mRNA Therapy Products 2025

Schedule

Thursday, 29 May, 2025

07:30-09:00 Foyer

Breakfast

Breakfast will be available until 09:00

07:30-09:00 Foyer

Registration

Registration is open until 17:00

09:00-09:10 Salons D-G

CASSS Welcome & mRNA 2025 Introduction

IP -In Person

09:10-09:15 Salons D-G

AMM Welcome and mRNA 2025 Introduction

IP -In Person

09:15-10:40 Salons D-G

Session I: Enabling the True Potential of mRNA

Tyler Goodwin, Carmilia Jimenez Ramirez
IP -In Person

mRNA technology is rapidly advancing as a versatile tool in the therapeutic space, extending far beyond vaccines. These promising applications are augmented by technological advances that provide additional avenues for enhancing the power of these therapies. This includes sustainable and efficient production platforms that increase speed to market. Notable advancements such as combination therapies with immunomodulators, the use of modified nucleotides, stabilizing sequences and self-replication systems can reduce immunogenicity and toxicity and increase stability and half-life.

Recent innovations include its potential for gene editing, epigenetic modulation, and cancer immunotherapies, offering new avenues for personalized treatment. Additionally, mRNA-based gene replacement therapies hold promise for addressing genetic disorders, presenting an exciting frontier in precision medicine.

This session will focus on these new advances that expand the therapeutic potential beyond prophylactic vaccines.

Session Speakers:

Metaphorical mRNA: The current and Future Shape(s) of the RNA Industry
Anna Rose Welch, *Advancing RNA*

Lunar®- mRNA Development for Therapy of Cystic Fibrosis and Ornithine Transcarbamylase Deficiency
Juergen Froehlich, *Arcturus*

Developing an In Vivo eRNA Encoded CAR-T for the Treatment of Autoimmune Diseases
Jim Nolan, *Sail Biomedicines*

Quality by Design for mRNA Products
Julia O'Neill, *Direxa Consulting*

10:40-11:00 Salon C

Networking Break

IP -In Person

11:00-12:30 Salons D-G

Session I Panel Discussion

Tyler Goodwin, Carmilia Jimenez Ramirez
IP -In Person

Additional Panelist:

Celia Witten, *Eliquent Life Sciences*
Brian Dooley, *EMA*
John Schiel, *ARPA-H*

12:30-13:30 Salons D-G

Lunch

IP -In Person

13:30-14:55 Salons D-G

Session II: Manufacturing Challenges and Innovations

May Guo, Andreas Kuhn, Jim Nolan
IP -In Person

Session Speaker:

A Trailblazing Digital Approach Coupled With PAT-Enabled Rapid Manufacturing From MIT and ReciBioPharm (Case Study No. 1 xRNA)
Aaron Cowley, *ReciBioPharm*

Analytical Comparability of mRNA Vaccines: Supporting the Global Rollout of Comirnaty and Streamlining the Strategy for the mRNA Vaccine Pipeline
Neil Eschmann, *Pfizer, Inc.*

Development of mRNA-LNP Manufacturing Process Platform : Focus on LNP Formation Unit Operation
Sumit Luthra, Sanofi

Scaling Up Circular RNA Production for RNA Medicines
Drew Cunningham, *Orbital Therapeutics*

14:55-15:15 Salon C

Networking Break

IP -In Person

15:15-16:45 Salons D-G

Session II Panel Discussion

May Guo, Andreas Kuhn
IP -In Person

Additional Panelist:

Aaron Larsen, *Terrain Biosciences, Inc.*
Ka-Wai Wan, *MHRA-UK*
Jason Fernandes, *Health Canada*

16:45-18:30 Foyer

mRNA 2025 Welcome Reception

IP -In Person

Join us for a welcome reception to celebrate the start of mRNA 2025!

Friday, 30 May, 2025

07:30-08:30 Foyer

Registration

Registration is open until 16:00

07:30-08:30 Salon C

Breakfast

IP -In Person

Breakfast will be available until 09:00

08:30-08:45 Salons D-G

Day 2 - Opening Remarks

IP -In Person

08:45-10:10 Salons D-G

Session III: Quality Control, Analytics and Assay Development

Taro Fujimori, Eric Levenson, Khaled Yamount
IP -In Person

This session will focus on control strategies for early and late phase development of mRNA medicines. The session will start with a discussion of establishing quality benchmarks using bulk reference materials and a defined set of analytical assays for linear and alternative forms of RNA. Then, the evolution of the analytical controls for an mRNA vaccine will be discussed, including how these controls can be applied to new products as part of a platform. Additionally, optimization of a cell-based potency assay will be presented as a case study in the context of current regulatory guidance for potency assays. Finally, lessons learned in the development of a flow-based potency assay will be discussed as three case studies highlighting challenges with cross reactivity, multivalent formulations, and seasonal variants.

Session Speaker:

Establishing Quality Benchmarks: Platform Technology Approach to mRNA Product Quality
Sarita Kattel, *US Pharmacopeia*

Evolution of Analytical Control Strategy for mRNA Vaccine Products
Erin Tulip, *Moderna, Inc.*

Understanding Multiple Factors That Can Affect In-vitro Protein Expression of mRNA-LNP Vaccine Products
Jianmei D Kochling, *Sanofi*

A to Z of IVE: From Single Antigen to Multiplex Flow Cytometry and LC-MS/MS Monitoring of In Vitro Expression
Emilia Byrne, *Pfizer, Inc.*

10:10-10:30 Salon C

Networking Break

IP -In Person

10:30-12:00 Salons D-G

Session III Panel Discussion

Taro Fujimori, Eric Levenson
IP -In Person

Additional Panelists:

Petra Schlick, *AGES*

Khaled Yamout, *Yamout Chem Consulting*

Christopher Yu, *Genentech*

12:00-13:05 Salon C

Lunch

IP -In Person

13:05-14:30 Salon C

Session IV: Regulatory Considerations

Brian Dooley, Ye Zhang
IP -In Person

The regulatory session will focus on key regulatory considerations for the quality, safety, and efficacy of mRNA-based products including vaccines and cancer immunotherapies. Regulators will discuss their perspectives, ongoing initiatives and guidelines for ensuring the quality of mRNA-based products. Industry experts will share their regulatory experience on the development and registration of mRNA-based products. The session will also feature a panel discussion that will offer valuable insights into the challenges faced by the industry, the importance of global regulatory harmonization, and the leverage of platform technology to advance mRNA products.

Session Speakers:

mRNA Vaccines: From First Approvals to a Platform Technology
Brian Doyle, *Moderna, Inc.*

Early Regulatory Considerations for RNA Therapies for Rare Diseases
Julie Hagan, *Korro Bio*

mRNA Vaccines: EU Regulator's Perspective
Petra Schlick, *AGES-Austria*

MHRA's Draft Guidance on the Licensing of Individualised mRNA Cancer Immunotherapies
Ka-Wai Wan, *The Medicines and Healthcare Products Regulatory Agency MHRA-UK*

14:30-15:00 Salon C

Networking Break

IP -In Person

15:00-16:30 Salons D-G

Session IV Panel Discussion

Brian Dooley, Ye Zhang
IP -In Person

Additional Panelists:

Jason Fernandes, *Health Canada*

Tiffany Lucas, *Eliquent Life Sciences*

16:30-16:45 Salons D-G

mRNA 2025 Closing Remarks

IP -In Person