

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