



## EATRIS on-going projects in ATMP

- EATRIS institutions are currently running several clinical trials on gene therapy and cell therapy.
- Development and manufacturing of ATMP for numerous clinical trials. EATRIS institutions have provided viral vectors for eight clinical trials.
- Coordination of late stage clinical development of ATMP up to randomized controlled multi-center phase III trials.
- More than 30 patients suffering from bone or soft tissue defects have been treated by stem cell transplants, while an investigational medicinal product for bone reconstruction from mesenchymal stem cells has been developed.
- The European Medicines Agency (EMA) has recommended Holoclar developed by an EATRIS institution, the first advanced therapy medicinal product (ATMP) containing stem cells, for marketing approval in the European Union (EU).

Access to  
multiple **GMP**  
**facilities** for  
your **ATMP**  
**development**  
needs

**eatris**

# **ACADEMIC GMP MANUFACTURING:**

**ADVANCED THERAPY MEDICINAL PRODUCTS**

# ACCESS EXPERTISE, IMPROVE QUALITY, DECREASE RISK



**A**dvanced Therapies are an increasingly important frontier in the development of novel therapeutic treatments in many disease areas. Gene transfer vectors are important tools of molecular medicine in the application of innovative Advance Therapy Medicinal Products (ATMP), while cell therapy medicinal products and tissue-engineered products represent a new category of drugs that hold vast therapeutic potential for treating an extensive range of indications. Clinical trials employing ATMP require high-quality investigational medicinal products manufactured according to European Good Manufacturing Practice (GMP) and the guidelines of the European Medicinal Agency (EMA). EATRIS academic and hospital-based GMP facilities are major contributors to the development of ATMP, providing high-quality medicinal products combined with expertise.

**Complete workflow**  
from manufacturing with documentation QA/QC, Drug Master File filing, distribution under GDP traceability to therapy or disease specific regulatory assistance and clinical trials in joint academic medical centres.

Technical and scientific **expertise**, in addition to product development and RA, presenting an effective option for development and early stage clinical trial manufacturing. EATRIS offers therapy-specific knowledge and flexibility in production.

Assay validation along with personnel to operate and perform QA/QC. Customised training courses, GMP training for the client's personnel, and an option for clients to work on-site.

## How can EATRIS academic manufacturing guide your ATMP development programme?

- Fast and affordable access to ATMP product manufacturing for implementation in Phase I/II/III clinical trials. Manufacturing for multi-centre trials and Good Distribution Practice transport across Europe available. Support of the trial design and execution under Good Clinical Practice in joint clinical centres.
- Dedicated translational support teams for rapid development of manufacturing and a quality control programme, including documentation.
- Isolated processing suites, class A and B rooms, and dedicated personnel, with qualified cleanroom operators in experienced product-specific teams.
- Upscaling and pre-clinical testing capabilities.
- Production of ATMP in several disease areas, including: orthopaedics; dermatology; ophthalmology; cancer; diabetes; and cardiology.
- Offering of general applicability tools including MSCs and viral vectors.
- In-house GMP manufacturing of customized ATMP raw materials.
- Clinical tissue-banking operations according to 2004/23/EU.

## Quality Assurance and Regulatory Assistance aspects

- Facilities with a GMP compliant organisational structure for extensive cell manipulation with integrated quality systems in compliance with ISO, GMP and other specific standards - EU GMP Manufacturing License.
- Separate units for Manufacturing, Quality Control, and Quality Assurance - Qualified equipment and cleanrooms.
- Validated safety, sterility, and quality tests of the client's manufacturing process.
- Protocols for production processes, analytical methods, and instrument validation.

## Reports on the investigation process and the quality control procedures.

- Staff training and quality audit procedures
- Support for Genetically Modified Organisms (GMO) issues and required permissions.
- Support for regulatory processes with EMA and local authorities - preparing, reviewing, and submitting of clinical trial application in CTD format to European Regulatory Authorities (IMPD and IB).
- Preparation, maintenance, definition, classification, and change management of the product documentation.

### A selection of EATRIS institutes

Regea Cell and Tissue Center, [Tampere, Finland](#)

National Virus Vector Laboratory (NVVL), [Kuopio, Finland](#)

Leiden University Medical Centre (LUMC), [Leiden, the Netherlands](#)

Istituto Ortopedico Rizzoli (IOR), [Bologna, Italy](#)

Centro di Medicina Rigenerativa 'Stefano Ferrari' (CMR) [Modena, Italy](#)

Istituto Superiore di Sanità (ISS) [Rome, Italy](#)