

## ***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: Advances in Analytical Methods**

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08:00 a.m. – 09:00 a.m. **Check-In & Breakfast**

09:00 a.m. – 09:10 a.m. **USP Welcome & Opening Remarks**  
Niomi Peckham, USP Global Biologics

09:10 a.m. – 09:20 a.m. **AMM Introduction**  
Clay Alspach, AMM

09:20 a.m. – 09:25 a.m. **Chair Remarks and Introduction of Speakers**  
Brian McNally, USP Global Biologics

#### **Advances in Analytical Methodologies for mRNA Characterization**

09:25 a.m. – 09:55 a.m. **Advances in mRNA Analysis with Liquid Chromatography Methods**  
Martin Gilar, Waters Corporation

09:55 a.m. – 10:25 a.m. **Integrating Sequencing Analytics into mRNA Manufacturing and Quality Control**  
Wayne Doyle, Eclipsebio

10:25 a.m. – 10:55 a.m. **A Novel RIG I Based Assay for Quantitative Detection of dsRNA Contaminants in RNA therapeutics**  
Mohamad Toutounji, Molgenium

10:55 a.m. – 11:10 a.m. **Morning Break**

11:10 a.m. – 11:40 p.m. **Development and Qualification of a Dual-Parameter Potency Assay for a Phase I Clinical Self-Replicating RNA (srRNA)**  
Shigeki Miyake-Stoner, Replicate Bioscience

11:40 a.m. – 12:10 a.m. **Mass Photometry as a Multiple-Attribute Tool for mRNA Therapeutic Development**  
Matt Ranaghan, Refeyn

12:10 p.m. – 01:00 p.m. **Lunch (Provided)**



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- 01:00 p.m. – 01:05 p.m. **Introduction of speakers**  
Brian McNally, USP Global Biologics
- 01:05 p.m. – 01:35 p.m. **Critical Material, Standards and Techniques to Support mRNA**  
**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: From pDNA to mRNA-LNP: Integrating Platforms & Manufacturing

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- 08:30 a.m. – 09:00 a.m. **Breakfast**
- 09:00 a.m. – 09:05 a.m. **Chair Remarks and Introduction of Speakers**  
Brian McNally, USP Global Biologics
- 09:05 a.m. – 09:35 a.m. **Analytical Methods Platforms to Support mRNA**  
**mRNA Therapeutics - Last Chance for Platform Methods**  
Jan Falcke, BioNtech



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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

10:05 a.m. – 10:35 a.m.

**CLiC Analytical Platform for Single-Particle Multi-Parametric Characterization of mRNA–LNP Therapeutics**

Albert Kamanzi, ScopeSys Inc

10:35 a.m. – 10:50 a.m.

**Morning Break**

10:50 a.m. – 11:20 p.m.

**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**

Sixuan Li, Johns Hopkins University

11:20 a.m. – 11:50 a.m.

**Untangling the Analytical Complexities of Targeted Lipid Nanoparticles (tLNPs)**

Adam Crowe, Cytiva

11:50 a.m. – 12:20 p.m.

**Development of a Rapid, High-Throughput Luminescent Assay for mRNA 5' Capping Efficiency**

Jonathan Mitchell, Promega

12:20 p.m. – 01:30 p.m.

**Lunch (Provided)**

01:30 p.m. – 01:35 p.m.

**Introduction of Speakers**

Brian McNally, USP Global Biologics

01:35 p.m. – 02:05 p.m.

**A Mechanistic and Knowledge-Based Perspective on mRNA Manufacturing Processes**

Chiara Bruckmann, Thermo Fisher Scientific

02:05 p.m. – 02:55 p.m.

**Panel Discussion**

Addressing Analytical Needs to Advance mRNA Modality

02:55 p.m. – 03:00 p.m.

**Next Steps & Closing Remarks**

Brian McNally, USP Global Biologics

03:00 p.m.

**Adjourn**