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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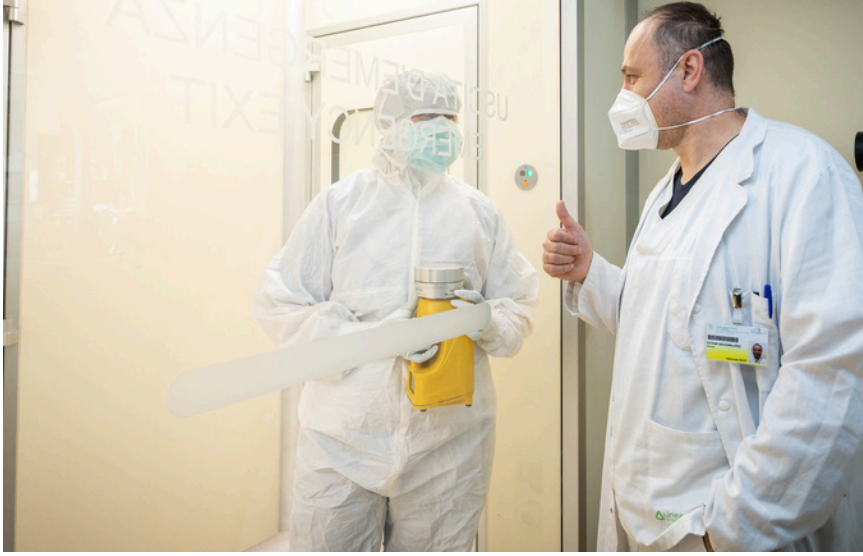

DESCRIPTION

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_2 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.

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