Speaker Biographies

(Listed in speaking order)
As of April 8, 2024

FOUAD ATOUF, Ph.D.

Senior Vice President of Global Biologics
United States Pharmacopeia Convention (USP)

Dr. Fouad Atouf, Ph.D., is Senior Vice President, Global Biologics at the United States Pharmacopeia Convention (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, the biopharma industry, and global government agencies. Dr. Atouf has a strong background in regulating and standardizing 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.

MICHAEL R. De FILIPPIS, Ph.D.

Chair, USP Peptide and Oligonucleotide Therapeutics Workshop Steering Committee, and Chair, USP BIO1 – Peptides and Insulins Expert Committee

Dr. Michael R. De Filippis is the Senior Vice President of Research in the Bioproduct Research and Development Organization of Eli Lilly and Company. He is responsible for providing strategic scientific oversight of the CMC activities for the biopharmaceutical product portfolio, emphasizing analytical, process, and product development, control strategy definition, and preparation of CMC-related regulatory documentation supporting global licensure. Professional activities external to Lilly include being a member of the USP Council of Experts, Chair of the USP Expert Committee on Therapeutic Peptides and Oligonucleotides, member of the European Pharmacopoeia Gene Therapy Products Working Party, and member of the EFPIA ATMP Manufacturing and GMP Sub-team.

VED SRIVASTAVA, Ph.D.

Chief Technology Officer

Dr. Ved Srivastava is the Chief Technology Officer – Dr. Srivastava brings to Perpetual Medicines more than 25 years of experience in the discovery and development of peptide therapeutics. He joined Perpetual from Aktis Oncology. He was instrumental in the development of several peptide-based drugs, including Byetta™, Symlin™ and Bydureon™. He has served as Head of Peptide Chemistry at both GlaxoSmithKline and Amylin Pharmaceuticals. He was also a co-founder at Phoundry Pharma and Vice President of Chemistry at both Intarcia and Aktis. Ved is a former president of the American Peptide Society (APS).

KEVIN CARRICK, Ph.D.

Senior Director Biologics Science & Standards
United States Pharmacopeia Convention (USP)

Dr. Kevin Carrick is a Senior Director of Science & Standards in USP's Global Biologics Department. Dr. Carrick and his team work with the five USP Expert Committees and multiple Expert Panels in the area of biologics to develop standards that support biopharmaceutical quality assessment. These standards include documentary (monographs and general chapters) and physical reference standards for varied products from peptides to cell therapies.

RENÉ THÜRMER, Ph.D.

CMC reviewer and Deputy Head of the Unit Pharmaceutical Biotechnology
BfArM - Federal Institute for Drugs and Medical Devices

Dr. René Thürmer received his diploma in chemistry and his Ph.D. in biochemistry from the University of Tübingen. He joined the BfArM (Federal Institute for Drugs and Medical Devices, Bonn, Germany) in 2000. He is a CMC reviewer and Deputy Head of the Unit Pharmaceutical Biotechnology. His experience is in the field of formulation, manufacture, and control of medicinal products, in particular in the field of oligonucleotides, peptides, proteins, liposomes, sustained-release polymer-drug products, depot formulations, polymer-conjugated drug products, natural and synthetic surfactants, nanomedicine and others. He is a member of the EMA Quality Innovation Group (QIG), established in 2022.

LAWRENCE B. PEREZ, Ph.D.

Senior Pharmaceutical Quality Assessor
U.S. Food and Drug Administration

Dr. Lawrence B. Perez obtained his Ph.D. from Massachusetts Institute of Technology under the direction of Professor George Whitesides, and he did a post-doctoral study with Professor Dale Poulter at the University of Utah. Lawrence joined Sandoz Pharmaceuticals in 1987 as a medicinal chemist working in atherosclerosis. In 1996, he joined the oncology group at Novartis, where he designed and first synthesized the market drug Farydak® for treating multiple myeloma and co-discovered the CDK4/6 inhibitor Kisqali® for treating breast cancer. In 2016, Lawrence moved to the FDA, where he is a Senior Pharmaceutical Quality Assessor in the Office of Pharmaceutical Quality.

KATHARINE DUNCAN, Ph.D.

Senior Pharmaceutical Quality Assessor
U.S. Food and Drug Administration

Dr. Katharine Duncan is a Senior Pharmaceutical Quality Assessor with the Office of Pharmaceutical Quality Assessment III within the Office of Pharmaceutical Quality at the Food and Drug Administration. Dr. Duncan joined the FDA in 2019 after several years working in medicinal chemistry at a pharmaceutical company in San Diego. Her Ph.D. research was conducted in the laboratory of Dr. Dale Boger at the Scripps Research Institute in La Jolla, California. She received her undergraduate degree in chemistry from Amherst College in Amherst, Massachusetts.

MARC M. LEMAITRE, Ph.D.

Independent Consultant

Dr. Marc Lemaitre holds a Ph.D. in organic chemistry and a Ph.D. in biochemistry; since 1985, Marc's professional interest has been the study and manufacturing of Nucleic Acids therapeutic as well as diagnostic applications.
Since 2013, Marc has been working as an independent consultant specializing in Oligonucleotide Therapeutics CMC and regulatory. He is also a member of the USP Peptides and Oligonucleotides Expert Committee.

DAVID BUTLER, Ph.D.

Chief Technology Officer
Hongene Biotech Corporation

Dr. David Butler, Ph.D., is the Chief Technology Officer at Hongene Biotech Corporation, a vertically integrated raw materials supplier and CDMO services provider that is focused on the RNA manufacturing space, the scope of which includes mRNA, vaccines, oligonucleotides, gene editing, and gene therapy. Before Hongene, he led organizations driving drug discovery and development of oligonucleotide therapeutics as V.P. and Head of Medicinal Chemistry at Wave Life Sciences, V.P. and Head of Therapeutics Development at Alltrna, and V.P. and Head of Chemistry at Korro Bio. He also spent time as a Principal Scientist at Alnylam Pharmaceuticals, developing early LNP technologies for siRNA delivery that were the progenitors of those used for mRNA-related products today. He is passionate about team building, working with individuals and companies to help them succeed, and leveraging novel technologies to advance RNA medicines more efficiently and safely.

MARTINA AUSTERI, Ph.D.

Director Quality Control
Bachem

Dr. Martina Austeri joined Bachem (Bubendorf, Switzerland) in 2020 as a Senior Chemist in the analytical development department of Q.C. She then transitioned to a Group Leader role, where she was responsible for the release of raw and starting materials. In her current position as Director QC, she is responsible for the analytical development, method validation, and release of raw and starting materials. Therefore, her primary focus lies in the establishment of suitable control strategies to guarantee high API quality. Martina holds a Ph.D. in organic chemistry in the field of enantioselective organometallic catalysis at the University of Geneva (C.H.). She completed her education with two post-doctoral stays at the Manchester Institute of Biotechnology (U.K.) and the Karlsruhe Institute of Technology (D.E.)

.

DENNIS RHODES, Ph.D.

Associate Director in Analytical Development and Quality Control
Ionis Pharmaceuticals

Dennis Rhodes joined Ionis Pharmaceuticals in 2008 and is currently an Associate Director in Analytical Development and Quality Control. He and his group focus on GMP release and retesting of raw and starting materials for oligonucleotide therapeutics. He is an SME on the control strategy, analysis, method development, and method validation of nucleoside phosphoramidites and other oligonucleotide starting materials.

GERHARD HAAS, Ph.D.

Vice President of Quality Europe
Bachem AG

Dr. Gerhard Haas was heading the Central Function Quality of Bachem's European sites until he partially retired in 2023. Before, he had led the QA/RA department of the Bubendorf site for more than ten years. Gerhard has been with Bachem in Switzerland and the U.S. since 1992 in various positions, including Q.A., QC, R.A., Production, and R&D. He holds a Ph.D. in Organic Chemistry from the University of Stuttgart, Germany.

TIM HELLENBRAND, Ph.D.

Senior Group Leader for Analytical Development
Bachem AG

Dr. Tim Hellenbrand is a chemist by training, with a Ph.D. in pharmaceutical chemistry from the Ludwig-Maximilians University Munich, studying synthesis and evaluation of GABA Reuptake Inhibitors. Tim joined the industry in 2016 and held various roles of increasing responsibility in Bioanalytics. Tim joined Bachem AG in 2021 as a Senior Group Leader for Analytical Development. Currently, he is responsible for developing chromatographical methods of peptides and oligonucleotide NCE projects, assuring successful CMC development.

YING QING YU, Ph.D.

Biopharmaceutical Program Science Team Leader
Waters

Ying Qing is the Biopharmaceutical Program Science Team Leader at Waters Corporation. She joined Waters Corporation in 2001, shortly after she received her Ph.D. from the Analytical Chemistry Department at Purdue University. Her area of expertise is in analytical method development for various Biotherapeutics using the UPLC/QTOF MS platform, including sample preparations, LC-MS optimization, and development of application-specific software tools. Recently, her team has been taking on the challenges of developing LC-MS solutions for nucleic acid characterization.

ANNA CODINA, Ph.D.

Senior Director Biopharma and Strategic Market Development
Bruker BioSpin

Dr. Anna Codina has a degree in Chemistry and a PhD in Protein NMR from the University of Barcelona, Spain. She undertook her post-doc in protein NMR at the MRC Laboratory of Molecular Biology in Cambridge, UK, and following that, worked in the Analytical R&D department of Pfizer for eight years, becoming proficient in low-level impurity structure elucidation, reaction monitoring, qNMR, and the preparation of regulatory documentation. She received a Pfizer Worldwide Achievement Award for implementing reaction monitoring by NMR in an open-access environment. She joined Bruker in 2011 as Material Characterisation Laboratory Manager and is now Senior Biopharma and Strategic Market Development Director.

RANAJOY MAJUMDAR, Ph.D.

Director (Scientific), Analytical Development Bioproducts Research and Development
Eli Lilly and Company

Dr. Ranajoy Majumdar, Ph.D., joined the Lilly Research Laboratories of Eli Lilly and Company in 2014 after earning his doctorate in Pharmaceutical Chemistry from the University of Kansas. He is working on developing peptides, oligonucleotides, and protein biotherapeutics, focusing on characterizing higher-order structures and interactions needed to understand physicochemical properties and analytical control strategies. His team also supports preparing and justifying CMC data packages to support worldwide regulatory submissions. He has published several manuscripts, review articles, and a book chapter on the interrelationship between protein higher order structure, its dynamics, and its pharmaceutical properties, such as stability. He actively participates in industry consortia (CASSS and EPOC) sub-teams working on the higher-order structure and aggregation. He is also a co-inventor on patents for insulin compositions.

KUI YANG, Ph.D.

Senior Research Scientist
U.S. Food and Drug Administration

Dr. Kui Yang is a Senior Research Scientist in the Office of Pharmaceutical Quality Research at CDER FDA. She specializes in mass spectrometry-based analytical method development. Her research in regulatory science centers on the analysis of complex drug products to provide scientific inputs on drug quality questions. She leads an oligonucleotide research team and cross-office working group and serves as a subject matter expert in oligonucleotide product-specific guidance development at FDA. Before joining the FDA in 2016, Dr. Yang held the position of Instructor in Medicine at Washington University School of Medicine, conducting mass spectrometry-based lipidomics and biomarker research related to diabetes, heart disease, and Alzheimer's disease for over ten years.

MOHAN DHOTE, Ph.D.

Assistant General Manager,
Synthetic Peptide Department,
Enzene Biosciences, Pune, India

Mohan Dhote is masters in Organic Chemistry and is pursuing his Ph.D. in JNTU Hyderabad.
He has worked with Biological E. Aurobindo Pharma, Jupiter life sciences and 3A Chemie.
He brings around 25 years of rich industrial experience in R&D, scale up and Manufacturing in Pharma API drugs & peptides.
He has expertise in pharmaceutical drugs API, Intermediate, Fine chemicals, custom synthesis and peptide synthesis & has proven track record of successfully launching new products and optimizing processes to improve quality and efficiency.

Chandrakant Kulkarni, Ph.D.

Principal Scientist – Synthetic Peptide Department R&D Center
Enzene Biosciences, Pune, India

Chandrakant has a master's degree in Organic Chemistry. He has worked with Dr. Reddy's Laboratories, Piramal Pharmaceuticals (formyl Hemmo Pharmaceuticals), Emcure. He brings around 14 years of industrial experience in R&D and Technology Transfer in generic peptide drugs. He has expertise in generic peptide process developments, scale-up, process transfer, and process validations on a commercial scale. He has been part of Enzene for the past 8 years. Chandrakant is part of a team that has 2 international process patents for process optimization of complex generic peptides. He has experience in complex peptide process development and custom peptide synthesis.

DANIEL SAMSON, Ph.D.

Head Oligonucleotides
BACHEM

Dr. Daniel has 17 years of industry experience with an emphasis on TIDES process R&D, manufacturing, and CMC development. He currently leads Bachem's oligonucleotide unit, which includes innovation projects, process R&D, and manufacturing activities. Daniel holds a PhD in organic chemistry from the University of Konstanz (Germany) and an MBA from the International Institute for Management Development (IMD), Lausanne (Switzerland). In previous career stages, he was a lab head for process optimization, technology transfer, Quality by Design, and scale-up of synthetic peptide manufacturing procedures. From 2012, Daniel was a Vice President of API Manufacturing. He was responsible for all large-scale solid-phase peptide and oligonucleotide syntheses, downstream operations, and CMC activities within Bachem AG.

MARCO MACIS, Ph.D.

Research & Development Manager for Peptides API
Fresenius Kabi iPSUM

Dr. Marco Macis is the Research & Development Manager for Peptides API at Fresenius Kabi. After the conclusion of his Ph.D. in Chemistry at Bologna University, he started to work in the Research & Development team of Fresenius Kabi as a research assistant, becoming 2021 the Research & Development Manager for Peptides API. His work is focused on process development and scale-up together with all the aspects of analytical characterization of Peptides.

ANTONIO RICCI, Ph.D.

Vice President of API Research & Development and Regulatory Affairs
FRESENIUS KABI.

Dr. Antonio Ricci is the Vice President of API Research & Development and Regulatory Affairs at Fresenius Kabi. His work is focused on developing innovative synthetical and purification routes of Small Molecules and Peptides API at an industrial scale and designing tailored analytical methods for their characterization. Since 2020, he has been a member of the USP Expert Committee for TIDES (Peptides & Oligonucleotides). He is the co-author/inventor of more than 60 publications between scientific papers and patents.

BRIAN W. PACK, Ph.D.

Executive Director
Eli Lilly and Company

Dr. Brian W. Pack received his Ph.D. in analytical chemistry from Indiana University and joined Eli Lilly as a senior analytical chemist in 2001. At Eli Lilly and Company, he has contributed regulatory specifications to all phases of development, from first in human studies to marketing applications. He is an Executive Director in early phase analytical development, overseeing control strategy development for small organic molecules, peptides, and oligonucleotides. Dr. Pack is responsible for specification review for all synthetic molecules in the portfolio and is passionate about this topic. He has over 25 publications, including three book chapters, mainly focused on the issues of cleaning verification and chromatographic applications, and has given presentations on the topics of HILIC separations, colorimetric determinations for pharmaceuticals, genotoxic impurity control strategy, and nasal delivery of peptides.

ANNIE DE GROOT, M.D.

CSO and Chairman of the Board
EpiVax, Inc.

Dr. Annie De Groot served as Chief Executive Officer and Chief Scientific Officer of the biotech company EpiVax for 25 years. Currently, she maintains her role as CSO and continues to lead EpiVax as Chairman of the Board. She is a University of Chicago and Smith College graduate, trained in Infectious Disease at New England Medical Center and Vaccines and Immunology at the National Institutes of Health. She is the author of 228 publications and 46 patents. In addition to engaging in a wide range of research at EpiVax, Brown, URI, and the University of Georgia, she actively participates in two not-for-profits, Clinica Esperanza and the GAIA Vaccine Foundation.

ERIC PANG, Ph.D.

Senior Chemist
U.S. Food and Drug Administration

Dr. Eric Pang specializes in analyzing peptide and large-molecule drugs. As the senior chemist and subject matter expert, he is involved with developing policies to support the review of generic peptide products. He is mainly responsible for drafting product-specific guidance for complex drug products, responding to queries submitted through controlled correspondences and pre-ANDA meeting requests, and supporting the Agency's responses to citizen petitions. He also manages several regulatory science projects on generic complex drug substances and products. Eric has over eleven years of experience in the Agency as a research chemist, a CMC reviewer, and a policy lead.