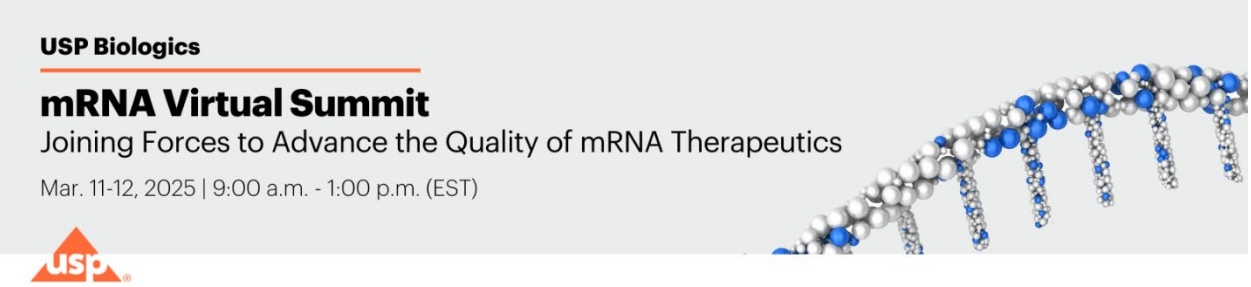

Speaker Biographies

Day One: Tuesday, March 11th, 2025 – mRNA Virtual Summit

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.

Bruce Carpick, Ph.D.

Global Analytical Expert
Sanofi

Dr. Bruce Carpick received his BSc in Biology and Physics and his PhD in Medical Biophysics from the University of Toronto, Canada and did postdoctoral research in Cancer Biology at the Cleveland Clinic Foundation, USA. His initial research focus was on purification, characterization, and structure-function analyses of peptides and proteins. Bruce joined Sanofi Vaccines R&D, Toronto, Canada in 1998 and has held positions as Development Scientist, Senior Research Scientist, Principal Scientist, and Director, Biochemistry Platform, Analytical R&D North America. At Sanofi, he has focused on vaccine adjuvant formulation development, biochemical/biophysical characterization release and stability testing, new product development and analytical strategy, Regulatory science, GMP and Pharmacopoeial compliance, troubleshooting & investigations, and commercial product life cycle management. His current role is as Global Analytical Expert Biochemistry. Bruce leads global cross-functional teams focused on development and implementation of new and innovative analytical technologies and has been involved in multiple scientific collaborations with external academic, industrial, and government laboratories. He was a member of the Innovative Medicines Initiative VAC2VAC consortium. He is currently Secretary and Board Member, IABS North America, member of the USP BIO3 Expert Committee on Complex Biologics and Vaccines and is co-chair of the USP Expert Panel for mRNA Vaccines and Therapeutics.

Huixin Lu, Ph.D.

Research Scientist
Health Canada

Dr. Huixin Lu (or Lulu) is a Research Scientist at the Regulatory Research Division of Health Canada, where she works on developing methods to assess the physicochemical quality of complex biotherapeutics including peptides, vaccines, and gene therapies. Beyond research, she collaborates closely with international organizations on improving the safety and efficacy of biotherapeutics through global standardization of methods and reference standards. Before joining Health Canada, Dr. Lu worked as a Research Scientist at a CDMO, gaining experience in both biomanufacturing processes and analytical characterization across a diverse range of biotherapeutics.

Jamison Grailer

Senior Research Scientist
Promega Corporation

Jamison Grailer is a Senior Research Scientist at Promega Corporation, where he leads the Biologics R&D Group. His lab focuses on leveraging Promega's cutting-edge technology to create innovative bioanalytical tools that drive the discovery and development of biological therapeutics. Dr. Grailer has over a decade of experience in assay development and has authored more than 50 peer-reviewed publications, book chapters, and patents. Prior to joining Promega, he completed postdoctoral training in innate immunity at the University of Michigan Medical School.

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

Jane Luo, Ph.D.

Senior Scientist in the Cell and Gene Therapy Applications Group of Scientific Marketing
SCIEX

Dr. Jane Luo is a senior scientist in the Cell and Gene Therapy Applications Group of Scientific Marketing at SCIEX. She earned her Ph. D. in Biochemistry from the City University of New York, received postdoctoral training in Molecular Biology and Cell Biology at Weill Cornell Medical College and Harvard Medical School, and conducted cancer research as an assistant adjunct professor at UC Irvine. In 2002, she moved to industry to develop capillary electrophoresis-based products and applications.

Shubhadra Pillay

Solutions Product Manager
Bruker

I am a structural biologist and Solutions Product Manager with expertise in NMR spectroscopy, molecular biophysics, and structure-based drug design. At Bruker BioSpin, I manage the development of pharmaceutical solutions by integrating systems, software, procedures, and services to drive market expansion. My research experience includes elucidating protein-ligand interactions and conformational dynamics to advance drug discovery. Earlier, at Takeda pharmaceuticals, I co-led biophysics efforts in fragment-based lead optimization against challenging targets. My postdoctoral work at the Max Planck Institute explored ubiquitin dynamics using residual dipolar couplings and during my PhD at Nanyang Technological University, I investigated protein-nucleic acid interactions and transcription factor inhibition using NMR. I have experience in computational modeling, docking, and SAR analysis to guide rational drug design. I thrive in interdisciplinary teams, working across R&D, applications, sales, and marketing to ensure innovative solutions meet scientific and commercial needs. With a strategic mindset and strong problem-solving skills, I contribute to cutting-edge research and market-driven innovation. My goal is to drive impactful discoveries at the interface of structural biology, pharmaceutical solutions, and drug development.

Philippe Talaga, Ph.D.

Global Head of CMC Analytical Leaders & Experts, mRNA Center of Excellence
Sanofi |Sanofi, France

Dr Philippe TALAGA works at Sanofi for 26 years. He received his diploma in Biochemistry and his Ph.D. in Biochemistry from the University of Lille (France). He joined Sanofi in 1999. He currently serves as Global Head of CMC Analytical Leaders & experts within mRNA Center of Excellence. His experience is in the field of glycoproteins, polysaccharides, glycoconjugates and mRNA-based human vaccines CMC. He is currently member of the EDQM mRNA working party and USP mRNA Expert Panel.

Camila Ortega, Ph.D.

Associate Director of Analytical Services
TriLink Biotechnologies

Dr. Ortega holds a doctorate in Molecular Biology and Analytical Chemistry from the University of Hawaii at Manoa. With a strong background in mass spectrometry, she serves as the Associate Director of Analytical Services at TriLink Biotechnologies. As part of the Analytical Development team, Dr. Ortega specializes in the physicochemical analysis of mRNA, oligonucleotides, and small molecules such as NTPs and CleanCap® analogs. Her commitment to analytical excellence, combined with her scientific expertise, drives the development of robust methodologies to effectively fulfill client analytical requests and expand TriLink's portfolio of analytical testing services.

Tomasz Witkos, Ph.D.

Associate Director
AstraZeneca

Tomasz Witkos holds a PhD in Cell Biology from the University of Manchester, UK. Throughout his academic career as a student and postdoctoral researcher, he investigated the pathology of rare genetic diseases, focusing on RNA gain-of-function diseases, microRNA editing, and non-coding RNA-mediated gene regulation. In 2018, he joined AstraZeneca, where he is currently the Associate Director within CMC Analytical Sciences. In this role, he leads a team and oversees the development of bioassays for clinical release, characterization and process development of AstraZeneca's biologics, including RNA-based therapeutics. .

Scott Gorman, Ph.D.

Field Applications Scientist
RedShiftBio

Scott Gorman, PhD is an Applications Scientist at RedShift Bioanalytics, specializing in biophysical assay development and the application of Microfluidic Modulation Spectroscopy (MMS) for RNA characterization. He earned his PhD at Penn State under Dr. David Boehr, experimentally studying protein allostery and ligand-modulated dynamics, followed by a postdoctoral fellowship at St. Jude, where he investigated phase separation in intrinsically disordered regions of patient-derived fusion oncoproteins. After his postdoc, Scott began his industry career at Arrakis Therapeutics, applying biophysical techniques to characterize RNA-small molecule interactions to drive structure-activity relationship studies. Now at RedShift Bioanalytics, he focuses on expanding RNA-specific applications of MMS, leveraging his expertise in biomolecular spectroscopy and RNA biophysics to support the adoption of MMS by the RNA therapeutics industry.

Day Two: Wednesday March 12th ,2025: mRNA Virtual Summit

Khalid Yamout

Founder and CEO of Yamout Chem Consulting, LLC
USP mRNA Expert Panel Chair

Khaled Yamout is the Senior Director, Analytical Services and Quality Control at TriLink Biotechnologies where he oversees 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

Astrid Trimmel, Ph.D.

R&D Analytics Lead
Afrigen Biologics

Dr. Astrid Trimmel is an accomplished scientist and leader in analytical research and development. She holds a PhD in Chemistry from the University of Cape Town, where her research focused on conjugate vaccines. With a strong background in analytical chemistry and biopharmaceutical development, Astrid currently leads the R&D Analytics team in advancing cutting-edge mRNA and mRNA-LNP assay development. Her expertise lies in optimizing analytical methodologies to support innovative therapeutic solutions. Passionate about scientific innovation and precision analytics, she is dedicated to driving impactful advancements in the field of mRNA technology.

Mohamad Toutounji, Ph.D.

CEO & Founder

Molgenium

Dr. Mohamad Toutounji is a senior consultant specializing in analytical sciences and process development for biologics, including mRNA-based therapeutics. With extensive experience in CMC strategy, method validation, and regulatory compliance, he has contributed to multiple projects optimizing mRNA manufacturing processes and ensuring product quality. His expertise spans process characterization, CQAs/CPPs identification, and technology transfer to support robust analytical frameworks for regulatory submissions. Dr. Toutounji has successfully developed innovative analytical methods to enhance mRNA vaccine characterization, accelerating development timelines and improving manufacturing efficiency. Holding a Ph.D. in Biochemistry and Molecular Biology from the University of Veterinary Medicine Hannover, he brings a strong scientific foundation to his work.

Lea Schneider, Ph.D.

Senior Manager ASAT

CureVac

Lea is a trained pharmacist with a PhD in protein biochemistry. In 2013, Lea joined Sanofi, where she held several positions within quality control for insulin APIs, eventually leading a newly established group focused on analytical life cycle management. In 2021, Lea joined Curevac as an analytical transfer manager within Quality Control. Later, she took the opportunity to establish a new ASAT group. In this role, Lea and her team are responsible for overseeing analytical validations, transfers, stability studies, and reference materials for mRNA products, as well as continuously improving QC strategy and concepts.

Jan M. Falcke, Ph.D.

Director AS&T Projects & Strategy
BioNTech

Dr. Jan M. Falcke is Director, global Analytical Science and Technology at BioNTech SE. In his current role, he is leading the Projects & strategy team which develops and drives the analytical control strategy for late stage and commercial products including mRNA. Jan has over 7 years of QC and CMC experience in the development and commercialization of Antibodies, Antibody drug conjugates and mRNA products with a strong background in analytical development and life cycle management of analytical methods. 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.

Kamalakar Chatla, Ph.D.

Technical Development Scientist -Principal Scientist Genomics
Genentech

Kamalakar chatla, Molecular biologist specializing in genome engineering and next-generation sequencing (NGS). With a strong background in CRISPR/Cas9 and TALENs, I have worked extensively on recombinant virus generation and gene editing during his PhD and postdoctoral research. Over the past eight years, focused on NGS, both experimentally and computationally, utilizing short and long-read sequencing technologies (Illumina, PacBio, ONT), as well as Hi-C, ChIP-seq, and RNA-seq. I have successfully assembled and annotated over 20+ genomes, including Sebastinae (rockfish), non-model Drosophila, and various plant species. My expertise extends to data processing, structural variant analysis, and analytical strategy development.

Currently at Genentech, I am working in the field of individualized, cell and gene therapies, focusing on developing NGS analytical methods for Whole genome, plasmid, and RNA sequencing. These analytical methods are critical for ensuring the accuracy, integrity, and safety of Cell and gene therapies.

Andrew Geall , Ph.D.

Chief Development Officer
Replicate Bioscience

Dr. Andrew Geall is the Chief Development Officer at Replicate Bioscience and cofounder of the company. Dr. Geall has over 20 years of professional experience in the development of drug delivery systems and is a pioneer in the fields of mRNA vaccines and nucleic acid delivery. He is an inventor on 41 patent families, with 505 applications and 203 issued patents in multiple jurisdictions. Prior to joining Replicate, Dr. Geall was Chief Scientific Officer at Precision NanoSystems Inc. (1 year). He has also held positions as Vice President of Formulations, Analytics and Chemistry at Avidity Biosciences (5 years), where he helped pioneered the development of their antibody-oligonucleotide conjugate delivery platform. Prior to Avidity, he led the mRNA vaccines Platform in the Vaccine division of Novartis (7 years). During his tenure, he created a global team and was Principal Investigator on a Defense Advanced Research Project Agency (DARPA) contract to develop self-amplifying mRNA vaccines.

Mark J. Dickman, Ph.D.

Professor Dept of Chemical and Biological Engineering, School of Chemical, Materials and Biological Engineering
University of Sheffield, UK

I obtained my PhD at the Krebs Institute at the University of Sheffield. Following my PhD I joined a biotechnology company, Transgenomic LTD where I worked as a research scientist developing analytical techniques including DNA/RNA Chromatography. I joined the Dept of Chemical and Biological Engineering in 2003. My research focuses on the development and application of analytical techniques to study biological molecules. In particular, bioseparations in conjunction with biological mass spectrometry are used to characterize and analyze nucleic acid therapeutics.

Bradley Hasson

Director of Lab Operations
MilliporeSigma

Bradley Hasson is the Director of Lab Operations for Next Generation Sequencing Services at MilliporeSigma (BioReliance Testing Services). Brad leads a global team of Scientists, laboratory technicians and bioinformaticians that perform regulated GMP NGS-based testing services in support of product characterization, adventitious agent detection and product release for biologically derived products worldwide. He has over 20 years of industry experience, including 16 years developing, validating and commercializing molecular-based methods for the purposes of biosafety testing and characterization in a variety of biologically derived products.

Jeremy Henderson, Ph.D.

Development Scientist
New England Biolabs

Jeremy Henderson joined New England Biolabs in 2022 as a Development Scientist for the RNA and Genome Editing portfolio. His first commercial products: RNase 4 and RNase 4 Digestion and 3' End Repair Mix were released in 2024. His interest in RNA biochemistry extends from early efforts as an undergraduate researcher investigating the enzymology of a broadly conserved tRNA methyltransferase implicated in diabetes and human developmental disorders. Jeremy obtained a PhD in Microbiology from The University of Texas, where he used biochemical, and mass-spectrometry based approaches to characterize bacterial cell surface remodeling of pandemic Vibrio cholerae. His postdoctoral efforts investigated how tRNAs are sorted into extracellular vesicles released by human cancer and stem cells, with later work studying a nutrient sensitive tRNA modification in the classical model parasite Trypanosoma brucei. Outside of work, Jeremy is an avid trail runner and a dead-eye dart thrower.

Bala Addepalli

Director - Evaluation and Application Science
Waters Corporation

Bala Addepalli has an impressive background in the field of cell and gene therapy product analysis. Currently, he is the Director of the Evaluations and Application Science Team under the Genomic Medicine portfolio at Waters Corporation. His work focuses on developing efficient approaches for analyzing genetic medicines such as mRNA, LNP, and viral vectors using advanced techniques like liquid chromatography coupled with mass spectrometry or light scattering.

Before joining Waters, Bala made significant contributions at the University of Cincinnati, where he developed novel enzymes and analytical methods for RNA characterization. His earlier work includes research on mRNA polyadenylation at the University of Kentucky and viral RNA characterization during his graduate studies in India.

With over 60 publications and numerous presentations at scientific meetings, Bala's expertise is well-recognized in the scientific community.