



# **Cell and Gene Therapy Foundations and Delivery Course**

23 – 27 August 2027  
Rome



**AGILE LEADERS**  
Training Center

## Cell and Gene Therapy Foundations and Delivery Course

**Ref:** 1490\_210003 **Date:** 23 – 27 August 2027 **Location:** Rome **Fees:** 5700 Euro

### Overview

Cell and Gene Therapy Foundations and Delivery Course is a one-week foundation course for healthcare, biotechnology, pharmaceutical, quality, clinical operations, and patient-access personnel, who leave with a Cell and Gene Therapy Pathway Map. The course explains product types, scientific concepts, development and manufacturing interfaces, identity controls, clinical handoffs, safety monitoring, and cross-functional governance without laboratory or prescribing instruction. Agile Leaders Training Center presents cell and gene therapy foundations for coordinated product delivery.

### Who Should Attend

- Teams responsible for cell and gene therapy service readiness
- Personnel supporting biotechnology and pharmaceutical operations
- Functions responsible for quality, logistics, and product handoffs
- Teams supporting clinical operations and patient pathways
- Personnel responsible for access, governance, and safety interfaces

The course assumes no laboratory specialization and leaves out product manufacture, clinical prescribing, patient-specific decisions, and jurisdiction-specific regulatory advice.

### Departments and Industries

The course supports organizations that coordinate advanced therapy products across development, supply, care delivery, and follow-up.

- Biotechnology and biopharmaceutical organizations
- Hospital cell therapy and specialist care services
- Clinical research and trial operations units
- Quality, supply chain, laboratory, and pharmacy interfaces
- Patient access, health technology, and service-planning teams

### Learning Objectives

By the end of this course, participants will be able to:



- Compare major cell, tissue, and gene therapy product types
- Use in vivo, ex vivo, autologous, and allogeneic distinctions
- Analyze development, manufacturing, and release interfaces
- Build chain-of-identity and chain-of-custody process maps
- Evaluate clinical handoffs and long-term safety monitoring needs
- Prioritize cross-functional readiness and governance actions

## **Course Agenda**

### **Day 1: Products and Scientific Foundations**

- Cell, Tissue, and Gene Therapy Product Classification Map
- In Vivo and Ex Vivo Delivery Comparison
- Autologous and Allogeneic Product Decision Grid
- Viral and Nonviral Vector Concept Map
- Gene Addition, Editing, and Cell Engineering Overview

### **Day 2: Development and Manufacturing Lifecycle**

- Discovery-to-Delivery Lifecycle Map
- Starting Material and Donor Source Trace
- Process Development and Critical Quality Attribute Matrix
- Manufacturing Change and Comparability Concept Guide
- Product Testing and Release Interface Map

### **Day 3: Identity, Custody, and Logistics**

- Patient and Product Chain-of-Identity Map
- Chain-of-Custody Handoff Record
- Collection and Apheresis Process Interface
- Cryopreservation, Storage, and Transport Control Map
- Exception, Deviation, and Escalation Decision Tree

### **Day 4: Clinical Delivery and Follow-Up**

- Center Readiness and Multidisciplinary Role Matrix
- Patient Journey and Scheduling Dependency Map
- Product Receipt, Preparation, and Administration Handoff
- Immediate Safety Observation and Reporting Interface
- Long-Term Follow-Up and Pharmacovigilance Map



## Day 5: Cell and Gene Therapy Pathway Practice

- Suggested Exercise: Product Classification Decisions
- Suggested Exercise: Lifecycle and Quality Interface Mapping
- Suggested Exercise: Identity and Custody Control Review
- Suggested Exercise: Clinical Delivery and Follow-Up Planning
- Capstone Exercise: Cell and Gene Therapy Pathway Map

## Practical Exercises

The course uses suggested activities with fictional product-development, manufacturing, logistics, hospital, and follow-up scenarios.

- Suggested activity: classify product examples and map in vivo, ex vivo, autologous, and allogeneic features.
- Suggested activity: trace lifecycle interfaces, quality information, and release dependencies.
- Suggested activity: identify patient-product handoffs and failure points in identity and custody.
- Suggested activity: build a service pathway linking readiness, delivery, monitoring, and governance.

## FAQs

### Who suits cell and gene therapy foundations training, and what does it assume?

Healthcare, biotechnology, pharmaceutical, quality, clinical operations, logistics, access, and service-planning personnel suit the course; it assumes no laboratory specialization.

### How does cell and gene therapy foundations training differ from laboratory training?

Cell and gene therapy foundations training explains product categories, lifecycle interfaces, identity controls, delivery pathways, and safety follow-up rather than teaching laboratory methods, manufacturing execution, or clinical procedures.

### What is the difference between in vivo and ex vivo gene therapy?

In vivo gene therapy delivers genetic material within the body, while ex vivo approaches modify cells outside the body before they are returned through a controlled clinical pathway.

### Why do cell and gene therapies require chain-of-identity controls?

Chain-of-identity controls maintain the documented link between a patient, collected material, manufactured product, transport stages, receipt, and administration so that each handoff preserves the intended match.



## Conclusion

Participants leave with a Cell and Gene Therapy Pathway Map containing classification, lifecycle, quality-interface, identity, custody, logistics, delivery, monitoring, and governance tools. The map turns specialist terminology into connected cross-functional responsibilities. It helps teams locate handoffs, dependencies, evidence needs, and escalation points across the product-to-patient pathway.