

USP mRNA Virtual Summit

Joining Forces to Advance the Quality of mRNA Therapeutics

March 11-12, 2025

Virtual Event 9:00 a.m. – 1:00 p.m.

All times are in Eastern Daylight Time (EDT) – Washington DC time zone

Agenda

Day One: Tuesday, March 11th, 2025

Session 1: Analytical Techniques for mRNA Characterization

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| 09:00 a.m. – 09:10 a.m. | USP Welcome and Opening Remarks
Fouad Atouf, Senior Vice President, Global Biologics, USP |
| 09:10 a.m. – 09:15 a.m. | Introduction of Speakers
Bruce Carpick, Global Analytical Expert, Sanofi |
| 09:15 a.m. – 09:35 a.m. | An Evaluation of Key Analytical Method Parameters Relevant to the Reliable Assessment of mRNA Vaccine Integrity by CGE-LIF and IP-RPLC
Huixin Lu, Research Scientist, Health Canada |
| 09:35 a.m. – 09:55 a.m. | Development of a Novel luminescent Assay for Sensitive and Specific Quantitation of double-stranded RNA
Jamison Grailer, Sr. Research Scientist and R&D Group Leader, Promega |
| 09:55 a.m. – 10:15 a.m. | Analytical Strategies for dsRNA Detection in IVT mRNA
Weicheng Zhang, Principal Scientist -Tech Lead, CATUG |
| 10:15 a.m. – 10:35 a.m. | Analytical Case Studies of mRNA-based Vaccine and Therapeutics by Capillary Electrophoresis
Jane Luo, Senior Scientist, Cell and Gene Therapy Applications, SCIEX |
| 10:35 a.m. – 10:55 a.m. | Advancing mRNA Therapeutics with NMR Spectroscopy: Insights into Structure, Process Optimization, and Quality Control
Shubhadra Pillay, Solutions Product Manager, Bruker |
| 10:55 a.m. – 11:10 a.m. | Q&A/Moderated Discussion
Moderator: Bruce Carpick, Global Analytical Expert, Sanofi |
| 11:10 a.m. – 11:20 a.m. | Break |

Session 2: Structural and Functional Characterization of mRNA

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| 11:20 a.m. – 11:40 a.m. | Comprehensive Approach to Shape Relevant Analytical Strategy for mRNA Vaccines
Philippe Talaga, Global Head of CMC Analytical Leaders & Experts, mRNA Center of Excellence, Sanofi |
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11:40 a.m. – 12:00 p.m.	Analytical Insights in Characterization of Poly(A) Tail by Complementary Techniques Camila Ortega Ramirez, Associate Director, Analytical Services, TriLink
12:00 p.m. – 12:20 p.m.	The Role of Cell-Based Assays in Quality Control of mRNA Therapeutics: A Life-Cycle Perspective Tomasz Witkos, Associate Director, AstraZeneca
12:20 p.m. – 12:40 p.m.	Probing RNA Base Pairing and Ligand Interactions in Solution with Infrared-based Microfluidic Modulation Spectroscopy Scott Gorman, Field Applications Scientist, RedShiftBio
12:40 p.m. – 12:55 p.m.	Q&A/Moderated Discussion Moderator: Bruce Carpick, Global Analytical Expert, Sanofi
12:55 p.m. – 1:00 p.m.	Next Steps/Closing Remarks Bruce Carpick, Global Analytical Expert, Sanofi
1:00 p.m.	Adjourn

Day Two: Wednesday, March 12th, 2025

Session 3: Quality Control and Platform Analytics

09:00 a.m. – 09:05 a.m.	Welcome & Introduction of Opening Speaker Khaled Yamout, USP Expert Panel on mRNA, Chair
09:05 a.m. – 09:25 a.m.	Afrigen' s Experience of Analytical challenges in mRNA vaccines: Current solutions and future directions Astrid Trimmel, R&D Analytics Lead, Afrigen Biologics
09:25 a.m. – 09:45 a.m.	Harnessing Platform Methods for mRNA Quality Control: Challenges, Solutions, and Future Perspectives Mohamad Toutounji, CEO & Founder, Molgenium
09:45 a.m. – 10:05 a.m.	Analytical Platform Validation in the Development of mRNA Therapeutics Lea Schneider, Head Analytical Sciences & Technologies, CureVac
10:05 a.m. – 10:25 a.m.	mRNA Therapeutics - Last Chance for Platform Methods? Jan M. Falcke, Director AS&T Projects & Strategy, BioNTech
10:25 a.m. – 10:35 a.m.	Q&A/Moderated Discussion Moderator: Khaled Yamout, USP Expert Panel on mRNA, Chair
10:35 a.m. – 10:45 a.m.	Break

Session 4: Advanced Analytical Techniques and Characterization

10:45 a.m. – 11:05 a.m.	Advancing mRNA Therapeutics: Evaluating Critical Quality Attributes with Oxford Nanopore Long-Read Sequencing Kamalakar Chatla, Technical Development Scientist -Principal Scientist Genomics, Genentech
11:05 a.m. – 11:25 a.m.	Advances in Capillary Electrophoresis (CE) Analytical Techniques are Enabling the RNA Vaccine Revolution Andrew Geall, Chief Development Officer, Replicate Bioscience
11:25 a.m. – 11:45 a.m.	Direct Sequence Mapping and Characterization of mRNA Using Mass Spectrometry Mark J. Dickman, Professor Dept of Chemical and Biological Engineering, School of Chemical, Materials and Biological Engineering, University of Sheffield, UK
11:45 a.m. – 12:05 p.m.	Superior Quality Control for Next Generation mRNA Therapeutics Bradley Hasson, Director of Lab Operations, MilliporeSigma
12:05 p.m. – 12:25 p.m.	Comprehensive mRNA Characterization by LC-MS/MS using RNase 4 Jeremy Henderson, Development Scientist, New England Biolabs
12:25 p.m. – 12:45 p.m.	Novel RNases to Characterize 5' cap Impurities and Poly(A) Tail During Oligonucleotide Mapping of mRNA Bala Addepalli, Director - Evaluation and Application Science, Waters Corporation
12:45 p.m. – 12:55 p.m.	Q&A/Moderated Discussion Moderator: Khaled Yamout, USP Expert Panel on mRNA, Chair
12:55 p.m. – 1:00 p.m.	Next Steps/Closing Remarks Khaled Yamout, USP Expert Panel on mRNA, Chair
1:00 p.m.	Adjourn