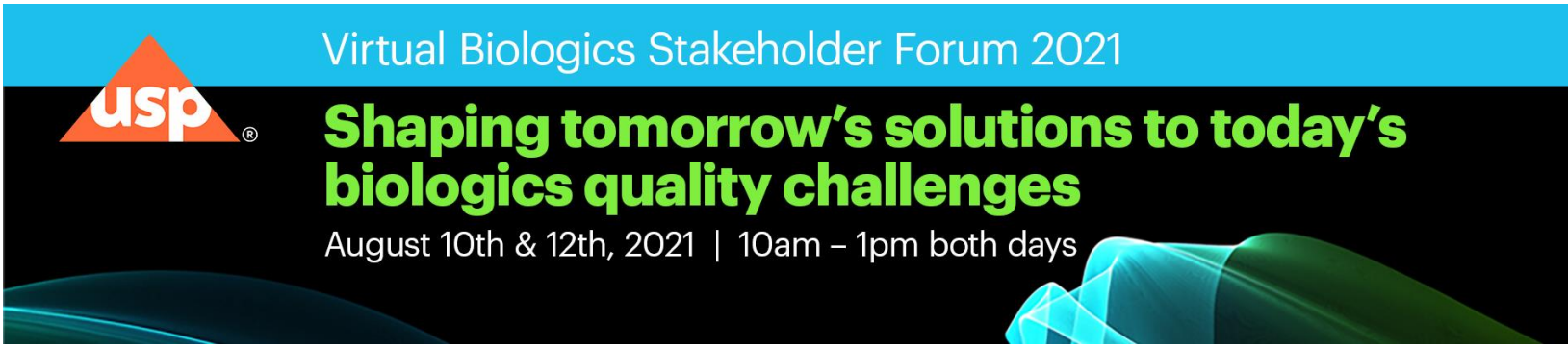


# Innovative Analytical and Digital Solutions to Advance Biomanufacturing and Product Quality

## Speaker Biographies

(Listed by order of appearance)
Updated as of August 5, 2021

## Day 1:

***Presentation: Welcome and Logistics (both Day 1 and Day 2)***

**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.

***Presentation: Welcome and Opening Remarks***

**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.

***Presentation: Introduction and Objectives for the Forum***

**Edward 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, 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.

***Presentation: CHO Cell Process Monitoring of Quality Attributes using Raman Spectroscopy at Manufacturing Scale***

**Caitlin O'Mahony Hartnett, Ph.D.**
Scientist
Janssen Sciences Ireland

Dr Caitlin O'Mahony Hartnett is a Scientist in BioTherapeutics Development at Janssen Sciences Ireland. Caitlin leads several Advanced Process Control initiatives and is responsible for the BioTD Raman Modeling

effort at Janssen developing APC models for cell culture processes in for development programs and Raman model deployment at manufacturing scale.

*Abstract:*
Current methods to measure API drug substance release Critical Quality Attributes (CQAs) such as glycation and glycosylation are time and resource intensive, often only tested offline once the production process is complete. Process Analytical Technology (PAT) tools such as Raman Spectroscopy can provide real time measurements of a range of process variables, and when combined with chemometric modelling, is aligned with the Quality by Design approach.

This study utilizes the functionality of Raman spectroscopy and chemometric modelling to build Partial Least Squares (PLS) regression models to provide real time monitoring tools of glycation and glycosylation profiles at manufacturing scale.

In total, seven cell line specific chemometric PLS models; % mono-glycated, % non-glycated, % G0F-GlcNac, % G0, % G0F, % G1F and % G2F were considered. PLS models were initially developed using 15 batches of reduced scale data to verify the capability of Raman to measure these CQAs effectively.

Improving model robustness was considered for each of the seven PLS models presented by supplementing the reduced scale models with manufacturing scale data. This data addition, while only representative of 4.4% of the total model building data, had a significant impact on the predictive capability of each of the seven models presented, with an improvement in prediction error observed in all models. A significant improvement of 77.5% was observed in the case of the % G2F PLS model.

The finalized models show the capability of Raman as a PAT tool to deliver real time monitoring of glycation and glycosylation profiles, with consideration given for monitoring these CQAs at 2000L manufacturing scale.

***Presentation: In-Line Viral Inactivation: Characterization of Key Design and Process Parameters to Ensure Effectiveness***

**Michael Phillips, Ph.D.**
Director – Bioprocess Development
MilliporeSigma

Dr. Michael W. Phillips is currently the Technical Director of the Next Generation BioProcessing R&D team at MilliporeSigma focused on Applications and Innovation supporting the BioContinuum™ Platform. He is responsible for identifying, developing, and implementing innovative upstream and downstream processing technologies, novel process analytical technologies and sensors, and advanced software and automation that enable process intensification for mAb processing, including integrated, connected, and continuous processing. Dr. Phillips has

more than 30 years of experience at MilliporeSigma developing new bioprocess technologies and applications. Dr. Phillips holds a PhD in chemical engineering from Rensselaer Polytechnic Institute.

*Abstract:*
Changing market drivers have forced biomanufacturers to set aggressive 90% reduction targets in both cost and speed for the production of new biotherapeutics without sacrificing quality and robustness. Biomanufacturers are attempting to achieve these targets through the adoption of higher productivity technologies that enable more connected and continuous processing. As such, continuous low-pH viral inactivation can be a key enabler for intensified downstream processing. As low-pH virus inactivation is an important component of an overall viral control strategy, it is critical that an intensified technology designed to replace the traditional batch process is fully characterized so as to deliver a robust solution. In this presentation, data to support both the characterization of a well-designed continuous flow incubation chamber and the viral inactivation kinetics of an in-line process are presented.

***Presentation: Enabling Real Time Release Testing (RTRT) with Multi-Attribute Methods***

**Galahad Deperalta, Ph.D.**
Senior Scientist and Innovation Group Leader, Analytical Development and Quality Control
Genentech, a member of the Roche Group

Galahad Deperalta is a Technical Development Senior Scientist with 20 years of experience in the Protein Analytical Chemistry Department in Genentech, a member of the Roche Group. His areas of expertise include protein chemistry, chromatography, and mass spectrometry. He has extensive experience in recombinant antibody characterization and process development, providing leadership and key support for numerous clinical and commercial products. He has authored or co-authored several publications and characterization sections for health authority filings, led cross-functional early and late-stage Technical Development (CMC) Teams and Analytical Subteams, and, as a people leader, managed a lab group of Scientists and Engineers providing key analytical support across the Pharma Technical organization. He is currently the Analytical Development and Quality Control Innovation Leader, overseeing teams exploring real-time release strategies, new technologies, and digital transformation tools for biotherapeutic characterization.

*Abstract:*
Multi-attribute methods promise to bring control system efficiencies for biotherapeutics, and contribute to reducing lead times and lead time variability in supply chains. In this presentation, the combination of MAM (multi-attribute method) by LC-MS and MARS (Multi-Attribute Raman Spectroscopy) for release testing will be discussed, with the vision of a path towards QC testing and enabling Real Time Release Testing (RTRT). Notable

challenges and considerations for MAM by LC-MS and MARS as key enablers for RTRT will also be presented.

## Day 2:

***Presentation: Day 1 Summary and Objectives for Day 2***

**Linda Narhi, Ph.D.**
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 BS Chemistry from the Univ. of Michigan, and her PhD in Biological Chemistry from UCLA. She joined Amgen over 30 years ago and has been involved in the process and product development of biotherapeutics 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 immunogencity of the molecules, and 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 is 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.

***Co-Presentation: How Can in Silico Models be Accepted in lieu of Lab Experiments and Manufacturing Runs?***

**Marcus Fiadeiro**
Associate Director, Purification Development
Sanofi

Marcus Fiadeiro is an associate director in global purification development at Sanofi, based in Framingham, Massachusetts. He has worked in biopharma for 20+ years and the last 15 in purification process development at Pfizer and previously Amgen. His experience includes mabs, non-mabs, vaccines, polysaccharides, and conjugation in both early and late stage projects. He holds an M.S. from Johns Hopkins in Biotechnology and a B.S. in Biochemistry from Virginia Tech.

*Abstract:*
In silico models are being developed within the biopharmaceutical industry to guide process development and process scale-up. These models have a potential to transform the ways of working within the biopharmaceutical industry through greater predictability and insight into our processes. In this presentation, we present the opportunities that the in silico models provide for transforming from process development through

manufacturing. We will also discuss the challenges that we must overcome for the acceptability of these models through a concerted industry effort.

***Co-Presentation: How Can in Silico Models be Accepted in lieu of Lab Experiments and Manufacturing Runs?***

**Siddhartha Jain, Ph.D.**
Director, MSAT Digital
Sanofi

Siddhartha Jain is Director of MSAT Digital at Sanofi based in Framingham, Massachusetts. He has worked in biopharma for 15+ years in a diversity of roles including scientific, strategy and digital transformation for the development and commercialization of mAbs, non-mAbs and vaccines. He holds a PhD in Bioengineering from MIT and B.Tech./M.Tech. in Biochemical Engineering from Indian Institute of Technology.

*Abstract:*
In silico models are being developed within the biopharmaceutical industry to guide process development and process scale-up. These models have a potential to transform the ways of working within the biopharmaceutical industry through greater predictability and insight into our processes. In this presentation, we present the opportunities that the in silico models provide for transforming from process development through manufacturing. We will also discuss the challenges that we must overcome for the acceptability of these models through a concerted industry effort.

***Presentation: The Potential of Hybrid Process Modeling and Digital Twins to Master the Goals of Industry 4.0 in Bioprocessing***

**Michael Sokolov, Ph.D.**
COO and Co-Founder
DataHow AG

***Presentation: Advanced Technology for Manufacturing Process Control***

**Riley Myers, Ph.D.**
Emerging Technology Team/OPQ and Lead Biologics, Office of Biotechnology Products
CDER, US FDA

Riley Myers is a member of the Emerging Technology Team (ETT) in the Office of Pharmaceutical Quality and a Team Lead in the Office of Biotechnology Products in the Center for Drug Evaluation and Research (CDER) at FDA. He serves as

a project lead for technologies accepted into the Emerging Technology Program where he assembles Agency-wide, multidisciplinary teams to work with sponsor developing these technologies. He also works with a team of assessors evaluating regulatory submissions. Dr. Myers was previously a microbiologist in the Center for Devices and Radiological Health prior to CDER where he assessed medical devices that contain antimicrobial agents as well as sterilization devices. Before joining FDA, Dr. Myers studied mechanisms to program immune responses against infectious diseases at Boston Children's Hospital. His scientific expertise is in B cell and dendritic cell biology and their role in regulating the humoral immune response. Dr. Myers received his Ph.D. in Immunology from the University of Alabama at Birmingham.