

# FormuTech Summit 2024

mRNA Process Development & Manufacturing | LNP Formulations



**17-18 October 2024**

Palacio de los Duques Gran Meliá  
Madrid, Spain



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The **FormuTech Summit** brings together over 50+ senior industry experts, uniting leaders in pharmaceutical and biotechnology sectors, as well as academia, to redefine mRNA process development, LNP formulations, and manufacturing. Key topics include empowering mRNA advancements to ensure efficiency and therapeutic relevance, mastering LNP characterization for enhanced efficacy and safety, and overcoming global manufacturing challenges to build a resilient production landscape. Attendees will also explore the expanding applications of LNPs in gene editing and CRISPR technologies, envision an optimized CMC roadmap for consistent mRNA therapeutic quality, and navigate the technical and regulatory landscapes to ensure compliance and safety.

# EPM GROUP EXECUTIVE SUMMARY

## WHO You Will Meet



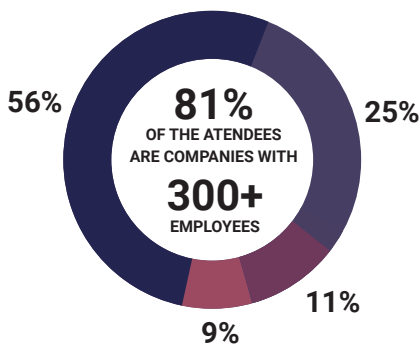
**50+**  
Attendees

**15+**  
Speakers

### RATIO

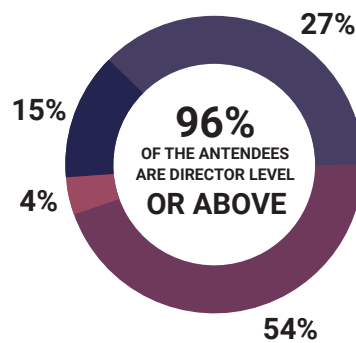
Bio/pharmaceutical manufacturing **65:35** Vendor/Solution Providers

#### Company Size of Attendees



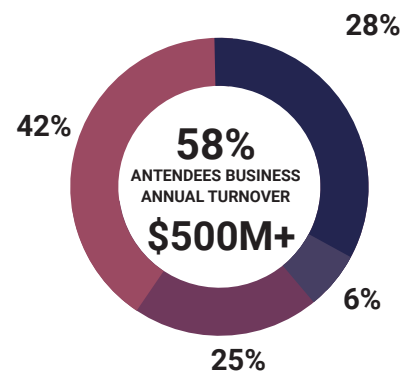
- 1000+ employees
- 300-999 employees
- 50-299 employees
- less than 49 employees

#### Job Title of Attendees



- C-level
- SVP/VP
- Snr Director/Director
- Snr Manager/Manager

#### Attendee Company Annual Turnover



- 1 Billion
- \$500-999Million
- \$50-499 Million
- <50 Million

# HOW You Will Benefit



**x1000+**

Relive the conference.  
Full access to  
documentation,  
footages and videos.



**x10+**

Hours of Networking.  
Forge new  
professional  
contacts.



**x20+**

Case Studies  
Analysis

## COMPANIES ATTENDING



## FEEDBACK

**94%**

RATED EVENT AS



Quality of the speakers  
Sharing of the best practices  
Spectrum of industries  
Intimate atmosphere  
Short-quick presentations

**98%**

WOULD RECOMMEND  
THE EVENT TO  
COLLEAGUES

# Key Practical Points

## **1. Empowering mRNA Advancements**

Accelerate the journey of mRNA processes from research to commercial scale, ensuring heightened efficiency, stability, and therapeutic relevance to meet stringent regulatory and market demands.

## **2. Mastering LNP Characterization**

Navigate the intricate landscape of Lipid Nanoparticles, unraveling their pharmacokinetic-pharmacodynamic profiles, biodistribution patterns, and re-dosing considerations for enhanced therapeutic efficacy and safety.

## **3. Global mRNA Manufacturing Challenges**

Gain valuable insights into overcoming hurdles and bottlenecks faced in the worldwide manufacturing of mRNA vaccines, forging a path toward a more resilient and responsive production landscape.

## **4. Expanding LNP Applications**

Harness the power of LNPs for gene editing, RNA and DNA applications, as well as CRISPR technologies. Explore strategies to encapsulate intricate payloads, including oligonucleotides, for unparalleled therapeutic potential.

## **5. Envisioning an Optimized CMC Roadmap**

Chart the course toward an advanced Chemistry, Manufacturing, and Controls (CMC) strategy for the production of mRNA therapeutics, empowering a future of consistent quality and long-term efficacy.

## **6. Navigating Technical and Regulatory Landscapes**

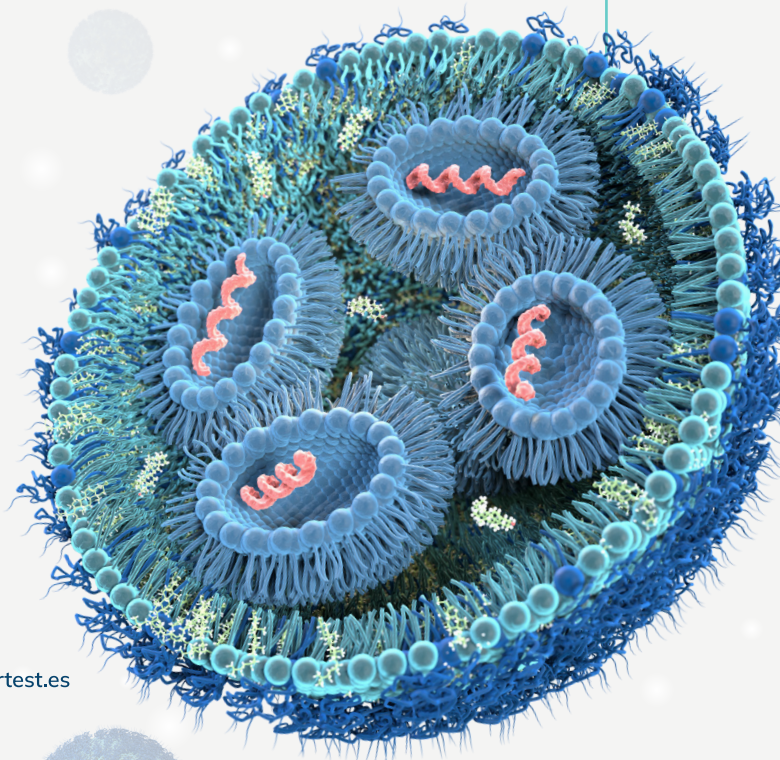
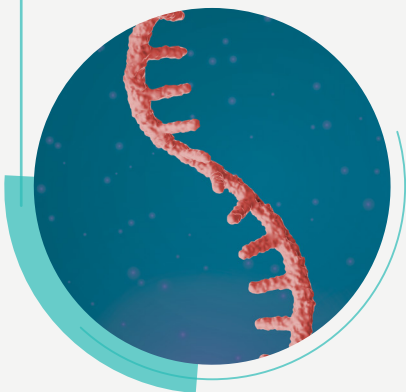
Overcome technical and regulatory hurdles inherent in the development and manufacturing of mRNA vaccines, ensuring compliance, safety, and efficacy.



**certest**

**Targeting & LNPs**  
Technology

**Oligonucleotides**  
& RNA Development



# Meet the Speakers



**Romy M. Dalton**

Chief Operating Officer at Cocoon Bioscience



**Karl Bertram**

Co-founder | Managing Director at ATEM Structural Discovery



**Chiara Bruckmann**

Lab Head, mRNA Process, Formulation and Analytical Development group at ThermoFisher



**Ashish Sarode**

Director, Delivery and Formulations at Sanofi, mRNA Center of Excellence (CoE)



**Mabrouka Maamra**

Project Manager at The University of Sheffield



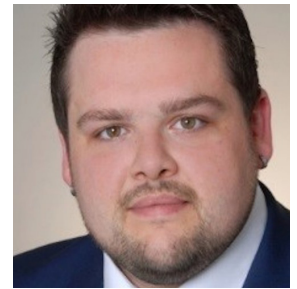
**Ajit Magadum**

Assistant Professor in the Department of Cardiovascular Sciences & ACDC at Temple University in Philadelphia, USA



**Serra Gürcan**

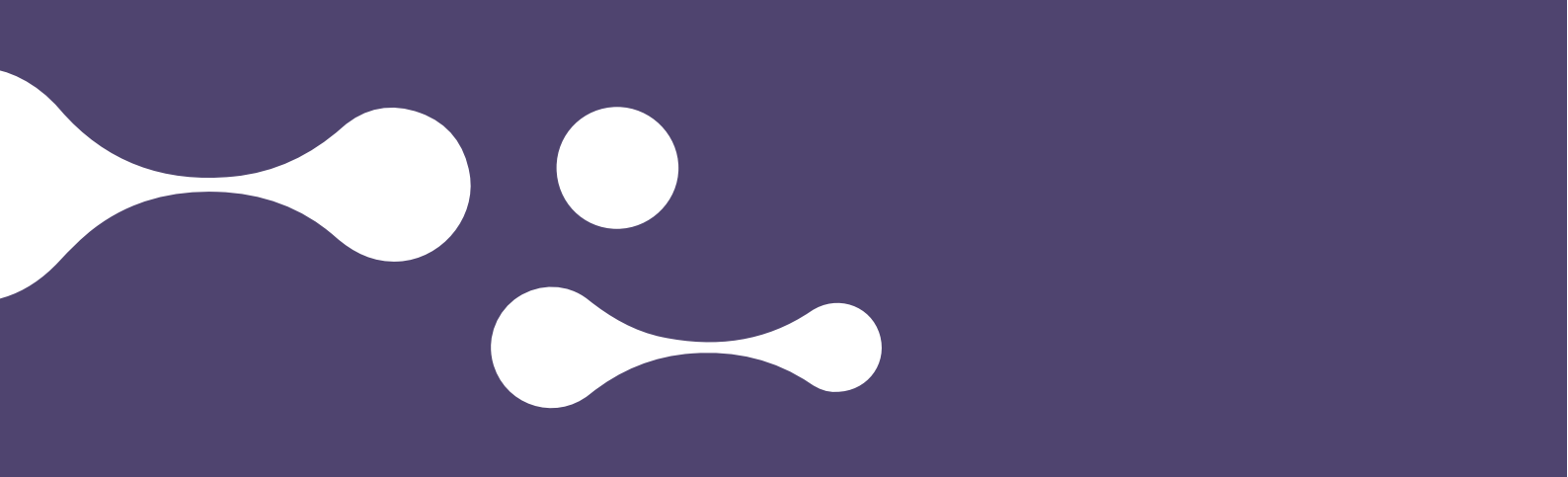
Subject Matter Expert at Corden Pharma



**Alexander Schwenger**

Head of LNP Process Development at Lonza





**Eike F.  
Joest**

Principal Scientist at  
Merck Life Science  
KGaA



**Renske  
Hesselink**

Director Innovations  
at Coalition for  
Epidemic Preparedness  
Innovations (CEPI)



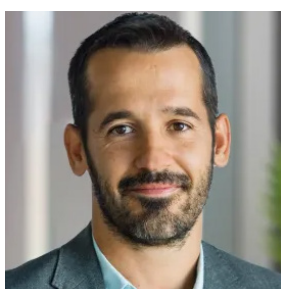
**Harris  
Makatsoris**

Founder at Centillion  
Technology Limited



**Juliana  
Haggerty**

Head of Centre of  
Excellence - LNP  
at CPI



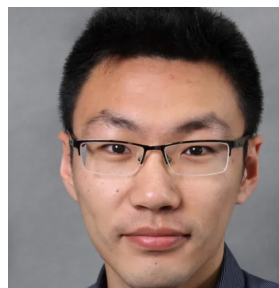
**Juan  
Martinez**

Chief Scientific  
Officer at CerTest  
Biotec



**Setu  
Kasera**

Chief Scientific  
Officer at LEON



**Sixuan  
Li**

Postdoctoral research  
associate at Johns  
Hopkins University



**Maria Jose  
Alonso**

Professor of  
Pharmaceutical  
Technology at  
the University  
of Santiago de  
Compostela

# Scientific Agenda

**DAY 0**

WEDNESDAY, OCT. 16<sup>TH</sup>

**06:00PM**

Pre-Conference  
Cocktail Reception

Address:  
Nice to Meet You  
Restaurant & Lounge  
Gran Vía, 80, Centro, 28013  
Madrid, Spain

**DAY 1**

THURSDAY, OCT. 17<sup>TH</sup>

**09:00AM**

FormuTech Summit  
Registration

**Session 1:  
Pioneering mRNA Innovations**

**Morning Chairperson:**

Alexander Schwenger, Lonza

**09:30AM**

**Quality by Digital Design for  
Developing Platform RNA  
Vaccine and Therapeutic  
Manufacturing Processes**

Dr. Mabrouka Maamra,  
Project Manager at University  
of Sheffield

**10:00AM**

**Enhanced mRNA  
Performance by PCR-based  
Manufacturing**

Eike Joest, Principal  
Scientist at Merck Life  
Science KGaA

**10:30AM**

**Speed Networking**

**11:00AM**

**Morning Coffee Break**

**Session 2:  
LNP Mastery**

**11:30AM**

**Lipid Nanoparticles for  
mRNA Delivery**

Ashish Sarode, Director,  
Delivery and Formulations at  
Sanofi, mRNA Center of  
Excellence (CoE)

**12:00PM**

**Next-Gen Cryo-EM Based  
LNP Characterization**

Karl Bertram  
Co-founder, Managing  
Director at ATEM Structural  
Discovery

**12:30PM**

**Next Generation of Encapsulation - Optimizing GMP Manufacturing of Lipid Nanoparticles**

Dr. Alexander Schwenger,  
Head of LNP Process  
Development at Lonza

**1:00PM**

Lunch Break

**Afternoon Chairperson:**

Eike F. Joest, Merck Life Science KGaA

**Session 3:**

**Advanced Manufacturing Techniques**

**2:00PM**

**A holistic approach to reliable GMP manufacturing of nanoparticle formulations at all scales**

Setu Kasera  
Chief Scientific Officer at  
LEON

**2:30PM**

**Biofoundry-in-A-Box™: Modular micro factories for powering the global RNA manufacturing network**

Harris Makatsoris,  
Founder at Centillion  
Technology Limited

**3:00PM**

**Innovative Ionizable Lipids: Crafting the Next Generation of Targeted and Thermostable LNPs**

Juan Martinez  
Chief Scientific Officer at  
CerTest Biotec

**3:30PM**

**An efficient lipid library is available, containing a variety of lipid components for creating RNA-LNPs.**

Serra Gürcan, Subject Matter  
Expert at Corden Pharma

**4:00PM**

Afternoon Coffee Break

**4:30PM**

**Panel Discussion:**

**"Optimizing mRNA Therapies: Manufacturing, Characterization, and Delivery Challenges"**

- Key Techniques for LNP Characterization and Ensuring Safety in mRNA Therapeutics
  - Advances in GMP Manufacturing for Scalable, High-Quality mRNA Production
  - Strategies to Enhance mRNA Delivery by Overcoming Biological Barriers
- Panelists:**
- Ashish Sarode, Sanofi
  - Juan Martinez, Certest
  - Harris Makatsoris, Centillion Technology
  - Eike Joest, Merck Life Science KGaA
- Moderated by:**  
Alexander Schwenger, Lonza

**5:30PM**

End of the 1 st day of  
FormuTech Summit

**08:00PM**

FormuTech Conference  
Dinner  
Address:  
Nice to Meet You  
Restaurant & Lounge  
Gran Vía, 80, Centro, 28013  
Madrid, Spain

**DAY 2**

FRIDAY, OCT. 18<sup>TH</sup>

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**Session 4:  
Global Challenges and Solutions**

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**Morning Chairperson:**

Chiara Bruckmann, ThermoFisher

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**9:20AM**

**Opening of 2nd day  
FormuTech Summit**

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**9:30AM**

**CrisBio@: A novel, natural  
and scalable protein  
expression system**  
Romy M. Dalton, Chief  
Operating Officer at  
CocoonBioscience

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**10:00AM**

**Targeting: Global mRNA  
Manufacturing Challenges:  
Overcome Worldwide  
Manufacturing Hurdles for  
a Resilient and Responsive  
Production Landscape**  
Chiara Bruckmann, Lab  
Head, mRNA Process,  
Formulation and Analytical  
Development group at  
ThermoFisher

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**10:30AM**

**RNA Nanomedicines: Helping  
RNA overcoming Biological  
Barriers**  
Maria Jose Alonso,  
Professor of Pharmaceutical  
Technology at the University  
of Santiago de Compostela  
at University of Santiago de  
Compostel

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**11:00AM**

Morning Coffee Break

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**Session 5:  
Collaborative and Innovative Approaches**

**11:30AM**

**UK Intracellular Drug Delivery  
Centre: A Collaborative  
Programme Using Advanced  
Technology Solution to  
Accelerate and De-risk RNA  
Formulation Development**  
Juliana Haggerty, Head of  
Centre of Excellence - LNP  
at CPI

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**12:00PM**

**Panel Discussion:**  
Global mRNA Manufacturing  
Challenges

- Strategies to overcome bottlenecks and hurdles in manufacturing.
- Ensuring a resilient and responsive production landscape.
- Collaborative efforts to enhance global mRNA manufacturing capabilities.

**Panelists:**

- Juliana Haggerty, CPI
- Chiara Bruckmann, ThermoFisher
- Maria Jose Alonso, University of Santiago de Compostela
- Karl Bertram, ATEM

**Moderated by:**

Renske Hesselink, CEPI

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**1:00PM**

Lunch Break

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**Afternoon Chairperson:**

Renske Hesselink, CEPI

## Session 6: Expanding Horizons

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**02:00PM**

**Innovative Technologies for mRNA Thermostability, and Distribution and Delivery for Equitable Access**

Renske Hesselink, Director  
Innovations at Coalition for  
Epidemic Preparedness  
Innovations (CEPI)

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**02:30PM**

**mRNA therapeutics design and development of cardiovascular and metabolic diseases / cell and tissue-specific mRNA delivery and targeting (non-LNP based) [Virtual].**

Ajit Magadum  
Assistant Professor  
in the Department of  
Cardiovascular Sciences &  
ACDC at Temple University in  
Philadelphia, USA

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**3:00PM**

**Empowering mRNA Therapies: Advanced Single-Particle Analysis for Optimizing LNP Characterization and Drug Formulation. [Virtual]**

Sixuan Li  
Postdoctoral research  
associate at Johns Hopkins  
University

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**3:30PM**

End of FormuTech Summit



# Biographies



## **Romy M. Dalton** Chief Operating Officer at Cocoon Bioscience

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Romy M. Dalton has a PhD in Molecular Biology and Virology, and more than 23 years of experience in the field, with 14 scientific publications in peer reviewed journals. She has dedicated 17 years of her professional life to virology applied to biotech, 9 of

them in biotech operations management. Currently, she is the COO and CSO at Cocoon Bioscience, managing operations and development of the unique CrisBio® technology, in which development she has been involved for the last 9 years.



## **Chiara Bruckmann** Lab Head, mRNA Process, Formulation and Analytical Development group at ThermoFisher

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Chiara Bruckmann has over 20 years of experience in the field of life sciences and possesses strong expertise in downstream processes. She specializes in developing analytical tools and techniques that aid in understanding complex protein-nucleic acid systems. Her previous experience includes working in the R&D pre-clinical division of a small Italian

biotech company where she contributed to moving the company's lead candidate into the clinical phase. Her educational background includes a BS in Biology, an MS in Biochemistry from the University of Rome (Italy), and a PhD in Structural Biology from the University of Edinburgh (UK).

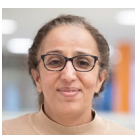


## **Ashish Sarode** Director, Delivery and Formulations at Sanofi, mRNA Center of Excellence (CoE)

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Educational background in Pharmaceutical Sciences. More than 15 years of combined academic and industrial experience in pharmaceutical and biotechnology field. Experience of leading teams in a matrix structure and representing those cross functionally. Expertise in developing formulations for various modalities such as nucleic acid-based

drugs, small molecules, and cyclic peptides. Expertise in formulation development of lipid and polymer-based nanoparticles, amorphous solid dosage form development, and controlled release formulation development using polymer nano- and microparticles and depot forming lipid formulations.



## **Mabrouka Maamra** Project Manager at The University of Sheffield

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Dr. Mabrouka Maamra earned a Nature Sciences degree at the "Universite Paris XII," and a Master in Technical Sciences and Techniques in Chemistry applied to Biology. Her PhD was in Molecular Endocrinology at the University of Sheffield. As a postdoctoral scientist, she worked on developing therapeutics for endocrine and kidney diseases

using a wide range of molecular/cellular and animal models. In 2023, she joined Dr. Zoltan Kis's team, working on the development and modelling of rapid-response vaccine production platform technologies funded by the Wellcome R3 program as a project manager.



**Ajit Magadum** Assistant Professor in the Department of Cardiovascular Sciences & ACDC at Temple University in Philadelphia, USA

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Assistant Professor in the Department of Cardiovascular Sciences & ACDC at the Lewis Katz School of Medicine, Temple University in Philadelphia, USA. He earned his Ph.D. from the Max Planck Institute for Heart and Lung Research in Germany in 2014. During his postdoctoral tenure at Mount Sinai in New York, he made significant advancements in developing mRNA or modified

mRNA (modRNA) delivery systems tailored for the cardiovascular system, utilizing various carriers to ensure robust and sustained mRNA expression within cardiac tissues. In 2016, he developed the first-of-its-kind cell-specific mRNA delivery platform known as SMRTs (Specific Modified mRNA Translation System).

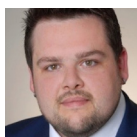


**Serra Gürcan** Subject Matter Expert at Corden Pharma

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Serra earned her bachelor's in Chemistry before transitioning her focus to formulation sciences. She continued her academic journey by obtaining a Master's in Science from the Pharmaceutical Technology Department at the University of Ege in Turkey. During this time, she dedicated six months to research at the University of Pavia, focusing on developing polymeric micelles. Her educational

journey culminated in a doctoral research project where she explored combined formulations in a joint program with the University Paris Saclay. Specifically, she investigated cationic lipid nanoparticles complexed with anti-TNF alpha siRNA encapsulated an anti-inflammatory drug to create a novel combined therapy approach.

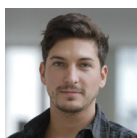


**Alexander Schwenger** Head of LNP Process Development at Lonza

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Alexander has more than 10 years of experience in the field of mRNA/LNP gained in academia and the pharmaceutical industry. After completing his Diploma degree, he specialized in nucleic acid chemistry and nano structuring and received his PhD from the University of Stuttgart. He has a long

list of publications and has worked in various roles of increasing responsibility at Curevac SE Germany. Since June 2023, Alex is leading the process development for nucleic acid delivery systems at Lonza (Netherlands) and strives to bring this modality to a new level.



**Eike F. Joest** Principal Scientist at Merck Life Science KGaA

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Eike is Principal Scientist for innovations and technologies in mRNA service offering. He was responsible for development of the upscaled mRNA manufacturing process and implementation of AmpTec™ technologies in R&D. Before joining Merck Life Science KGaA in Darmstadt, Germany, he

demonstrated broad technical expertise in synthetic biology and molecular biology by publishing in several peer-reviewed journals. Eike holds a M.Sc. with distinction in Biochemistry from Wuerzburg University and a summa cum laude Ph.D. in cellular Biochemistry from Frankfurt University.

# Biographies



## **Renske Hesselink** Director Innovations at Coalition for Epidemic Preparedness Innovations (CEPI)

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Dr Renske Hesselink is a biochemist with a background in the vaccine industry, who is currently working as Director Innovations at CEPI, the Coalition for Epidemic Preparedness Innovations. At CEPI, she works on technology innovations that enable the rapid development and suitably scaled

manufacturing of equitably accessible vaccines for outbreak response. Prior to joining CEPI, Renske worked in the pharmaceutical industry for over 10 years, mainly in formulation, analytical, and drug product development for various vaccines and biologics.



## **Harris Makatsoris** Founder at Centillion Technology Limited

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Harris is the founder and director of Centillion Technology Limited, based in Cambridge, UK, a biotech specialising in the rapid scaling and manufacture of RNA-based therapeutics and vaccines. He is also Professor in the Department of Engineering at King's College London. He has a process engineering background with 28-years experience in both industry and academia. In

all his past and present roles, he is managing interdisciplinary projects that require integration and coordination. Harris is an expert in continuous RNA manufacturing. His work is focusing on addressing the challenges in the rapid design, development and scalable manufacture of RNA and other nucleic acids and has pioneered the application of flow technologies in RNA manufacture, of various types.

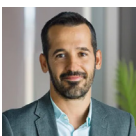


## **Juliana Haggerty** Head of Centre of Excellence - LNP at CPI

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Juliana (Jules) Haggerty is leading a new UK Centre of Excellence to enable radical innovation in the field of Intracellular Drug Delivery for nucleic acid therapies and vaccines, working with partners across the UK's academic and research ecosystem. She has worked at CPI since 2014, supporting their RNA vaccine programmes for the UK Vaccine Taskforce in 2020 and providing expert advice and due diligence on legacy activities and onshoring throughout

2021. Jules sits on the Technology and Innovation committee of the UK Medicines Manufacturing Industry Partnership and has significant expertise in the use of public/ private funding and collaborative R&D models to advance technology and innovation. Jules has a BSc (Hons) degree in Physiological Sciences and an EngDoc in Biopharmaceutical Process Development from Newcastle University.



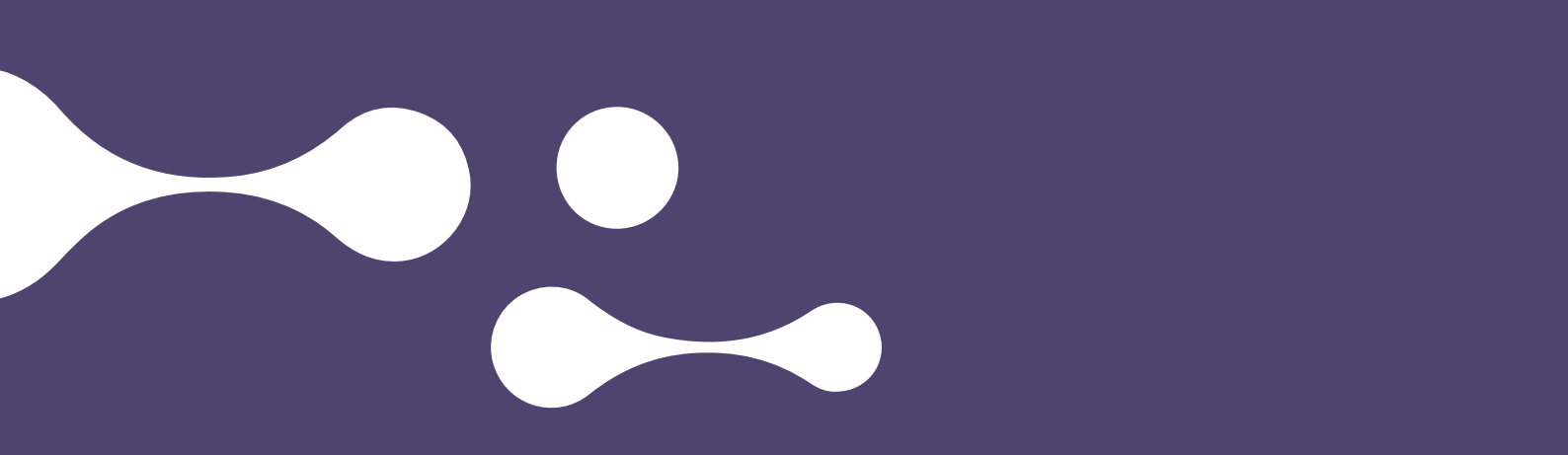
## **Juan Martinez** Chief Scientific Officer at CerTest Biotec

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Juan Martinez is a seasoned professional with over 15 years of experience in the Life Sciences, In-vitro Diagnostics, and RNA Therapeutics industries. Currently, he serves as the Chief Scientific Officer at Certest Biotec. In this position, he oversees the scientific direction of the Pharma division, focusing

on RNA and Oligonucleotides, delivery systems, and therapeutics. His leadership includes spearheading the development of innovative technologies, such as mRNA vaccines, and discovering new ionizable lipids and thermostable LNPs for targeted delivery.



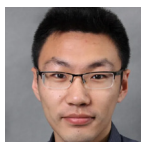


**Setu Kasera** Chief Scientific Officer at LEON

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With more than a decade of hands-on experience in nanotechnology and industry background in drug development, Setu spearheads research and product development at LEON. She received her PhD and MPhil degree in Chemistry at the University of Cambridge, UK. Before moving into the role of Chief

Scientific Officer, Setu was the Head of Science & Engineering at LEON and held various positions in research and business strategy in the biotech industry, across medical diagnostics, drug discovery and Chemistry, Manufacturing & Controls (CMC).

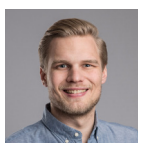


**Sixuan Li** Postdoctoral research associate at Johns Hopkins University

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Dr. Sixuan Li is a postdoctoral research associate in the BioMEMS and Single Molecule Dynamics laboratory at Johns Hopkins University. He obtained his PhD in the same lab under advised by Dr. Jeff (Tza-Huei) Wang. His research focuses on developing and applying innovative methods in single-molecule analysis including nucleic acids, proteins, and

nanoparticles to help understand the fundamental questions of drug delivery. His multidisciplinary approach draws from biophysics, chemistry, optics, and engineering to push the boundaries of scientific knowledge. He has published 10 peer reviewed research articles, and he holds one patent on the characterization of nanoparticles.



**Karl Bertram** Co-founder | Managing Director at ATEM Structural Discovery

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Dr. Karl Bertram completed his PhD and postdoctoral position at the Max Planck Institute for Biophysical Chemistry, where he focused on the 3D structures of human spliceosomes. With his strong background

in cryo-EM, he co-founded ATEM, providing his knowledge to develop an entirely novel cryo-EM platform.



**María José Alonso** Professor of Biopharmaceutics and Pharm. Tehcnology, University of Santiago de Compostel

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María José Alonso is Professor of Pharmaceutical Technology at the University of Santiago de Compostela, Spain. Her lab has pioneered numerous discoveries in the

field of nanomedicine, notably in the area a vaccination, transmucosal drug delivery and precision medicine in oncology.



# Palacio de los Duques Gran Meliá

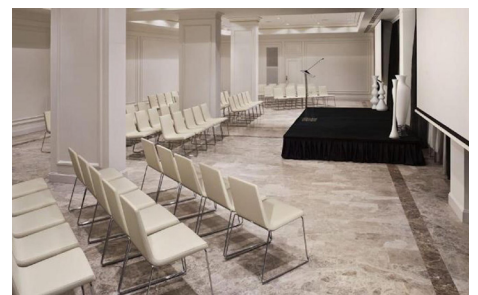
The FormuTech Summit 2024 will be held at the Palacio de los Duques Gran Meliá, a luxurious hotel set in a 19th-century Isabelline palace, located in the heart of Madrid's historic "Madrid de los Austrias" district.



Inspired by the masterpieces of the renowned painter Velázquez, the Palacio de los Duques Gran Meliá provides an exceptional setting with its stunning façade, lush historic gardens, and breathtaking views from its rooftop terrace.



As a member of The Leading Hotels of the World, the Palacio de los Duques Gran Meliá promises the highest standards of quality and service, making it the perfect venue to host the FormuTech Summit 2024. Join us in this elegant environment where tradition meets innovation, right in the vibrant heart of Madrid.



Cuesta Santo Domingo, 5 y 7  
Centro de Madrid, 28013  
Madrid, Spain

