



Collaborating to solve CMC challenges and support efficient development of lentiviral-mediated CAR T cell therapies

October 26, 2022, 9am – 5pm EDT at
USP Headquarters in Rockville, MD USA

Speaker Biographies

(Listed in speaking order)
as of October 25, 2022



MAURA KIBBEY, Ph.D.
Director, Biologics Marketing
USP

Maura Kibbey is Director, Biologics Marketing in USP's Global Biologics Department. Dr. Kibbey's team helps inform and raise awareness of USP's standards, educational courses, and stakeholder events. Previously, Maura directed a team of liaisons working with USP Expert Committees and Expert Panels for biologics, peptides, and antibiotics to develop standards that support biopharmaceutical quality assessment and development. Before joining USP, Dr. Kibbey worked for several biotechnology and diagnostic companies in the Washington, DC, area and at the National Institutes of Health. Her scientific expertise includes developing and validating many different assay types for measuring individual molecules, their activities, or binding interactions. She has published over 40 peer-reviewed articles and has been an invited speaker or workshop organizer for numerous scientific conferences.



ED CHESS, Ph.D.
USP Biologics Stakeholder Forum Planning Committee, Chair

Edward Chess received his B.S. in Chemistry and Mathematics from the College of Idaho in 1976 and his Ph.D. in Chemistry from the University of Nebraska-Lincoln in 1982. Dr. Chess was employed with Pacific Northwest Laboratories from 1981 to 1988 as a Research Scientist, after which he joined Baxter Healthcare Corporation. During his time at Baxter, Dr. Chess worked as an Analytical Chemist as well as a Group and Department Manager, supervising and managing small specialty groups and larger departments of analytical chemists and microscopists. His primary areas of interest were the application of mass spectrometry and chromatographic methods to organic compound structure elucidation and industrial problem-solving. He has experience in complex mixture analysis, including the characterization of extractables and leachables from primary and secondary pharmaceutical packaging systems, and some experience in the application of mass spectrometry to protein and complex carbohydrate analysis. Dr. Chess oversaw the core analytical facilities for mass spectrometry, nuclear magnetic resonance spectrometry, extractables, and leachables at Baxter Healthcare before his retirement in 2014. He now consults for BioPhia Consulting, Inc. Dr. Chess has enjoyed volunteering at the USP since 2008 and has served on various Expert Panels, Expert Committees, and the Biologics Stakeholder Forum Planning Committee. When not attending USP teleconferences, Dr. Chess enjoys building and flying model rockets and woodworking.



BEN CLARKE, Ph.D.

**Senior Scientist II, Global Biologics
USP**

Ben Clarke supports USP's portfolio of documentary and physical reference standards for the Global Biologics group. He specializes in cell and gene therapy, vaccines, and monoclonal antibodies. Before joining USP, Ben developed analytical bioassays at GSK Vaccines for RSV and self-amplifying mRNA vaccines. Before GSK Vaccines, he pioneered the development of mouse models of sphingolipid biology using CRISPR/Cas9 genome editing technology at the National Institute for Health. Before NIH, he optimized upstream PER.C6 cell culture for the production of adenovirus at Janssen. He received his Ph.D. from Cornell University for his work on mammalian membrane biology and lipid remodeling enzymes. He received his B.S. from Pennsylvania State University in Biochemistry, Molecular, and Cell Biology.



ANDREW TIMMONS, Ph.D.

**Biologist
U.S. Food and Drug Administration (FDA)**

Andrew Timmons received his Ph.D. in 2019 in the Pharmacology and Molecular Sciences program at Johns Hopkins University. He completed his thesis work in the lab of Robert Siliciano, where he investigated the dynamics of the HIV-1 latent reservoir. He moved to a Postdoctoral position in the lab of Jakob Reiser at the FDA, where I worked on developing ddPCR methods for the rapid titration of lentiviral vectors. In 2020, he accepted a reviewer position in the Gene Therapy Branch within the Office of Tissues and Advanced Therapies (OTAT). In the Gene Therapy branch, he focuses on the review of CAR T products.



SHREE JOSHI, Ph.D.

**Senior Scientist, BioTD, Analytical Development
Janssen Pharmaceutical**

Shree Joshi is Senior Scientist within Janssen's, BioTherapeutics Development (BioTD), where she works as a lead in cellular characterization group within the Cell & Gene Therapy and Vaccine (CGTV), Analytical Development (A.D.) Team. In her current role, she is working on developing cell characterization tools for better understanding CAR T cell products.

Before joining Janssen, she spent about 6 years working on different areas like – molecular mechanisms in metabolism and circadian system regulation, as well as oncology. Following this, she spent about 10 years working in discovery oncology and cell therapy space, starting with her training at UPenn, followed by positions of increasing responsibilities at Novartis and Bristol Myers Squibb. She has extensive cellular and molecular biology experience in engineering and characterization of Chimeric antigen receptors.



KIM NGUYEN, Ph.D.
Head of Product Attribute Sciences
Kite Pharma

Kim Nguyen is the Head of Product Attribute Sciences (PAS) in Analytical Development at Kite Pharma. Kim leads a team that establishes the analytical control strategy, including identification of CQAs, that inform specification development and comparability and process validations campaigns to support product life cycle management. Her team drives the continued study of starting material, vector, and apheresis to better enable insights into their impact on the process and product performance and identify opportunities for process improvements. Kim joined Kite Pharma in 2017 as Research Scientist and contributed her knowledge of T-cell biology to enhance early-stage process development work. In her tenure at Kite, Kim has held roles in the process and analytical development and contributed to multiple IND, BLA, and PAS filings. Kim has a B.S. in Biology and Psychology, M.S. in Biology, and Ph.D. in Biomedical Sciences.



LINDA NARHI
USP Biologics Stakeholder Forum Planning Committee, Vice Chair

Linda recently retired as a Scientific Executive Director in the Attribute Science group in Process Development at Amgen but continues to support therapeutic development as a consultant for this organization. She received her B.S. in Chemistry from the Univ. of Michigan and her Ph.D. in Biological Chemistry from UCLA. She joined Amgen over 30 years ago and has been involved in biotherapeutics and product development throughout her career. This includes protein candidate selection, characterization of protein higher order structure and protein aggregate and particles, and studying the impact of protein attributes, especially aggregates, on the potential immunogenicity of the molecules. She has published extensively on these topics. Linda is a member of the USP expert committee on subvisible particle analysis for Biologics, an adjunct professor at UCSB, and the former chair of the AAPS focus group on Protein Aggregation and Biological Consequences. She is leading the AAPS community undertaking the cross-lab study on the generation and characterization of Mab aggregate and their effects on in vitro and in vivo model systems



Kok-Seong (KS) Lim
Metagenomi

Kok-Seong Lim is a Senior Director of Analytical Sciences and Quality Control at Metagenomi, developing CRISPR-based medicines for the treatments of cancer (ex vivo therapies) and rare diseases (in vivo therapies). Previously, he was a director of Analytical Sciences at Aura Biosciences and a director of AAV Process and Analytical Development at Editas Medicine, where he helped develop small molecule drug-conjugated virus-like particle technology for the treatment of ocular melanoma and CRISPR-based adeno-associated virus technology for the treatment of ocular disorders like Leber Congenital Amaurosis (LCA10) and Autosomal Dominant Retinitis Pigmentosa 4. Before that, he was the Head of Analytical Sciences in Viral Vector Services at Thermo Fisher Scientific, previously known as Brammer Bio, where he managed multiple late-stage analytical programs for viral vector-based gene therapies. He also held various scientist roles at Brammer Bio, Avitide, Massachusetts Institute of Technology (MIT), and University of California San Diego (UCSD). Kok Seong Lim holds a Ph.D. in Biochemistry from the National University of Singapore (Singapore) and a BSc in Pharmacy from the University of Strathclyde (Scotland, UK).