Speakers

Dr Mohamad Toutounji
Molgenium

Dr Christoph Peter
Peter Auditing

Selina Roth
Lonza

Dr Julia Schüler
Charles River Laboratories

Virus-free Transduction in Cell Therapy

Live Online Training on 06/07 May 2025

Highlights

- RNA-based Technologies and Applications
- Advances in Cell Therapies without Viral Transduction
- Latest Technologies in Cell Engineering and Manufacturing

Objectives

The primary objective of this two-day course, is to provide participants with a comprehensive understanding of the latest breakthroughs in non-viral transduction methods for cell therapy. Designed for professionals in the pharmaceutical and biotechnology sectors, the course aims to foster a deeper appreciation of RNA-based medicinal products, non-viral delivery systems, and their transformative potential in advancing cell therapies.

By the end of the course, participants will have a robust understanding of both the scientific principles and practical applications of RNA and non-viral technologies, enabling them to contribute to the development of innovative and patient-centric therapies.

Background

Innovations in cell therapies have revolutionized the pharmaceutical and biotech industries, unlocking unprecedented possibilities for treating previously incurable diseases. Traditional viral transduction methods, while effective, face significant challenges, including scalability, high production costs, and potential immunogenicity. To address these limitations, virus-free transduction technologies have emerged as promising alternatives, enabling safer, more efficient, and scalable cell engineering solutions.

At the forefront of these innovations is the use of RNA, a versatile biomolecule that has transformed therapeutic approaches in various domains. The success of mRNA-based vaccines, exemplified by the BioNTech COVID-19 vaccine, has demonstrated the molecule's potential to drive rapid and targeted therapeutic development. Beyond vaccines, RNA is increasingly utilized in personalized medicine, particularly in cancer therapies, where patient-specific RNA-based treatments are being explored.

Non-viral delivery platforms, including lipid nanoparticles (LNPs), electroporation, and cell squeeze technologies, have emerged as game-changing tools in cell therapy. These systems offer distinct advantages, such as reduced toxicity, enhanced delivery efficiency, and streamlined manufacturing processes. By eliminating the risks associated with viral vectors, these technologies pave the way for more accessible and patient-friendly therapies.

Despite these advancements, the regulatory and manufacturing landscapes for virus-free transduction methods remain complex. Developing robust quality control measures and adhering to stringent GMP requirements are critical for ensuring the safety and efficacy of these therapies. Furthermore, understanding the comparative strengths and weaknesses of viral and non-viral systems is essential for informed decision-making in therapeutic development.

This course is designed to address the knowledge gaps in this rapidly evolving field, offering professionals a unique opportunity to engage with experts and gain practical insights into the future of RNA and non-viral cell therapy platforms.

With a focus on real-world applications, cutting-edge research, and regulatory considerations, the program equips participants with the tools to drive innovation in their respective fields.

Target Audience

This training is tailored for professionals in the pharmaceutical, biotechnology, and life sciences sectors who are actively involved in the development, manufacturing, or regulation of advanced therapies. It is designed for individuals seeking to expand their knowledge of RNA-based products and non-viral transduction technologies, particularly as they pertain to cell therapy and precision medicine. Whether you are an academic, an industry professional, or a regulatory expert, this course provides valuable knowledge to enhance your expertise and contribute to advancing the field of cell therapies.

Programme

Introduction to RNA as an API
Dr Christoph Peter

- The biology, mode of action and current formulations of RNA
- RNA-based medicinal products: Overview over current clinical trials and approved products
- The current regulatory landscape for RNA-based products

Advances in Virus-free Transduction for Cell Therapies
Dr Julia Schüler

- Introduction to cell therapy across different disease areas
- Different non-viral platforms and their applications
- Outlook and future directions

Comparison of Viral vs. Non-viral Delivery in Cell Engineering
Dr Julia Schüler

- Introduction to cell therapy across different disease areas
- Challenges of viral delivery: manufacturing, transduction efficiency, toxicities
- How can non-viral delivery systems solve these challenges
- Summary overview of viral vs non-viral delivery systems

Lipid Nanoparticles (LNPs) for Cell Engineering
Dr Mohamad Toutounji

- Introduction to LNPs: Structure and function
- Use of LNPs in cell manipulation
- Comparison of LNP technologies with alternative systems
- Future prospects for LNPs in research and clinical applications

mRNA Delivery Systems in CAR-T and other Cell Therapies
Dr Mohamad Toutounji

- Overview of mRNA technologies in cell therapy
- Optimizing mRNA transfection for CAR-T cells
- Challenges and advances in mRNA delivery
- Applications beyond CAR-T: next generation mRNA-based cell therapies

GMP-Compliant Manufacturing of Virus-free engineered Cells
Selina Roth

- Introduction to GMP-compliant cell therapy manufacturing
- Process control and quality assurance
- Scalability challenges and new emerging technologies

Ensuring the Safety and Functionality of engineered Cells: Quality Control and Characterization
Selina Roth

- Standards and quality control strategies for engineered cells
- Characterization techniques for engineered cells
- Defining appropriate release criteria for virus-free cells

Clinical Trial Design Considerations
Dr Mohamad Toutounji

- Outline key endpoints and safety monitoring specific to viral-free engineered cells
- Discuss manufacturing challenges and solutions during clinical development
- Address patient stratification and dosing strategies
- Present strategies for demonstrating comparability to viral vector-based approaches

Emerging Technologies: Electroporation and Cell Squeeze
Dr Mohamad Toutounji

- Principles and mechanisms of electroporation and cell squeeze
- Advantages and limitations of the two methods
- Comparison with other cell-manipulating technologies
- Application examples and future developments

In Vivo Use of RNAs – a closer Look
Dr Christoph Peter

- The development of the BioNTech Covid-19 vaccine
- Current developments in RNA-based vaccines
- Development of a patient individualized RNA-based cancer vaccine

Speakers

Dr Mohamad Toutounji
Molgenium
CEO

Dr Mohamad Toutounji has 10 years of experience in ATMP and has worked in various positions in R&D, CMC, Manufacturing at Molgenium, Sanofi and GE Healthcare during these years. He is also the CEO and founder of Molgenium.

Dr Christoph Peter
Peter Auditing

Dr Peter studied at the University of Heidelberg and obtained his PhD at the Max Planck Institute for Medical Research. After a postdoctoral fellowship at Stanford University, he joined Apceth, a CMO for cell-based ATMPs, in 2008 as Head of Production. In 2011 he became Deputy QP and later Head of Quality Assurance. In 2016, he joined BioNTech and, after holding various positions, was appointed Vice President Global Systems Quality. Since 2024, he has been a consultant, assisting companies with GMP audits.

Selina Roth
Lonza
QC Supply and Strategy Lead

Dr Selina Roth is currently working as QC Biologics Supply and Strategy Lead by Lonza Visp. She has 10 years experience in Quality control and has worked in multiple positions within QC at Lonza and Crucell.

Dr Julia Schüler
Charles River Laboratories
Therapeutic Area Lead Oncology

Dr Schüler serves as Therapeutic Area Lead Oncology at Charles River Germany (CRL), in Freiburg and as Scientific Oncology lead in the global scientific strategy group. She held several leading positions at Oncotest GmbH in Freiburg focusing on in vivo tumorbiology and operations. As a tumor-biologist, Julia is an expert in preclinical oncology drug testing platforms. She leads the oncology strategy team within CRL and represents oncology in the global scientific strategy group at CRL. Overall, Julia Schueler has co-authored >80 publications, including several landmark papers in the field of preclinical cancer models and PDX development.

Moderator

Clemens Mundo, Concept Heidelberg

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Reservation Form (Please complete in full)

Virus-free Transduction in Cell Therapy
Live Online Training on 06/07 May 2025

Title, first name, surname

Department | Company

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Date of the Live Online Training

Tuesday, 06 May 2025, 09.00 h – 15.30 h CEST
Wednesday, 07 May 2025, 09.00 h – 15.00 h CEST

Technical Requirements

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Fees (per delegate, plus VAT)

ECA Members € 1,890
APIC Members € 1,990
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EU GMP Inspectorates € 1,045
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 22136.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

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Conference Language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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