Emerging Technologies and Innovation in Manufacturing Regenerative Medicine Therapies: A Workshop

Committee

Scott Steele

Co-Chair

Scott Steele, PhD (Co-chair), is the Senior Advisor for Translational Science in the Center for Biologics Evaluation and Research (CBER) at the U.S. Food and Drug Administration (FDA). He is responsible for advising on CBER's horizon scanning initiatives and identifying areas of emerging science, technology, and novel methods/tools that are of significant impact to CBER. In this role, Dr. Steele also provides strategic leadership in the development of partnerships and outreach in the area of translational science. He received his BS in Biology from Union College and then performed research at the General Electric Center for Research and Development and at the University of Geneva, followed by a fellowship at the National Institutes of Health. Dr. Steele completed his MA and PhD in Molecular Biology at Princeton University. He later served in the White House Office of Science and Technology Policy, initially as a policy analyst and then as the Executive Director of the President's Council of Advisors on Science and Technology. Prior to Dr. Steele's current appointment, he was at the University of Rochester where he served as the Director of Regulatory Science and Personalized Medicine Programs at the Clinical and Translational Science Institute, Founding Director of the Data Science Center of Excellence, and Associate Professor of Public Health Sciences.

Claudia Zylberberg

Co-Chair

Claudia Zylberberg, PhD (Co-chair), is the Founder and former CEO of Akron Bio, and a current Board member. She has more than 25 years of experience in the biomedical research and biotechnology industries and first-hand knowledge of what it takes to bring products through R&D and on to approval and commercialization. She is highly knowledgeable about current FDA regulations, qualification of raw materials, process design and validation, and bioassay development. Dr. Zylberberg also has expertise in recombinant proteins, media development, combinational (devices), and platform technologies. She is the inventor of numerous patented proprietary technologies and has an extensive peer-reviewed publication record. Dr. Zylberberg is proud to act as an advisor and consultant to organizations worldwide regarding the regulatory roadmap and commercialization of cell therapies and stem cell banking. She is part of the strategic advisory council of the International Society for Cell and Gene Therapy (ISCT) and holds many non-executive positions: Co-founder and Board Member, the Standard Coordinating Body for Regenerative Medicine; Board Member, Canadian Consortia for Regenerative Medicine; Chair of the Board, ARScience Biotherapeutics; Scientific Board Member and Advisor, Jurata Thin Film; Advisor, Phacilitate; Co-founder and Board Member, Amcyte; Board Member, BDB Palm Beach Life Sciences; Co-founder, Florida Organization for Regenerative Medicine; and Mentor, Creative Destruction Lab. Previous roles include the following: Board Member, BioFlorida; Board Member and Senior Advisor, Octomera; former Treasurer and Executive Board Member of the Alliance for Regenerative Medicine (ARM); Chair of the Industry Advisory Board, West Palm Beach, Florida, among others.

Thomas Greenwell

Member

Thomas Greenwell, PhD, is the Acting Associate Director at the Office of Regenerative Medicine at the National Eye Institute (NEI) of the National Institutes of Health (NIH). He has previously served as the Program Director of Retinal Neuroscience and is a health scientist administrator with over 16 years of experience in science administration and portfolio management at the NIH. He specializes in knowledge and administration of grants in cellular neuroscience and technology applications, especially related to vision. Dr. Greenwell has experience in behavioral models of addiction and stress, fetal alcohol syndrome, and opioid peptides. His interests remain in furthering the public health of the nation, new health science technologies, and government collaborations with pharma and medical device companies.

Kelvin H. Lee

Member

Kelvin H. Lee, PhD, is Institute Director of the Manufacturing USA National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL), a public-private partnership, and the Gore Professor of Chemical and Biomolecular Engineering at the University of Delaware. He is the Principal Investigator and Site Lead for the Advanced Mammalian Biomanufacturing Innovation Center (AMBIC) and is affiliated with the United States Manufacturing Innovation Council, a new non-profit for U.S. competitiveness in advanced manufacturing across various sectors. He previously served as Director of the Delaware Biotechnology Institute. Dr. Lee received a B.S.E. in Chemical Engineering from Princeton and Ph.D. in Chemical Engineering from Caltech. He spent several years in the Biotechnology Institute at the ETH in Zurich, Switzerland and completed a postdoc in Caltech's Biology Division. Prior to Dr. Lee's current appointment, 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.

Anne Plant

Member

Anne Plant, PhD, is a Fellow at the National Institute of Standards and Technology (NIST), where she was previously Chief of the Biosystems and Biomaterials Division. She served for a year in the White House Office of Science and Technology Policy. Dr. Plant has also served in a number of other capacities, including as the NIST Representative to the National Science and Technology Council Life Science Sub-Committee, a member of the National Advisory Council for Biomedical Imaging and Bioengineering, co-chair of the ASTM International Committee F04.46 on Standards for Cell Signaling, and a member of the Editorial Advisory Board of the journal, Biointerphases. Dr. Plant has also served on a review panel for the California Institute of Regenerative Medicine, and as a government liaison to the Standards Coordinating Body for Regenerative Medicine. She is a Fellow of the American Institute for Medical and Biological Engineering (AIMBE) and a Fellow of the American Association for the Advancement of Science. Dr. Plant's research has focused on robust quantification of cell response through quantitative cell imaging and theoretical approaches for prediction of complex biological response. She received her Ph.D. from Baylor College of Medicine in Houston, TX in Biochemistry.

Rachel Salzman

Member

Rachel Salzman, DVM, is the Global Head of Corporate Strategy at Armatus Bio, which uses AAV technology to develop novel therapies for neuromuscular diseases. Prior to joining Armatus, Rachel was EVP of Portfolio, External Affairs & Development at Alcyone Therapeutics, a precision medicines company advancing therapies in serious neurological disorders by integrating novel delivery technologies with innovative genetic platforms. In 2017, Dr. Salzman co-founded SwanBio Therapeutics and served as Chief Executive Officer (CEO) and Director. Prior to her time at Swan, she was the Chief Science Officer (CSO) of The Stop ALD Foundation, which is a non-profit Medical Research Organization dedicated to employing entrepreneurial approaches and innovative methodology towards effective therapies, cures, and prevention of X-linked adrenoleukodystrophy (ALD), an often-fatal neurodegenerative disease. As CSO, she made critical contributions in driving forward the world's first ex vivo lentiviral gene therapy clinical trial conducted in non-HIV infected patients. Dr. Salzman has been an active member of ASGCT (American Society of Gene and Cell Therapy) for over 20 years and has served in a leadership capacity including elected membership to the Board of Directors, along with multiple committees and task forces designed to build and enhance the state of gene and cell therapy in both the US and EU. In recognition of her many contributions, she was the Sonia Skarlatos Public Service Award recipient in 2015. She has a D.V.M. from Oklahoma State University and a B.S. from Rutgers University.

Sohel Talib

Member

Sohel Talib, PhD, is a Senior Science Officer and the Director of Therapeutics at California Institute for Regenerative Medicine (CIRM). He is responsible for developing and implementing CIRM's scientific programs and managing a portfolio of clinical stage grants utilizing hematopoietic stem cell gene therapy approaches for the treatment of hemoglobinopathies, Primary Immune Deficiency diseases (PID), HIV AIDS, and cancer. His scientific background is in stem cell and gene therapy research, and he has spent 20 years in the biotech industry. Before joining CIRM, Dr. Talib was the Director of Product Development at Geron Corporation, where he directed immune-oncology program on the development of an autologous dendritic cell vaccine for cancer (Geron VAC-1). Prior to Geron Corporation, he served as the Director of Immunology at Cerus Corporation, a biotech company developing novel allogeneic stem cell therapy for the hematological malignancies. Dr. Talib was a cofounder of Applied Immune Sciences (AIS), which was acquired by Rhone Poulenc Rorer (RPR, currently Sanofi). At RPR Gen Cell, he directed the development and execution of adoptive immunotherapy programs. Dr. Talib received his post-doctoral training at Stanford University, University of California, Berkeley and Roche Institute of Molecular Biology, Nutley. He obtained his Ph.D. in Biochemistry from Aligarh University, India and International DANIDA fellowship from Danish Institute of Protein Chemistry, Copenhagen.

Phil Vanek

Member

Phil Vanek, PhD, is the Chief Technology Officer at Gamma Biosciences. An entrepreneurial and strategic international business leader, he joined Gamma Biosciences in 2020 from Cytiva's Cell and Gene Therapy business. At Gamma, Dr. Vanek is responsible for technical diligence of potential investments, as well as guiding operational, R&D, and strategic initiatives carried out at portfolio companies. Dr. Vanek received his Ph.D. in Biochemistry and Molecular Biology at Georgetown University Medical Center, with research focused on molecular oncology. He was an instructor at Johns Hopkins University Advanced Academic Programs teaching Biotechnology Marketing in the Master of Biotechnology/MBA program and has held strategy and innovation leadership positions in a number of life sciences companies including Life Technologies, Becton Dickinson, and Lonza. Dr. Vanek is a Board Member of Centre for Commercialization of Regenerative Medicine (CCRM) and CCRM Enterprises in Toronto, Canada and a Board Member of the Foundation for Cell and Gene Medicine (formerly the Alliance for Regenerative Medicine (ARM) Foundation). Dr. Vanek also serves on the advisory boards for Rooster Bio, Biobridge Global, Culture Biosciences, and Curate Biosciences.