

Identifying Innovative Technologies to Advance Pharmaceutical Manufacturing

Committee

Gintaras V. Reklaitis

Chair

Gintaras V. Reklaitis (Chair), NAE, is Gedge Distinguished Professor of Chemical Engineering and Professor of Industrial and Physical Pharmacy (by courtesy) at Purdue University. Dr. Reklaitis' research involves the application of computing and systems technology to support the design and operation of processing systems. Areas of emphasis are investigation of Industry 4.0 approaches to support batch and semi-continuous manufacturing operations and methodology for plant- and enterprise-wide planning and optimization. Recent work has been in continuous manufacturing of pharmaceutical solid oral dosage forms and use of drop on demand technology for individualized dosage production. He has served on the Board of Directors of American Institute of Chemical Engineers, the Council for Chemical Research, and the CACHE Corporation and continues to serve on the editorial boards of several journals. He has published 300 papers and book chapters and edited or authored nine books. Dr. Reklaitis became a member of the National Academy of Engineering in 2007. He has served on multiple National Academies committees, including chairing the Planning Committee for Continuous Manufacturing for the Modernization of Pharmaceutical Production. Dr. Reklaitis received his PhD in chemical engineering from Stanford University.

Timothy Charlebois

Member

Timothy Charlebois is Vice President of Technology and Innovation Strategy for BioTherapeutics Pharmaceutical Sciences at Pfizer. In this role, he is responsible for developing, integrating, and maintaining strategy for process, product, and analytical technologies in support of the biotherapeutics and vaccines portfolio at Pfizer. He is also responsible for supporting biologics in-licensing and out-licensing due diligence activities. He has 20 years of experience in mammalian and microbial process development, including expression vector design, cell line selection and screening, GMP cell banking and characterization, genetic stability and viral safety testing, cell culture and purification process design and validation, and biochemical and microbial assay development and quality control. He has extensive experience with the preparation and submission of regulatory dossiers pertaining to the manufacture and control of biopharmaceutical products. Dr. Charlebois received his PhD from the University of Virginia in biology.

Matthew P. DeLisa

Member

Matthew DeLisa is William L. Lewis Professor in the Smith School of Chemical and Biomolecular Engineering at Cornell University. His research focuses on the molecular machines of protein biosynthesis as a target for understanding and reprogramming cellular function and as a toolbox for the creation of therapeutically and industrially relevant molecules. His unique approach involves probing and exploiting the function and specificity of cellular protein machinery by integrating protein engineering—the science of redesigning natural biomolecular scaffolds—with microbial genetics, biochemistry, and molecular biology to address these problems. The end result is a deep understanding of the complexities of intracellular protein machinery that can ultimately be used to inform the engineering of cellular processes for the purpose of discovery, design, and production of a diverse array of useful products and processes. His contributions to science and engineering include the invention of numerous commercially important technologies for facilitating the discovery, design, and manufacturing of human drugs and seminal discoveries in the areas of cellular protein folding and protein translocation. Dr. DeLisa received his PhD in chemical engineering from the University of Maryland.

Christopher Earnhart

Member

Christopher Earnhart is the Chief Technology Officer for the Enabling Biotechnologies (EB) office in the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (CBRN). He is responsible for assessing and implementing technologies and infrastructure capabilities to accelerate the development of CBRN medical countermeasures (MCM) and enable a rapid response MCM capability for the Department of Defense. Prior to his role in EB, he was the Joint Product Lead for the Platforms for the Rapid Integrated Solutions for Medical Countermeasures (PRISM) office and provided programmatic and technical leadership to implement platform-based discovery, design, manufacturing, and testing technologies to streamline MCM development and reduce risk. Dr. Earnhart was a key member of the Department of Defense's Advanced Development and Manufacturing (DoD-ADM) Capabilities team that oversaw planning, construction, and commissioning of the DoD-ADM biomanufacturing facility. Dr. Earnhart earned his PhD from the College of William and Mary, Virginia Institute of Marine Science as a National Science Foundation fellow studying comparative immunology. He completed postdoctoral training in bacterial pathogenesis and vaccine research at the Medical College of Virginia, Virginia Commonwealth University as an American Heart Association fellow where he studied virulence factors and developed vaccines for Lyme disease and other spirochetal diseases.

Stephen W. Hadley

Member

Stephen W. Hadley is a Senior Program Officer for Vaccine Development at the Bill and Melinda Gates Foundation. His role at the Foundation is to provide support to Problem Solving Treatment's (PST) that require process development, manufacturing, and analytical testing of recombinant proteins and monoclonal antibodies to further their strategies. He is also involved in assessing new bioprocessing technologies that enable low cost production of biologics. Before arriving at the Foundation, Dr. Hadley was Vice President of Quality for Chemistry, Manufacturing, and Control (CMC) Biologics, a biologics contract development and manufacturing organization and was responsible for oversight of the quality assurance, quality control, and analytical and formulation development activities for the company. During his tenure at CMC Biologics, the organization executed several facility expansion projects and Good Manufacturing Practice compliance initiatives to prepare for successful European Medicines Agency and US Food and Drug Administration preapproval inspections. Dr. Hadley received his PhD from the University of Washington in organic chemistry and natural products chemistry.

Arlene Joyner

Member

Arlene Joyner is a branch chief at the Biomedical Advanced Research and Development Authority (BARDA) of the U.S. Department of Health and Human Services and the deputy director of the Pharmaceutical Countermeasure Infrastructure Division that leads several mission critical program activities focusing on public private partnerships. Within BARDA, she is also the program manager for Fill Finish Manufacturing (FFMN) and Contract Development and Manufacturing Organization (CDMO) Networks that oversee essential BARDA Core Service programs. Ms Joyner is also the continuous manufacturing program lead and is the technical monitor for all contractor staff that specialize in small molecules, large molecules and vaccines, technology transfers, manufacturing and product development, analytical methods, IP issues, and supply chain and logistics. Before joining BARDA, she spent six years at Merck & Co. conducting quality auditing and supervising vaccine manufacturing operations. She also worked at Baxter in the vaccines division for 16 years where her responsibilities included upstream manufacturing/fermentation, downstream/purification manufacturing, column chromatography, buffer preparation, supply chain and program management operations. Ms Joyner received her MS in Chemical Engineering from Villanova University.

Katherine Lewis

Member

Katherine Lewis is Division Leader in Application, Simulation, and Quality Program at Lawrence Livermore National Laboratory (LLNL). In this role, she leads about 160 computer scientists primarily to support the Weapons and Complex Integration Directorate. Additionally, she leads a LLNL project to investigate artificial intelligence and machine learning techniques for solutions in physics simulations. A large part of this project relates to integrating physics knowledge into models and understanding uncertainties in model predictions. Her expertise is in the area of physics simulations with a focus on setup/workflows, involvement of the user community, and machine learning. She began her career at LLNL in June of 1998 in the field of massively parallel mesh generation. Ms. Lewis received her BS in mathematics, with a minor in computer science, from the University of San Francisco.

Paul Mort

Member

Paul Mort is a Professor in the Department of Materials Engineering Center for Particulate Products and Processes at Purdue University. Dr. Mort recently joined the Materials Engineering faculty in support of Purdue's Center for Particulate Products and Processes (CP3). He is globally recognized as an expert in particulate processing and powder technology. He has a demonstrated history of product innovation and driving process efficiency in the consumer goods industry, including 24 years with Procter & Gamble specializing in granular detergents. Dr. Mort is an editor for the journal Powder Technology and consultant with the International Fine Particle Research Institute (IFPRI), working to develop a pipeline of perspective articles for the journal. He is active in linking particle technology with adjacent technical communities, including pharmaceutical processing and process control. Dr. Mort received his PhD from Rutgers University.

Todd Przybycien

Member

Todd Przybycien is a Professor in the Howard P. Isermann Department of Chemical and Biological Engineering at Rensselaer Polytechnic Institute. He works on industrial downstream bioprocessing and on drug delivery and medical device development. Those activities are linked via fundamental interests in biophysics and in colloid and interface science. His approach is to use spectroscopic, optical, physical, simulation, and informatics tools to connect microscopic, molecular-level behavior to macroscopic, process-level engineering decision variables. His current research topics include downstream processing development of next-generation macromolecular affinity chromatography media based on PEGylated ligands; chromatographic performance as a function of systematic and stochastic uncertainty in mobile phase delivery; continuous precipitation-based processes for protein purification; protein-drug delivery to overcome interfacial denaturation in the delivery of proteins from poly(lactide-co-glycolide) microspheres via protein PEGylation; enhancing spreading, mucolysis, and antimicrobial activity in pulmonary drug delivery with surfactants; and protein adsorption topics impact of micro-scale and nano-scale surface features on protein adsorption behavior. Dr. Przybycien received his PhD in chemical engineering from California Institute of Technology

Kelley Rogers

Member

Kelley Rogers is the Technical Program Manager for the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) at the National Institute of Standards and Technology (NIST) Office of Advanced Manufacturing (OAM). As the Technical Program Manager, Dr. Rogers is responsible for technical quality and coordination with NIIMBL, a NIST-sponsored Manufacturing USA institute whose mission is to accelerate biopharmaceutical manufacturing innovation in the United States. She is currently on detail from NIST's Material Measurement Laboratory, where she serves as the Technical Program Director for Biosciences and Health. In previous positions, Dr. Rogers worked as a Principal Investigator identifying novel targets for antimicrobial drugs within the pharmaceutical industry. She was a postdoctoral fellow and staff fellow in the National Institute of Digestive, Diabetes, and Kidney Diseases (NIDDK) at the National Institutes of Health. Her research background is in bacterial protein synthesis and gene expression. Dr. Rogers received a PhD in molecular biophysics and biochemistry from Yale University.

Saly Romero-Torres

Member

Saly Romero-Torres is Senior Director of Digital Quality Systems at Pantheon by Thermo Fisher Scientific. Previously, she was Senior Manager of Advanced Data Analytics at Biogen where she led a team of mathematicians, statisticians, and advanced process control engineers. She has over 15 years of experience in the field of process analytical technologies and advanced manufacturing of biopharmaceuticals with a focus in the use of advanced sensors, advanced process control, data analytics, machine learning and operational excellence tools. Her personal mission is advancing pharmaceutical manufacturing processes to enhance plant operations and, more important, improving patients' access to critical therapies. Dr. Romero-Torres received her PhD from Purdue University in analytical chemistry and is also an NC State BTEC (Biomufacturing Training and Education Center) fellow.

Gregory Stephanopoulos

Member

Gregory Stephanopoulos, NAE, is the W. H. Dow Professor of Chemical Engineering and Biotechnology in the Department of Chemical Engineering at Massachusetts Institute of Technology (MIT). His laboratory applies metabolic engineering and synthetic biology to understand and synthesize isoprenoids at industrially relevant levels. His group focuses on the upstream pathway, responsible for supplying the building blocks for all isoprenoids, primarily through the microbial 2-methyl-(D)-erythritol-4-phosphate pathway. The work is performed through methods, such as multivariate modular engineering of pathways, to find the optimal expression levels of pathway genes and through the use of novel arrangements of co-cultured organisms. Those strategies, among others, have enabled his laboratory to create platforms for high-level production of isoprenoids. His group also focuses on production of individual isoprenoids, with a large focus on heterologous production of the anticancer drug Taxol (Paclitaxel). They have successfully produced gram-scale titers of the first cyclized precursor and have performed enzymatic studies to reveal previously unknown bottlenecks and methods by which these bottlenecks may be alleviated. Dr. Stephanopoulos has co-authored or edited five books, more than 360 papers, and 50 patents. He is presently the editor-in-chief of Metabolic Engineering and Current Opinion in Biotechnology and serves on the editorial boards of seven scientific journals and the advisory boards of five chemical engineering departments. For his research and educational contributions, Dr. Stephanopoulos has been recognized with numerous awards. In 2003, he was inducted into the National Academy of Engineering (NAE). Dr. Stephanopoulos received his PhD in chemical engineering from the University of Minnesota.

Seongkyu Yoon

Member

Seongkyu Yoon is Professor in the Francis College of Engineering at the University of Massachusetts (UMass), Lowell. Currently Dr. Yoon is working as a co-director of Massachusetts Biomanufacturing Center, is the UMass site director of the National Science Foundation Industry–University Cooperative Research Centers Program Research Center and the Advanced Mammalian Biomanufacturing Innovation Center, and the UMass technical lead for ManufacturingUSA in Biomanufacturing. His research interests include process system engineering, systems biotechnology, bioprocess innovation, regulatory sciences, and biomanufacturing innovation. He is leading a systems biology research group while conducting research in systems biotechnology, life science informatics, and regulatory sciences with goals to develop an innovative biomanufacturing platform of protein-cell-gene biotherapeutics. Dr. Yoon received his PhD in chemical engineering from McMaster University, Canada, and his MBA from Babson College.