USP Biologics Stakeholder Forum

Innovative Analytical Approaches to Cell and Gene Therapy

NGS and other methods

February 22, 2024
8:30a.m. - 4:00p.m. (ET)
USP Headquarters in Rockville, MD

Speaker Biographies

(Listed in speaking order)
As of February 19, 2024

FOUAD ATOUF, Ph.D.

Senior Vice President of Global Biologics
USP

Fouad leads USP's Biologics program. His work focuses on developing and launching solutions-based products and approaches for complex biologics such as monoclonal antibodies, proteins, vaccines, and cell and gene therapies. He leads USP's collaboration with stakeholders in these areas and the exploration of new tools to enable manufacturing and quality of emerging therapeutic modalities.

Fouad joined USP in 2006 and has served in multiple scientific leadership roles, developing quality tools for biologics and establishing relevant reference material programs. In addition to leading the modernization of existing standards, Fouad played a central role in launching USP's biologics strategy in 2017. Since then, it has led its implementation, focusing on technologies used to manufacture and test biological medicines.

In 2021, Fouad's role expanded to include management and accountability for USP's Biologics business unit. He has used innovative approaches to launch USP biological offerings and implemented new models for engagement and collaboration with academia, the biopharma industry, and global government agencies.
Recognized as a thought leader in the life sciences sector, Fouad is relied upon for his expertise, frequently representing USP at global pharmaceutical science events. Fouad has built a network of strong relationships with global stakeholders and continues to execute collaborations with key partners that increase the visibility and growth of the USP biologics portfolio.

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ED CHESS, Ph.D.

Biologics Stakeholder Forum Planning Committee Chair, USP

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 and 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, extractables, and leachables at Baxter Healthcare before 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 the Biologics Stakeholder Forum Planning Committee. When not attending USP teleconferences, Dr. Chess enjoys building and flying model rockets and woodworking.

BEN CLARKE, Ph.D.

Senior Scientist II, Global Biologics USP

Ben Clarke supports USP's documentary and physical reference standards portfolio for the Global Biologics group. He specializes in cell and gene therapy, vaccines, and monoclonal antibodies. Before joining USP, Ben developed analytical bioassays at GSK Vaccines for RSV and self-amplifying mRNA vaccines. Before GSK Vaccines, he pioneered the development of mouse models of sphingolipid biology using CRISPR/Cas9 genome editing technology at the National Institute for Health. Before NIH, he optimized upstream PER.C6 cell culture for the production of adenovirus at Janssen. He received his Ph.D. from Cornell University for his work on mammalian membrane biology and lipid

remodeling enzymes. He received his B.S. in biochemistry, molecular biology, and cell biology from Pennsylvania State University.

GAËL DEBAUVE, Ph.D.

Head Of Gene Therapeutics Cmc Analytics
Ucb Pharma S.A.

Gaël has worked in Quality Control roles within the Biotech industry for 16+ years, including nine years supporting bioassay development. Since Feb 2020, he has led the Gene Therapy Analytical Sciences team, whose focus is to build a solid analytical package to characterize and release viral vector-based gene therapy products. Gaël holds a Ph.D. in Biomedical Sciences (University of Mons, Belgium) and a master's degree in management (Louvain School of Management, Belgium). On top of the activities at UCB, Gael is Associate Professor at the University of Mons (Belgium) and is contributing to Official International Organizations both in Europe (European Directorate for the Quality of Medicines and HealthCare (EDQM, mAb & G.T. Product working parties), Belgian Pharmacopeia Commission) and in the U.S. (U.S. Pharmacopeia (USP AAV Gene Therapy Expert Panel and Biologics Stakeholder Forum Steering Committee)).

GWENAËL CIRÉFICE, Ph.D.

Scientific Programme Manager
EDQM

Gwenaël Ciréfice holds a PharmD degree from the University of Strasbourg, France. He began his career in the vaccine industry in 2007 as a regulatory affairs manager before later joining the Quality of Medicines department of the European Medicines Agency in 2010, with responsibilities in the field of human vaccines and recombinant proteins. He joined the EDQM in 2014 as a Scientific Programme Manager in the European Pharmacopoeia Department, supporting the work of Expert Groups in the area of biologicals, including Group 15 (Vaccines and sera for human use), Group 6 (Biological substances), Working Parties on Host-cell protein assays, Endotoxin and pyrogen testing, and more recently the Working Party on High Throughput Sequencing.

ARIFA S. KHAN, Ph.D.

Supervisory Microbiologist
U.S. Food and Drug Administration

Dr. Arifa S. Khan is a Supervisory Microbiologist and Head of the Molecular Retrovirology Unit Division of Viral Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration. She moved from NIAD/NIH to CBER in 1991, where she is currently leading efforts on high-throughput sequencing to detect adventitious viruses and endogenous retroviruses for the safety evaluation of cell substrates and biologics. Her primary regulatory responsibilities include viral vaccines, such as HIV-1, influenza virus, RSV, and SARS-COV-2. Dr. Khan also provides expert consultation on viral safety and testing to OTAT/CBER and CDER. She has been involved in the licensure of several viral vaccines and contributed to developing various guidelines from the FDA, ICH, PHS, and USP. She is the FDA Deputy Topic Lead in the ICH Q5A(R2) Implementation Working Group. Dr. Khan obtained her Ph.D. in Microbiology from George Washington University, Washington, D.C. She has authored over 100 publications. Over 40 peer-reviewed articles and has been an invited speaker or workshop organizer for numerous.

KOK-SEONG (KS) LIM, Ph.D.

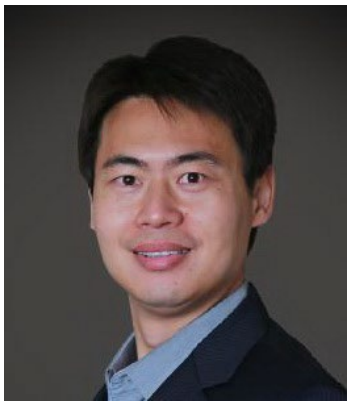
Metagenomi

Kok-Seong Lim is a Senior Director of Analytical Sciences and Quality Control at Metagenomi, developing CRISPR-based medicines for the treatments of cancer (ex vivo therapies) and rare diseases (in vivo therapies). Previously, he was a director of Analytical Sciences at Aura Biosciences and a director of AAV Process and Analytical Development at Editas Medicine, where he helped develop small molecule drug-conjugated virus-like particle technology for the treatment of ocular melanoma and CRISPR-based adeno-associated virus technology for the treatment of ocular disorders like Leber Congenital Amaurosis (LCA10) and Autosomal Dominant Retinities Pigmentosa 4. Before that, he was the Head of Analytical Sciences in Viral Vector Services at Thermo Fisher Scientific, previously known as Brammer Bio, where he managed multiple late-stage analytical programs for viral vector-based gene therapies. He also held various scientist roles at Brammer Bio, Avitide, Massachusetts Institute of Technology (MIT), and University of California San Diego (UCSD). Kok Seong Lim holds a Ph.D. in Biochemistry from the National University of Singapore (Singapore) and a BSc in Pharmacy from the University of Strathclyde (Scotland, UK).

COLETTE CÔTÉ, Ph.D.

Chief Scientific & Portfolio Officer and U.S. General Manager

Colette joined PathoQuest's U.S. subsidiary as General Manager and Chief Scientific and Portfolio Officer in March 2021. Dr. Côté's expertise and long history of innovating, developing, and applying tailored NGS-based assays to the biopharma biosafety testing space has driven the expansion and growth of NGS far beyond its early applications, with a view towards the future. Before joining PathoQuest, Dr. Côté was Director and Head of NGS R&D Testing Services at MilliporeSigma, with responsibilities for overseeing MilliporeSigma's global NGS operations for the testing services business. This included being integral to developing a wide range of novel NGS applications over the past 16 years. As a part of this previous role, Dr. Côté worked closely with key stakeholders in the industry and has spoken as a key opinion leader in consortiums and conferences to highlight the advantages of NGS in this field. This vast experience, ranging from the initial build-out of an NGS laboratory focused on biosafety testing to assay development and deployment to meet industry and regulatory expectations worldwide, has been pivotal to the advancement of the use of NGS technology in this field. Dr. Côté's experience also includes the development of novel therapeutics and applications at several small start-up companies. Dr. Côté received a Ph.D. in Molecular Biology, Cell Biology, and Biochemistry from Brown University and was a postdoctoral fellow in the Genetics and Biochemistry Branch of the National Institutes of Health (NIH).



AARON ZHANG-CHEN, Ph.D.

Chief Technology Officer
Genegocell

Dr. Aaron Zhang-Chen received his Ph.D. with honors in Molecular Genetics at the University of Kansas Medical Center and completed his postdoctoral training at UCSD and Salk Institute. At Pathway Genomics, Dr. Zhang-Chen managed a team focusing on CLIA assay development and validation and the bioinformatics pipeline. In 2017, Dr. Zhang-Chen founded Genenius Genetics, focusing on platform development for genetic testing. After co-founding GeneGoCell in 2020, Dr. Zhang-Chen served as chief technology officer and focused on developing innovative technologies for genome editing verification.

JARROD DEAN, Ph.D.

Director of the NGS group
Sanofi

Jarrod Dean is an associate director of the NGS group within the Genomic Medicine Unit, BioAnalytics CMC of Sanofi (Waltham, MA). He leads a team of scientists dedicated to establishing internal, end-to-end NGS solutions supporting viral and non-viral gene therapy programs. He has been with Sanofi for the past 13 years and serves as a molecular subject matter expert and technology innovation champion.

Michael Jesudoss, Ph.D.

Senior Scientist, NGS,
BioMartin Pharmaceutical Inc.

Dr.Jesudoss earned his Ph.D. degree in Stem Cell Biology and Functional Genomics from University of Cologne, Germany. Currently, he is a Senior Scientist, Technology Development, at BioMarin Pharmaceutical Inc, California. His primary focus is on improving NGS methods for gene therapy vector (including rAAV) genome sequencing with the goal of transforming NGS technologies into reliable tools for gene therapy product and process characterizations. Before joining BioMarin, Dr.Jesudoss served as the Director of the Stem Cell Center at Masonic Medical Research Laboratory, Utica, NY. Dr.Jesudoss has a long-standing, multifaceted experience in stem cell biology, developmental cardiology, cell-based assays, molecular biology, tissue engineering, 'Omics technologies, Artificial Intelligence/Deep Learning and bioinformatics. One of his scientific articles, *Current Challenges of iPSC-Based Disease Modeling and Therapeutic Implications. Cells: 2019 Apr 30;8(5)*, has been one of the extremely highly cited articles with >280 citations, as of the year 2023.