September 17-19, 2024 | Boston, MA
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AGENDA
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3rd Annual

mRNA Process Development & Manufacturing Summit

Accelerate, Economize & Scale Your mRNA Drugs

Your Roadmap for mRNA Process Development & Manufacturing with Optimized Purification, Process Analytics & Enhanced Formulation to Improve Cost-Effectiveness & Scalability into the Clinic & Beyond

Expert Speakers Include:

Lena Wicke
Senior Director of RNA Process Development
BioNTech

John Stubenrauch
Chief Operating Officer
Nutcracker Therapeutics

Yadu Balachandran
Senior Scientist, mRNA Process Development
Moderna

Nicole Eschmann
Principal Scientist, Bioprocess R&D
Pfizer

Florent Peral
Senior Scientist, Process Development
Sanofi

Alexander Lemaire
Associate Director of Process Development
Strand Therapeutics

Lead Partner

BIA separations, inc

Expertise Partners

aldevron

Quantem Biosciences

Hosting Partner

Roche

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Welcome to the 3rd mRNA Process Development & Manufacturing Summit!

mRNA Process Development & Manufacturing Summit

September 17- 19, 2024 | Boston, MA

With the development of cancer vaccines, emerging therapeutics and novel gene editing tools, the mRNA manufacturing industry is experiencing a new wave of innovations. However, significant challenges are posed by the speed, cost of production and limited flexibility to improve current processes with new technologies. As a result, the mRNA industry is actively seeking end-to-end process development and manufacturing solutions that can keep pace with research and development.

The 3rd mRNA Process Development & Manufacturing Summit returns to Boston as the world's most comprehensive, technically focused mRNA forum, poised to help you boost your mRNA drug substance to product by implementing high throughput process development, optimizing mRNA synthesis and purification, speeding up process analytics and innovating formulation to unlock the unlimited potential of mRNA for all applications.

Accelerate scale up your mRNA production with data driven case studies from **VPs**, **Directors** and **Heads of Process Development**, ***In Vitro*** **Transcription**, **CMC** and **MSAT** from large pharma, exciting biotechs and leading service providers.

This is your chance to create a roadmap to minimize costs and maximize speed while maintaining yield and quality to create efficacious mRNA drugs.

Experience 3 jam-packed days with two refreshed tracks dedicated to 'Research Scale' and 'IND-Enabling & Clinical Scale' mRNA process development bursting with insights from industry pioneers including Moderna, Pfizer, Sanofi, BioNTech and more.

This is your chance to join **200+ technical mRNA experts** to equip your team with the knowledge, technology and meaningful networks needed to set the next wave of manufacturing frameworks, and support your R&D and analytical teams to produce safe and effective mRNA drugs for patients in need.

Looking forward to welcoming you in September.

Ashe (Shashwat) Goyal

Senior Program Director

Hanson Wade

KEY BENEFITS OF ATTENDING

Optimize Your mRNA Manufacturing with End-to-End Solutions

Create the roadmap from drug substance to drug product with our refreshed program guiding you from research to commercial scale mRNA production

Achieve Quality Without Compromising Yield

Remove dsRNA and simplify the purification train from pDNA to mRNA drug product with our brand new 'Purification Focus Day'

Master the Art of Formulating the Perfect mRNA Drug Product

Explore cutting-edge mixing systems to customize your manufacturing process for formulating efficacious mRNA drugs

Upgrade Your mRNA Manufacturing for Novel mRNA Applications

Dive into the latest technical insights on producing saRNA, circRNA, personalized cancer vaccines and adapting your process for novel gene editing systems

Collaborate with the Right External Partner to Support Your mRNA Manufacturing

FInd the best external partner to support you at every stage of mRNA manufacturing with case studies from leading industry specialists and dedicated networking time

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2024 Agenda Highlights

3rd Annual mRNA Process Development & Manufacturing Summit

September 17- 19, 2024 | Boston, MA

mRNA PURIFICATION FOCUS DAY

NEW

- Enhance upstream purification processes to isolate pDNA and mRNA at high yields and quality
- Advance downstream purification to reduce dsRNA and increase drug product quality
- Hear from **Merck & Co.**, **Novo Nordisk**, **Beam Therapeutics** and more

PRE-CONFERENCE WORKSHOP DAY

- Accelerate your mRNA production with end-to-end high throughput process development and automation to reduce the time from proof of concept to patient
- Select the right CDMO to support your specific needs from raw materials to clinical scale manufacturing to ensure quality from start to finish
- Learn from **Nutcracker Therapeutics**, **HDT Bio**, **Orna Therapeutics** and more

RESEARCH SCALE TRACK

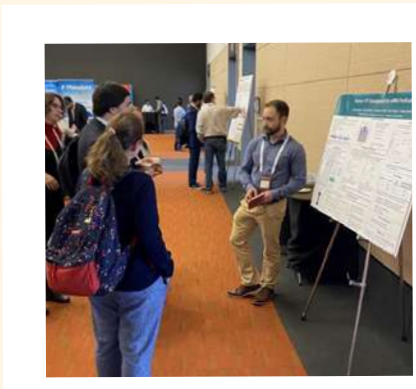
- Optimize IVT reactions and tailor your process development for optimal production of self-amplifying and circular RNA
- Enhance drug product thermostability with lyophilization, and develop early stage vaccine platforms to ensure patient access
- Hear from **BioNTech**, **Strand Therapeutics**, **Kernal Biologics** and more

IND-ENABLING & CLINICAL SCALE TRACK

- Implement process analytical technologies and conduct risk assessments to ensure patient safety in the clinic
- Scale up your mRNA vaccines for the clinic, including accelerating personalized cancer vaccine manufacturing, to get better drugs to patients faster
- Insights from **Pfizer**, **Sanofi**, **Gritstone Bio** and more

Present Your Work in Our Poster Session!

Catch up with old peers and form new connections in our dedicated poster session. Contribute to the conversation by sharing your cutting edge research and engaging with authors discussing their latest data.



NEW TO THE AGENDA FOR 2024:

GENEVATION LTD

gritstone bio

GreenLight™ Biosciences

LineaRx

STRAND THERAPEUTICS

TechImmune

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Your End-to-End Roadmap of mRNA Process Development

Can't isolate your pDNA? Not sure how to scale up to the next clinical phase? This summit is the one solution to your bottlenecks across the entire mRNA value chain. Here's a snapshot of the topics our expert speakers are covering:

Advancing Design & Synthesis of mRNA & DNA

- MERCK
- BIONTECH
- kernalbio
- CHROMA MEDICINE

Accelerating mRNA Drug Substance Production

- Beam THERAPEUTICS
- STRAND THERAPEUTICS

Supercharging mRNA-LNP Drug Product Manufacturing

- sanofi
- CSL

Innovating Quality-by-Design & Analytics

- moderna
- University of Massachusetts Amherst

Scaling Up Production to the Clinic

- Innovac THERAPEUTICS
- NUTCRACKER

Preparing for Commercial Scale mRNA Manufacturing

- ARCTURUS therapeutics
- OMEGA THERAPEUTICS

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Agenda at a Glance

mRNA Process Development & Manufacturing Summit

September 17- 19, 2024 | Boston, MA

Pre-Conference Day | Tuesday, September 17

Check In & Networking Coffee

mRNA Purification Focus Day	Workshop Day
Optimizing Upstream Synthesis to Simplify Purification Processes & Obtain High Quality mRNA (NEW)	Workshop A: Harnessing the Power of High Throughput Process Development Technology to Accelerate mRNA Production

Morning Networking Break

Enhancing dsRNA Purification & Characterization Through Chromatography for High Quality Drug Substance Production	Workshop B: Mastering mRNA Process Changes, Drug Quality, & Patient Safety to Expedite Your Journey to the Clinic

Lunch Networking Break

Supercharging Purification from pDNA to mRNA Drug Product Without Compromising Yield to Achieve Desired Quality	Workshop C: Choosing the Right External Partner for Seamless mRNA Manufacturing & Supply Chain Management

End of Pre-Conference Day

Conference Day One
Wednesday, September 18

Check In & Networking Coffee

Accelerating mRNA Process Development Through Platform-Level Advancement to Expedite Drug Manufacturing

Morning Break & Speed Networking

Research Scale Track	IND-Enabling & Clinical Scale Track
Overcoming Bottlenecks with IVT Reactions for Faster Scale Up While Maintaining mRNA Yield & Quality	Highlighting Process Analytical Technologies (PATs) to Predict & Control mRNA Quality, Stability & Potency

Lunch Networking Break

Enhancing Next-Generation mRNA Process Development to Accelerate the Production of Novel Modalities	Getting a Fast Start into the Clinic: Tackling Bottlenecks when Scaling Up mRNA Drug Product Manufacturing

Afternoon Networking Break & Poster Session

Approaching mRNA Process Development & Manufacturing Bottlenecks for Gene Editing Therapeutics to Achieve High Quality mRNA for Enhanced Editing Efficiency

Drinks Reception & End of Conference Day One

Conference Day Two
Thursday, September 19

Morning Networking Coffee

Implementing Quality by Design Principles to Optimize mRNA Drug Manufacturing for Cost, Speed & Effectiveness

Morning Networking Break

Research Scale Track	IND-Enabling & Clinical Scale Track
Enhancing mRNA-LNP Stability: Scaling Up Drug Product Manufacturing through Lyophilization	Accelerating Scale Out into the Clinic for Personalized mRNA Therapeutics & Vaccines to Ensure Cost Effectiveness & Speed

Lunch Networking Break

Accelerating the Development of Novel mRNA Vaccine Platforms to Combat Infectious & Oncological Diseases	Scaling Up Drug Product Manufacturing: Improving Formulations Through Novel Mixing Systems

Afternoon Networking Break

Transitioning from Early Phase Clinical to Commercial Scale: Planning for the Future of Successful mRNA Manufacturing

End of 3rd mRNA Process Development & Manufacturing Summit

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Your Expert Speakers

Charles Cabral
Senior Director, MSAT
Arcturus Therapeutics

Nate Spangler, Ph.D.
Senior Director, Product Strategy & Management
Aldevron

Brenda Clemente
Associate Director, Head of Formulation and Process Development
Arcturus Therapeutics

Ales Strancar
Chief Executive Officer
Sartorius BIA Separations

Krishna Sapkota
Scientist II, mRNA Process Development
Beam Therapeutics

Lena Wicke
Senior Director, RNA Process Development
BioNTech

Thomas Zieganhals
Director, *In Vitro* Transcription
BioNTech

Azadeh Zaker
Scientist II, Bioprocess Development
CSL Seqirus

Shani Levit
Scientist II
CSL Seqirus

Shefal Parikh
Director, RNA Process Development
Chroma Medicine

John Zuris
Director, Editing Technologies
Editas Medicine

Jeffrey Kuan
Senior Manager, Drug Product Development & Process Engineering
Gritstone Bio

Prasun Chakraborty
Founder & CEO
Genevation LTD.

Diana Posadas
Director, Strategic Research
Greenlight Biosciences

Jesse Erasmus
Director, Virology
HDT Bio

Hang Yuan
Chief Technology Officer
Innovac Therapeutics

Joseph Parrella
Vice President, Chemistry Manufacturing Controls
Kernal Biologics

James Osborn
Senior Scientist
Merck & Co.

Kaixi Zhao
Senior Scientist
Merck & Co.

Emily Dewar
Associate Principal Scientist
Merck & Co.

Yadu Balachandran
Senior Scientist, mRNA Process Development
Moderna

John Stubenrauch
Chief Operating Officer
Nutcracker Therapeutics

Bill Grier
Associate Director, Drug Substance Process Development
Omega Therapeutics

Harshal Zope
Director, MSAT
Orna Therapeutics

Rajesh Krishnan
Senior Director, Formulation
Providence Therapeutics

Nicole Eschmann
Principal Scientist, Bioprocess R&D
Pfizer

Georges Belfort
Institute Professor of Chemical and Biological Engineering
Rensselaer Polytechnic Institute

Your Expert Speakers

Oladimeji Fashola
Chief Technology Officer
Quantoom Biosciences

Jim Nolan
Vice President, Head of Technical Operations
Sail Biomedicines

Florent Peral
Senior Scientist, Process Development
Sanofi

Sarah Muse
Senior Scientist
Sanofi

Soumyajit Chowdhuri
Senior Associate Engineer, CMC Drug Product Development
Sanofi

Alexander Lemaire
Associate Director, Process Development
Strand Therapeutics

Julen Oyarzabal
Chief Scientific Officer & Founder
Syngoi

Jeffrey Ulmer
President & CEO
TechImmune LLC

Travis McQuiston
Senior Director, Scientific Research
Turn Biotechnologies

Qiuheng Jin
R&D Director
Vazyme

Craig Martin
Professor
University of Massachusetts Amherst

Marco Marques
Lecturer, Biochemical Engineering
University College London

Zoltán Kis
Senior Lecturer, Associate Professor
University of Sheffield

> "I am looking forward to connecting and sharing experiences with other scientists and industry leaders who are helping to advance mRNA vaccines and therapeutics"
>
> **Nicole Eschmann**, Principal Scientist, Bioprocess R&D, **Pfizer**

mRNA Purification Focus Day
Tuesday, September 17

This dedicated day is crafted to support you in refining and optimizing your existing purification methods spanning from pDNA to mRNA drug substance and drug product. Delve deeply into overcoming the bottleneck challenges in mRNA process development, enhancing your yield of top-quality RNA.

8.00 **Morning Check In & Coffee**

Shefal Parikh
Director, RNA Process Development
Chroma Medicine

8.50 **Chair's Opening Remarks**

Optimizing Upstream Synthesis to Simplify Purification Processes & Obtain High Quality mRNA

9.00 **Supercharging IVT Reactions for Co-Transcriptional Removal of dsRNA to Produce High Purity mRNA & Simplify Post-Translation Steps**

Thomas Zieganhals
Director of IVT
BioNTech

NEW DATA

- Optimizing IVT reactions for co-transcriptionally reducing dsRNA production to produce high purity mRNA
- Discussing strategies to rate-limit UTP feeding into the reaction to maintain yield while increasing purity
- Balancing multiple parameters like enzyme efficiency, reaction rate and raw material feeding for optimal IVT reactions

9.30 **Panel Discussion: Simplifying the Purification Process: Optimizing for High Quality DNA & mRNA Synthesis to Reduce Impurities**

- Identifying critical parameters during DNA production that can enable simpler and more cost-efficient downstream purification of DNA
- How to optimize pre-purification processes, such as IVT reactions, to increase purity and organically reduce purification steps and time
- How do the above optimizations to DNA and mRNA synthesis change when considering circRNA?

Moderator: Shefal Parikh
Director, RNA Process Development
Chroma Medicine

James Osborn
Senior Scientist
Merck & Co.

Thomas Zieganhals
Director of IVT
BioNTech

Alexander Lemaire
Associate Director of Process Development
Strand Therapeutics

10.30 **Morning Break & Networking**

Enhancing dsRNA Purification & Characterization Through Chromatography for High Quality Drug Substance Production

11.30 **Improving Binding Capacity & Throughput of Therapeutic mRNA with Oligo dT (OdT) Immobilized Fibro Prototype Chromatography Media**

Emily Dewar
Associate Principal Scientist
Merck & Co

NEW DATA

- • Evaluation of two commercially available OdT matrices and one prototype media for affinity chromatography of mRNA vaccine candidates
- Assessing OdT membrane for purification of mRNA vaccine candidates presented in recent manuscript
- Showcasing the impact of improved binding capacity and throughput afforded by novel OdT affinity chromatography media type

12.00 **Panel Discussion: Boosting Assay Development for Purification Processes to Accurately Measure & Characterize dsRNA to Improve Drug Substance Safety**

- Understanding dsRNA impurity profiles and assessing the best standards by which to characterize it
- Optimizing current cell-based assays to assess immunogenicity with greater sensitivity evoked by dsRNA
- Adopting and selecting appropriate process controls to enhance purification assays for dsRNA characterization

Moderator: Shefal Parikh
Director, RNA Process Development
Chroma Medicine

Craig Martin
Professor
University of Massachusetts Amherst

Krishna Sapkota
Scientist II, mRNA Process Development
Beam Therapeutics

Emily Dewar
Associate Principal Scientist
Merck & Co

mRNA Purification Focus Day
Tuesday, September 17

1.00 **Lunch Break & Networking**

Supercharging Purification from pDNA to mRNA Drug Product Without Compromising Yield to Achieve Desired Quality

James Osborn
Senior Scientist
Merck & Co.

2.00 **Navigating DNA Linearization in its Supercoiled Form & Topology to Enhance DNA Purification Strategies**

- Discussing how to optimize DNA linearization in its supercoiled form for faster and more cost effective pDNA isolation
- Assessing methods to differentiate between supercoiled and linear DNA with PLC assays
- Addressing the effect of initial plasmid purity on linearization efficiency and subsequent purifications

Krishna Sapkota
Scientist II, mRNA Process Development
Beam Therapeutics

2.30 **Highlighting Scale Up Considerations for Purification Processes to Maintain mRNA Purity & Integrity**

- Maintaining parameters and controls when scaling up from small to large batches to ensure purification processes achieve desired mRNA yield and quality
- Ensuring novel resins meet standards for clinical grade material production
- Implementing scalable purification strategies into a GMP setting for cost-effective, efficient and GMP-compliant processes

Georges Belfort
Institute Professor of Chemical and Biological Engineering
Rensselaer Polytechnic Institute

3.00 **Decontamination of Purified mRNA Vaccines & Therapeutics**

- Small amounts of contaminants remain in purified vaccines and are often the cause of a range of uncomfortable (but not deadly) immunogenic responses
- We present a methodology that, in principle, will allow one to remove selected contaminants from purified mRNA vaccines and therapeutics with fast, efficient and scaleup bioprocessing

Our approach combines 2 steps:

- (i) discovery and development of peptide affinity ligands that bind to a selected contaminant in preference to ss-RNA (desired product) or vice versa, and
- (ii) grafting and testing of these ligands to microporous synthetic polymer membranes to determine their binding affinity and selectivity in static and dynamic process modes

Shani Levit
Scientist II
CSL Seqirus

NEW DATA

3.30 **Rapid Screening of Materials of Contact for Scale-Up of mRNA-LNP Manufacturing**

- Early screening of leachables and extractables during scale-up can reduce challenges with technical transfer and manufacturing
- As the process is scaled, the material contact time can increase several fold which would increase levels of E&L in your drug product
- We have developed a strategy for rapid screening of E&L to facilitate selecting materials of contact

Shefal Parikh
Director, RNA Process Development
Chroma Medicine

4.00 **Chair's Closing Remarks**

4.15 **End of mRNA Purification Focus Day**

> "This is a wonderful meeting for connecting with other leaders in RNA Manufacturing and Quality Control, but also for connecting with those who want to learn more"
>
> **Craig Martin**, Professor, **University of Massachusetts Amherst**

Pre-Conference Workshop Day
Tuesday, September 17

Check In & Morning Coffee — **8.00**

Workshop A — 8.30 – 10.30

Harnessing the Power of High-Throughput Process Development Technology to Accelerate mRNA Production

Join this session to unlock the potential of high-throughput process development. This is your chance to delve into how to reshape each step of mRNA production into a high throughput process, revolutionizing the speed and efficiency of mRNA production. Learn about small scale bioreactors, automation and continuous manufacturing techniques to accelerate mRNA synthesis, mRNA purification, and end-to-end manufacturing.

Gain practical insights into tailoring these techniques to your specific manufacturing needs, and discover how high-throughput technology can further streamline processes, improve scalability, and reduce costs.

Join your peers as we:

- Harness quality by design to accelerate mRNA production
- Discuss the advantages and challenges of continuous mRNA production
- Utilize small-scale bioreactors, automation, and continuous manufacturing to accelerate mRNA synthesis
- Tailor high-throughput techniques to your manufacturing needs for enhanced scalability and cost reduction

Workshop Leaders:

Diana Posadas
Director, Strategic Research
Greenlight Biosciences

Marco Marques
Lecturer Biochemical Engineering
University College London

Zoltán Kis
Senior Lecturer, Associate Professor
University of Sheffield

Morning Break & Networking — **10.30**

Workshop B — 11.00 - 1.00

Mastering mRNA Process Changes, Drug Quality, & Patient Safety to Expedite Your Journey into the Clinic

Delve into the distinct challenges and considerations inherent in the development and production of mRNA therapeutics, and gain valuable insights into the impact of process development changes on product quality and safety. Uncover practical strategies for seamlessly implementing customized process changes within your mRNA drug development pipeline, while also understanding their downstream effects on product quality and the safety profile of your drug.

Join this workshop to gain insights into:

- Optimizing mRNA process development through experimentation
- Navigating drug quality complexities to ensure your mRNA processes meet your quality standards
- Implementing practical strategies for ensuring patient safety during process development of your mRNA

Workshop Leaders:

Jesse Erasmus
Director of Viology
HDT Bio

Travis McQuiston
Senior Director of Scientific Research
Turn Biotechnologies

Lunch Break & Networking — **1.00**

Pre-Conference Workshop Day
Tuesday, September 17

Workshop C — 2.00 - 4.00

Choosing the Right External Partner for Seamless mRNA Manufacturing & Supply Chain Management

Following COVID-19, an abundance of CDMOs have entered the RNA market, and the selection criteria in choosing the right supplier based on requirements and flexibility remains a significant challenge. Join this workshop to determine the right CDMO for you, depending on your stage in the pipeline. Whether you are in early research proof-of-concept phase, need a rapid start into the clinic with GMP manufacturing, or are scaling up to commercial, this workshop can help you assess which CDMO or solutions to aid your drug substance and drug product production and release, ensuring your long-term needs are met with quality and efficiency.

Join the discussion on:

- How to choose and evaluate an appropriate CDMO for you depending on your pipeline needs
- How to select the right CDMO for a fast, cost-effective start into the clinic for GMP-grade manufacturing
- How to work in harmony with your chosen CDMO for quicker drug substance and drug product release

Workshop Leaders:

Harshal Zope
Director – MSAT
Orna Therapeutics

John Stubenrauch
Chief Operating Officer
Nutcracker Therapeutics

End of Pre-Conference Workshop Day — 4.00

> "Taking part in the opportunity to discuss both the successes and the challenges facing those working towards the common goal of developing a robust and cost-effective mRNA vaccine manufacturing platform is invaluable. There are very few opportunities like this to collaborate and share experiences across industry leaders to help impact the future of mRNA technology."
>
> **Emily Dewar**, Associate Principal Scientist, **Merck & Co.**

Conference Day One
Wednesday, September 18

7.30 **Check In & Morning Coffee**

Diana Posadas
Director, Strategic Research
Greenlight Biosciences

8.20 **Chair's Opening Remarks**

Accelerating mRNA Process Development Through Platform-Level Advancement to Expedite Drug Manufacturing

8.30 **Panel Discussion: Planning for the Future of mRNA Drugs: How Can CMC Platforms Support the Next Wave of Approvals in the mRNA Field?**

- How to unlock platform technology designation to fast-track the approval of mRNA drugs into the clinic
- How to leverage learnings and prior knowledge from an established CMC platform for a novel mRNA drug submission
- How to utilize existing CMC platforms when expanding into new indications and disease areas

Moderator: Diana Posadas
Director, Strategic Research
Greenlight Biosciences

Bill Grier
Associate Director – Drug Substance Process Development
Omega Therapeutics

Zoltán Kis
Senior Lecturer, Associate Professor
University of Sheffield

Jim Nolan
Vice President, Head of Technical Operations
Sail Biomedicines

Nicole Eschmann
Principal Scientist – Bioprocess R&D
Pfizer

9.00 **Platform-Based Approaches to Streamline mRNA Drug Substance Process Development & Validation**

- Components of a robust mRNA platform technology
- Platform approach to process development and validation
- Optimization of the platform and continuous learning to feed forward to future mRNA programs

Ales Strancar
Chief Executive Officer
Sartorius BIA Separations

9.30 **mRNA-LNP Manufacturing Platform**

- Typical mRNA production process involves four key steps: 1) plasmid DNA (pDNA) expression in E.coli, linearization and pDNA purification, 2) in-vitro transcription (IVT) reaction, 3) mRNA purification and 4) mRNA encapsulation
- Orthogonal analytics are required to enable safer product and cheaper manufacturing process
- Critical steps to lower the manufacturing costs will be presented

10.00 **Morning Break & Speed Networking**

This networking session is your opportunity to get face-to-face with many of the brightest minds working in the mRNA process development and manufacturing field and establish meaningful business relationships to pursue for the rest of the conference.

Research Scale Track

Overcoming Bottlenecks with IVT Reactions for Faster Scale Up While Maintaining mRNA Yield & Quality

11.00 Optimizing IVT Reactions to Effectively Scale-Up mRNA Production from Research to Pre-Clinical Scale & Beyond

- Minimizing dsRNA production in your IVT reactions to reduce impurities and increase speed of downstream purification
- Scaling up IVT reactions from research to pre-clinical scale without losing quality or yield
- Recommendations for seamless transition from pre-clinical to clinical scale mRNA production

Kaixi Zhao, Senior Scientist, **Merck & Co.**

NEW DATA

IND-Enabling & Clinical Scale Track

Chair: Diana Posadas, Director, Strategic Research, **Greenlight Biosciences**

Highlighting Process Analytical Technologies (PATs) to Predict & Control mRNA Quality, Stability & Potency

11.00 Spotlighting a Novel Fluidics Approach to the Manufacturing of RNA That is Fully Pure at the Outset & Implementing a Novel On-Line Assay to Determine RNA Quality

- Co-immobilized polymerase-DNA stays in the reactor for long production runs of pure RNA
- Co-immobilization combined with continuous flow prevents the RNA rebinding that generates dsRNA
- A new on-line (and off-line) assay to determine full length ssRNA quantity and quality, for RNA of any length

Craig Martin, Professor, **University of Massachusetts Amherst**

Conference Day One
Wednesday, September 18

11.30 Session Reserved For Syngoi

Julen Oyarzabal, Chief Scientific Officer & Founder, **Syngoi**

11.30 Session Available For Partnership – Get in Touch to Learn More

12.00 Addressing Purification Challenges Resulting from Scale Up of Design of Experiments (DOE) Optimized IVT Reactions NEW DATA

- Optimizing IVT reactions via DOE is a well-established tool for improving mRNA quality
- These optimum IVT recipes can result solution conditions that create precipitation challenges both at the IVT step and at subsequent downstream purification impacting product quality and yield even after traditional UFDF steps
- Highlighting novel UFDF strategies that can be implemented to address these precipitation challenges to improve yield and product quality

Joseph Parrella, Vice President of CMC, **Kernal Biologics**

12.00 Outlining Analytical & Potency Assays for RNA Product Predictability of Efficacy for Multivalent Drug Products

- Highlighting analytical methods to assess RNA integrity and stability for multivalent products
- Clarifying the potency assays required to screen and confirm differential protein expression for multivalent products and assessing the right combination
- Choosing the appropriate cell line expression depending on your RNA target product profile to stay in-line with regulatory expectations

Sarah Muse, Senior Scientist, **Sanofi**

12.30 Lunch Break & Networking

Enhancing Next Generation mRNA Process Development to Accelerate the Production of Novel Modalities

1.30 Improving the Purification Process for Self-Amplifying mRNA (sa-mRNA) to Enhance Encapsulated LNP Vaccine Drug Products

- Evaluating the efficacy of chromatographic tools on product quality and impurity reduction
- Optimizing tangential flow filtration to enhance chromatographic performance
- Performing Design of Experiments (DOE) studies to evaluate the impact of impurities derived from the IVT process on column efficiency

Azadeh Zaker, Scientist II, Bioprocess Development, **CSL Seqirus**

NEW DATA

2.00 Overcome dsRNA Challenge: Innovation in Assays & Enzymes

- Enhanced Mitigation of dsRNA is Imperative
- ds-SensorTM: State-of-the-Art dsRNA Assay
- Next-Generation T7 Showcases Comprehensive Performance Enhancements

Qiuheng Jin, R&D Director, **Vazyme**

2.30 Selecting the Optimal Circularization Method for Circular RNA-Based Therapeutics, Depending on the Target Product Profile

- Outlining novel strategies to optimize efficient circularization and reduced immunogenicity
- Highlighting bottlenecks and learnings from enzymatic and chemical circularization such as autocatalytic circularization
- Assessing the best method for circularization depending on your target product profile

Alexander Lemaire, Associate Director of Process Development, **Strand Therapeutics**

Getting a Fast Start into the Clinic: Tackling Bottlenecks While Scaling Up mRNA Drug Product Manufacturing

1.30 LNP Process Characterization & Optimization for Phase III Readiness for a Personalized Cancer Therapy

- Reflecting upon a scale down approach to manufacture LNP for Personalized medicine
- Exploring the process of conducting FMEA/risk assessments, and identifying critical quality attributes and critical process parameters
- Prioritizing CPPs to design characterization studies that identify acceptable process ranges
- Analyzing experimental results and implementing improved process parameters as part of a robust phase III manufacturing process

Jeff Kuan, Senior Manager, Drug Product Development & Process Engineering, **Gritstone Bio**

2.00 Hitchhikers Guide to Lean Manufacturing: Redefining the concept of mRNA development

- Moving towards higher sensitivity for detection of residuals
- Developing manufacturing flexibility to meet patient needs.
- Optimizing upstream operations regarding integrity, capping efficiency, and potency
- Navigating regulatory restrictions on raw materials and process

Speaker TBD

2.30 Maintaining High Yield & Drug Product Quality to Confidently Accelerate your mRNA Candidate into the Clinic

- Minimizing major changes in drug product quality profiles when moving from pre-clinical to clinical use while maintaining a high yield
- Tackling platform optimization and understanding the best analytical assays to implement for faster and more cost-effective entry to the clinic
- Assessing methods to optimize screening in the pre-clinical phase to provide confidence with the candidate moving forward into the clinic

Lena Wicke, Senior Director of RNA Process Development, **BioNTech**

Conference Day One
Wednesday, September 18

3.00 Afternoon Networking Break & Poster Session
As the landscape of innovation is enabling scalable, cost-effective, and commercially viable mRNA production, it is more important than ever to collaborate and learn to continue the growth of this field. Join our dedicated poster session to share your latest data and have a first look into what your peers are working on!

Approaching mRNA Process Development & Manufacturing Bottlenecks for Gene Editing Therapeutics to Achieve High Quality mRNA for Enhanced Editing Efficiency

Chair: John Zuris, Director – Editing Technologies, **Editas Medicine**

3.45 Fireside Chat: Spotlighting mRNA Manufacturing Considerations Specific to Gene Editing Therapeutics

- Outlining unique bottlenecks associated with gene editing mRNA therapeutic manufacturing compared to mRNA vaccines
- What mRNA design expectations need to be considered for extrahepatic and potent programmable therapeutic expression?

John Zuris
Director – Editing Technologies
Editas Medicine

Shefal Parikh
Director, RNA Process Development
Chroma Medicine

Nate Spangler, Ph.D.
Senior Director, Product Strategy & Management
Aldevron

4.15 Details TBC

Shefal Parikh
Director, RNA Process Development
Chroma Medicine

4.45 The Journey into mRNA-Based Epigenetic Editor Process Development for Improved Gene Activation, Silencing & Multiplex Editing

- Optimizing the template design for an mRNA-based gene editing system
- Accelerating the mRNA process development for the efficient manufacture of an epigenetic editor
- Scaling up the manufacturing for an mRNA-based epigenetic editor system

NEW DATA

John Zuris
Director – Editing Technologies
Editas Medicine

5.15 Chair's Closing Remarks

5.20 End of Day One & Drinks Reception

> "Participating in the mRNA production and delivery community is important to increasing our success in delivering powerful therapeutics to patients. It allows us to share our success and learn from each other in meaningful ways"
>
> **Azadeh Zaker**, Scientist II, **CSL Seqirus**

Conference Day Two
Thursday, September 19

8.00 **Morning Networking Coffee**

Jim Nolan
Vice President, Head of Technical Operations
Sail Biomedicines

8.50 **Chair's Opening Remarks**

Implementing Quality by Design Principles to Optimize mRNA Drug Manufacturing for Cost, Speed & Effectiveness

9.00 **Leveraging Quality by Digital Design for Flexible Continuous mRNA Manufacturing**

Zoltán Kis
Senior Lecturer, Associate Professor
University of Sheffield

- Quality by Design principles to map out the intricate design space of mRNA medicines manufacturing
- Using modelling techniques to assess the impact of process parameters on process performance and product quality, facilitating informed decision-making without extensive experimentation
- Continuous oligo-dT chromatography for affinity purification of mRNA

9.30 **Accelerating mRNA Vaccine Development through Quality by Design (QbD) Integration**

Yadu Balachandran
Senior Scientist, mRNA Process Development
Moderna

- Overview of QbD approach and applications in pharma
- Outlining a QbD approach for RNA manufacturing
- Understanding a platform approach and regulatory packages

NEW DATA

10.00 **Exploring the Innovation Journey & Real-World Application of NtensifyTM Technology**

Oladimeji Fashola
Chief Technology Officer
Quantoom Biosciences

- Through its unique redesign, optimization, and integration, NtensifyTM offers a de-risked construct-agnostic mRNA process ensuring high yields and quality, reduced reagent consumption, and minimized resource-intensive scale-up needs.
- NtensifyTM process's performance yields above standard high-quality mRNA vaccines with no safety concern, yet able to elicit directed immune response.
- NtensifyTM technology is a transformative solution not only optimizing RNA manufacturing but also driving substantial cost and time effectiveness.

10.30 **Morning Networking Break**

Research Scale Track

Chair: Travis McQuiston, Senior Director of Scientific Research, **Turn Biotechnologies**

Enhancing mRNA-LNP Stability: Scaling Up Drug Product Manufacturing Through Lyophilization

11.30 **mRNA-LNP Drug Product Stability: Leveraging Freeze Drying for Thermostability Improvement & Stability Kinetics Modelling as a Decision Tool For Formulation Selection**

NEW DATA

- Sharing a use case on freeze drying and formulation development for LNP mRNA stability improvement
- Highlighting a selection method for freeze drying formulation of LNP mRNA
- Presentation of stability program allowing in silico kinetics CQA prediction as decision helping tool for formulation selection

Florent Peral, Senior Scientist, Process Development, **Sanofi**

IND-Enabling & Clinical Scale Track

Accelerating Scale Out into the Clinic for Personalized mRNA Therapeutics & Vaccines to Ensure Cost Effectiveness & Speed

11.30 **Development of an End-to-End Manufacturing Process for mRNA-Based Personalized Cancer Vaccines**

- Accelerating personalized GMP batch production while ensuring meeting regulatory requirements
- Optimizing the process and streamlining the supply chain to reduce the COGs and make the therapy more affordable

Hang Yuan, Chief Technology Officer, **Innovac Therapeutics**

Conference Day Two
Thursday, September 19

12.00 Development & Qualification of Small-Scale mRNA Lipid Nanoparticle Manufacture

- Establish critical operating parameters from DOE study results
- Determine optimized operating parameters for each unit operation
- Finalize qualification of small-scale manufacturing model by conducting consecutive runs with resulting drug product CQAs meeting all acceptance criteria

Brenda Clemente, Associate Director, Head of Formulation and Process Development, **Arcturus Therapeutics**

12.00 Manufacturing Personalized mRNA Therapeutics & Vaccines with Time Efficient & Cost-Effective GMP Production

- Designing mRNA production processes with a Target Product Profile in mind
- Accelerating personalized batch production and economic viability through flexible process designs and precision controls
- The importance of process characterization, optimization, and robustness to enable reduction in cycle times for product delivery

John Stubenrauch, Chief Operating Officer, **Nutcracker Therapeutics**

12.30 Lunch Break & Networking

Accelerating the Development of Novel mRNA Vaccine Platforms to Combat Infectious & Oncological Diseases

1.30 Setting Up a Faster, More Cost-Efficient & Effective Platform to Manufacture Personalized Cancer Vaccines

- Creating a cell free system for mRNA synthesis from DNA to vaccine delivery
- Shortening the time between biopsy and vaccine administration through a faster neoantigen discovery platform
- Reducing the cost to produce a personalized cancer vaccine and enhancing accessibility to patients

Prasun Chakraborty, Founder & CEO, **Genevation LTD.**

NEW DATA

2.00 Toward the Development of a Broad-Spectrum Multi-Antigen Next Generation SARS-CoV-2 Vaccine

- Discovery of conserved non-spike antigen targets for cross-protective T Cell responses
- Obviating the need for frequent vaccine updating and boosting
- Considerations of delivering multiple antigens by mRNA technology

Jeffrey Ulmer, President & CEO, **TechImmune LLC**

NEW DATA

2.30 Session Reserved for InDevR

InDevR

Scaling Up Drug Product Manufacturing: Improving Formulations Through Novel Mixing Systems

1.30 Evolving Vaccine Delivery: Point-of-Care Systems vs. LNP Platforms

- Introduction to Point-of-Care Systems and exploring their role in redefining mRNA vaccine distribution dynamics
- Highlighting the cost-effectiveness and versatility of Point-of-Care Systems, in the event of pandemics and beyond
- Discussing how to scale up point-of-care LNP systems from research to clinical scale

Rajesh Krishnan, Senior Director, Formulation, **Providence Therapeutics**

2.00 Translatability Between Mixing Systems & Scale Up For mRNA-LNP Drug Product Manufacturing

- Levers for optimizing mRNA-LNP formulations to scale up into the clinic
- Challenges of adapting mRNA-LNP formulations with different mixing systems
- Assessing the feasibility of the formulation for a successful push into the clinic

Soumyajit Chowdhuri, Senior Associate Engineer, CMC Drug Product Development, **Sanofi**

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2.40 Afternoon Networking Break

Conference Day Two
Thursday, September 19

Transitioning from Early Phase Clinical to Commercial Scale: Planning for the Future of Successful mRNA Manufacturing

Bill Grier
Associate Director – Drug Substance Process Development
Omega Therapeutics

3.30 **Looking Ahead to a Commercial Ready Process: Beyond the IND**

- Platform process architecture considerations for scalability and robustness
- What you don't realize, you don't know: implementation of a risk-based gap assessment
- Identifying potential critical parameters from a limited data set

Charles Cabral
Senior Director – MSAT
Arcturus Therapeutics

4.00 **Tech Transfer of Late Phase & Commercial mRNA Manufacturing**

- New challenges compared to early phase tech transfer
- Building a tech transfer strategy to ensure compliance and success
- Assessing completion: how do we know we've been successful?

Jim Nolan
Vice President, Head of Technical Operations
Sail Biomedicines

4.30 **Chair's Closing Remarks**

4.45 **Close of 3rd mRNA Process Development & Manufacturing Summit**

"This meeting is a unique gathering of professionals working to develop best processes to bring mRNA-based vaccines and therapeutics to patients. It is a great opportunity to learn from colleagues, share recent developments, and discuss the challenges of the fields to find best solutions."

Krishna Sapkota, Scientist II, mRNA Process Development, Beam Therapeutics

"The meeting offers a unique chance to network with global RNA experts, stay up to date on the newest trends and technologies, and learn about cutting-edge developments in industry. All while making meaningful contributions to the field by sharing knowledge and expertise."

Diana Posadas, Director, Strategic Research, **Greenlight Biosciences**

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mRNA Process Development & Manufacturing Summit

September 17- 19, 2024 | Boston, MA

Showcase Your Cutting-Edge Solutions Alongside Leading Drug Developers at the World's Largest Forum for mRNA Manufacturing Experts

As drug developers branch into mRNA cancer vaccines, emerging therapeutics and novel gene editing tools, the mRNA manufacturing industry is surging. Despite this progress, significant bottlenecks lie in the speed, cost of production, and lack of tailored approaches for each modality.

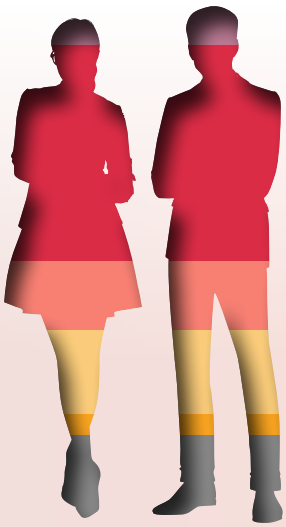
The mRNA industry are seeking the right partners to upgrade their manufacturing capabilities.

The **3rd mRNA Process Development & Manufacturing Summit** presents a unique platform to connect with and showcase your services and solutions to a global audience of 200+ technical mRNA manufacturing experts. Network with DNA manufacturers, IVT leaders and purification experts to hear what services are desired by those working in the lab.

If you offer solutions in **DNA and mRNA synthesis, purification technology, formulation and drug product assembly, end-to-end manufacturing platforms** or **scale-up support**, then this meeting is your unmissable opportunity to form long-lasting and meaningful business connections with VPs and Heads of **CMC**, **process development** and **MSAT** actively

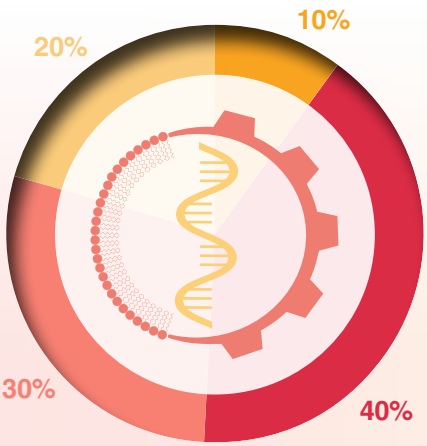
- Data-driven or case study-led presentations to position yourself as a thought-leader
- Expert panel inclusion to shape forward-thinking discussions
- Exhibition booth to raise brand awareness and answer questions from prospective customers
- Exclusive access to the Blind Delegate List to plan your conversations in advance
- On-site and website branding to highlight your company at the forefront of the mRNA space
- Organized networking to generate commercial collaborations
- Hosted lunch, drinks reception, or dinner for exclusive time with your target audience

SENIORITY OF ATTENDEES*



- 6% Chief/CxO
- 41% Director/Manager
- 13% Head/President/VP
- 16% Other
- 4% Professor
- 20% Scientist

TYPES OF COMPANIES ATTENDING*



- Other
- Drug Developer
- Equipment & Service Providers
- Academia

*Based on the 2nd mRNA Process Development & Manufacturing Summit

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JOIN YOUR PEERS TO:

Accelerate your process development from pDNA to mRNA drug product

Scale up mRNA-based vaccines, therapeutics and gene editing systems to the clinic and beyond

Economize your cost of production without losing quality, yield or speed

Drug Developer Pricing*	Early Bird Rate Expires Friday, June 28	On the Door Rate
Conference + Focus Day	$3,347 (save $850)	$4,197
Conference + Workshop Day***	$3,347 (save $850)	$4,197
Conference Only	$2,449 (save $550)	$2,999
Academic Pricing**	**Early Bird Rate Expires Friday, June 28**	**On the Door Rate**
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Conference + Workshop Day***	$2,747 (save $850)	$3,597
Conference Only	$2,049 (save $550)	$2,599
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Conference + Workshop Day***	$4,347 (save $850)	$5,197
Conference Only	$3,249 (save $550)	$3,799

*To qualify for the drug developer rate your company must have a public drug pipeline and not offer any paid for services. Please visit the website for full pricing options or email info@hansonwade.com

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