The National Academies of
SCIENCES • ENGINEERING • MEDICINE

VIRTUAL WORKSHOP ON TECHNICAL AND REGULATORY BARRIERS TO INNOVATIONS IN PHARMACEUTICAL MANUFACTURING

Speaker Biographies

June 2-3, 2020

Noubar Afeyan is Chief Executive Officer and Founder at Flagship Pioneering. Flagship Pioneering has fostered the development of more than 100 scientific ventures, thousands of patents and patent applications, and more than 50 drugs in clinical development. Dr. Afeyan has cofounded and helped build over 40 life science and technology startups. Prior to founding Flagship Pioneering, he was the founder and CEO of PerSeptive Biosystems, a leader in bio-instrumentation. After PerSeptive's acquisition by Perkin Elmer/Applera Corporation in 1998, he became senior vice president and chief business officer of Applera, where he initiated and oversaw the creation of Celera Genomics. He serves on the boards of a number of companies, including Rubius Therapeutics and Moderna. Previously, he was a member of the founding team, director, and investor in Chemgenics Pharmaceuticals (acquired by Millenium Pharmaceuticals), Adnexus Therapeutics (acquired by Bristol-Myers Squibb), and Affinnova (acquired by AC Nielsen). He is currently a lecturer at Harvard Business School and was formerly a senior lecturer at the Massachusetts Institute of Technology's (MIT) Sloan School of Management. Dr. Afeyan has coauthored numerous scientific publications and is the inventor of more than 100 patents. As a United States citizen of foreign birth, Dr. Afeyan has received numerous awards including Golden Door Award in 2017 from the International Institute of New England, a Great Immigrant honor from the Carnegie Corporation in 2016, the Technology Pioneer award from the World Economic Forum in 2012, and the Ellis Island Medal of Honor in 2008. Dr. Afeyan received his PhD in biochemical engineering at MIT.

Paul Collins is Senior Director in Small Molecule Design and Development at Eli Lilly and Company in Indianapolis. Dr. Collins is responsible for product and process development activities for Lilly's pre-first human dose synthetic molecule development portfolio. Before this, he oversaw ongoing efforts for technology platform development, including continuous manufacturing of both active pharmaceutical ingredient and drug product. Dr. Collins was a director in Bioprocess Development, Chemical Technology Development, and Chemical Process Development. During his time at Lilly, Dr. Collins has been instrumental in recruiting and developing both new and experienced engineers, as well as starting new technical capabilities necessary for Lilly's current efforts in continuous manufacturing and modeling. He started his career with Merck, working in both manufacturing and research and development. Across both companies, he has been involved in the process development, registration, and commercialization of six marketed pharmaceuticals. Outside of Lilly, Dr. Collins is heavily involved with American Institute of Chemical Engineers' Pharmaceutical, and chaired the pharmaceutical forum in 2015 and 2016. He is a part of International Society for Pharmaceutical Engineering's Product Quality Lifecycle Implementation programming team looking at future technical-regulatory interaction topics for advanced manufacturing platforms. Dr. Collins received his PhD in biochemical engineering from Northwestern University.

Mauricio Futran, NAE, is the Vice President of Advanced Technology in the Global Tech Services group of Janssen Supply Chain at Johnson and Johnson (JnJ). His areas of expertise include process development, technology transfer, validation, regulatory compliance, new product registration, external manufacturing, and partnership development. In his current role, Dr. Futran focuses on manufacturing process understanding and reliability, which is done by incorporating predictive modeling, in line measurements, data analytics and other technologies into the full range of activities from research and development through scale-up, tech transfer, and life cycle management. The ultimate goal of his role is to model predictive control and real-time release. Before joining JnJ, Dr. Futran was professor and chair of Chemical and Biochemical Engineering at Rutgers University and has worked in various positions in pharmaceutical product and process development at Merck and Co. and Bristol-Myers Squibb. Dr. Futran is a member of the National Academy of Engineering, where he has been chair of its Chemical Engineering section and has served on its peer committee, the Board of Chemical Sciences and Technology, and on a National Research Council panel. As an American Institute of Chemical Engineers member he has served on the awards committee. He has been a member and chair of the Princeton Chemical and Biological Engineering external board and has been a member of the external boards for the University of Illinois at Urbana Champaign, Georgia Tech, and Rutgers University. Dr. Futran has chemical engineering degrees from Rice University and Princeton University.

Susan Hershenson is the Deputy Director of Chemistry, Manufacturing, and Controls at the Bill and Melinda Gates Foundation. Dr. Hershenson works closely with the Foundation's strategy teams and partners to provide technical expertise and strategic guidance for the therapeutics projects. Dr. Hershenson has over 30 years of experience in drug development. Before joining the Foundation she founded Pharmaceutical Transformations LLC, a consulting service for the pharmaceutical, biotechnology, drug delivery, and related industries. Her clients included a wide range of biotechnology, pharmaceutical, and drug delivery companies, venture capitalists, university labs, and non-profit organizations. Before starting her own practice she served in a variety of roles in the biopharmaceutical industry, including most recently Vice President of Pharmaceutical and Device Development at Genentech and Vice President of Pharmaceutics at Amgen. During her career, Dr. Hershenson has made significant contributions to the development and commercialization of numerous therapeutic products. Dr. Hershenson publishes and speaks actively and serves on Scientific Advisory Boards. She received her PhD in biochemistry from Yale University and held a postdoctoral fellowship in the laboratory of Dr. Robert Stroud at the University of California, San Francisco.

Amy Jenkins is Program Manager at the Defense Advanced Research Projects Agency (DARPA). Her research interests include the development of platforms for combatting infectious disease threats as well as novel manufacturing methods to enable rapid response. Before to joining DARPA, Dr. Jenkins was a Senior Scientist at Gryphon Schafer where she contributed to development of programs targeting infectious disease threats within the Biological Technologies Office. Previously, Dr. Jenkins studied the

virulence factors of, and antibodies targeting, multi-drug resistant bacterial pathogens at MedImmune. She served as a National Research Council Postdoctoral Fellow at the United State Army Medical Research Institute of Infectious Diseases where she studied virulence mechanisms of biodefense pathogens. She received her PhD in chemistry and chemical biology from Cornell University.

Mansoor A. Khan is Professor and Vice Dean of Texas A&M University Rangel College of Pharmacy at College Station, Texas. Before joining Texas A&M, he was the director of Product Quality Research and a senior biomedical research scientist at Center for Drug Evaluation and Research (CDER) in the U.S. Food and Drug Administration (FDA). At FDA, he led the research and review teams to promote manufacturing science, and served as a founding member of the FDA Emerging Technology Team. Dr. Khan has held leadership positions at the American Association of Pharmaceutical Scientists (AAPS) including elected chair of formulations design and development section. He has served as FDA representative to the World Health Organization, United States Pharmacopoeia, European Medicine Agency, Defense Advanced Research Projects Agency, National Institutes of Health, National Institute of Pharmaceutical Technology and Education, and International Pharmaceutical Federation. He serves on the editorial board of Pharmaceutical Technology, International Journal of Pharmaceutics, AAPS PharmSciTech, and the Drug Delivery and Translational Research. He has published over 300 peer-reviewed manuscripts in pharmaceutical formulations and manufacturing sciences, and delivered over 300 presentations world-wide. He is an Association of American Physicians and Surgeons and Association of Indian Pharmaceutical Scientists fellow, as well as a member of the European Union Academy of Sciences. Dr. Khan has received numerous awards, including around 20 FDA/CDER review, research, and exemplary achievement awards, the outstanding alumni award at St. Johns University College of Pharmacy, the Excellence Award from Texas A&M University, and the 2012 AAPS Research Achievement Award in Formulations Design and Development. Dr. Khan received his PhD in industrial pharmacy from St. Johns University in New York.

Michael Kopcha is Director of the U.S. Food and Drug Administration's Office of Pharmaceutical Quality (OPQ). His 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, abbreviated new drug applications, and biologics license applications, including 351(k) applications (i.e., biosimilars). Additionally, OPQ performs the quality assessment of investigational new drug applications and establishes quality standards for over-the-counter drug products and facilities. Before 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. He served as an adjunct assistant professor in the Department of Pharmaceutics at Ernest Mario

School of Pharmacy at Rutgers University. Dr. Kopcha earned his PhD in pharmaceutical science from Rutgers University.

Kelvin H. Lee is Director of the Manufacturing USA National Institute for Innovation in Manufacturing Biopharmaceuticals and is the Gore Professor of Chemical and Biomolecular Engineering at the University of Delaware. He is a member of the U.S. Food and Drug Administration's Pharmaceutical Science and Clinical Pharmacology Advisory Committee and currently serves on the Academies' Safeguarding the Bioeconomy consensus study committee. He previously served as the director of the Delaware Biotechnology Institute, and 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 spent several years in the Biotechnology Institute at the ETH in Zurich, Switzerland, and completed his post doctorate in at the California Institute of Technology's (CalTech) Biology Division. He received his PhD in chemical engineering from CalTech.

Brent Lieffers is Senior Director of Operations at Singota Solutions, a contract development and manufacturing organization helping pharmaceutical companies move products through the drug development pipeline faster. Mr. Lieffers has nearly 30 years in the pharmaceutical industry, with both domestic and international experience in active pharmaceutical ingredient manufacturing and fill-finish operations. His responsibilities have included operations management, new technology implementation, facility start-up, process and equipment validation, technology transfer, process investigation, regulatory submission preparation, and managing regulatory inspections. He has expertise in continuous improvement, process optimization, and cross-function/facility harmonization. Mr. Lieffers is a graduate of Pepperdine University.

Kerry Love is Chief Executive Officer and President of Sunflower Therapeutics, a public benefit corporation focused on the development of innovative and efficient solutions for manufacturing proteins for use in biopharmaceuticals and vaccines. Dr. Love is also the Associate Director of the AltHost Consortium, a Massachusetts Institute of Technology (MIT)-led consortium of biopharmaceutical organizations for the advancement of alternative hosts in biomanufacturing. Previously, she co-founded and directed research and development at Enumeral Biomedical by using technologies for single-cell analysis in antibody discovery. She served as technical program manager for the Love lab at the Koch Cancer Institute at MIT for programs sponsored by the Defense Advanced Research Projects Agency and the Bill and Melinda Gates Foundation. These programs aimed at advancing new technologies and biological hosts for integrated manufacturing of recombinant proteins. She is the author of more than 30 scientific papers and patents. Dr. Love received her PhD in organic chemistry from MIT and was a post-doctoral fellow at Harvard Medical School and the Whitehead Institute.

Gustavo Mahler is Managing Partner at Dynamk Capital. At Dynamik, he provides industry knowledge specifically related to the development and commercialization of biologics. Throughout his career, which includes the role of vice president of Technical Operations at Bayer Healthcare, Dr. Mahler has been involved in all aspects of bio manufacturing including large scale cell culture and protein manufacturing, purification, solid and liquid formulation including aseptic filling, and facility operation under current good manufacturing practice guidelines. Before joining Dynamik, Dr. Mahler was chief executive officer of AGC Biologics (formerly CMC Biologics). Under his leadership, AGC Biologics became a leader in biologics contract development and manufacturing. While at AGC Biologics, he successfully supported clients from pre-clinical through commercial production for over 150 biologics programs and successfully guiding customers through the regulatory approval processes. Dr. Mahler was a key player in the sale of CMC Biologics to the Asahi Glass in 2017. Dr. Mahler received his PhD in biochemistry from the University of Buenos Aires and his MBA from the University of Madrid.

Christine Moore is Global Head and Executive Director of the Global Regulatory Affairs and Clinical Safety Chemistry, Manufacturing, and Controls (CMC) – Policy at Merck. In this role, she provides oversight of new CMC and good manufacturing practices related policy for all modalities worldwide, coordinates' advocacy and outreach efforts, and helps advance progressive regulatory approaches. Her experience includes the development of scientific and regulatory approaches for advancing pharmaceutical manufacturing technologies, modernizing regulatory guidance, and progressing international harmonization. Dr. Moore joined Merck after more than a decade in various positions in the U.S. Food and Drug Administration, where she led the offices responsible for small molecule new drug review and manufacturing process assessment. Before moving into the regulatory CMC area, she spent 10 years at Pfizer and Searle/Pharmacia in active pharmaceutical ingredients process development, process analytical technologies, scale-up, and technology transfer. She is a leader in progressive regulatory approaches to pharmaceutical manufacturing in the areas of quality by design, process analytical technology, and continuous pharmaceutical manufacturing. Dr. Moore contributed to multiple International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guidelines, including ICH Q8(R2) and ICH Q12. Dr. Moore received her PhD in chemical engineering from the Massachusetts Institute of Technology.

Steven L. Nail is Principal Scientist in the Research and Development organization of Baxter Pharmaceutical Solutions. Previously, he was a research fellow in the Pharmaceutical Sciences Research and Development organization at Eli Lilly & Co, worked at the Upjohn Company, and was a professor in the School of Pharmacy at Purdue University. His research interests at Purdue focused on the physical chemistry of freezing and freeze-drying, characterization of frozen systems and freeze-dried solids, the stability of proteins as freeze-dried products, pharmaceutical thermal analysis, and pharmaceutical applications of supercritical fluid technology. Outside of Baxter, Dr. Nail has served on the U.S. Pharmacopeia (USP) Committee of Experts in Parenteral Products from 1995-2005, and served as Chair from 2005-2010. During that time, he was a member of the executive Committee of the Council of Experts at USP. Dr. Nail is a Fellow of the American Association of Pharmaceutical Scientists (AAPS). He

has been the recipient of numerous awards, including the AAPS Research Achievement Award in Pharmaceutical Technology and the Distinguished Baxter Career Award. In 2013, he was recognized as a Distinguished Alumnus by the School of Pharmacy, Purdue University. Dr. Nail received his PhD in pharmaceutics from Purdue.

Roger Nosal is Vice President and Head of Global Chemistry, Manufacturing and Controls at Pfizer. In this role, Dr. Nosal is accountable for development, preparation and prosecution of regulatory chemistry, manufacturing and controls applications for new commercial products, and investigational applications (small and large molecules, combination products, vaccines, gene/cell therapies) globally. As a Pharmaceutical Research and Manufacturers of America (PhRMA) representative, Dr. Nosal was instrumental in the development and implementation of quality by design, and is an advocate for global regulatory harmonization and mutual reliance at several International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Expert and Implementation Working Groups (EWG and IWG) as well as 170 presentations at industry technical conferences. He is currently Rapporteur for the ICH Informal Quality Discussion Group (IQDG) and PhRMA lead to ICH M9 EWG, Biopharmaceutics Classification System Biowaivers. In 2013 Dr. Nosal was awarded the Pharmaceutical Discovery, Development and Manufacturing Forum Award from the American Institute of Chemical Engineers for outstanding contributions to advancing quality by design. Dr. Nosal's 39 years of experience at G. D. Searle, Monsanto, Pharmacia and Pfizer, includes 26 years of experience in regulatory affairs. Before his regulatory role, Dr. Nosal was a medicinal and process chemist, and is the author of 24 patents. He received his PhD from Northwestern University.

Patricia Seymour is a Managing Director at BDO. Her expertise spans the development and commercialization spectrum, including biologics and small molecule development, supply chain strategy and operations, quality, regulatory and manufacturing, and management, and operations leadership. Her current activities include developing overall chemistry, manufacturing and control (CMC) strategies for diverse product pipelines, developing and implementing supply chain strategies, managing outsourced process development and manufacturing activities from drug substances through to distribution, steering clients through CMC quality and regulatory requirements, and overall CMC operations including project management. Before BDO, Ms. Seymour was a principal consultant with BioProcess Technology Consultants and a senior director of Global Investigational Supply Operations at Millennium Pharmaceuticals, Inc., where she worked with other senior leaders to develop and implement CMC strategies including outsourcing. She was previously director of Business Development at Covance Biotechnology Services (now part of the FujiFilm Diosynth) where her responsibilities included negotiating contact manufacturing projects. Ms. Seymour previously held research and development positions at ImmunoGen, Dana Farber and Sloan Kettering. She is a Certified Supply Chain Professional (APICS). Ms. Seymour received her BS from Villanova University and her MBA from Boston University.

Jason Starkey is Senior Director in Analytical Research and Development at Pfizer, Inc. Dr. Starkey is in the Biotherapeutics Pharmaceutical Sciences division leading a team responsible for method validations and analytical technology transfers from clinical development into commercial testing laboratories for biologic and vaccine programs. Dr. Starkey joined Pfizer in 2007 after he received his PhD in analytical chemistry from Indiana University-Bloomington.

Patrick Swann is Vice President of the Quality Science and Technology Group at Amgen. Dr. Swann's previous positions include the leader of the Analytical Development group and of the Regulatory Chemistry, Manufacturing, and Controls group at Biogen. Before that, Dr. Swann was a part of the U.S. Food and Drug Administration's (FDA) Division of Monoclonal Antibodies (DMA) in 1998 where he directly participated in the approval of over 30 new molecular entities. He also served as the FDA lead for biologics on the expert working group for ICH Q11 (Development and Manufacture of Drug Substances) and was FDA's expert on the application of quality by design principles to monoclonal antibody drug substances. Dr. Swann is the co-author of more than 20 peer-reviewed publications and has presented at over 60 conferences on topics including Assay Development/Validation, QbD approaches to biotechnology products, and Process Controls and Validation across a product's lifecycle. Dr. Swann received his PhD in pharmacology from the University of Illinois at Chicago and held postdoctoral positions at Receptor Laboratories and the National Institute of Health where he worked on peptide libraries and IgE receptor signal transduction pathways, respectively.

Jim N. Thomas is Executive Vice President and Global Head of Just Biotherapeutics, and President of U.S. Operations at Just - Evotec Biologics. At Evotec, Dr. Thomas builds biologics capability into the broader offerings and capabilities of Evotec SE, and works with partners to greatly improve global access to biologics. Prior to this role, he served as president, chief executive officer, and founding partner of Just Biotherapeutics, a technology platform company focused on improving global access to important biotherapeutics. Before founding Just Biotherapeutics, Dr. Thomas served as vice president of Process and Product Development in the Translational Sciences Research and Development organization at Amgen. In this role, he led the development and application of all process, analytical and formulation technologies used to manufacture both clinical and commercial large molecule (protein) products. Dr. Thomas was first exposed to biotechnology as a postdoctoral fellow at Massachusetts Institute of Technology, and has worked as a scientist and leader at leading biotechnology companies including Genentech, Immunex and Amgen. During the course of his career he has contributed to the advancement of many important therapeutics including Activase®, Vectibix®, Enbrel®, Prolia®/Xgeva® and Repatha™. Dr. Thomas received his PhD from Purdue University.

Kim Wolfram is Director of Global Regulatory Affairs Chemistry, Manufacturing, and Controls at Biogen. In this role, she leads the biologics and gene therapy team. Ms. Wolfram is committed to advancing novel manufacturing technologies and defining the future for regulatory science. Her previous regulatory experiences include acting as the global regulatory lead for programs at various stages in

development. Prior to Biogen, she was in Quality Assurance at Abbott Bioresearch Center (now AbbVie), where she supported the contract manufacturing for Seattle Genetics and Zymogenetics. Ms. Wolfram is a member of the PhRMA Goal Question Metric Workgroup and is an active participant in regulatory policy development. She is the Global Co-Chair for ReachOUT and passionate about diversity, inclusion, and belonging. Ms. Wolfram received her MS degree in Regulatory Affairs and Health Policy from the Massachusetts College of Pharmacy and Health Sciences.

Jae Yoo is Chief Technology Officer at Aprecia Pharmaceuticals LLC. Dr. Yoo co-founded Aprecia Pharmaceuticals in 2003 and headed its research and engineering efforts to develop a high-speed, additive manufacturing process suitable for current good manufacturing practice operation. Previously, Dr. Yoo's research with 3D printing started at the Massachusetts Institute of Technology (MIT) in the early 1990s where he developed and used an inkjet printing based 3D printing (3DP) process to fabricate advanced ceramic materials with compositional gradient. He explored and demonstrated a wide range of pharmaceutical and biomedical applications of 3DP while working for Therics, Inc. His work set the foundation for first-ever U.S. Food and Drug Administration approval of a 3D printed pharmaceutical product, SPRITAM®, manufactured and marketed by Aprecia. Dr. Yoo was part of GlaxoSmithKline (2014-2018) and explored automation for research and development productivity gain and evaluated platform capabilities for the Advanced Manufacturing Technology initiative. He is a co-inventor of many U.S. and international patents on additive manufacturing of pharmaceutical products and medical devices. Dr. Yoo received his PhD from MIT and his MBA from the Wharton School at the University of Pennsylvania.

Ping Zhao is Senior Program Officer of Integrated Development-Quantitative Sciences at the Bill & Melinda Gates Foundation. In this role, Dr. Zhao applies pharmacology concepts and manages Model-informed Drug development efforts in programs funded by the Foundation to academic centers, product development partners, and regulatory agencies around the world. Previously, Dr. Zhao worked as a Drug Metabolism Pharmacokinetics scientist at Pfizer, as a pharmacokineticist at Sonus Pharmaceuticals, as a clinical pharmacologist at Amgen, and as the Scientific Lead of Physiologically-based Pharmacokinetic (PBPK) Modeling Program and Expert Pharmacologist at the Office of Clinical Pharmacology at the U.S. Food and Drug Administration (FDA). At FDA, Dr. Zhao led a review of PBPK submissions in investigational new drug applications, new drug applications, and biologics license applications, research in PBPK, and development of policy on PBPK, including authoring the agency's first draft PBPK guidance in 2016 and updated in vitro and in vivo drug-drug interaction guidance in 2017. Dr. Zhao received his PhD in pharmaceutics from the University of Washington.