Innovations in Pharmaceutical Manufacturing on the Horizon: A Virtual Dissemination Workshop

Speaker Biographies

Sponsor Speaker

Michael Kopcha, Ph.D., R.Ph. is the Director of the FDA's Office of Pharmaceutical Quality (OPQ). This office has over 1,300 staff responsible for assuring the availability of quality medicines for the American public through assessment, inspection, surveillance, research, and policy. OPQ contributes to the assessment of nearly every type of human drug marketing application including New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and Biologics License Applications (BLAs), including 351(k) applications (i.e., biosimilars). OPQ also performs the quality assessment of Investigational New Drug Applications (INDs) and establishes quality standards for over-the-counter drug products and facilities. Prior to joining the FDA, Dr. Kopcha amassed more than 25 years of experience in major and mid-sized innovator, generic, drug/device, and over-the counter (OTC) pharmaceutical and consumer health companies. He developed expertise in areas including formulation and process development, product scale-up, process validation, technology transfer, project management, change management, and off-shoring/outsourcing. Dr. Kopcha most recently served as Vice President, and global research and development franchise head, for cough, cold, and respiratory products at Novartis Consumer Health, Inc. Dr. Kopcha earned his doctorate and master's degrees in pharmaceutical science, and a bachelor's degree in pharmacy from Rutgers University. He also served as an adjunct assistant professor in the Department of Pharmaceutics at Ernest Mario School of Pharmacy at Rutgers.

Session One

Narendra Bam is the Senior Vice President Biopharmaceutical Development and Supply at GlaxoSmithKline. Narendra has more than 25 years of experience leading various Biopharmaceutical Research and Development groups. He joined SmithKline Beecham as an Investigator in 1995 and has held various roles of increasing responsibility in Pharmaceutical Development, Process development and Biopharm Discovery. His current role involves managing a complex global organization responsible for CMC development of all biopharmaceuticals in the GSK R&D portfolio. He lectures at the University of Maryland in a Biotechnology graduate course. He has numerous publications, book chapters and patents in the field of biotechnology. Narendra has a Chemical Engineering degree from University of Bombay, India and a Ph.D. in Chemical Engineering from Yale University.

Jessica Settimi is *Sr. Director Continuous Manufacturing Business* at *Thermo Fisher Scientific***.** She is responsible for the operations, strategy and commercial growth of the continuous

manufacturing businesses which is centered around a novel processing technology for the pharmaceutical industry. Jessica joined Patheon in 2013 and has served in several roles including Strategy, Innovation and Marketing. Patheon was acquired by Thermo Fisher Scientific in 2017. Master of Business Administration and Master of Microbial Biotechnology from North Carolina State University and holds a Bachelor of Science in Biotechnology from Rochester Institute of Technology.

Session Two

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.

Joel Welch is the Associate Director for Biosimilar & Regulatory Strategy in the Office of Biotechnology Products in the Office of Pharmaceutical Quality 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 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) revision to Q5A(R1) and the Vice Chair for the Emerging Technology Team. Prior to his current role, he served as a Review Chief where he oversaw assessors who evaluate CMC information for monoclonal antibodies and therapeutic proteins. In his time at FDA, he has also worked as a regulatory project manager, a product quality reviewer, and a product quality/CMC team leader. He received a B.S. in Chemistry from the University of Kansas in 1999, and a Ph.D. in bioinorganic chemistry in 2004 from the University of Iowa. Prior to joining FDA in 2010, he spent six years in industry supporting late state analytical development of small molecules.

Rohin Mhatre has worked in the pharma/biotech industry for the past 30 years. He has been with Biogen for 25 years and is presently Sr. Vice President of Product and Technology

Development. His dept is responsible for the process and product development of all the Biogen products including associated devices and digital tools. Prior to this role, he has also headed the Global Engineering and Manufacturing Sciences Depts. Rohin has also managed the Regulatory CMC dept and has been involved in the approval of over a dozen products. He has several publications and patents in the area of biopharmaceutical development and analytics including a co-edited book.

Sarah Arden, PhD is Director of Global Regulatory Affairs**,** Discovery and Early Development, US Research and Development Center at GlaxoSmithKline. Dr. Arden serves as the Director of Global Regulatory Affairs to the discovery and early development projects unit at GSK. She has 15 years of combined experience in regulatory affairs, intellectual property, pharmaceuticals and vaccines development and research, including impact investing. Dr. Arden previously served at the U.S. Food and Drug Administration as a regulatory reviewer and facility inspector, and directed emerging technology research, policy and development programs. Prior to joining the FDA, Dr. Arden founded an AI-based technology startup, served as a life sciences consultant and IP advisor to startups, law firms, and government clients. Earlier in her career, Dr. Arden conducted scientific research with Bayer at the RWTH Aachen Biomedical and Computational Engineering Institutes and served as an NIH Fellow in clinical research and informatics at Stanford University and ETH Zurich. She received her PhD from Johns Hopkins University and BS from the University of California, San Diego.

Session Three

Thomas C. Ransohoff, M.S is currently Technical Head, Biologicals Franchise at National Resilience, Inc. ("Resilience") and has over 30 years of experience in the biopharmaceutical industry. Mr. Ransohoff's areas of expertise include development and scale-up of biopharmaceutical processes; separations and purification technologies; cGMP manufacturing; and management of technology-based start-up ventures. Before joining Resilience, Mr. Ransohoff was a Managing Director at BDO and its precursor BPTC, a leading CMC consulting firm that he helped build over a 20 year period. Prior to that, he held senior level positions at TranXenoGen, Dyax, Repligen, and Xoma. He is also a co-founder of several successful start-ups, including 4th Dimension Bioprocess, Tarpon Biosystems and BioFlash Partners. He serves on a number of scientific and professional advisory boards and holds a Bachelor's degree from MIT and a Master's degree from the University of California, Berkeley, both in Chemical Engineering.

Dolores Hernan Perez de la Ossa, PhD *Quality Specialist and Quality Working Party Scientific Secretary, European Medicines Agency, Amsterdam, NL.* Dolores obtained a Pharmacy degree and a European PhD in Pharmaceutical Technology from the Complutense University, Madrid, Spain conducting research stays at USA Virginia Commonwealth University and the Institute of Biomolecular Chemistry of the Italian National Research Council. She joined the Quality Office of the European Medicines Agency in London in 2010, first in the biologicals section and then

moved to the small molecules team. Since then she has been Product Team Leader/Quality Specialist for numerous medicinal products applications and supported the development of several scientific guidelines. She is also responsible of the Scientific Secretariat of the Quality Working Party and the PAT team. She is topic lead for QbD/continuous manufacturing, nanomedicines, and CMC aspects of PRIority MEdicines/early access schemes, among others. She represents EMA at the ICH Q13 EWG, IPRP nanomedicines working group and ASTM E55.

Dr Malcolm Barratt--Johnson is the Managing Director at PharmaMedic Consultancy Ltd. Malcolm has over 22 years experience as a UK and European based Consultant Pharmaceutical Physician to Industry and Government, specialising in Medical Affairs, Product Development and Regulatory Strategy. He has lectured in both Europe and the United States on medicinal development, and is lecturer on the MSc Drug Development Course at King's College, London and in Medical Device Regulation at Imperial College, London. Following a first degree in Physiology at King's College London, Malcolm qualified in medicine from St Bartholomew's Hospital, in 1993. After postgraduate training in General Medicine and Anaesthesiology he joined the then UK Government's Medicines Control Agency (now MHRA), the UK Medicines Regulatory Agency, as a new medicines Medical Assessor in 1997. Lead Medical Assessor to the UK Dept of Health's Clinical Trials Unit on it's formation in 2005, he worked with European Medicines Evaluation Agency (EMEA) colleagues on the development of the trans-- European clinical trial pharmacovigilance systems. Leaving full time employment with the Agency in February 2007, Malcolm was appointed as an Independent Consultant to the MHRA.] He has worked extensively in senior UK and Global consultancy positions with a number of companies including AstraZeneca, Eisai, Roche, Novartis, MSD, GSK, Celgene and Amgen, in addition to having advisory development roles in the wider biotech and generic pharma sectors. He holds Non-Executive Director positions with NovaBiotics Limited, an innovative and World leading antimicrobial company based in Scotland and MirZyme a biotechnology company focused on the diagnosis and treatment of pre-eclampsia. Malcolm has acted for many years as a Clinical Specialist and Chair to the European Commission's Biomedical Research Programme (Horizon 2020). In 2012 he was appointed President to the Section of Pharmaceutical Medicine and Research at the Royal Society of Medicine, London and in 2014, a Fellow of The Royal Society of Biology.

Mike Hourigan is founder and managing director at Horizon Controls Group and Founder and President at International Academy of Automation Engineering.

Session Four

Adam Fisher, Ph.D. is the Associate Director of Science and Outreach (Acting) in the Immediate Office of the Office of Pharmaceutical Quality (OPQ) in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration. In this position, Dr. Fisher focuses on engaging FDA stakeholders and supporting advanced manufacturing technologies. He previously served as a Team Lead on OPQ's Science and Research Staff and focused on research and assessment of complex drug substances and manufacturing processes. He joined the FDA in 2014 as a chemical engineer with expertise in the synthesis of biomolecules. Dr. Fisher's work prior to joining the FDA focused on the microbial production of proteins and glycoproteins for a host of applications. His Ph.D. dissertation concentrated on the use of the secretion pathways of bacteria to perform protein engineering. Prior to the FDA, Dr. Fisher was the co-founder and Chief Science Officer of a startup company focused on microbial technologies for the production of glycoproteins. He earned his B.S. degree at the University of Maryland College Park (Chemical Engineering) and his Ph.D. at Cornell University (Chemical & Biomolecular Engineering).

Thomas O'Connor, Ph.D. is Director Division of Product Quality Research Office of Testing Research, Office of Pharmaceutical Quality for CDER at the Food and Drug Administration. 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 (ETT). His responsibilities include managing research and testing projects that answer and anticipate pharmaceutical quality-related regulatory challenges through scientific approaches. The impact of OTR research and testing is utilized to support regulatory assessment and policy development in areas such advanced manufacturing, drug quality standards, characterization of complex drug substances and drug products, and post market product quality and public health issues. Tom is a co-author of several papers on emerging pharmaceutical technology (such as continuous manufacturing, 3D printing, and the utilization of modeling and simulation for quality assurance). Through the ETT he has contributed to the review of several regulatory applications utilizing novel technologies. 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 originally joined the FDA as chemistry reviewer in the Office Generic Drugs and 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.

Dr. Kelvin H. Lee is the Gore Professor of Chemical and Biomolecular Engineering at the University of Delaware. He currently serves as the director of the National Institute for Innovation in Manufacturing Biopharmaceuticals (a Manufacturing USA Institute) and he previously served as the director of the Delaware Biotechnology Institute. Dr. Lee received a

B.S.E. in chemical engineering from Princeton University and both his M.S. and Ph.D. in chemical engineering from Caltech. He also completed a postdoc in Caltech's Biology Division and spent several years at the Biotechnology Institute at the ETH in Zurich, Switzerland. Previously, he was on the faculty at Cornell University where he held the titles of Samuel C. and Nancy M. Fleming Chair Professor, professor in the School of Chemical and Biomolecular Engineering, director of the Cornell Institute for Biotechnology, and director of the New York State Center for Life Science Enterprise. He is a fellow of the American Association for the Advancement of Science and of the American Institute for Medical and Biological Engineers. His research expertise is in systems and synthetic biology applied to biopharmaceutical manufacturing as well as in the diagnosis and treatment of Alzheimer's disease.

Gillian Sanders-Schmidler, PhD, is Professor of Population Health Sciences and Medicine at Duke University and Deputy Director of the Duke-Margolis Center for Health Policy. She served as Director of Duke's Evidence-based Practice Center (EPC) from 2009 through 2020. Dr. Sanders-Schmidler received her PhD in Medical Informatics from Stanford and was an Assistant Professor of Medicine at Stanford's Center for Primary Care and Outcomes Research from 1998 until the fall of 2003 when she joined the faculty at Duke University. In addition to her leadership role within the Duke-Margolis Center, she is core faculty within the Duke Clinical Research Institute. Dr. Sanders-Schmidler's research focuses on the development of evidence-based decision models to evaluate the comparative effectiveness of alternative prevention, treatment, and management strategies for chronic diseases – and the translation of such models into formats/tools that patients, healthcare providers, and policymakers can use in their decision-making process. Dr. Sanders-Schmidler is Past President of the Society for Medical Decision Making (SMDM) and she co-chaired the Second Panel on Cost Effectiveness in Health and Medicine. She is currently co-chairing SMDM's COVID19 Decision Modeling Committee.

Stephen Colvill is a 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.

Dr. Fernando J. Muzzio is a distinguished Professor of Chemical and Biochemical Engineering at Rutgers University. For the last 30 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. He is a frequent participant at FDA events, and in 2010-2014 he was appointed a voting member of the FDA committee on Pharmaceutical Sciences and clinical pharmacology. Dr. Muzzio is the director of the National Science Foundation Engineering Research Center on Structured Organic Particulate Systems. Dr. Muzzio is also the director of the Rutgers/Janssen partnership in Advanced Manufacturing and the Principal Investigator of major FDA research awards focused on material properties, sensing, and process control in Continuous Manufacturing. Dr. Muzzio is also the chair of the Faculty COmmittee of NIPTE. Dr Muzzio is also the president of Integra Continuous Manufacturing Systems, a supplier of comprehensive consulting services in continuous manufacturing and the Chief Scientific Officer of Acumen Biopharma.