FDA Scientific Public Workshop: Next-Generation Sequencing for Adventitious Agent Detection in Biologics – September 23, 2026

Speaker Biographies

Session 1: Perspectives from FDA CBER

Arifa Khan, PhD

Head, Molecular Retrovirology Unit, Laboratory of Retroviruses, Division of Viral Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration

Dr. Arifa S. Khan is Head, Molecular Retrovirology Unit, Division of Viral Products, Office of Vaccines Research and Review, in the Center for Biologics Evaluation and Research, U.S. Food and Drug Administration. Her current research efforts are focused on implementation of high-throughput sequencing technologies for adventitious virus and endogenous retrovirus detection for safety evaluation of cell substrates and biological products. Dr. Khan's primary regulatory responsibilities include review submissions related to viral vaccines, including HIV-1, influenza virus, RSV and SARS-COV-2. She also provides expert consultation on viral safety testing to OTAT/CBER and CDER offices. Dr. Khan has been involved in licensure of several viral vaccines and has contributed to the development of FDA, ICH, PHS, USP, and WHO documents. She served as the FDA Deputy Topic Lead in the Expert Working Group for updating the ICH Q5A(R2) guideline on viral safety of biotechnology products and contributed to the development of the Ph. Eur. 2.6.41 chapter on High Throughput Sequencing. Dr. Khan obtained her PhD in Microbiology from the George Washington University, Washington, D.C. She has authored more than 100 publications.

Sandip De, PhD

Principal Investigator and CMC/BI Reviewer, Office of Cellular Therapies and Human Tissues, Office of Therapeutic Products, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration

Dr. Sandip De is a Principal Investigator at the U.S. Food and Drug Administration's Center for Biologics Evaluation and Research (CBER), where his team develops next-generation sequencing (NGS) and bioinformatics approaches for pathogen detection and biologics safety. His expertise spans genomics, molecular biology, infectious diseases, and regulatory science, with prior research experience at the NIH and the University of Maryland. Dr. De has led studies on NGS-based adventitious agent detection and viral genomics and has authored numerous peer-reviewed publications. He earned his PhD in Molecular and Cellular Biology from the University of Birmingham, UK, and is committed to advancing innovative technologies for biologics evaluation and mentoring the next generation of scientists.

Session 2: CRO's Efforts for NGS Implementation

Marc Eloit, PhD

Professor of Virology, Veterinary School of Maisons-Alfort and Founder and Scientific Advisor, PathoQuest

Dr. Marc Eloit served as a Professor of Virology at the Veterinary School of Maisons-Alfort and held the position of Head of the Pathogen Discovery laboratory at Institut Pasteur Paris until October 2023. He is a pioneer and consultant in virus discovery and safety of biologicals. He has published a large number of scientific papers in the field of virology. He was a member of the Virus Safety of Medicinal Products Committee, French Agency of Medicinal Products (1992-2013). In 2010, he founded PathoQuest, a spin-out of Institut Pasteur dedicated to the comprehensive testing of biologicals using untargeted Next Generation Sequencing. Serving as its Chief Scientific Officer till 2016, he currently acts as a Scientific Advisor for the company.

Bradley Hasson

Director of Lab Operations for Next Generation Sequencing Services, BioReliance

Bradley Hasson is the Director of Lab Operations for Next Generation Sequencing Services at MilliporeSigma, supporting BioReliance Testing Services. Brad leads a global team of scientists, lab technicians, and bioinformaticians that develop and 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 20+ years of industry experience, including 18 years developing, validating and commercializing molecular-based methods for the purposes of biosafety testing and characterization in a variety of biologically derived products.

Andy Bailey, PhD

Chief Scientific Advisor, ViruSure

Dr. Andy Bailey, originally a chemist/biochemist, later specialized in virology during his 9-year tenure at the MRC Virology Unit in Glasgow, Scotland, where he focused on studying Herpesviruses and Adenoviruses. In 1995, he transitioned to industry, first as Director of Virus Validation Services at Q-One Biotech Ltd, and later as part of the Pathogen Safety group of Baxter Healthcare in Vienna, Austria. With over 30 years of expertise in virus and prion safety, Andy has presented at numerous regulatory agencies and conferences, supporting product registrations, and contributing as an invited speaker at expert workshops. Additionally, Andy served as an external expert for the EU SCENIHR committee on emerging human health risks, coauthoring an opinion on "The Safety of Human-derived Products with regard to Variant Creutzfeldt-Jakob Disease". In 2005, Andy founded ViruSure, driven by a commitment to delivering reliable, high-quality testing services to the biopharmaceutical industry, a philosophy that remains a key focal point to the company today.

Sivan Bercovici, PhD

Chief Technology and Business Officer, Karius Diagnostics

Dr. Sivan Bercovici is Chief Technology Officer and Chief Business Officer at Karius, where he has led the data and AI vision and the computational development behind the company's clinical metagenomics platform since its earliest days. His work covers the computational side of microbial cell-free DNA sequencing, spanning analytical performance, quality control, validation strategy, and result interpretation. The platform has since supported more than 150,000 clinical cases across hundreds of institutions and generated data underlying more than 300 peer-reviewed publications. The Karius Test has been granted designation as a Breakthrough Device by FDA for use in the diagnosis and management of immunocompromised patients with suspected lung infections. Prior to Karius, he was co-founder and Chief Technology Officer at Lifecode, leading the development and validation of clinical assays across oncology and rare disease. He holds a PhD in Computer Science from the Technion, Israel Institute of Technology, and completed postdoctoral research at Stanford's Artificial Intelligence Lab.

Session 3: NGS Applications for Adventitious Virus Detection

Sandra Fuentes, PhD

Microbiologist, Laboratory of Retroviruses, Division of Viral Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration

Dr. Sandra M. Fuentes is a virologist and regulatory scientist with more than 15 years of experience in virology, molecular biology, and vaccine research. She earned her Doctorate in Pathobiology from Pennsylvania State University, where her research focused on respiratory syncytial virus (RSV) protein function and host-virus interactions. Dr. Fuentes joined the Center for Biologics Evaluation and Research (CBER) at the FDA in 2011 as a postdoctoral ORISE Fellow in the Office of Vaccines Research and Review, where she investigated the antibody repertoires of RSV-infected and vaccinated individuals to identify protective epitopes. She currently serves as a Researcher and Product Reviewer in the Division of Viral Products (DVP), where her research focuses on the development and characterization of standards for evaluating next-generation sequencing (NGS) workflows used in the detection of adventitious viruses in biological products.

Siemon Ng, PhD

Scientific Lead – Genomics, Canadian Blood Services

Dr. Siemon Ng is the Scientific Lead for Genomics for the Canadian Blood Services. Dr. Ng has over 15 years of experience in analytical development, QC testing, and assay validation including next generation sequencing across biotech, pharmaceutical, and non-profit organizations. He has contributed to regulatory and scientific initiatives that advanced the use of NGS across cell and gene therapies, vaccines, and other biologics. Dr. Ng is a co-chair and an active member of the

Advanced Virus Detection Technologies Working Group and has participated in multiple collaborative studies.

Binsheng Gong, PhD

Bioinformatician, Division of Bioinformatics and Biostatistics, National Center for Toxicological Research, U.S. Food and Drug Administration

Dr. Binsheng Gong is a bioinformatician at the U.S. FDA's National Center for Toxicological Research. Since joining NCTR in 2012, his research has focused on next-generation sequencing, bioinformatics pipeline development, genomic technology evaluation, regulatory science, and AI applications in biomedical research. He has contributed extensively to FDA-led Sequencing Quality Control projects, including SEQC1 and SEQC2. His recent work includes the development of the AdventSeq pipeline for the detection of adventitious viral agents using RNA-seq, as well as the application of LLM-based reasoning to extract drug safety insights from biomedical literature. He has authored more than 30 research articles, which have received over 3,200 citations.

Session 4: NGS Detection of Nonviral Agenda

Scott Jackson, PhD

Founder and Principal, The NEST

Dr. Scott Jackson is founder and principal of The NEST. He is a former federal scientist with expertise in microbiology, genomics, and biotechnology and has over 22 years of leadership experience at the U.S. Food and Drug Administration and the National Institute of Standards and Technology (NIST). At NIST, Dr. Jackson founded and led the NIST Microbiome and Biosurveillance Programs, pioneering the development of critical measurement standards to advance microbiome science, public health, environmental biosurveillance, and biodefense. He also co-founded and led the International Microbiome and Multi-omics Standards Alliance, which now includes over 900 members worldwide, and the Rapid Microbial Testing Methods consortium, which brings together over 50 member institutions to advance innovation in microbial detection and quality assurance. Dr. Jackson holds leadership roles in the Genomic Standards Consortium, the United States Pharmacopeia Probiotics Expert Committee, and is an adjunct assistant professor at the George Washington University School of Medicine and Health Sciences.

Jason Kralj, PhD

Researcher, National Institute of Standards and Technology

Dr. Jason Kralj works at the U.S. National Institute of Standards and Technology, focusing on metagenomic applications of pathogen detection in biosurveillance, microbiome, and biomanufacturing. He co-leads the Interlaboratory Studies Working Group in the Rapid Microbial Testing Methods Consortium, which seeks to address the need for rapid sterility testing in short

shelf-life CGT products. Recently, he has begun establishing a NIST microbial strain bank to collect and characterize strains for use in the areas listed above for reference materials and developing complex engineered communities.

Tyler Laird, PhD

Bioinformatician, National Institute of Standards and Technology

Dr. Tyler Laird is a bioinformatician in the Complex Microbial Systems Group at the National Institute of Standards and Technology (NIST), where he develops and applies computational approaches to advance biosurveillance in pathogen detection, nucleic acid synthesis sequence screening, and sterility testing. He holds a PhD in Microbiology from the University of California, Davis, with a focus on comparative bacterial genomics. Within the NIST Rapid Microbial Testing Methods (RMTM) Consortium, he co-leads the Methods and Validation Working Group, currently focused on advancing NGS-based approaches to sterility testing.

Joe DeRisi, PhD

Professor, Biochemistry and Biophysics, University of California, San Francisco

Dr. Joe DeRisi's work combines genomics, bioinformatics, biochemistry, and bioengineering to study infectious (viral, fungal, amoebic, and parasitic) and non-infectious (autoimmune) diseases in a wide range of species. His patient-based research has focused on the use of metagenomics to diagnose difficult to detect pathogens. He is a co-Founder of Delve Bio, providing metagenomic diagnostics to hospitals throughout the United States. He is a member of the National Academy of Science, the National Academy of Medicine, and the National Academy of Arts and Sciences, and was awarded a MacArthur Fellowship in 2004 as one of the pioneers of DNA microarray technology and whole-genome expression profiling.

Padmini Ramachandran, PhD

Research Microbiologist, Office of Applied Microbiology and Technology, Human Foods Program, U.S. Food and Drug Administration

Dr. Padmini Ramachandran is a scientist in the Division of Food Safety and Genomics within FDA's Human Foods Program. She has spent 16 years in FDA, applying metagenomics to food safety, developing pipelines and methodologies for pathogen detection in environmental samples and complex food matrices. Her work spans both targeted and non-targeted metagenomic approaches to characterize microbial ecologies associated with high-risk crops and identify filth in complex food commodities. She also leads the Gen-FS Salmonella serotyping working group, focused on improving geno-serotyping of Salmonella through genome indexing approaches.