Speaker Biographies

(Listed in speaking order)

MAURA KIBBEY, Ph.D.

Director, Biologics Marketing
USP

Maura Kibbey is the Director of 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.

JARED R. AUCLAIR, Ph.D.

Vice Provost Research Economic Development and Director of Bioinnovation in the Office of the Provost
Northeastern University

Jared R. Auclair, Ph.D. is currently the Vice Provost Research Economic Development and Director of Bioinnovation in the Office of the Provost at Northeastern University. As Vice Provost Research Economic Development, Dr. Auclair works to strengthen the bonds between our education and research missions by strengthening the integration of

work-integrated credentialed learning and use-inspired research, co-creating with communities and partners while expanding our global mindset. As Director of Bioinnovation, Dr. Auclair works to leverage important University activities around biotechnology, bringing together experts from a wide range of disciplines and backgrounds to advance the expansion of Northeastern life sciences programs. In addition to these roles, Dr. Auclair holds a faculty appointment in the Department of Chemistry and Chemical Biology where he collaborates with academic researchers, industry and government in the area of biopharmaceutical development and analysis.

ELVIRA ARGUS, Ph.D.

CMC Biological Reviewer
FDA CBER

Elvira Argus joined the Office of Gene Therapies at FDA/CBER as a biological reviewer in September 2022. Elvira conducts review of CMC data for gene therapies, with a focus on ex vivo gene-modified autologous and allogeneic products. Prior to joining the FDA, Elvira worked as a scientist in pharmaceutical industry to advance IND-enabling and discovery CAR T programs. Elvira received her Bachelor's in Bioengineering and PhD in Molecular Biology from UCLA.

ALEXANDRA BEUMER SASSI, Ph.D., RAC

Senior Director CMC & Quality
Voisin Consulting Life Sciences (VCLS)

As a Senior Director, Chemistry, Manufacturing and Controls (CMC) at VCLS, Alexandra (Alex) is responsible for providing CMC and regulatory consulting services to clients to help them take their products from early clinical phases to marketing authorization, particularly for biological, cell and gene therapy products. Her expertise covers the US and European markets.

Alex has over 20 years of experience in the pharmaceutical/biopharmaceutical industry and consulting services. She brings significant expertise in analytical method development, quality control, formulation development, product manufacturing scale-up, stability, and CMC matrix team leadership. In the past 7 years, Alex has focused on cell and gene therapy products.

Prior to joining VCLS, Alex was a Regulatory Affairs CMC Consultant at Cardinal Health Regulatory Sciences. She was responsible for providing regulatory strategy and assisting clients on regulatory submissions. She was responsible for a range of products including biopharmaceuticals, gene therapy, cell therapy, combination products and medical devices.

Prior to joining Cardinal Health, Alex was a CMC Regulatory Executive at GlaxoSmithKline, where she developed CMC strategy and coordinated regulatory submissions for Marketing Authorization in US, EU, Japan, and emerging markets. Previously to her regulatory role, Alex authored several CMC sections for Clinical Trial Applications for biopharmaceutical compounds. She was also responsible for formulation, characterization and tech transfer of monoclonal antibodies at different phases of development. Prior to

GSK, she held several positions at a generic pharmaceutical company in Brazil in quality control, formulation, and manufacturing.
Alex is US RAC certified, and a member of the Regulatory Affairs Professional Society (RAPS), the Association of Women in Bio, and the Alliance for Regenerative Medicine. In addition, Alex is an Associate Director for the Advisory Committee of CASSS and an active member of the Scientific Organizing Committee for the Cell and Gene Therapy Products Symposium.
Alex received her PhD in Pharmaceutical Sciences from the University of Pittsburgh, School of Pharmacy. Her dissertation work was with pre-clinical and formulation development of biopharmaceutical microbicides. She received her Pharmacy degree from the University of Sao Paulo, Brazil. She completed her post-doctoral studies at Magee-Womens Research Institute.

BEN CLARKE, Ph.D.

Senior Scientist, Global Biologics
USP

Dr. Ben Clarke comes from the United States Pharmacopeia's Global Biologics group, where he coordinates collaborative multi-laboratory studies for USP's physical reference standards. The standards he supports include those for monoclonal antibodies, cell, and gene therapy. Before joining USP, Ben developed potency bioassays at GSK Vaccines for RSV and mRNA vaccines. His post-doctoral research at the National Institutes of Health involved the development of mouse models using the emerging CRISPR/Cas9 genome editing technology. He received his Ph.D. in Cell Biology from Cornell University and his B.S. in Biochemistry from Pennsylvania State University.

SRINIVASAN KELLATHUR, Ph.D.

Regulatory policy lead APAC
Roche

Srinivasan KELLATHUR is currently the regulatory policy lead for APAC at Roche Pharma Singapore. At Roche he drives regulatory convergence initiatives with a focus on CMC topics and ensures the implementation of reliance pathways across the region.
Srini spent 16 years with the Health Sciences Authority (HSA), Singapore where he headed the Advanced Therapy Products Branch, responsible for policy and legislation and implementation of the regulation of cell, tissue, and gene therapy products (CTGTP) that came into force in March 2021. Singapore was the first country to implement a comprehensive regulatory framework that covers both lower- and higher-risk CTGTP in ASEAN. At HSA, Srini was also actively engaged in the discussions regarding establishment of an electronic end-2-end licensing and registration system for CTGTP. In addition, to promote and advance prospective regulatory convergence efforts for advanced therapies, a priority work area was established under the auspices of Asia Pacific Economic Cooperation. Srini, representing HSA, together with the US FDA, co-championed the convergence efforts, and three

Centres of Excellence (Singapore Duke–NUS Centre of Regulatory Excellence [CoRE], Northeastern University, and USP) were formed to formulate relevant training curricula for regulators. Srini also holds an adjunct assistant professor position at Duke–NUS CoRE.
Prior to joining HSA, Srini was a Research Associate at the Johns Hopkins School of Medicine, where he had applied several bioinformatics tools to identify T-cell epitope targets from viral antigens and validated them in HLA transgenic mouse models.

SHUYUAN ZHANG, Ph.D.

CTO
Forecyte Bio

Dr. Shuyuan Zhang worked continuously in the cell and gene therapy field for nearly 30 years since joining the World first gene therapy company in the early 1990s. Altogether, he worked in six innovative cell and gene therapy companies and led the process development and GMP production functions for successful filing of more than 10 cell and gene therapy INDs with the FDA. He is a recognized expert in plasmid, viral vector (AAV, lentiviral, adenoviral, retroviral vector), and cell (CAR-T) product process development and cGMP production. He is the inventor of numerous manufacturing process patents and completed a gene therapy product BLA CMC filing. During his long career, he had close working relationships with many top CGT CDMO companies and learned the “best practices” in this field. He is the co-founder, and CTO of Forecyte Bio, a Sino-American full-service cell gene therapy CDMO company.

MEHRSHID ALAI, Ph.D.

VP of Global Regulatory CMC
Kite Pharma

Mehrshid Alai is the Vice President of Regulatory Affairs, CMC and Early Development at Kite, a Gilead Company, and is involved with new product development and life cycle management of genetically modified cell therapy products. Prior to joining Kite, she was the head of Regulatory CMC at Baxter/Baxalta/Shire. Dr. Alai has extensive experience in biological product development, quality requirements and regulatory approval and management of post-approval changes. Prior to her regulatory affairs experience, she was part of quality organization with extensive experience in different areas such as quality control, quality assurance of new products, stability and device and combo product development. Dr. Alai also worked in research and development as a protein characterization scientist and managed a group of scientists in that area. She has 30 years of experience in biologics development, biological product life cycle, quality and regulatory affairs. Prior to joining Baxter, she was an assistant professor at Simon Fraser University. She holds a Ph.D. from Johns Hopkins School of Medicine.

LUCAS CHAN, Ph.D., FRSB
Scientific Founder & CSO
CellVec Pte Ltd

Dr. Lucas Chan is the Scientific Founder of CellVec in Singapore, SE Asia's first accredited CDMO dedicated to the development and manufacture of viral vectors for human gene therapy. Lucas received his PhD at Imperial College London and was a Senior Investigator and Head of Manufacture for Advanced Therapies at King's Health Partners in London, where he led translational development of Advanced Cell and Gene Therapies for clinical trials and established UK's first GMP viral vector core. He is an elected Fellow of the Royal Society of Biology and an advisory member to Singapore's Ministry of Health on Cell and Gene Therapy regulations.