drug delivery. Dr. Jog has 15 research publications, 02 book chapters, and several oral and poster presentations.

Panelists:

Celeste Frankenfeld Lamm,
Ph.D. Director, Merck & Co.
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Celeste Frankenfeld Lamm, Ph.D., is a Director of Global Regulatory Affairs – CMC at Merck & Co, Inc. with 14 years of industry experience. In this capacity she is responsible for regulatory strategy, engagement with regulatory authorities, and preparation of clinical CMC dossiers as well as marketing applications. In previous roles within the company, she led analytical development efforts to support both drug substance and formulation development, as well as a cross-functional team tasked with advancing a candidate from pre-clinical through clinical studies. Dr. Frankenfeld Lamm holds a B.A. in Chemistry and Biology from Greenville University, and a Ph.D. in Pharmaceutical Chemistry from the University of Kansas.

Peter Makowenskyj, MEng.
Director of Design Consulting
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Peter Makowenskyj has over 16 years of experience in pharmaceutical and biopharmaceutical industries. Peter held various roles within industry, primarily around process solutions and engineering for drug substance facilities. He has extensive knowledge of bioprocess manufacturing and helped design new facilities and retrofit existing facilities. Peter joined G-CON Manufacturing in 2016 where he now consults with clients in the design of their facilities utilizing G-CON's pre-fabricated autonomous clean rooms.

Peter received his Bachelor of Science in Chemical Engineering and a Minor in Biomedical Engineering from Cornell University. He received is M. Eng in Chemical Engineering from Cornell University.

Christine M. V. Moore, Ph.D.
Executive Director
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Dr. Christine Moore is a founding member of Organon where she leads Global External Advocacy and Policy, providing oversight for review and implementation of new GMP-related policy. Christine started her career as an API process development engineer at Pfizer and Searle/Pharmacia, then moved to US FDA where she led the offices responsible for small molecule new drug review and manufacturing process assessment, and most recently returned to industry to advance regulatory policy and innovation at Merck and now Organon. Christine is a global thought leader in scientific and regulatory approaches for advancing pharmaceutical manufacturing technologies including continuous manufacturing, process analytical technologies, and portable/point of care manufacturing. She holds a PhD in chemical engineering from Massachusetts Institute of Technology and a BS in Chemical Engineering from Northwestern University.

Sau (Larry) Lee, Ph.D.
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Dr. Sau (Larry) Lee is the Deputy Super Office Director of Science in the Office of Pharmaceutical Quality. He directs the activities of staff members in OPQ sub-offices responsible for the quality assessment of regulatory submissions (OBP, OLDP, ONDP and OPMA). He represents OPQ in programs and activities that impact quality assessments by coordinating with OPQ, CDER, and ORA. He also serves as the point person for the pharmaceutical industry and scientific/academic groups in developing programs to support science- and risk-based application assessment and approval.

Dr. Lee has been with the FDA since 2005, serving as a regulatory scientist, team lead, Associate Director for Science, Deputy Office Director, and Office Director. He has provided exemplary leadership in developing OPQ science, research and testing programs to support quality assessment, inspection, surveillance and policy. In 2016, Dr. Lee was appointed to the Senior Biomedical Research Service (SBRS) because of his extensive regulatory and scientific contributions to manufacturing science, complex drug substances and products, and emerging pharmaceutical technologies. Prior to joining the FDA, Dr. Lee 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.