

## ***End-to-End Analytical Solutions for mRNA Therapeutics: Supporting Manufacturing and CMC Needs***

**April 14-15, 2026 – In-person and Virtual Event**

Day 1: 8:00 a.m. – 5:00 p.m. EDT

Day 2: 8:30 a.m. – 3:00 p.m. EDT

### **Tuesday, April 14, 2026**

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08:00 a.m. – 09:00 a.m.	<b>Check-In &amp; Breakfast</b>
09:00 a.m. – 09:10 a.m.	<b>USP Welcome &amp; Opening Remarks</b> Niomi Peckham, USP Global Biologics
09:10 a.m. – 09:20 a.m.	<b>AMM Introduction</b> Clay Alspach, AMM
09:20 a.m. – 09:25 a.m.	<b>Chair Remarks and Introduction of Speakers</b> Brian McNally, USP Global Biologics
<b><u>Advances in Analytical Methodologies for mRNA Characterization</u></b>	
09:25 a.m. – 09:55 a.m.	<b>Advances in mRNA Analysis with Liquid Chromatography Methods</b> Martin Gilar, Waters Corporation
09:55 a.m. – 10:25 a.m.	<b>Integrating Sequencing Analytics into mRNA Manufacturing and Quality Control</b> Wayne Doyle, Eclipsebio
10:25 a.m. – 10:55 a.m.	<b>A Novel RIG I Based Assay for Quantitative Detection of dsRNA Contaminants in RNA therapeutics</b> Mohamad Toutounji, Molgenium
10:55 a.m. – 11:10 a.m.	<b>Morning Break</b>
11:10 a.m. – 11:40 p.m.	<b>Development and Qualification of a Dual-Parameter Potency Assay for a Phase I Clinical Self-Replicating RNA (srRNA)</b> Shigeki Miyake-Stoner, Replicate Bioscience
11:40 a.m. – 12:10 a.m.	<b>Mass Photometry as a Multiple-Attribute Tool for mRNA Therapeutic Development</b> Matt Ranaghan, Refeyn
12:10 p.m. – 01:00 p.m.	<b>Lunch (Provided)</b>



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01:00 p.m. – 01:05 p.m.

**Introduction of speakers**

Brian McNally, USP Global Biologics

**Critical Material, Standards and Techniques to Support mRNA**

01:05 p.m. – 01:35 p.m.

**Building mRNA Quality: The USP Standards Approach**

Sarita Kattel, USP Global Biologics

01:35 p.m. – 02:05 p.m.

**Comparability of Analytical Techniques that Assess mRNA Drug-Substance CQAs: NIST RGTM 10202 FLuc mRNA**

Mark Lowenthal, NIST

02:05 p.m. – 02:35 p.m.

**Assessing the Correlation between Physical and Functional Characterization of mRNA**

Khaled Yamout, Yamout Chem Consulting

02:35 p.m. – 02:50 p.m.

**Afternoon Break (15 min)**

02:50 p.m. – 03:20 p.m.

**DNA Starting Material Control Strategy**

Sonia Taktak, Pfizer

03:20 p.m. – 03:50 p.m.

**Rapid and Sequence Independent mRNA Capping Efficiency Method on Oxford Nanopore Platform**

Jean de Seze, Dillico

03:50 p.m. – 04:50 p.m.

**Panel Discussion**

Advancing Policies to Support mRNA Modality

04:50 p.m. – 05:00 p.m.

**Day 1 Closing Remarks**

Brian McNally, USP Global Biologics

**Wednesday, April 15, 2026**

08:30 a.m. – 09:00 a.m.

**Breakfast**

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09:00 a.m. – 09:05 a.m.

**Chair Remarks and Introduction of Speakers**

Brian McNally, USP Global Biologics

**Analytical Methods Platforms to Support mRNA**

09:05 a.m. – 09:35 a.m.

**mRNA Therapeutics - Last Chance for Platform Methods**

Jan Falcke, BioNtech

09:35 a.m. – 10:05 a.m.

**Platform-Based Analytical Strategies to Accelerate mRNA-LNP Product Development: Applicability and Case Studies**

Kala Dasuri, Sanofi



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10:05 a.m. – 10:35 a.m.	<b>CLiC Analytical Platform for Single-Particle Multi-Parametric Characterization of mRNA–LNP Therapeutics</b> Albert Kamanzi, ScopeSys Inc
10:35 a.m. – 10:50 a.m.	<b>Morning Break</b>
10:50 a.m. – 11:20 p.m.	<b>Messenger RNA and Guide RNA Distributions in Lipid Nanoparticles Impact Gene Editing Efficiency In Vivo: A Framework for RNA LNP Rational Design Guided by Single-Particle Attributes</b> Sixuan Li, Johns Hopkins University
11:20 a.m. – 11:50 a.m.	<b>Untangling the Analytical Complexities of Targeted Lipid Nanoparticles (tLNPs)</b> Adam Crowe, Cytiva
11:50 a.m. – 12:20 p.m.	<b>Development of a Rapid, High-Throughput Luminescent Assay for mRNA 5' Capping Efficiency</b> Jonathan Mitchell, Promega
12:20 p.m. – 01:30 p.m.	<b>Lunch (Provided)</b>
01:30 p.m. – 01:35 p.m.	<b>Introduction of Speakers</b> Brian McNally, USP Global Biologics
01:35 p.m. – 02:05 p.m.	<b>A Mechanistic and Knowledge-Based Perspective on mRNA Manufacturing Processes</b> Chiara Bruckmann, Thermo Fisher Scientific
02:05 p.m. – 02:55 p.m.	<b>Panel Discussion</b> Addressing Analytical Needs to Advance mRNA Modality
02:55 p.m. – 03:00 p.m.	<b>Next Steps &amp; Closing Remarks</b> Brian McNally, USP Global Biologics
03:00 p.m.	<b>Adjourn</b>