September 26 - 28, 2023 | Boston, MA

www.mrna-processandmanufacturing.com

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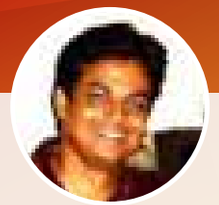
2nd Annual

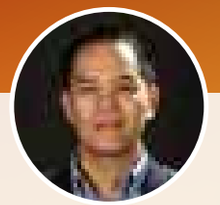
mRNA Process Development & Manufacturing Summit

Enabling Scalable, Cost-Effective & Commercially Viable mRNA Production

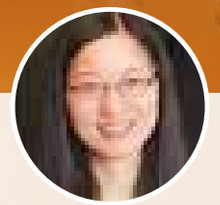
Accelerating mRNA Process Development & Manufacturing from Research to Commercial Scale with Increased Efficiency, Stability & Therapeutic Applicability for Regulatory & Market Readiness



Aravindan Rajendran
Senior Principal Scientist – Group Leader
Pfizer

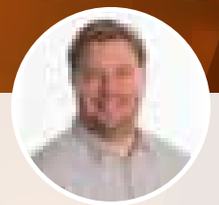


Christopher Cheng
VP – Process Development & RNA Technology
Verve Therapeutics



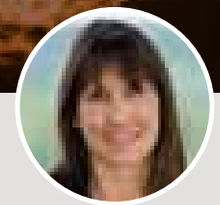
Yimin Hua
Head of Biochemistry – Analytical Development, mRNA Centre of Excellence
Sanofi

Andreas Kuhn
SVP - RNA Biochemistry & Manufacturing
BioNTech SE



Joseph Schariter
Director – Process Development
Moderna

Sung-Hye Grieco
VP – Process Development & Program Management
Nutcracker Therapeutics



Monica Dommel
Associate Director - Regulatory Affairs CMC
CureVac SE

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Welcome to the 2nd mRNA Process Development & Manufacturing Summit!

The mRNA industry is at an inflexion point, with a new wave of players pursuing innovative plug-and-play approaches, continuous-flow manufacturing, and microchip-based technology to meet growing demand for new viral strains, novel therapeutic designs, and personalized medicine. Ultimately resulting in a new era of low-cost on-demand mRNA process development and manufacturing.

The **mRNA Process Development & Manufacturing Summit** returns to Boston for the **2nd year** as the world's only industry dedicated forum dedicated to overcoming key bottlenecks such as **quality by design, automated large-scale manufacturing,** methods for **cost reduction to match global needs,** and harmonizing standards and regulatory expectations.

VPs, Directors and **Heads of Process Development, Drug Substance, CMC, MSAT** and more will be showcasing their latest developments and technological advancements in the field, with this year's meeting expanding into a **brand new 3-track agenda** providing technical insight on:

- **Research Scale Track** – Optimizing process efficiencies from **mRNA sequence design, *in vitro* transcription,** and **purification** strategies to produce high quality drug substance applicable to next generation mRNA-based therapeutics and vaccines
- **IND-Enabling & Clinical Scale Track** – Improving **potency** and **quality** assays to **characterize, analyze** and **release** mRNA drugs for successful **IND clearance** and fast-track translation into clinical development
- **Commercial Scale Track** – Unravelling automated and large scale **GMP production** and **manufacturing** of mRNA drug product, overcoming **raw material supply challenges** and **combating stability** to reduce the footprint, improve global accessibility and accelerate the road to market

Developed with global expert insights from industry pioneers including **Moderna, BioNTech, CureVac, Pfizer, Nutcracker Therapeutics, Sanofi,** and many more, join **250+ industry trailblazers** and be at the forefront of the mRNA industrial revolution, paving the way to support the development of scalable, cost-effective and commercially viable mRNA for patients faster.

I look forward to welcoming you this September!

Huzefa Rupawala, Ph.D.
Brand Director – World RNA Series
Hanson Wade

WHAT'S NEW FOR 2023?

Hear From a Speaker Faculty of 50+ mRNA World-Class Experts

3 Tracks Dedicated to Research Scale, IND-Enabling & Clinical Scale, & Commercial Scale

Brand New Pre-Conference Focus Day on Plasmid DNA Manufacturing

3 Deep Dive Interactive Pre-Conference Workshops

"This summit provides a great overview of mRNA process and analytics development efforts across the industry"

Himanshu Dhamankar, Senior Director - Platform, Research & Development, **GreenLight BioSciences**

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NEW TO THE AGENDA FOR 2023:

AGENDA HIGHLIGHTS

PRE-CONFERENCE FOCUS DAY: PLASMID DNA MANUFACTURING

- Heighten your plasmid DNA manufacturing methods from fermentation to purification to ensure cost-effectiveness and scalability
- Discover the future of DNA manufacturing with novel cell-free synthesis methods to speed up the process
- Insights from **BioNTech SE**, **Merck & Co**, **Ultragenyx Pharmaceutical** and more

PRE-CONFERENCE WORKSHOP DAY

- Broaden your insights into leveraging past modality experiences for future mRNA process development and manufacturing
- Optimize the development of your multivalent mRNA products to combat novel variants at pace
- Accelerate your manufacturing with modular facility implementation and ensure global accessibility of your platform
- Insights from **Capstan Therapeutics**, **GlaxoSmithKline**, **King's College London** and more

RESEARCH SCALE

- Unlock next generation mRNA sequence optimization, from capping to poly-A tails, to enhance chemical stability and protein expression
- Unravel the latest process tools to improve your IVT reaction and mRNA production and take it to new heights
- Insights from **GreenLight Biosciences**, **Kernal Bio**, **Pfizer** and more

IND-ENABLING & CLINICAL SCALE

- Explore analytical tools and quality control attributes for IND-readiness
- Enhance your process scale-up principles and protocols to go from bench to clinic with ease
- Insights from **Orna Therapeutics**, **Immunomic Therapeutics**, **Sanofi** and more

COMMERCIAL SCALE

- Discover new methods for mRNA-LNP characterization to create the ultimate formulation
- Elevate your mRNA drug product manufacturing at scale to accelerate drugs to market
- Insights from **Moderna**, **CEPI**, **Medicines Patent Pool** and more

> "Excellent opportunity to engage with fellow scientists operating in this technically complex space"
>
> **Derek O'Hagen**, Senior Advisor – R&D Vaccines, **GlaxoSmithKline**

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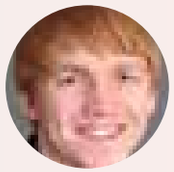
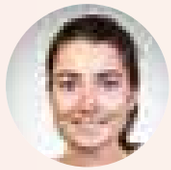
BIOPHARMA & ACADEMIC THOUGHT LEADERS

Hui Zhi
Senior Scientist II
Beam Therapeutics

Andreas Kuhn
SVP - RNA Biochemistry & Manufacturing
BioNTech SE

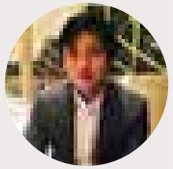


Simon Unthan
Senior Director - RNA Manufacturing Technology Development & Automation
BioNTech SE

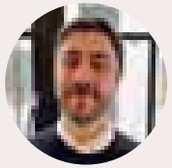


Anna Ernst
Associate Director – DNA Process Development
BioNTech SE

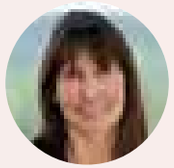
Lili Belcastro
Senior Principal Scientist
Bristol Myers Squibb



John Li
Director – mRNA Drug Substance
Capstan Therapeutics



Ramin Sabet-Azad
CMC Lead
CEPI



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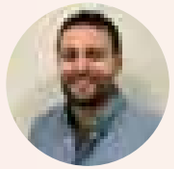
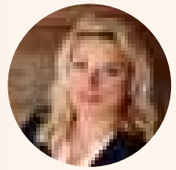
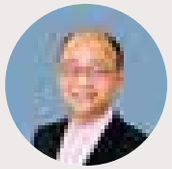
Associate Director - Regulatory Affairs CMC
CureVac SE



John Zuris
Director - Editing Technologies
Editas Medicine



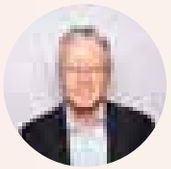
Nicole Ruggiero
CEO
EpiVax Therapeutics



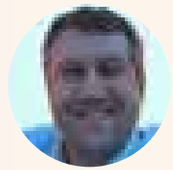
Xinyue Zhang
Manager - mRNA Process & Analytical Development
GeneLeap Biotech

Nethaniah Dorh
Associate Director – Bioanalytical Sciences
GreenLight Biosciences

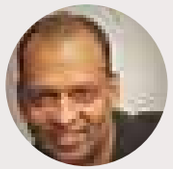
Stephen Kaba
Director – mRNA-Based Antigen Design
GreenLight Biosciences



Derek O'Hagen
Senior Advisor – R&D Vaccines
GlaxoSmithKline



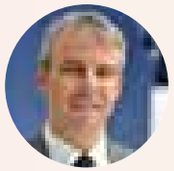
Danny Crawford
Director – Nucleic Acid Process Sciences
Intellia Therapeutics



Prakash Koodathingal
Director – RNA Therapeutics Development
Immunomic Therapeutics

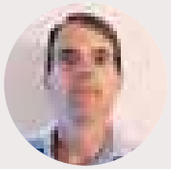
Hang Yuan
CTO & Co-Founder
Innovac Therapeutics

Burak Yilmaz
Co-Founder & President
Kernal Bio

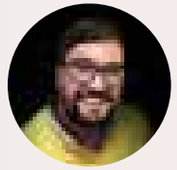


Harris Makatsoris
Professor – Manufacturing Systems
King's College London

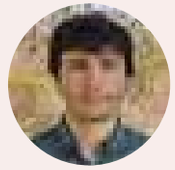
Richard Braatz
Professor
Massachusetts Institute of Technology



Ike James
Head of Technology Transfer
Medicines Patent Pool

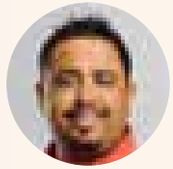


Antonio Grilo
Technology Transfer Expert
Medicines Patent Pool



Michael Homsy
Senior Scientist
Merck & Co

Joshua McNeely
Senior Scientist – Vaccines Process Development
Merck & Co



Dipendra Gyawali
Senior Scientist Team Lead – Process Development
Moderna

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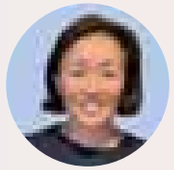
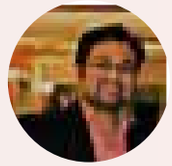
Joseph Schariter
Director – Process Development
Moderna



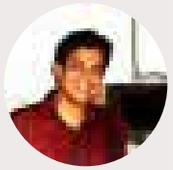
Sung-Hye Grieco
VP – Process Development & Program Management
Nutcracker Therapeutics



Harshal Zope
Director – Manufacturing Science & Technology
Orna Therapeutics

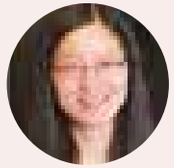
Bill Grier
Associate Director - Drug Substance Process Development
Omega Therapeutics

Lakshmi Khandke
Senior Program Advisor
Path



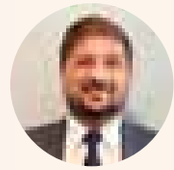
Aravindan Rajendran
Senior Principal Scientist – Group Leader
Pfizer

Mohamed ElSayed
EVP & CTO
RVAC Medicines



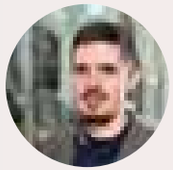
Yimin Hua
Head of Biochemistry – Analytical Development, mRNA Centre of Excellence
Sanofi

Hongyue Guo
Principal Scientist, mRNA Centre of Excellence
Sanofi



Sujit Jain
Director – External Manufacturing
SalioGen Therapeutics

Craig Martin
Professor – Chemistry
University of Massachusetts Amherst

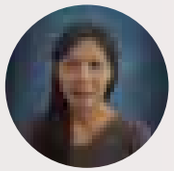


Zoltan Kis
Assistant Professor
University of Sheffield

Jin Zhou
Executive Director, Technical Development, mRNA & Protein Biologics
Ultragenyx Pharmaceutical

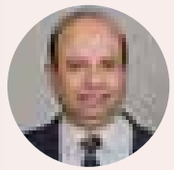
Akhilesh Bhambhani
Executive Director, Biologics & mRNA Drug Product Development
Ultragenyx Pharmaceutical

Vu Thai
Associate Director - Technology Development
Ultragenyx Pharmaceutical

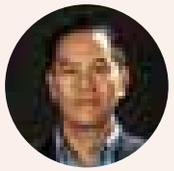


Vivian Chang
Associate Director - Upstream Process Development
Ultragenyx Pharmaceutical

Gautam Sanyal
Principal Consultant
Vaccine Analytics



Rajesh Beri
Owner & Principal Consultant
Vial 2 Vial Bio Solutions



Christopher Cheng
VP – Process Development & RNA Technology
Verve Therapeutics

Patrick Arbuthnot
Personal Professor & Director
University of Witwatersrand

> "This summit provides the opportunity to exchange ideas with and learn from fellow scientists dedicated to advancing the mRNA technology for preventing and treating deadly diseases"
>
> **Gautam Sanyal**, Principal Consultant, **Vaccine Analytics**

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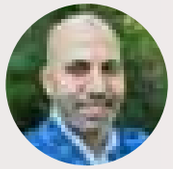
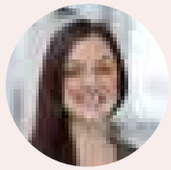


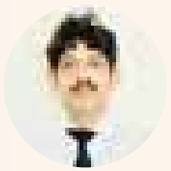
Yasser Kehail
Business & Product Leader - mRNA CDMO Services
Aldevron

Aleš Štrancar
Managing Director
BIA Separations



Jessica Sayers
MSAT Lead
CPI

Scott Alderucc
Director - mRNA Process Development & GMP
Curia Global



Sudhakar Voruganti
Director - Business Development
Pfanstiehl

Jose Castillo
CEO
Quantoom Biosciences

Julen Oyarzabal
CSO & Founder
Syngoi Technologies

"The success story of the COVID-19 pandemic demonstrated the potential of the mRNA technology to change the way to make future medicines. The **2nd mRNA Process Development & Manufacturing Summit** presents players in the field with the perfect opportunity to connect, learn and explore this new tool kit"

Stephen Kaba, Director – mRNA-Based Antigen Design, **GreenLight Biosciences**

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WHY ARE INDUSTRY EXPERTS ATTENDING:

"The **2nd mRNA-Process Development & Manufacturing Summit** creates the avenue for discussion with the hope of crafting solutions and advancing the modality"

Nethaniah Dorh,
Associate Director – Bioanalytical Sciences,
GreenLight BIOSCIENCES

"This is the perfect place to connect with mRNA experts, a portal to learn and a get-together to form the mRNA future"

Xinyue Zhang,
Manager,

"The **2nd mRNA Process Development & Manufacturing Summit** will be an avenue to connect with mRNA experts and together carve out a path for quantum improvements in mRNA manufacturing"

Rajesh Beri,
Owner & Principal Consultant,
Vial 2 Vial Bio Solutions

"This **2nd mRNA Process Development & Manufacturing Summit** provides a great opportunity to connect with colleagues across academia, industry, and regulatory organizations to share learnings and contemplate solutions that hamper the development of mRNA vaccines and therapeutics. I'd recommend it for all interested in contributing to the development of novel mRNA-based medicines"

Mohamed ElSayed,
EVP & CTO,

"I look forward to staying up-to-date with recent trends and advances in mRNA development, from early-stage to commercial development"

Sujit Jain,
Director – External Manufacturing,
SalioGen THERAPEUTICS

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AGENDA AT A GLANCE

Pre-Conference Day
Tuesday, September 26

Pre-Conference Focus Day: Plasmid DNA Manufacturing	Pre-Conference Workshop Day
Optimizing Plasmid DNA Manufacturing Controls from Fermentation to Purification to Ensure Cost-Effectiveness & Scalability	**Workshop A** Trailblazing Innovations & Technologies from Past Modality Experience to Accelerate mRNA Manufacturing & Ensure Future Success
Morning Break & Networking	
Harnessing Cell-Free Synthesis Technology to Advance Next Generation DNA Manufacturing	**Workshop B** Leveraging Opportunities & Overcoming Challenges for the Design & Development of Mono- & Multi- Valent mRNA Products
Lunch Break & Networking	
Optimizing Plasmid DNA Production Methodsto Improve Speed & Effectiveness for Next Phase mRNA Production	**Workshop C** Accelerating Manufacturing Facility Design of the Future to Advance Modular & Large-Scale Manufacturing Development

End of Pre-Conference Day

Day One | Wednesday, September 27

Opening Plenary: Navigating the Future mRNA Process Development & Manufacturing Landscape to Match Growing Demand & Development of mRNA 2.0 Medicines

Morning Break & Speed Networking

Research Scale	IND-Enabling & Clinical Scale	Commercial Scale
Evolving mRNA Drug Substance Design to Optimize Drug Effectiveness	Establishing a Robust Analytical Framework to Ensure a Standardized mRNA Production	Scaling Up mRNA-LNP Chemistry & Characteristics to Ensure Smooth Global Production
Lunch Break & Networking		
Spotlighting Technological Advances in mRNA Drug Development to Improve Efficiency & Control of the Process	Implementing mRNA Quality Control Considerations to Improve Overall Drug Product & Efficacy	Improving Cost Effectiveness of mRNA Production & Cold-Chain Stability to Enable Equitable Access

Tech Slam

Afternoon Plenary: Perfecting Purification: Enhancing Current Techniques to Overcome dsRNA Impurities & Increase Yield

End of Conference Day One

Day Two | Thursday, September 28

Morning Plenary: Harnessing Current mRNA Process Requirements for Scalable Production of Personalized Medicines

Morning Networking Break & Poster Session

Research Scale	IND-Enabling & Clinical Scale	Commercial Scale
Redesigning Production Processes to Ensure High Quality mRNA Drug Substance	Redefining mRNA Process Scale-Up to Advance Candidates from Bench to Clinic Whilst Maintaining Quality	Unravelling Manufacturing Considerations to Develop the Best mRNA Drug Product
Lunch Break & Networking		
Creating the Ultimate IVT Cocktail with Latest Technology Implementation to Streamline mRNA Production	Leveraging Experiences of Scale-Up to Reduce Barriers in Clinical Advancement	Scaling mRNA Process Development & Manufacturing to Meet the Demands of a Changing Global Market

Afternoon Break & Networking

Closing Plenary: Ensuring a Successful Technology Transfer & Cost-Effective Route from Discovery to Commercialization to Ensure Consistency Across Different Scales of Development

End of 2nd mRNA Process Development & Manufacturing Summit

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PRE-CONFERENCE FOCUS DAY:
PLASMID DNA MANUFACTURING | TUESDAY, SEPTEMBER 26

Plasmid DNA is a critical component of mRNA therapeutic and vaccine development, and with the mRNA industry continuing to advance their clinical pipelines, there is increased pressure to scale plasmid DNA production processes whilst maintaining consistency in purification, quality and supply. This pre-conference focus day dedicated to **Plasmid DNA Manufacturing** will dive deep into the plasmid DNA process from **template design to next generation methods of DNA manufacturing**, sparking conversations between peers, striving to produce high quality mRNA.

7.30 **Registration & Morning Coffee**

Danny Crawford
Director – Nucleic Acid Process Sciences
Intellia Therapeutics

8.20 **Chair's Opening Remarks**

Optimizing Plasmid DNA Manufacturing Controls from Fermentation to Purification to Ensure Cost-Effectiveness & Scalability

Lili Belcastro
Senior Principal Scientist
Bristol Myers Squibb

8.30 **Defining USP Standards for Plasmid DNA as a Starting Material for Cell & Gene Therapy**
- Reporting an overview of the USP general chapter process
- Describing key quality attributes recommended for plasmids
- Harnessing best practices for the manufacturing of plasmids and master cell banks

Vivian Chang
Associate Director - Upstream Process Development
Ultragenyx Pharmaceutical

9.00 **Enhancing Plasmid DNA Manufacturing Process Development for mRNA Applications**
- Advancing fermentation process development
- Clarifying purification process development
- Trailblazing process analytics

Michael Homsy
Senior Scientist
Merck & Co

9.30 **Evolving Strategies for Plasmid Purification**
- Exploring different chromatographic options for the purification of supercoiled plasmid and the linearized plasmid template
- Evaluating linearization at different levels of plasmid purity
- Determining the impact of linearized plasmid purity on product quality

10.00 **Morning Break & Networking**

Harnessing Cell-Free Synthesis Technology to Advance Next Generation DNA Manufacturing

Anna Ernst
Associate Director – DNA Process Development
BioNTech SE

11.00 **Unlocking DNA Matrices for mRNA Synthesis**
- Showcasing methods for production of linear DNA
- Harmonizing regulatory considerations
- Improving codon optimization

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PRE-CONFERENCE FOCUS DAY:
PLASMID DNA MANUFACTURING | TUESDAY, SEPTEMBER 26

Julen Oyarzabal
CSO & Founder
Syngoi Technologies

11.30 Optimized Linear Synthetic DNA as GMP Starting Mterial to Imrove mRNA Poduction & Delivery Times

- Improving IVT yield to lower the cost per dosage
- Developing more accurate and optimized linear DNA templates much faster for advanced therapies
- Delivering safer starting materials containing only the sequence of interest without any bacterial DNA

12.00 Round Table Discussion: Cell-Free vs Traditional Plasmid DNA Production – Establishing the Future of DNA Manufacturing to Reduce Costs & Maintain Quality

- How to establish the best DNA production method to producing step free, large quantities of DNA for multiple transcription reactions
- How to use the enzymatic method vs a high scale, plasmid DNA manufacturing method to eliminate costs and reduce time
- Discussing the advantages and disadvantages of cell-free synthesis to combat bottlenecks in plasmid DNA production

Lili Belcastro
Senior Principal Scientist
Bristol Myers Squibb

1.00 Lunch Break & Networking

Optimizing Plasmid DNA Production Methods to Improve Speed & Effectiveness for Next Phase mRNA Production

Joshua McNeely
Senior Scientist – Vaccines Process Development
Merck & Co

2.00 Reviving of a Legacy DNA Vaccine E. coli Plasmid Fermentation Process by Utilizing Single-Use Technology to Support a Modern mRNA Vaccine Program

- Adapting a legacy DNA vaccine that used stainless-steel reactors to develop a novel mRNA vaccine that uses single-use fermenters
- Overcoming a variety of roadblocks to success including pDNA construct stability, chemical compatibility with single-use fermenter materials, and capability limitations of the existing bioreactors
- Leveraging thoughtful development and knowledge-sharing to produce sufficient supply of pDNA in AMBR250 and BioBlu 3f SUF bioreactors to fuel IVT development activities

Hang Yuan
CTO & Co-Founder
Innovac Therapeutics

2.30 Optimizing the Process & Analytics for Poly A Sequences

- Improving Poly A loss, from 40% to less than 5%
- Scaling IVT from 5 g/L to 12 g/L

3.00 Round Table Discussion: Benchmarking Poly A Tail Challenges from Plasmid DNA to mRNA Production

- How to effectively sequence and measure poly A tails from DNA design to mRNA
- How to leverage the DNA process for a stable mRNA production
- How to overcome specificity challenges with longer Poly A sequences to ensure translational efficiency

Hang Yuan
CTO & Co-Founder
Innovac Therapeutics

Lili Belcastro
Senior Principal Scientist
Bristol Myers Squibb

3.30 Chair's Closing Remarks

3.40 End of Pre-Conference Focus Day

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PRE-CONFERENCE WORKSHOP DAY
TUESDAY, SEPTEMBER 26

With a new wave of innovation, automation, and production to ensure superior quality and scalability of novel mRNA therapeutics and vaccines, the mRNA manufacturing industry is beelining for success. To ensure the mRNA industry can keep pace with increasing developments in this space, we have put together an interactive **Pre-Conference Workshop Day** to address key challenges for the field, from leveraging experience using previous modalities to innovate the mRNA manufacturing process, to optimizing sequences for multivalent products and modular facility design for globally equitable mRNA production.

Registration & Morning Coffee — 7.00

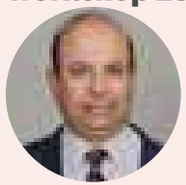
Workshop A — 8.00

Trailblazing Innovations & Technologies from Past Modality Experience to Accelerate mRNA Manufacturing & Ensure Future Success

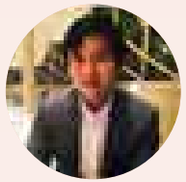
Innovation and technology are trailblazing the mRNA space, from batch production to automatic and digital design. However, a major challenge in mRNA manufacture is the need to modify existing procedures to effectively scale up the production process to meed global demand, while still complying with regulatory requirements.Join this workshop to discuss the future developments in the mRNA manufacturing industry and uncover the considerations required for scalability:

- Leveraging four decades of innovation from antibody development to ensure future success of mRNA manufacturing
- Overcoming major bottlenecks in continuous manufacturing platform development to boost productivity for mRNA therapeutics and vaccines
- Increasing manufacturing process efficiency through smart and innovative data-driven bioprocessing

Workshop Leaders:



Rajesh Beri
Owner & Principal Consultant
Vial 2 Vial Bio Solutions



John Li
Director – mRNA Drug Substance
Capstan Therapeutics

Morning Break & Networking — 10.00

Workshop B — 11.00

Leveraging Opportunities & Overcoming Challenges for the Design & Development of Multivalent mRNA Products

Multivalent and universal mRNA-based vaccines have entered clinical development, offering a one-stop solution to a long-standing issue. However, at present, there is uncertainty surrounding how current solutions to bring these vaccines and therapeutics from bench to bedside can be integrated into the manufacturing processes, to ensure regulatory compliance without compromising process efficiency. This workshop will facilitate discussions to better understand this challenge and visualize the future of these medicines that are fully integrated into the manufacturing process

- How to design multiple antigen sequence and transcripts, and implications for large scale production
- How to maximize process efficiency for each application, every drug modality and every therapeutic indication
- How to overcome bottlenecks for formulation changes and release testing, and formulation change for multivalent flu vaccine cocktails

Workshop Leaders:

Gautam Sanyal
Principal Consultant
Vaccine Analytics

Derek O'Hagen
Senior Advisor – R&D Vaccines
GlaxoSmithKline

Stephen Kaba
Director – mRNA-Based Antigen Design
GreenLight Biosciences

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Lunch Break & Networking 1.00

Workshop C 2.00

Accelerating Manufacturing Facility Design of the Future to Advance Modular & Large-Scale Manufacturing Development

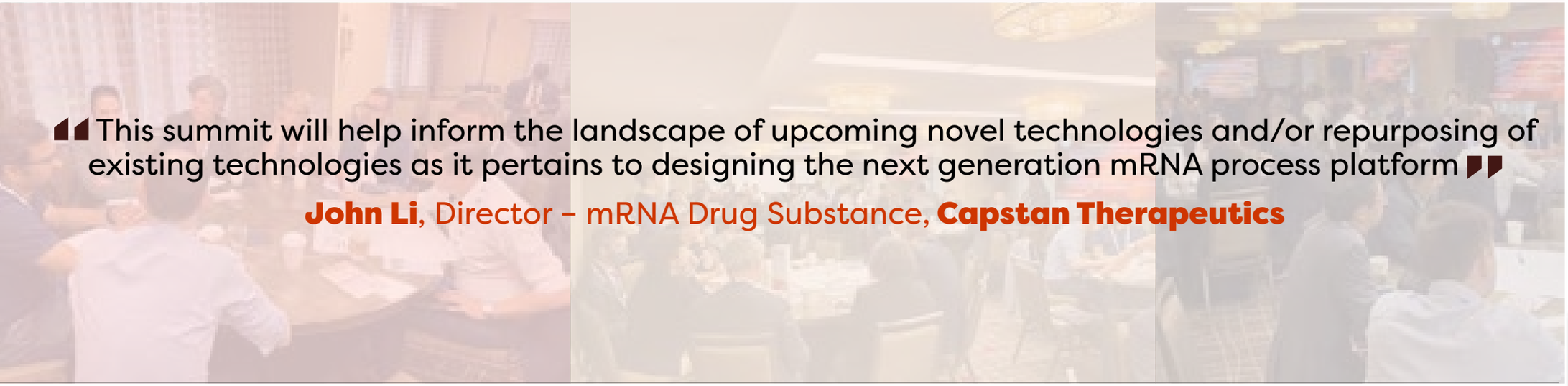
With the boom of the mRNA manufacturing industry and development of large-scale facilities to support the scale-up of mRNA-based COVID-19 vaccines, the industry has seen a surge of investment and opportunity to equitize these processes and miniaturize them into modular units, to advance the future of scale-upcapacity at reduced cost. Join this deep-dive workshop to find out how to leverage modular designs, internal architecture and resources to establish a regional solution to a global problem:

- Advancing next generation processing for single use, closed, continuous and modular design facilities
- Use of sigma modelling to reduce process time, facility design and internal bottlenecks
- Revolutionizing cost-effective facility builds with modular, small print manufacturing facilities to reduce development times
- Developing compartment-sized infrastructure, equipment and processes at GMP level for pandemic readiness

Workshop Leader:

Harris Makatsoris
Professor – Manufacturing Systems
King's College London

End of Pre-Conference Workshop Day 4.00



"This summit will help inform the landscape of upcoming novel technologies and/or repurposing of existing technologies as it pertains to designing the next generation mRNA process platform"

John Li, Director – mRNA Drug Substance, **Capstan Therapeutics**

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7.30 Registration & Morning Coffee

Christopher Cheng
VP – Process Development & RNA Technology
Verve Therapeutics

8.20 **Chair's Opening Remarks**

Navigating the Future mRNA Process Development & Manufacturing Landscape to Match Scale, Demand & Development of mRNA 2.0 Medicines

Sung-Hye Grieco
VP – Process Development & Program Management
Nutcracker Therapeutics

8.30 **Achieving Flexibility in mRNA Process Development for On-Demand mRNA-Based Therapeutics**

- Unlocking end-to-end mRNA drug development for scalable, affordable and commercially viable mRNA production
- Unleashing chip-based mRNA production to achieve scale out and up of mRNA manufacturing processes
- Advancing in-house quality control capabilities

9.00 ThermoFisher SCIENTIFIC

Bill Grier
Associate Director, Drug Substance Process Development
Omega Therapeutics

9.30 **Establishing a Scalable Next-Generation mRNA Process**

- Developing a streamlined enzymatic capping reaction to address scale-up hurdles
- Improving process robustness using orthogonal purification techniques
- Aligning mRNA production processes from µg to >10g scales

10.00 **Panel Discussion: To GMP or Not to GMP: Establishing Criteria to Meet GMP Requirements from Bench to Market**

Emergency use authorization of mRNA development and manufacturing for vaccines and therapeutics was established for COVID-19. Now, as more candidates enter the clinic, greater clarity is required on the use of GMP-grade materials and the perfect timeline to synchronize development and stage. This discussion will delve deeper into GMP-sourcing and level requirements to support and tailor for your projects from discovery through to market.

- Unlocking reagents, solvents, enzymes, and nucleic acids choices from non-GMP grade to GMP level
- Exploring the complexities around decision making and criterion for GMP-compliant products and timeline of use
- How to achieve a gold standard with next generation GMP-compliant technology, reliability and support to advance your candidates

Moderator:
ThermoFisher SCIENTIFIC

Bill Grier
Associate Director, Drug Substance Process Development
Omega Therapeutics

Harshal Zope
Director – Manufacturing Science & Technology
Orna Therapeutics

Jin Zhou
Executive Director, Technical Development, mRNA & Protein Biologics
Ultragenyx Pharmaceutical

10.30 Morning Break & Speed Networking

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TRACK A: RESEARCH SCALE	TRACK B: IND-ENABLING & CLINICAL SCALE **Chair Moderation: Andreas Kuhn**, SVP – RNA Biochemistry & Manufacturing, **BioNTech**	TRACK C: COMMERCIAL SCALE **Chair Moderation: Dipendra Gyawali**, Senior Scientist; Team Lead – Process Development, **Moderna**
Evolving mRNA Drug Substance Design to Optimize Drug Effectiveness	**Establishing a Robust Analytical Framework to Ensure a Standardized mRNA Production**	**Scaling Up mRNA-LNP Chemistry & Characteristics to Ensure Smooth Global Production**
11.30 Unlocking a Framework to Guide the Production of Next Generation RNA Molecules at Different Lengths to Enable RNA therapeutics • Establishing a toolbox to handle RNA molecules of various sizes • How to handle large RNA molecules, such as self-amplifying RNA and its complexities • Evaluating the process challenges of different types of RNA for production and scale-up	**11.30 Leveraging Analytical Control Strategies for Process-Related Impurities in mRNA Vaccines & Therapeutics** • Determining acceptable limits of residual process impurities • Implementing proper analytical control strategy for process impurities • Developing appropriate analytical methods for the control of process impurities **Yimin Hua**, Head of Biochemistry – Analytical Development, mRNA Centre of Excellence, **Sanofi**	**11.30 The Journey of mRNA LNPs into a Well-Characterized Biologic** • Reviewing characterization strategies of LNPs • Highlighting challenges of scale-up due to this process being one of physical chemistry, instead of chemistry and biochemistry • Striving for new technology and product development to transform LNPs into a well-characterized biologic **Joseph Schariter**, Director – Process Development, **Moderna**
12.00 aldevron **Yasser Kehail**, Business & Product Leader - mRNA CDMO Services, **Aldevron**	**12.00** MilliporeSigma	**12.00** LEVITRONIX
12.30 Harnessing a Fingerprinting-Based Method to Obtain Multiple Attributes of RNA & Facilitate mRNA Process Development • Simplifying mRNA process measurements from capping efficiency, poly A distribution, sequence and more into one unique method • Developing a fingerprinting-based method to test mRNA capping efficiency, polyA and more information revealed using this method • Applying this method to mRNA to facilitate its process development from a time and cost perspective **Xinyue Zhang,** Manager, **GeneLeap Biotech**	**12.30 Developing a saRNA Platform: Considerations for Discovery to Clinical Stage Programs** • Characterizing stage appropriate process and analytics • Adapting saRNA process and analytical methods **Prakash Koodathingal**, Director – RNA Therapeutics Development, **Immunomic Therapeutics**	**12.30 Revolutionizing mRNA Lipid Nanoparticles by Incorporation of Ionizable Lipids from Bio-Renewable Sources** • Synthesizing novel ionisable lipids from bio-renewable sources • Formulating a novel LNP carrier • Characterizing delivery and efficiency **Patrick Arbuthnot,** Personal Professor & Director, **University of Witwatersrand**

1.00 Lunch Break & Networking

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Spotlighting Technological Advances in mRNA Drug Development to Improve Efficiency & Control of the Process

2.00 Innovating & Digitalizing Production Processes of mRNA Vaccines & Therapeutics

- Developing a multiproduct, high productivity, continuous manufacturing platform process for low-cost and high-quality RNA vaccine and therapeutic production
- Enhancing digital twins and soft sensors for guiding process development and for enabling process automation
- Integrating Quality by Digital Design framework with new analytical methods, with models mapping product-process interactions, and with data analytics and visualization software for accelerating the development and mass-production of RNA vaccines and therapeutics

Zoltan Kis, Assistant Professor, **University of Sheffield**

2.30 Unlocking Access to mRNA-Based Vaccines & Therapeutics

- Outlining a simple, scalable, and cost-efficient way to intensify and chain manufacturing steps for continuous and automated production
- Significantly reducing the footprint to enable high portability and optimize the use of expensive cleanroom space, while minimizing manual steps to improve safety and product quality to the highest levels
- Improving the availability of expensive biologics, particularly for LMICs

Jose Castillo, CEO, **Quantoom Biosciences**

3.00 Using *In Silico* Sequence Design Strategies to Simplify the IVT mRNA Production Process & Increase Product Quantity

- Improving mRNA design strategies that decrease T7 by-products
- Optimizing IVT DNA template design strategies that increase T7 processivity
- Characterizing design strategies that help to generate better IVT DNA template

Burak Yilmaz, Co-Founder & President, **Kernal Bio**

Implementing mRNA Quality Control Considerations to Improve Overall Drug Product & Efficacy

Chair Moderation: Dipendra Gyawali, Senior Scientist; Team Lead - Process Development, **Moderna**

2.00 From Screening to Vaccine Efficacy: The Case for a Well-Defined Potency Assay

- Leveraging quality and appropriate analytics to define process characterization
- Realizing the importance of bioassays in process characterization
- Matching development speed of mRNA therapeutics with an equally responsive manufacturing strategy

Nethaniah Dorh, Associate Director – Bioanalytical Sciences, **GreenLight Biosciences**

2.30

ReciBio Pharm

3.00 Development of an Accurate & Robust Method to Support Process Development in Monitoring the mRNA Drug Product Content & Quality Control

- Troubleshooting of an mRNA content method based on mechanistic understanding and a QbD approach
- Applying an optimized method in process development
- Automating a mRNA content method for high-throughput analysis

Hongyue Guo, Principal Scientist, mRNA Centre of Excellence, **Sanofi**

Improving Cost Effectiveness of mRNA Production & Cold-Chain Stability to Enable Equitable Access

2.00 Fireside Discussion: Harnessing Tools to Improve Stability & Drug product Development to Enable Global Access

- Developing novel formulations to increase the shelf-life of high purity stabilizers for cold chain requirements
- Advancing knowledge into force degradation and mRNA thermo-stability to preserve mRNA functionality and longevity
- How to effectively overcome hurdles of storage for global distribution?

Mohamed ElSayed, EVP & CTO, **RVAC Medicines South Africa**

Patrick Arbuthnot, Personal Professor & Director, **University of Witwatersrand**

2.30 Tailoring Production: A Customized Approach to mRNA Manufacturing

- Identifying the variable/critical components
- Understanding the reasoning of revisiting procedures
- Learning what metrics to use to navigate the process

Scott Alderucci, Director - mRNA Process Development & GMP, **Curia Global**

3.00 Vaccine Stability & Access Through Manufacturing Technologies & Innovations

- Understanding the link between stability and equitable access to vaccines
- How existing manufacturing technologies support equitable access to vaccines
- Advancing technological innovations required for equitable access to vaccines

Ramin Sabet-Azad, CMC Lead, **CEPI**

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3.30 **Tech Slam** Syngoi

Perfecting Purification: Enhancing Current Techniques to Overcome dsRNA Impurities & Increase Yield

4.00 **Panel Discussion: The dsRNA Debate: Assessing dsRNA Formation Early & Optimizing the Process to Reduce Pressure on Purification Requirements**

- Determining the key controllable environmental factors that contribute towards the formation of dsRNA
- Outlining methods to measure dsRNA and to set standards for development of mRNA-based therapeutics and vaccines
- How could these methods affect the drug substance quality and immunogenicity?

Moderator: Jin Zhou
Executive Director, Technical Development, mRNA & Protein Biologics
Ultragenyx Pharmaceutical

Burak Yilmaz
Co-Founder & President
Kernal Bio

Craig Martin
Professor – Chemistry
University of Massachusetts Amherst

Zoltan Kis
Assistant Professor
University of Sheffield

Sung-Hye Grieco
VP – Process Development & Program Management
Nutcracker Therapeutics

Aleš Štrancar
Managing Director
BIA Separations

4.45 **Speeding mRNA Process Development & Securing Robust Manufacturing by Using Fast In-Process Analytics**
Sponsored by HPNE

- Overview of a chromatographic toolbox for in-process analytics of mRNA process development and manufacturing
- New analytical tools for characterization and optimization of mRNA-LNP formation
- Advancing mRNA-LNP purification

Craig Martin
Professor – Chemistry
University of Massachusetts Amherst

5.15 **Novel RNA Manufacturing: Eliminating dsRNA at Synthesis & Reducing Costs**

- Functionally co-immobilized reaction allows continuous flow synthesis
- Eliminatiing dsRNA and dramatically reduces purification needs
- Reducing costs and GMP-optimal

Andreas Kuhn
SVP - RNA Biochemistry & Manufacturing
BioNTech SE

5.45 **Chair's Closing Remarks**

5.50 **End of Conference Day One**

8.00 **Morning Networking & Coffee**

Mohamed ElSayed
EVP & CTO
RVAC Medicines

9.00 **Chair's Opening Remarks**

Harnessing Current mRNA Process Requirements for Scalable Production of Personalized Medicines

9.10 **Panel Discussion: Accelerating the Analytics, Production & Regulations of Personalized mRNA-Based Drugs for Individual Patient Needs**

- How to improve the efficacy and efficiency of the personalized mRNA-based medicines process
- How to overcome bottlenecks and accelerate the process from biopsy to treatment
- How to develop a suitable platform for sequence production, analytical parameters and release testing
- Analyzing the impact of personalized mRNA-medicines on GMP production and regulatory control

Moderator: Danny Crawford
Director – Nucleic Acid Process Sciences
Intellia Therapeutics

Andreas Kuhn
SVP – RNA Biochemistry & Manufacturing
BioNTech SE

Joseph Schariter
Director – Process Development
Moderna

Nicole Ruggiero
CEO
EpiVax Therapeutics

Monica Dommel
Associate Director - Regulatory Affairs CMC
CureVac SE

Simon Unthan
Senior Director – RNA Manufacturing Technology Development & Automation
BioNTech SE

10.00 **Accelerating Production Systems for Personalized mRNA Manufacturing**

- Introducing BioNTech's personalized mRNA therapies
- Overcoming key challenges of personalized GMP manufacturing
- Showcasing BioNTech's success to streamline personalized mRNA manufacturing

10.30 **Morning 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 for 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!

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TRACK A: RESEARCH SCALE

Chair Moderation: Aravindan Rajendran, Senior Principal Scientist – Group Leader, **Pfizer**

Redesigning Production Processes to Develop High Quality mRNA Drug Substance

11.00 Benchmarking IVT Reaction Conditions for Optimal mRNA Drug Substance Yield & Quality

- Optimizing one-step or multistep processes, for higher yield and cost efficiency
- How to improve the process with greater yield and less dsRNA, through optimizing of time, temperature, and other reagents
- Creating an mRNA process platform that is robust, reproducible, and scalable across different constructs and bioreactors

Hui Zhi, Senior Scientist II – mRNA Science & Process Development, **Beam Therapeutics**

11.30 Utilizing Trehalose, Sucrose & Amino Acids: Essential Components, Applications, Related Functionalities & Performance in Biologic Drug Product Formulations & mRNA Technologies

- Understanding important physicochemical properties of trehalose and sucrose
- Stabilizing commercial biotherapeutics with trehalose and sucrose
- Improving purity, quality and consistency in Pfanstiehl's trehalose, sucrose and amino acid products
- Sharing case studies for utilization and functionalities of essential components in COVID-19 related formulations and applications

Sudhakar Voruganti, Director - Business Development, **Pfanstiehl**

TRACK B: IND-ENABLING & CLINICAL SCALE

Chair Moderation: John Zuris, Director - Editing Technologies, **Editas Medicine**

Redefining mRNA Process Scale-Up to Advance Candidates from Bench to Clinic Whilst Maintaining Quality

11.00 Accelerating Process & Manufacturing Scale-Up into the Clinic with Next Generation Circular RNA Technology

- Leveraging circular RNA technology to develop next generation therapeutics
- Overcoming manufacturing challenges for emerging circular RNA technology
- Exercising on scales to meet clinical demand

Harshal Zope, Director – Manufacturing Science & Technology, **Orna Therapeutics**

11.30 End-to-End Manufacturing of Early-Phase RNA-LNP Candidates

- Overview of RNA and LNP process design and development at CPI
- Development of CPI's platform RNA-LNP manufacturing process to enable access to the clinic
- Inception of CPI's RNA Centre of Excellence – a purpose-built facility

Jessica Sayers , MSAT Lead, **CPI**

TRACK C: COMMERCIAL SCALE

Unravelling Manufacturing Considerations to Develop the Best mRNA Drug Product

11.00 Harnessing Digital Twin for mRNA Manufacturing

- Mechanistic models are being constructed for all unit operations for the manufacturing of mRNA biotherapeutics
- The models are integrated with models for constraints, uncertainties, and disturbances to form a digital twin for integrated manufacturing
- The digital twin is used to analyze the comparative performance for batch and continuous manufacturing

Richard Braatz, Professor, **Massachusetts Institute of Technology**

11.30

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11.50 Reduction of dsRNA Through IVT & Purification Optimization for Therapeutic Indications

- Highlighting dsRNA as an impurity in mRNA therapeutics
- Reducing dsRNA through IVT DOE
- Reducing dsRNA through purification

Vu Thai, Associate Director - Technology Development, **Ultragenyx Pharmaceutical**

11.50 CMC Strategy & Manufacturing Readiness for a Novel Modality at an Emerging Biotech – a Case Study

- Setting up appropriate capabilities internally and externally to meet demand
- Developing a CMC strategy for a complete supply chain
- Strategies for early engagement and speed to clinical batches

Sujit Jain, Director – External Manufacturing, **SalioGen Therapeutics**

11.50 Unlocking Considerations for Early to Late Phase Appropriate mRNA Drug Product Development

- Session Details TBC

Akhilesh Bhambhani, Executive Director, Biologics & mRNA Drug Product Development, **Ultragenyx Pharmaceutical**

12.20 Lunch Break & Networking

Creating the Ultimate IVT Cocktail with Latest Technology Implementation to Streamline mRNA Production

Chair Moderation: Aravindan Rajendran, Senior Principal Scientist – Group Leader, **Pfizer**

1.20 Round Table Discussion: Optimizing Upstream IVT Through Next-Generation Engineering to Maximise an Efficient mRNA Production Process

- How to reduce raw materials of the IVT but increase yield
- How to leverage the latest process advancements to ensure your IVT is up-to-date
- Leveraging experience and practical tips to enhance your IVT reaction for your modality of choice

Moderator: Aravindan Rajendran, Senior Principal Scientist – Group Leader, **Pfizer**

Leveraging Experiences of Scale-Up to Reduce Barriers in Clinical Advancement

Chair Moderation: John Zuris, Director - Editing Technologies , **Editas Medicine**

1.20 Round Table Discussion: Scaling up mRNA-Based Therapeutics & Vaccines from Bench to Clinic

- Step by step or jump big? Accelerating requirements (IVT, purification and analytics) for a scalable production process to support early phase clinical trials
- Exploring the relationships between structure, modifications, toxicity, and safety liabilities for mRNA to ensure effectivity at a larger scale
- Improving sensitivity between upstream and downstream processes to ensure appropriate method scale-up

Xinyue Zhang, Manager, **GeneLeap Biotech**

Prakash Koodathingal, Director – RNA Therapeutics Development, **Immunomic Therapeutics**

Scaling mRNA Process Development & Manufacturing to Meet the Demands of a Changing Global Market

1.20

cytiva

1.50 Round Table Discussion: Manufacturing mRNA Therapeutics to Combat Scalability Challenges in Low-Middle Income Countries

- How to effectively standardize the production scalability of mRNA therapeutics across different diseases
- How to advance the quality of mRNA synthesis to maintain effective scalability for low-middle income countries
- How to ensure capacities both from a development and analytical process to mitigate external sourcing

Ike James, Head of Technology Transfer, **Medicines Patent Pool**

Antonio Grilo, Technology Transfer Expert, **Medicines Patent Pool**

2.15 Afternoon Break & Networking

Achieving a Successful Technology Transfer & Cost-Effective Route from Discovery to Commercialization to Ensure Consistency Across Different Scales of Development

Ike James
Head of Technology Transfer
Medicines Patent Pool

Antonio Grilo
Technology Transfer Expert
Medicines Patent Pool

2.45 **Mapping the Ultimate Route to Equitable Global Process Training & Technology Transfer**

- Addressing the importance of local and regional manufacturing in ensuring equitable access to essential healthcare tools
- Combining needs to maximize resource effectiveness
- Utilizing technology transfer as a capacitation tool for pandemic readiness and interpandemic sustainability

Lakshmi Khandke
Senior Program Advisor
PATH

3.15 **Combating Challenges & Strategic Approaches in the Development of mRNA Vaccines for LMICs**

- Discussing key challenges related to scale up of processes, implementation of novel analytical methods, availability of raw materials and cost
- Leveraging and supporting cost effective new technologies and transfer to LMICs for development and regulatory approval of safe and efficacious mRNA-based therapeutics and vaccines
- Planning for readiness to obtain WHO Pre-Qualification in a timely manner to ensure global delivery of vaccines

Mohamed ElSayed
EVP & CTO
RVAC Medicines

3.45 **Chair's Closing Remarks**

4.00 **Close of 2nd mRNA Process Development & Manufacturing Summit**

> "Production of synthetic mRNAs of the first generation (linear, capped, polyadenylated mRNAs) allowed to provide the world in a very short time with efficient and safe vaccines against COVID-19. However, for the multiple possible utilizations of synthetic mRNA in medicine, other RNA formats may be preferred. This summit delves deeper into their characteristics, optimization and large scale production which is associated with new opportunities but also new challenges that must be well evaluated"
>
> **Steve Pascolo**, Professor, **University Hospital of Zurich**

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Do your 2023 objectives involve forming partnerships with mRNA companies at the forefront of mRNA-based therapeutic and vaccine development?

The 2nd **mRNA Process Development & Manufacturing Summit** provides the ultimate platform to showcase your expertise, raise brand awareness, and benchmark yourself as a key thought-leader and solutions provider within the mRNA community.

Uniting an audience of **250+ experts** eager to tackle the industry's biggest bottlenecks, this your opportunity to demonstrate how you can help drug developers overcome the hurdles of **pDNA manufacturing, mRNA engineering, production, stability and scale-up to accelerate their R&D platforms for regulatory and market readiness!**

Benefit from Market Intelligence

As mRNA technology continues to see positive progressions for therapeutic application, process development, scale up and manufacturing remain key bottlenecks. Hear how and where pharmaceutical giants are looking for services and solutions to facilitate their efforts to produce high-quality and increased yield of mRNA and match your solutions accordingly

Meet & Network In-Person with Industry Pioneers

Bringing together 'boots on the ground' scientists and senior decision makers all in one room who are keen to learn how they can effectively develop methods to improve their bench-to-clinic-to-commercial mRNA production, this is your opportunity to meet prospective clients during structured networking breaks, bespoke 1-2-1 meetings and informal networking receptions

Position Yourself as an Industry Expert

With new and innovative biotechs looking to fast-track their platforms by optimizing their production toolkits to successfully harness mRNA for a variety of therapeutic applications, this meeting is a dedicated platform to ensure your expertise is forefront of mind to the key decision makers in the field

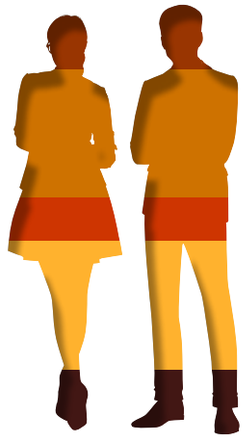
Raise Brand Awareness

Benefit from pre- and post-conference exposure to our community of mRNA key opinion leaders, and increase your market share through unique branding formats. Securing your partnership with this meeting is your ultimate differentiation opportunity to ensure you are positioned against your competitor production, process, and manufacturing solution providers

Generate Commercial Collaborations

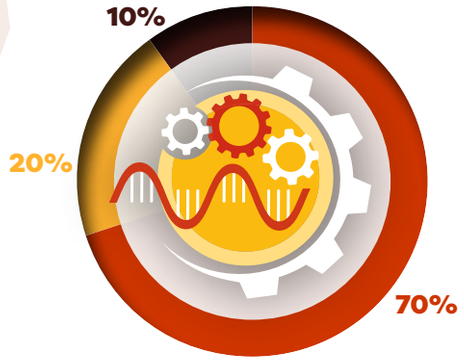
Ensure your top prospects are in the room and a part of the discussion, by having a wish-list of your choice contacted in advance of the event

Attendees by Seniority*



- C-Level/ Founder/ President/ VP: 15%
- Director/ Head of: 30%
- Professor/ Assistant Professor 10%
- Scientist: 30%
- Other: 15%

Attendees by Company Type*



- Large Pharma & Biotech
- Solution Providers
- Research & Academia

*Based on data from mRNA Process Development & Manufacturing Summit 2022

GET INVOLVED

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Team Discounts***

- 10% discount – 3 Attendees
- 15% discount – 4 Attendees
- 20% discount – 5+ Attendees

*To be eligible for this price, the group or individual must be from a biotech or pharma company that has a publicly available pipeline, and does not offer pay for services.

**To be eligible for this price, the group or individual must be full-time academic(s).

***Please note that group discounts are only valid when three or more delegates from one company book and pay at the same time.

Discounts cannot be used in conjunction with any other offer or discount. Only one discount offer may be applied to the current pricing rate.

GAIN insights into how leading companies are optimizing their tools and capabilities to enable scalability, cost-effective and commercially viable mRNA production

DEVELOP your understanding of the industry's bottlecks and solutions to advance the development of safe and stable mRNA-based therapeutics and vaccines

NETWORK with your mRNA community from large pharma and innovative biotechs to build long term collaborations and partnerships

All prices are in USD. Please select the appropriate rate when booking, bookings are subject to organizer approval.

Drug Developer Pricing*	Register & Pay by Friday, June 30	On the Door
Conference + Focus Day	$4,096 **(Save up to $1,300)**	$5,396
Conference + Workshop Day	$4,096 **(Save up to $1,300)**	$5,396
Conference Only	$2,599 **(Save up to $700)**	$3,299

Academic Insitutes & Not-for-Profit Pricing**	Register & Pay by Friday, June 30	On the Door
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Conference + Workshop Day	$3,396 **(Save up to $1,300)**	$4,696
Conference Only	$2,199 **(Save up to $700)**	$2,899

Service & Solution Provider Pricing	Register & Pay by Friday, June 30	On the Door
Conference + Focus Day	$5,096 **(Save up to $1,300)**	$6,396
Conference + Workshop Day	$5,096 **(Save up to $1,300)**	$6,396
Conference Only	$3,299 **(Save up to $700)**	$3,999

3 Easy Ways To Book www.mrna-processandmanufacturing.com/take-part/register Email: info@hansonwade.com Tel: : +1 617 455 4188

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