Advancing the Utilization and Supporting the Implementation of Innovative Manufacturing Approaches

Hybrid Public Workshop

June 8, 2023 | 9:00 a.m.–4:30 p.m. ET

Speaker Biographies

Opening Remarks

Mark McClellan is the Robert J. Margolis, M.D., Professor of Business, Medicine and Policy and Director of the Duke-Margolis Center for Health Policy. A physician-economist focused on advancing quality and value in health care, his COVID-19 response work spans virus containment and testing strategies, resilient care delivery, and accelerating therapeutics and vaccine development. Dr. McClellan is a former leader of the Centers for Medicare & Medicaid Services and the U.S. Food and Drug Administration. An independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomIQ, Dr. McClellan co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network and serves as an advisor for Arsenal Capital Partners, Blackstone Life Sciences, and MITRE.

Current Regulatory Frameworks and Tools

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. 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. He developed and established the Emerging Technology Program in CDER. He has been serving as a rapporteur for ICH Q13 on Continuous Manufacturing of Drug Substances and Drug Products. 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.

Manuel Osorio is the lead for the Advanced Technologies Program in the Center for Biologics Evaluation and Research (CBER) at the U.S. Food and Drug Administration (FDA). Prior to this role, Dr. Osorio was a researcher/reviewer for 16 years in the Office of Vaccines Research and Review in CBER. He received a BS degree from UCLA in Biochemistry and PhD degree in Cellular Immunology from the University of California at Santa Cruz. He was a postdoctoral fellow at the National Institutes of Health before joining the FDA.

Ahmad Almaya is a Senior Director of Global Regulatory Affairs – CMC at Eli Lilly and Company. In this role, he has scientific and regulatory leadership responsibility and management of CMC regulatory submissions and interactions with regulatory authorities for all of Lilly's small molecules, synthetic peptides, and oligonucleotides, from Phase 1 filings through MAAs in major and global markets. Ahmad is a subject matter expert in continuous manufacturing where he served as Lilly's Scientific Team Lead for investigation and optimization of Lilly's drug product continuous direct compression platform. He also served as the project lead for Verzenio® tablet development, Lilly's first marketed product with continuous manufacturing. Ahmad authored/co-authored multiple publications on continuous manufacturing and gave numerous presentations at various conferences in the US, Europe, Japan and China. He holds a bachelor's degree in pharmacy, a Ph.D. in Pharmaceutics, and an Executive Certificate in Business**.**

Thomas O'Connor is the deputy director of the Office of Testing and Research in the Office of Pharmaceutical Quality and is the vice-chair of CDER's Emerging Technology Team (ETT). His responsibilities include managing research and testing projects that answer and anticipate pharmaceutical quality-related regulatory challenges through scientific approaches. 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. Tom has been at the FDA since 2013 serving in various roles including as a chemistry reviewer in the Office Generic Drugs and a team leader in the immediate office of the Office of Pharmaceutical Quality. 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. Tom earned a B.S. in chemical engineering from the Cooper Union and a Ph.D. in chemical engineering from Princeton University.

J. Paul Kirwan is a Senior Manager, Regulatory Affairs CMC, with Amgen since 2018. Currently, Paul leads a team at Amgen that manages the CMC content and regulatory strategy of module 3 authoring templates used for regulatory filings for all products and stages of development. Paul also served as Global CMC Regulatory Lead for several clinical stage programs with multiple indications and filings in more than 30 countries. Prior to joining Amgen, Paul was a product quality CMC review chemist at FDA/CDER in the Office of Biotechnology Products from 2014-2018. His responsibilities included product quality review and assessment of biologic and biosimilar submissions across all stages of development, engaging in FDA meetings with sponsors, and contributing to pre-license inspections. He is also a former FDA Commissioner's Fellow (2013-2014). Paul holds a PhD in Biochemistry from the University of Colorado Anschutz Medical Campus, where he completed graduate and post-doctoral training in the laboratory of Robert S. Hodges.

Celeste Frankenfeld Lamm is a director within Global Regulatory Affairs at Merck and leads the CMC Policy and Advocacy Team. With 16 years of industry experience, Celeste has held several different roles within the company, including responsibilities for regulatory strategy, preparation of clinical and commercial regulatory dossiers, and leading analytical development for several small molecule programs. Celeste volunteers through multiple professional societies, including currently as ISPE's PQLI co-chair, as a member of PhRMA's Global Quality and Manufacturing group, and of Efpia's Agile Manufacturing team. Additionally, she has served as speaker/session chair/committee member of DIA, IFPAC, ISPE, and PQRI. Celeste holds a B.A. in chemistry and biology from Greenville University, and a Ph.D. in Pharmaceutical Chemistry from the University of Kansas.

Kimberly Schultz is currently the Chief of Gene Therapy Branch 4 in the Office of Gene Therapies which is part of the Office of Therapeutic Products at FDA's Center for Biologics Evaluation. She oversees the product review for pre-IND, IND, and BLA submissions for gene therapy products. Kim also contributes to stakeholder outreach and regulatory guidance documents. Kim joined the FDA in 2015 as a Commissioner's Fellow to conduct a cross-study analysis of CAR T cell CMC data and then transitioned to a full time reviewer. Prior to joining the FDA, she received her PhD from the University of Wisconsin and conducted postdoctoral studies at Johns Hopkins Bloomberg School of Public Health specializing in virology and immunology.

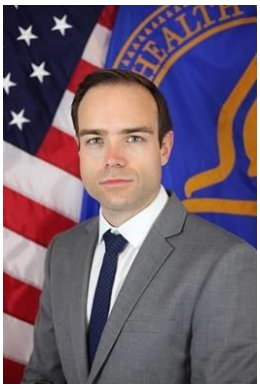
Nandita Vishwanathan is the process design lead expert for upstream processes in EMD Serono- Global Drug Substance Development. She is chemical engineer by training with a PhD thesis on 'Genomic and transcriptomic approaches for the advancement of CHO cell bioprocessing' at the University of Minnesota in 2014. She started her career in biotech as an upstream process development engineer with Takeda pharmaceuticals in Cambridge, Massachusetts. She joined EMD Serono, Corsier-sur-Vevey, Switzerland in 2017 as a scientist. In her current role as process lead expert, she has been developing end-to-end continuous manufacturing processes for clinical manufacturing. Specifically, she led the development of a QbD-based, high speed and lean workflow for producing clinical material for first-in-human (FIH) process by continuous manufacturing approach. Within the biotech community, she has actively contributed to NIIMBL workstream on biopharma process ontology and BioPhorum development group workstream on small scale model qualification.

Regulatory Challenges to Adoption

Adam Fisher is the Director of Science Staff in the Office of Pharmaceutical Quality in the Center for Drug Evaluation and Research at the U.S. FDA. He focuses on engaging FDA stakeholders and supporting advanced pharmaceutical manufacturing technologies. At the FDA, he has served as a primary and secondary reviewer of Abbreviated New Drug Applications (generics) and Drug Master Files, team lead, subject matter expert on complex drug substances and advanced biomanufacturing, and liaison to the United States Pharmacopeia BIO1 Expert Committee. He joined the FDA in 2014 as a chemical engineer with expertise in the synthesis of biomolecules. Prior to the FDA, he was co-founder and chief science officer of a biotechnology startup company. He earned his BS in chemical engineering at the University of Maryland College Park and his PhD in chemical and biomolecular engineering at Cornell University.

Ingrid Markovic serves as Senior Science Advisor and CMC Policy Lead in the CBER/FDA Immediate Office of the Center Director where she is responsible for providing leadership, strategic direction, and oversight for development, implementation, and integration of CMC policies for biological and biotechnological products. In the international arena, Ingrid serves as CBER ICH Quality Lead, and is/was FDA Topic Lead/(co)Lead for QDG, Q12 and M4Q. She had an opportunity to briefly serve as Q3E Rapporteur. Ingrid previously worked in the industry sector leading US & EU CMC Regulatory Policy efforts with focus on Technological Innovation and Cell & Gene Therapies collaborating with Trades Associations to support continual improvement and innovation in the Biopharmaceutical sector. Ingrid completed her Ph.D. training at University of Wisconsin, Madison and Post-Doctoral Training at the Laboratory of Cellular and Molecular Biophysics at the National Institutes of Health, Bethesda, MD.

Fernando J. Muzzio is a distinguished Professor of Chemical and Biochemical Engineering at Rutgers University. For the last 31 years, pharmaceutical product and process design has been his main research and educational focus, working on continuous manufacturing, powder mixing, powder flow, segregation, compression, mixing and flow of liquids and suspensions, capsule filling, tablet dissolution, and tablet coating. He is the author of over 300 peer-reviewed scientific articles and book chapters. Fernando Muzzio is the director of the National Science Foundation Engineering Research Center on Structured Organic Particulate Systems. Dr. Muzzio is also the chair of the faculty committee of the National Institute for Pharmaceutical Technology and Education (NIPTE), which he co-founded in 2004. He is also the president of Integra Continuous Manufacturing Systems, a supplier of comprehensive consulting services in continuous manufacturing, (www.integracms-pharma.com) and the Chief Scientific Officer of Acumen Biopharma.



Riley Myers is Chief of the Office of Pharmaceutical Quality's Advanced Pharmaceutical Manufacturing Laboratory in the Office of Testing and Research and a member of the Emerging Technology Team. Dr. Myers is also a member of the Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) initiative where he is evaluating a potential framework for regulating future advanced manufacturing technologies. He was previously a Lead Biologist in the Office of Biotechnology Products and a Microbiologist in the Center for Devices and Radiological Health. Prior to joining FDA, Dr. Myers studied mechanisms to program anti-pathogenic immune responses at Boston Children's Hospital. He received his Ph.D. in immunology from the University of Alabama at Birmingham.

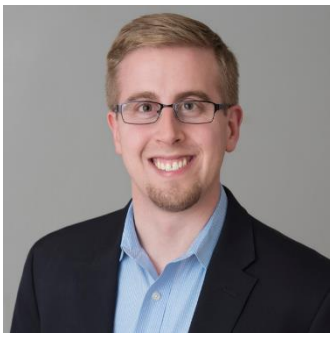
Roger Nosal is currently Principal Consultant with Roger Nosal PharmaCMC Regulatory Consultants and serves as Head of Regulatory Strategy for NGT BioPharma Consultants, a consortium of experienced experts and leaders in development of pharmaceutical products. For 12 years prior to September 2022, he was Vice President and Head of Global Chemistry, Manufacturing and Controls at Pfizer where he was accountable for all global regulatory CMC strategies and applications for innovative products and medical devices. Roger led the development of the CMC regulatory strategy and was responsible for negotiating clinical and commercial requirements with global regulatory authorities for authorization/ approval of the first mRNA vaccines to effectively address the COVID-19 virus. Roger's 41 years of experience at G. D. Searle, Monsanto, Pharmacia and Pfizer includes 28 years in regulatory CMC and 13 years as a Medicinal and Process Chemist. He is co-author of 24 patents and has publicly presented and published on a wide variety of regulatory and pharmaceutical policy initiatives and topics.

Gert Thurau is the Head of Manufacturing Technology and Innovation Advocacy in the CMC Reg PTR Policy team at Hoffmann- La Roche in Basel, Switzerland. His responsibility includes the regulatory advocacy for the adoption of advanced technologies in GMP manufacturing – covering the spectrum from continuous processing, use of process models, robotics and artificial intelligence, to name a few. Most recently, he participated on behalf of EFPIA in the first EMA Quality Innovation Group "Listen and Learn" session in March 2023. Over the last 20 years, he has been involved in many key initiatives and regulatory interactions in the field of technology innovation, Quality by Design, including Real-Time Release Applications, advanced control systems but also the implementation of ICH Q12. Previous responsibilities at Roche include the lead of the synthetic molecule Reg CMC team with 2 successful submissions to the FDA and Health Canada Pilot Program on Established Conditions.

Advanced Manufacturing Technologies Designation Program

Ranjani Prabhakara is a Policy Lead in FDA/CDER's Office of Policy for Pharmaceutical Quality within the Office of Pharmaceutical Quality. Her office is responsible for developing and communicating science and risk-based policies and standards related to drug product quality and works in conjunction with numerous review and policy offices across the Agency. Prior to her current role, Ranjani served as a Team Leader in CDER's Office of Manufacturing Quality and an Investigator at the Department of Health and Human Services, Office of Research Integrity. Ranjani joined FDA in 2013 as a reviewer in CBER's Office of Vaccine Research and Review. Ranjani received her PhD in immunology from the University of Maryland Baltimore and two bachelor's degrees, in microbiology and psychology, from the University of Maryland, College Park.

Regulatory Strategies for Adoption and Next Steps



Stephen Colvill is a Policy Research Associate at the Duke-Margolis Center for Health Policy, where his work focuses on drug supply chain resilience. Stephen is also the co-founder and Executive Director of RISCS, Inc., a non-profit organization with the mission of preventing drug shortages. Prior to co-founding RISCS in 2019, Stephen held roles of increasing responsibility in business analytics, marketing, portfolio management, finance and supply chain at Pfizer and Hospira. He worked at the Rocky Mount, NC manufacturing site and most recently was Director, Business Analytics Team Lead at the Pfizer Injectables headquarters in Lake Forest, IL.

Andrew Kuzmission is Vice President and Head of Global Regulatory Affairs CMC at Vertex Pharmaceuticals responsible for CMC regulatory strategy for all programs, including small molecule and cell and gene therapy. Prior to transitioning to Regulatory CMC Andrew spent 20 years in Analytical Development supporting late development small molecule programs in multiple therapeutic areas. He received a BS degree in chemistry from Bucknell University and a PhD in Analytical Chemistry from The Ohio State University. Prior to joining Vertex Pharmaceuticals in 2010 Andrew worked at Johnson & Johnson for 13 years within the Analytical Development group in positions of increasing responsibility.

Cornell Stamoran serves as Vice President of Corporate Strategy and Government Affairs for Catalent Inc (NYSE: CTLT), and is a founder and co-chair of Catalent's Applied Drug Delivery Institute. Cornell has worked in drug delivery for 30 years, spanning oral, injectable, respiratory, ophthalmic, and other routes of delivery, for drugs, biologics, cell and gene therapies, and consumer health products. Cornell is a trustee of the Pharma/Biopharma Outsourcing Association; past board member and treasurer of the Controlled Release Society; is an Inspiring Notes editor for Drug Delivery and Translational Research, and serves on the Editorial Advisory Board of Drug Development and Delivery magazine and for several key industry conferences. Cornell has published more than two dozen articles on drug delivery, patient-focused drug design, and pharmaceutical outsourcing, and frequently speaks and posts on these topics.

Cornell also served on the cross-Industry teams which negotiated GDUFA II, GDUFA III, and OMUFA I with the FDA.

Ben Stevens is a Director of CMC Policy and Advocacy at GSK and has nearly 15 years of drug discovery and regulatory experience. Prior to GSK, Ben was a Director of Regulatory Affairs CMC at Alnylam where he led the regulatory CMC program for vutrisiran prefilled syringe in over 30 countries. Before Ben joined Alnylam, he was a Principal Consultant at PAREXEL and an acting Branch Chief in the Office of New Drug Products (ONDP) at the FDA. Before FDA, Ben spent seven years in medicinal chemistry R&D at Pfizer and Merck. At GSK, Ben leads CMC policy and advocacy for several priority areas, including biologics, CGT, oligonucleotides, and advanced manufacturing. He received a Ph. D. in Chemistry from the University of Pittsburgh, a M.P.H. from the Johns Hopkins Bloomberg School of Public Health, and is a co-author of over 30 publications and patents.

Joel Welch is the Associate Director for Science & Biosimilar Strategy in the Office of Biotechnology Products in the Office of Pharmaceutical Quality in CDER at the US Food and Drug Administration. He is responsible for assessing emerging, complex, or precedent-setting issues impacting science policies of the office with particular emphasis on the biosimilar program. He also serves as the Rapporteur for the ICH revision to Q5A(R1) and the Chair for the Emerging Technology Program. In his time at FDA, he has also served as a Review Chief, Team Leader, Primary Assessor and Regulatory Project Manager. Prior to joining FDA, he spent 6 years in industry supporting late state analytical development of small molecules.

Closing Remarks

Gerrit Hamre is a Research Director in Medical Product Development and Regulatory Policy at the Duke-Margolis Center for Health Policy. Gerrit has worked for nearly 20 years in the pharmaceutical industry with a focus on clinical research, regulatory, and commercial roles. Central to much of his career work is extensive internal and external stakeholder engagement to advance innovative, evidence-based healthcare solutions. He has often worked in the drug development and approval environment. Highlights of Gerrit's career so far have included his work in the Food and Drug Administration's Office of Legislation and as a Peace Corps Volunteer in South Africa.

Funding Acknowledgement

This workshop is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award [U19FD006602] totaling $4,241,714 with 100 percent funded by FDA/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the U.S. Government.