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

Final Agenda

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

09:00 a.m. – 09:05 a.m.  USP Welcome and Opening Remarks
Fouad Atouf, Ph.D., Senior Vice President, Global Biologics, USP

09:05 a.m. – 09:20 a.m.  USP’s Tools to Support Quality and Consistency of mRNA Vaccines
Sarita K. Acharya, Principal Scientist, Global Biologics, USP

09:20 a.m. – 09:25 a.m.  Introduction of Speakers
Earl Zablackis, Ph.D., Chairman Bio 3, Complex Biologics and Vaccines Analytical Sciences, USP

09:25 a.m. – 09:45 a.m.  Analytical Challenges, Solutions, and Perspectives on the Future Analysis and Characterization of mRNA
Khaled Yamout, Analytical Sciences, Quality and Manufacturing Consultant
On behalf of TriLink Biotechnologies

09:45 a.m. – 10:05 a.m.  The Analytical Challenge of Particle Heterogeneity in the Development of mRNA Vaccines
Mark Brader, Research Fellow, Analytical Development, Moderna

10:05 a.m. – 10:25 a.m.  Analytical Lifecycle Management to Expand Analytical Capabilities with New Trending Techniques
Niels Delamotte, QC Director, etherna

10:25 a.m. – 10:45 a.m.  Analytical Challenges in mRNA and Circular RNA Integrity Analysis for Biopharmaceutical Development
Frank Zuo, Ph.D., Principal Scientist, Merck

10:45 a.m. – 11:00 a.m.  Break

11:00 a.m. – 11:20 a.m.  An Industry Consensus on Defining Critical Quality Attributes (CQAs) for mRNA/ LNP Products
Qin Yan, Senior Scientist, Department of Analytical Science, AstraZeneca

11:20 a.m. – 11:40 p.m.  Epidemic Preparedness: Towards Analytical Standardization for Rapid Response Vaccine Delivery
Franz Schnetzinger, Ph.D., CMC Lead, CEPI
11:40 a.m. – 12:00 p.m. **Consideration on mRNA Products Potency Testing**  
Jan Michel Falcke, Ph.D., Director AS&T Lifecycle Management, BioNTech

12:00 p.m. – 12:55 p.m. **Q&A/Moderated Discussion**  
Moderator: Khaled Yamout, Analytical Sciences, Quality and Manufacturing Consultant On behalf of TriLink Biotechnologies

12:55 p.m. – 01:00 p.m. **Closing Remarks – Day 1**  
Khaled Yamout, Analytical Sciences, Quality and Manufacturing Consultant On behalf of TriLink Biotechnologies

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

09:00 a.m. – 09:05 a.m. **Welcome & Introduction of Opening Speaker**  
Khaled Yamout, Analytical Sciences, Quality and Manufacturing Consultant On behalf of TriLink Biotechnologies

09:05 a.m. – 09:25 a.m. **Analytical Approaches for Profiling Polyadenylation (PolyA) Tails in mRNA**  
Weicheng Zhang, Ph.D., Principal Scientist – Analytical Development, CATUG

09:25 a.m. – 09:45 a.m. **Uncovering RNA Payload, Empty Particles, and Physicochemical Heterogeneity of Lipid Nanoparticles via A Single Nanoparticle Analyzer**  
Sixuan Li, Ph.D., Postdoctoral Research Associate, Department of Mechanical Engineering, John Hopkins University

09:45 a.m. – 10:05 a.m. **A Single-Nucleotide Resolution Capillary Gel Electrophoresis Workflow for Poly(A) Tail Characterization in the Development of mRNA Therapeutics and Vaccines**  
Yue Fu, Ph.D., Senior Principal Scientist, Regeneron Pharmaceuticals

10:05 a.m. – 10:25 a.m. **Effects of Ionizable and Non-ionizable Excipients on Lyophilized RNA Formulations Using FTIR/ATR Technology**  
Valentina Paolucci, Ph.D., Senior Application Scientist, PerkinElmer

10:25 a.m. – 10:45 a.m. **Advancing Gene Editing Therapeutics: Pivotal Assessment of mRNA Analytics for Phase 1 to Commercialization**  
Jeffrey Marshall, Ph.D., Director of Analytical Research and Development, Beam Therapeutics

10:45 a.m. – 11:00 a.m. **Break**

11:00 a.m. – 11:20 a.m. **Light Scattering Solutions for Multi-attribute Quantification of mRNA-lipid Nanoparticle Therapeutics**  
Martin Kurnik, Application Scientist II, Waters|Wyatt Technology

11:20 a.m. – 11:40 p.m. **The Analysis of mRNA Vaccines and Therapies Using RNA Sequencing**  
Tim Mercer, Ph.D., A/Prof and Director, Base mRNA Facility, University of Queensland
11:40 p.m. – 12:00 p.m.  **Vaxarray Platform for Rapid CQA Characterization of Multivalent mRNA Vaccines**  
Rachel Gao, Senior Scientist, InDevR

12:00 p.m. – 12:45 p.m.  **Q&A/Moderated Discussion**  
Moderator: Earl Zablackis, Ph.D., Chairman Bio 3, Complex Biologics and Vaccines Analytical Sciences, USP

12:45 p.m. – 12:55 p.m.  **Next Steps/Closing Remarks/Slido Survey**  
Earl Zablackis, Ph.D., USP Biologics Expert Committee Chair for Biologics Monographs 3 - Complex Biologics & Vaccines

1:00 p.m.  **Adjourn**