

ADVANCE

E-LEARNING COURSE

Online self-paced course on cell & gene therapy development



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 Dendritic 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 Chillón
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:



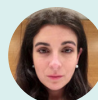
Patrick Celis
European Medicines Agency



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

Bonus: Career coaching



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
- ▶ Appreciated 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