1. Scientific

Experts will explain the different classes of Advanced Therapies, walking you through examples of gene & cell therapy, and tissue engineering.

After completing this learning unit you will be able to:

- Describe the structural biology & function of CAR-T cells
- Describe the role Mesenchymal Stem Cells (MSCs) in regenerative medicine
- Explain Dentric Cell (DC) biology, DC life cycle and what makes a good DC vaccine
- Define what gene therapy is and list the potential applications of gene editing
- Understand the importance of innovative preclinical models and cutting-edge technologies such as CRISPR-CAS
- Recall important development steps of the 1st market-approved stem-cell product

Speakers:

- Dr. Sébastien Wälchli
  Oslo University Hospital
- Dr. Graziella Pellegrini
  UNIMORE
- Dr. Miguel Chillon
  VHIR Barcelona
- Dr. Mangala Srinivas
  RadboudUMC
- Dr. Urban Svajger
  The Blood Transfusion Center of Slovenia
2. Manufacturing & quality control

An overview of manufacturing autologous and allogenic cell therapies, types of environments needed, how scale-up works, and what sets the manufacturing of ATMPs apart from other medicines.

After completing this learning unit you will be able to:

- Distinguish an Advance Therapy Medicinal Product (ATMP) from other products
- Differentiate between autologous vs allogenic cell therapies
- List the steps of the cell therapy manufacturing process
- Recognise and describe the basic GMP principles required for ATMP production
- Describe biosafety issues related to cell and tissue donation
- Understand the concept of induced Pluripotent Stem Cells (iPSCs), how they are generated and used for clinical application.

Speakers:

Dr. Melissa van Per
NECSTGEN

Dr. Cristina Galli
ISS

Dr. Stephen Sullivan
GAiT
3. Regulatory

You will receive an overview all the legislation that applies to ATMPs from regulators from the European Medicines Agency (EMA).

After completing this learning unit you will be able to:

- Describe what is ATMP Classification and why it is needed
- Define the EU regulatory concepts of Gene Therapy Medicinal Products, Somatic Cell Therapy Medicinal Products, Tissue Engineered Products
- Explain the objectives of conducting Environmental Risk Assessment (ERA)
- Distinguish between the ERA for GMO products and non-GMO products
- Use EMA Tools to support drug development including the process of scientific advice

Speakers:

Patrick Celis
European Medicines Agency

Victoria Palmi Reig
European Medicines Agency

Anna Tavridou,
European Medicines Agency

Dolça Rogers
European Medicines Agency
4. Reimbursement & Pricing

In this unit we will look at the main market access principles for medicinal products and innovative payment models for ATMP market access. You will also gain insight into some of the tools used to assess the future benefit of an ATMP including Health Technology Assessment (HTA) which is a key process to ascertain the potential value of an ATMP to the patient and society.

After completing this learning unit you will be able to:

- Explain the concept of Health technology Assessment (HTA)
- Differentiate between conventional vs ATMP reimbursement models.
- Understand the main market access principles for medicinal products and innovative payment models for ATMP market access.
- Discuss the role of patient organizations in making ATMPs a reality in the clinic.

Speakers:

Dr. Umberto Restelli
San Raffaele Hospital

Prof. Isabelle Huys
KU Leuven

Daniel Kostan
SMAci
In this final unit on career coaching, you will be get an understanding of the wide variety of career opportunities the field of ATMPs and receive some helpful guidance on enhancing personal effectiveness and future employability.

After completing this learning unit you will be able to:

- Optimise your CV and motivation letter
- Prepare for a job interview and speak about your skills and Unique Selling Points (UPS)
- Understand the hiring process
- Appreciate the diversity of career tracks in ATMPs
- Improve your well-being, work life balance & build up resilience

**Speakers:**

- Merel Ackx  
  KU Leuven
- Kim Verboomen  
  KU Leuven
- Melissa Van Beselaere  
  KU Leuven
- Mangala Srinivas  
  Wageningen University
- Stephen Sullivan  
  Lindville Bio
- Vincenzo Mercurio  
  BC Platforms
- Nicole Wedell von Leupoldt  
  KU Leuven
- Luigi Aurisicchio  
  Takis Biotech