Speaker Biographies

(Listed alphabetically by last name)

Fouad Atouf, Ph.D.
Vice President, Global Biologics
USP

Fouad Atouf is Vice President, Global Biologics, for USP. He leads all scientific activities related to the development and maintenance of documentary and reference standards for biologics and antibiotics and oversees the biologics laboratories in USP–U.S. and USP–India. His department supports the work of the associated USP Expert Committees. Dr. Atouf has been at USP for over 10 years and served in a variety of scientific leadership roles including being the regional champion for the Middle East and North Africa Region, where he helped facilitate programs designed to enhance the understanding of the role of regulations and standards in the registration of medicinal products. Dr. Atouf has strong background and experience in the development and regulation of *cellular and tissue-based products*. Prior to joining USP in 2006, his research at the U.S. National Institutes of Health focused on developing methods for the *in vitro* generation of cell-based therapies for diabetes. Dr. Atouf is the author of numerous publications in peer-reviewed journals and a frequent speaker at national and international scientific conferences. Dr. Atouf earned his Master's degree in Biochemistry and his Ph.D. in Cell Biology from the Pierre & Marie Curie University, Paris, France.

Edward Chess, Ph.D.
USP Biologics Stakeholder Forum Planning Committee and USP Multi-Attribute Method (MAM) Expert Panel, 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, and extractables and leachables at Baxter Healthcare prior to 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 on the Biologics Stakeholder Forum Planning Committee. When not attending USP teleconferences Dr. Chess enjoys building and flying model rockets and woodworking.

Maura Kibbey, Ph.D.
Senior Scientific Fellow, Global Biologics
USP

Dr. Maura Kibbey is Senior Scientific Fellow for Education and Training in USP's Global Biologics Department. Dr. Kibbey collaborates with scientific experts and trainers to bring more educational offerings to USP's biologics stakeholders. Previously, Maura directed a team of liaisons working with the five USP Expert Committees and multiple 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 as well as at the National Institutes of Health. Her scientific expertise includes development and validation of many different assay types for measurement of 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.

Diane McCarthy, Ph.D.
Director of Pipeline Development, Global Biologics
USP

Dr. McCarthy is Director of Pipeline Development in USP's Global Biologics Department. Diane leads a team that focuses on development of new standards that can help address common bottlenecks in the biotechnology industry. Prior to joining USP, Dr. McCarthy worked for several small CROs that focused on the use of mass spectrometry for characterization of biologics, host cell proteins, and biomarkers. Previous roles include Senior Scientific Director at Caprion Biosciences, where she focused on the use of mass spectrometry for characterization of biologics and host cell proteins, and Director of Scientific Affairs at Ezose Sciences, where she focused on identification and quantitation of glycans by mass spectrometry. Diane also has over a decade of experience in biomarker discovery and development. She has a B.A. in Chemistry and French from Franklin and Marshall College and a Ph.D. in Biochemistry from the University of Texas at Austin.