USP mRNA Open Forum

Collaborating to Pave the Way for mRNA
February 28-29, 2024
Virtual Event 9:00 a.m. – 1:00 p.m.
All times are in Eastern Daylight Time (EDT) – Washington DC time zone

Speaker Biographies

(Listed in speaking order)

Day One: Wednesday, February 28th, 2024: Analytical Challenges and Advances

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

Fouad Atouf, Ph.D., is Senior Vice President, Global Biologics at the United States Pharmacopeia (USP) where he oversees standards development, stakeholder engagement and industry collaborations, in support of the quality and safety of biological medicines. Dr. Atouf has been at USP for over 15 years and served in multiple leadership roles developing quality tools for biologics and establishing relevant reference material programs. In addition to leading the modernization of compendial standards, Dr. Atouf launched and implemented the biologics strategy focusing on technologies to support manufacturing and testing biological medicines. He has implemented new engagement models and collaboration approaches with academia, biopharma industry, and global government agencies. Dr. Atouf has a strong background in the regulation and standardization of pharmaceutical products including biologics and advanced therapies. Dr. Atouf is the author of numerous publications and is a frequent speaker at national and international pharmaceutical and regulatory scientific events. He holds a Ph.D. in Cell Biology from the Pierre & Marie Curie University, Paris, France.

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Sarita K. Acharya, M.S.
Principal Scientist, Global Biologics
USP

Sarita K. Acharya is a Principal Scientist within the Global Biologics Department at the United States Pharmacopeia (USP). In this role, she specializes in the development of both physical and documentary reference standards. Drawing upon her extensive background in vaccines, Sarita's current focus at USP involves identifying and advancing standards to bolster vaccine manufacturing processes. Additionally, she contributes to the creation of new standards tailored for the analytical testing of oligonucleotide products, while also exploring opportunities for standards in emerging areas. Before joining USP, Sarita amassed valuable experience across various sectors, including biotech firms, academia, contract research organizations, and pharmaceutical companies such as GlaxoSmithKline (GSK) and Janssen Pharmaceuticals. Throughout her career, she has held diverse roles spanning method development and validation, Chemistry, Manufacturing, and Controls (CMC), and quality control. Notably, Sarita has worked extensively with monoclonal antibodies, proteins, and mRNA-based vaccines. She holds a Master of Science degree from the University of Maryland Global Campus and a Bachelor of Science degree from Hunter College, State University of New York.

Earl Zablackis., Ph.D.
Chairman Bio 3, Complex Biologics and Vaccines Analytical Sciences, USP

Dr Zablackis is a retired analytical carbohydrate chemist with over 30 years' experience in academics (Station Biologique de Centre National de Recherche Scientific in Roscoff France and the Complex Carbohydrate Research Center at the University of Georgia) and the biopharmaceutical industry (Bayer Biologics and Sanofi) and is currently serving as the Chair of the USP Expert committee: Bio3-Complex Biologics and Vaccines. His academic work focused on chemical analysis, as well as structural, physical, and functional characterization of marine algal and higher plant cell wall polysaccharides, while his industrial expertise included work in method development and validation for test methods used for release and characterization of recombinant glyco-proteins, monoclonal antibodies, bacterial polysaccharides and glycoconjugate vaccines. Additionally, Dr Zablackis has spent the greater part of his career as a volunteer with the PDA in developing standard practices for method development, qualification, and validation (TR 57 and TR 57-2) and with the USP in developing standards (chapters <198>, <1235>, <1238>, <1239>, <1430.1>).

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Khalid Yamout

Analytical Sciences, Quality and Manufacturing Consultant
On behalf of TriLink Biotechnologies

Khaled Yamout is a thought leader in Analytical Sciences, Quality and Manufacturing. Previously held a positon as a Senior Director, Analytical Services and Quality Control at TriLink Biotechnologies where he oversaw the Analytical Sciences Center of Excellence and all analytical aspects of method development and validation to product release and stability to support regulatory filings for both small and large molecules. Prior to TriLink, Khaled held various positions in Quality Control, Research and Development, and Manufacturing where he supported several Drug substances and Drug products (both small molecules and biologics) from clinical phase to commercial. These include diverse experience and expertise ranging from discovery to manufacturing with Fortune 500 firms, as well as small entrepreneurial businesses in the areas of synthetic, analytical, colloidal, surface modification, protein, and antibody modification and purification covering both manufacturing and analytical testing and characterization.

Mark Brader, Ph.D.

Group Leader, Product Development Scientist
Moderna

Mark is a biophysical development scientist with over 20 years' experience leading technical teams. At Moderna he has contributed to understanding the fundamental structure of mRNA-lipid nanoparticles and was part of the team that developed the Covid-19 vaccine during the pandemic. He maintains a strong curiosity about the pharmaceutical significance of non-covalent phenomena and higher-order structures.

Dr. Brader graduated with a Ph.D. in Chemistry from Massey University in New Zealand then held postdoctoral positions in the Department of Biochemistry at the University of California at Riverside, and in the Department of Chemistry at Rutgers University. He has broad experience within the biopharmaceutical industry focused on formulation development, pharmaceutical biophysics, and specialized delivery systems. He has headed up the biophysical analytical development group since joining Moderna in 2016.

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Niels Delamotte

QC Director
etherna

Niels Delamotte holds a master's degree in biotechnology from the University of Ghent, which he received in 2001. He began his career at Sanofi, where he worked for 14 years in a range of positions within Quality Control & Manufacturing Science and Technology. In his last role at Sanofi, he was the Analytical Lifecycle Management Project Lead for enzyme products at the Geel Facility. In 2019 he joined etherna and moved from commercial protein to GMP clinical-stage mRNA manufacturing with the aim of bringing mRNA therapeutics to the clinic. As Quality Control Director he is currently responsible for the Analytical Lifecycle programs within etherna on both mRNA Drug Substance and Drug Product formulated in Lipid Nanoparticles. Furthermore, he is a member of the mRNA working party established by the European Pharmacopoeia (Ph. Eur.) Commission which has the task to develop a consolidated strategy for future standards on mRNA vaccines and their components.

Frank Zuo, Ph.D.

Principal Scientist
Merck

Frank holds his Bachelor of Science in Biochemical Engineering and later obtained a Ph.D. in Biochemistry. As an analytical scientist in the industry, he refined his expertise through method development, validation, and transfer in both GxP and non-GxP alalytical labs, with a strong command of chromatography and mass spectrometry techniques for different biological modalities.

Commencing his career post-college, Frank started his analytical career as a chromatographer and later pursued a doctorate in biochemistry under the guidance of Dr. Michael Trakselis at the University of Pittsburgh. Post-graduation, he returned to the industry, contributing as an analytical scientist at Boehringer Ingelheim, focusing on LC and LC/MS to support bioprocess development. Frank's analytical journey continued at Pfizer's vaccine department in Pearl River, NY, where he played a key role in the analytical support for development of already certified vaccines, including RSV, Prevnar 20, and the Covid-19 vaccine. Currently leading a team at Vaccine AR&D at Merck, Frank oversees the development of separation methods for RNA drug substance and drug product analysis.

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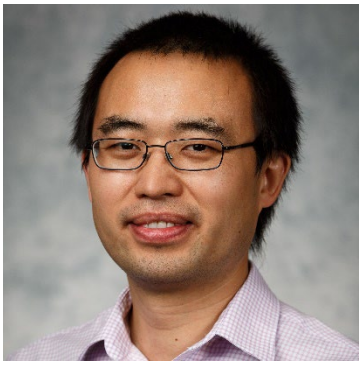

Qin Yan, Ph.D.

Senior Scientist
AstraZeneca

Qin Yan is currently a Senior Scientist in Analytical Science group at AstraZeneca located in Gaithersburg, MD. In this role, he is responsible for developing control strategies, analytical methods, and product characterization to support development of biopharmaceutical products. He is involved in advancing new modalities portfolio and building platform analytical capabilities for mRNA/LNP, antibody drug conjugates (ADCs), gene and cell therapies.

Dr. Yan received Ph.D. and master's degree in chemistry from Arizona State University, and a Bachelor of Science degree from Peking University. Before joining AstraZeneca, he worked at GSK, Novavax and Captozyme (now Arranta Bio). During his 12-year career in biopharmaceutical and vaccine industry, he provided CMC supports to drug development in various stages, from pre-clinical to BLA.

Franz Schnetzinger, Ph.D.

CMC Lead
CEPI

Franz joined CEPI in Oct 2023 as CMC Technology Lead. In this role he supports the evaluation of innovative science and technology for vaccine manufacturing and assists project teams in assay and reagent development and standardization. Franz was previously heading up the Analytical Development and QC team at Gyroscope Therapeutics - a Novartis gene therapy company - working on rAAV vectors for retinal diseases based in London, UK. Before moving to Gyroscope, Franz worked at GSK's Gene Therapy Unit in Stevenage, UK, where he led third party analytical development and validation work for two lentiviral based ex-vivo autologous gene therapy projects. Prior to GSK Franz worked at Baxter AG, Austria, where he developed, validated, and ran release methods for vaccines and recombinant proteins in his roles as QC laboratory technician and supervisor quality. Franz holds a BSc in Bioengineering & Bioinformatics from University of Applied Sciences Vienna, Austria, and a MSc in Analytical Biotechnology from Cranfield University, UK.

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Jan Falcke, Ph.D.

Director of AS&T Lifecycle Management, Global Analytical Science
BioNTech

Dr. Jan M. Falcke is Director, global Analytical Science and Technology at BioNTech. In his current role, he is leading the Life Cycle Management team which develops and drives the analytical control strategy for late stage and commercial mRNA products. Jan has over 7 years of QC and CMC experience in the development and commercialization of mRNA products with a strong background in analytical development and life cycle management of bioassays. He holds a B.S. degree in Biology and a M.S. in Biochemistry and Molecular Biology from the University of Bremen. He graduated with a Ph.D. in Biology from the Max Planck Institute for Biology at the University of Tübingen.

Day Two: Thursday, February 29th, 2024: Technology Trends

Weicheng Zhang, Ph.D.

Principal Scientist, Analytical Development
CATUG

Dr. Zhang Weicheng pursued his Ph.D. at Harvard University under the mentorship of Nobel laureate Jack Szostak. Throughout his academic journey, Dr. Zhang has consistently contributed to various genetic material-related projects, such as Morpholino nucleic acid, and the establishment of a LC-MS analysis service platform for biomolecules. With extensive expertise in nucleic acid research spanning over a decade, Dr. Zhang currently holds the position of Director of the Analytical Development Department at Catug Biotechnology. In this role, he has overseen the establishment and operation of comprehensive analysis platforms for plasmids, RNA, and lipid nanoparticle (LNP), leading the development of over 70 analytical methods capable of addressing over 50 distinct quality attributes.

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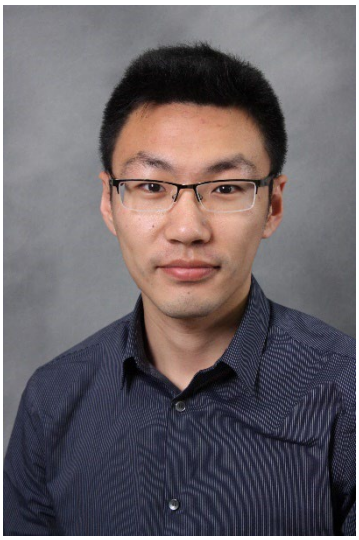

Sixuan Li, Ph.D.

Postdoctoral Research Associate, Department of Mechanical Engineering
John Hopkins University

Dr. Sixuan Li got his PhD at Johns Hopkins University in the Department of Mechanical Engineering advised by Dr. Jeff (Tza-Huei) Wang. He is currently a postdoctoral research associate in the same lab. His research focuses on developing and applying innovative methods in the single-molecule analysis, particularly focusing on nucleic acids, proteins, and nanoparticles. His multidisciplinary approach draws from biophysics, chemistry, optics, and engineering to push the boundaries of scientific knowledge. His work has been published in journals including Nature Communications, Analytical Chemistry, Lab on a Chip, and Small Methods, and he holds a patent on the characterization of nanoparticles.

Li is commercializing of the nanoparticles analysis platform, and has been working on the CICS Analytics, a startup company that leverages single molecule fluorescence spectroscopy and cutting-edge toolkits to provide comprehensive analyses of therapeutic nanoparticles. He is committed to develop more effective and safer nanomedicines and advancing the field of cell and gene therapy.

Yue Fu, Ph.D.

Senior Principal Scientist, Protein Biochemistry
Regeneron Pharmaceuticals

Yue Fu joined Regeneron in 2019. As a Senior Principal Scientist, he works on analytical method developments to characterize various therapeutics modalities, including antibody, AAV and mRNA. Prior to joining Regeneron, Yue worked at Genentech from 2015 to 2019. He holds a B.S. degree in Biochemistry from University of Science and Technology of China as well as a Ph.D. in Molecular and Cellular Biochemistry from Indiana University Bloomington.

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Valentina Paolucci, Ph.D.
Senior Application Scientist
PerkinElmer

Valentina Paolucci is a Sr. Application Scientist for the BioPharma market at PerkinElmer. She received her PhD in Chemistry from University of Copenhagen, Denmark on a preclinical study of protein-like polymers for the treatment of atherosclerosis. As a visiting researcher, she worked at the University of California San Diego on release studies of cancer drug liposomal formulation.

Before joining PerkinElmer, she worked for different industries as technical sales specialist supporting customers with material characterization process issues. She has expertise in molecular spectroscopy, microscopy, and chromatography for the development of biomolecules assays and purity protocols.

Jeffrey Marshall, Ph.D.
Director of Analytical Research and Development
Beam Therapeutics

Dr. Marshall earned his Ph.D. at UMass Lowell in chemistry/biochemistry studying the falciparum malarial genome focusing on histone positioning and other transcriptional regulation factors. He has worked in the biotechnology field as an analytical chemist for approximately 19 years studying the biophysical/chemical properties of a wide range of modalities and technologies including plasmid microparticles, mRNA vaccines, lipid nano particles, gene editing, monoclonal antibodies, and enzyme therapies. He has contributed to multiple publications in this space focused on gene circuits controlling glycosylation, metabolomics, and gene editing to cure sickle cell disease.

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Martin Kurnik, Ph.D.

Application Scientist II
Waters | Wyatt Technology

Martin Kurnik joined the Analytical Sciences team at Waters | Wyatt Technology in 2021, where he helps customers identify and develop the best solutions for their analytical needs. As an application scientist, Martin leverages his expertise in multi-angle light scattering and dynamic light scattering as well as a wide range of other leading techniques for biomolecular characterization. His postdoctoral research in protein folding and misfolding biophysics focused on understanding and preventing misfolding in bulk solution and on artificial surfaces used in medicine and biotechnology, and he has also developed protein- and aptamer-based electrochemical biosensors for continuous real-time measurements in vitro and in vivo. Martin received his M.Sc. in Chemistry and Ph.D. in Biochemistry from Stockholm University, Sweden.

Timothy Mercer, Ph.D.

Director of BASE Facility
The University of Queensland, Australia

Professor Timothy Mercer is the Director of the BASE facility at The University of Queensland, which is the leading Australian site for mRNA manufacture and research. Prof. Mercer has over two decades of experience in RNA biology, where his research has provided fundamental insights into gene structure and expression, leading to the development of novel RNA sequencing biotechnologies that have been widely adopted in research and clinical practice. The BASE Facility includes an advanced manufacturing unit developing new mRNA production and analytical processes, as well as a research unit focused on building innovative new mRNA therapies in oncology.

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Rachel Gao, Ph.D.
Senior Scientist
InDevR

Dr. Gao is a Senior Scientist in research and development at InDevR, a biotechnology company specializing in the development of tools and assays to improve the efficiency and accuracy of virus quantification. Her work is focused on developing the 5' capping efficiency assay, which offers quantitative or relative analysis results in under 2 hours. She also played a pivotal role in the feasibility phase for all InDevR mRNA projects.

Dr. Gao successfully completed her PhD in Toxicology at the University of Colorado Anschutz Medical Campus, Skaggs School of Pharmacy and Pharmaceutical Sciences. Her doctoral work delved deeply into immunological mechanisms in liver diseases. Throughout her graduate career, she was awarded three travel awards, including the "C. Werner and Kitty Hirs Merit Award" from the University of Colorado Anschutz. Dr. Gao was also the recipient of the "PISA 2020 Monga-Hans Trainee Scholar Award for Excellence in Liver Pathobiology Research".