

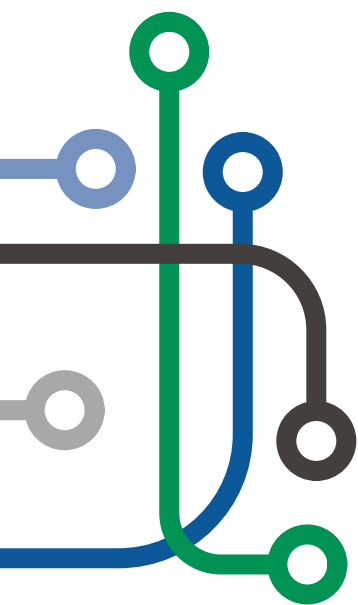


SERVIZIO SANITARIO REGIONALE  
EMILIA-ROMAGNA

Istituto Romagnolo per lo Studio dei Tumori "Dino Amadori"  
Istituto di Ricovero e Cura a Carattere Scientifico

ISTITUTO  
ROMAGNOLO  
PER LO STUDIO  
DEI TUMORI  
DINO AMADORI

# TECHNOLOGY ASSETS & SERVICES



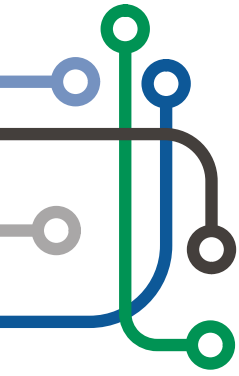
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## CLEAN ROOMS FOR ATMPs

IRST has a consolidated experience in the production of **Advanced Therapy Medicinal Products (ATMPs)** and in the treatment of patients with cell- and gene-based products.

The **GMP Pharmaceutical Facility** is authorized for the production of **cell therapies, gene therapies, and CAR-T cell products**.

The ATMP Clean Rooms include two main production areas:

- **Gene Therapy Area** – dedicated to genetic manipulation processes, including the production of CAR-T cells using lentiviral vectors or viral-free technologies.
- **Cell Therapy Area** – focused on the production of dendritic cell-based vaccines and other experimental cellular therapies.
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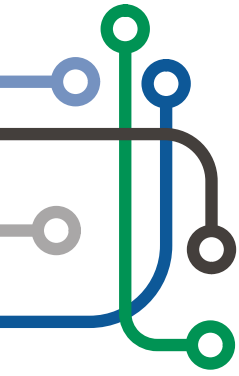
IRST produces and administers a **therapeutic vaccine based on autologous dendritic cells** pulsed with the patient's tumor lysate/homogenate.

To date, over 100 patients have received this treatment, with an average of **40-50 treatments per year**.

Several clinical trials are currently ongoing, evaluating ATMPs as monotherapy or in combination with radiotherapy, chemotherapy, and immunomodulatory agents.

In addition, IRST is developing a pipeline of innovative ATMP production processes, including tumor-infiltrating lymphocytes (TILs), natural killer (NK) cells, and genetically modified lymphocytes, building on previous clinical experience in patients with melanoma, colorectal carcinoma, and other cancer types.





# EQUIPMENT

The GMP Clean Rooms at IRST are equipped with certified infrastructures and instruments for the production of Advanced Therapy Medicinal Products (ATMPs), including:

- GMP-classified Clean Rooms (ISO 7 and ISO 8) for cellular and genetic manipulation.
- Biological Safety Cabinets (BSC class II and III) for the safe handling of cellular samples.
- CO<sub>2</sub> incubators for cell culture and expansion.
- Closed and semi-closed systems for cell culture, including bioreactors for the expansion of TILs, NK, and CAR-T cells.
- Cryopreservation systems (freezers, liquid nitrogen vaporizers) for the storage of cellular products.
- Equipment for genetic transfection and transduction using lentiviral vectors or viral-free technologies.
- Quality Control Laboratories dedicated to batch release, equipped for microbiological testing, immunophenotyping, and potency assays.

# SERVICES

The GMP Clean Rooms at IRST offer integrated services for the research and development of Advanced Therapy Medicinal Products (ATMPs), including:

- GMP production of autologous dendritic cell-based vaccines.
- Experimental manufacturing of gene (CAR-T) and advanced cell therapies.
- Support for national and international clinical trials involving innovative cellular products.
- Development and validation of new production processes for TILs, NK cells, and genetically modified lymphocytes.
- Regulatory and scientific consulting for clinical studies involving ATMPs.
- Technology transfer activities to facilitate the translation of research results into clinical practice.
- Collaborations with institutions, universities, and biotech companies for the development and industrialization of new cell and gene therapies.

# CONTACT

## Headquarters

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