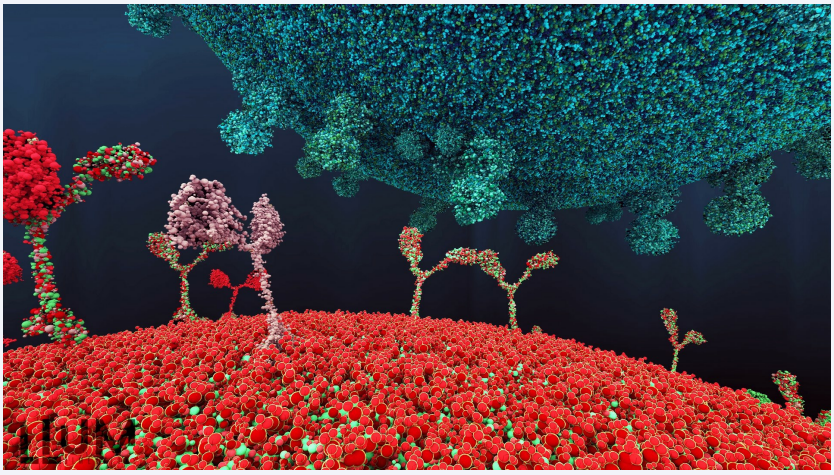
CENTER FOR MANUFACTURING OF ADVANCED THERAPIES

Advanced therapeutical medicinal products (ATMPs) are highly innovative therapies based on the use of genes (gene therapy), cells (cell therapy) or tissues (tissue engineering) to prevent or treat numerous diseases. ATMPs are novel therapeutic strategies with high potential for treatment of hard-to-treat diseases.



CAR-T cells are a type of ATMPs where T cells (a type of lymphocyte or white blood cell) are taken from a patient, brought into the lab and genetically modified so that they can recognise cancer cells as a threat. Then, the cells are injected back into the patient, attacking cancer cells when they encounter them. As CAR-T therapies are composed of cells but they are genetically modified, they are both a gene and a cell therapy.

At present in Spain we have access to commercial and academic CAR-T therapies, both through clinical trials and fully approved, for acute lymphoblastic leukaemia type B, Hodgkin lymphoma, non-Hogdkin lymphoma type B and type T, acute myeloid leukaemia and multiple myeloma.

New ATMPs are in development for many other diseases. In house manufacturing of ATMPs, taking advantage of the extensive research taking place both in Galicia and Spain, will allow the rapid development and clinical use of novel ATMPs.

About the department

The Centre for Manufacture of Advanced Therapies of Galicia (CTA) aims to manufacture ATMPs, for example CAR-T cells, adhering to a pharmaceutical quality management system based on Good Manufacturing Practices (GMPs).

The CTA services hospitals within the Galician Health System (SERGAS), but also other users requiring GMP-compliant infrastructure for development of ATMPs for clinical or pre-clinical studies.

The CTA was designed and built to meet EU standards and

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regulations for GMPs, so that therapeutic products may be manufactured under strict conditions of quality, safety and efficiency. The Centre also provides support for manufacture of therapeutics for research purposes with the aim to facilitate ATMPs reaching the clinic.

The CTA is located in the Monte da Condesa building, in Santiago de Compostela, with more than 800 sqm distributed in 6 production cleanrooms, a cryostorage room, quality control laboratories and simulation or research laboratories. The production cleanrooms are designed for either open manufacturing in class A safety cabinets or manufacture in single use closed bioreactors. The remaining laboratories are equipped for tissue culture and other techniques such as flow cytometry or RT-qPCR. Support areas include warehousing facilities, changing rooms and offices.

The centre and critical equipment are monitored 24/7 to ensure compliance with regulations.

About us

Director: Mariona Baliu Piqué, PhD

Manufacturing:

- Head of manufacturing: Nuria López Lorenzo, PhD
- Manufacturing laboratory technician: Cecilia Castelao Taboada

Quality Control (QC):

- Head of QC: Mariona Baliu Piqué, PhD
- QC laboratory technician: Margarita Caamaño Lago

Quality assurance (QA) and biosafety:

- Head of QA and biosafety: Lorena Boquete Vilariño, PhD

Industrial PhD students

- Joel Verísimo García
- Alberto Jiménez Lombo

About what we do

Pipeline

1. The Centre will initially run a pipeline of ATMPS in clinical trials, which may be supplemented with hospital exemption therapies. ARI-0003: The centre is at present working with Hospital Clínic de Barcelona to start production of a CAR-T therapy for a clinical trial. ARI-0003 is a CAR-T targeting CD19 and BCMA, two known antigens for lymphoma.
2. Other ATMPs: presently evaluating other collaborations.

Services

- Clinical manufacturing. The CTA is working towards accreditation for GMP-compliant manufacturing for clinical research. We also provide quality control (QC) for products and processes, and can support the development of protocols and documentation for GMP manufacturing.
- GMP translation. We have areas for simulation of GMP-compliant manufacturing and can advise on translation of pre-clinical to clinical studies.
- Consulting. The personnel working at the CTA provide support for development of new processes in the field of ATMPs as well as pre-clinical and clinical testing under GMP conditions, as well as their implementation and monitoring.

Our equipment

Our manufacturing and QC laboratories are furnished with the necessary equipment for ATMP manufacturing:

- Biological safety cabinets Telstar Advance Plus 4
- Refrigerated centrifuges Hermle Z446K and Z216MK
- Flow cytometry analyser BD FACSLyric
- CliniMACS Prodigy
- Sterile tube connectors Terumo BCT TSCD-II
- Sterile tube sealers Terumo BCT T-SEAL mobile T5460
- Endotoxin detector Charles River Nexgen-PTS
- Volumetric sampler Biomerieux Air Ideal 3P
- RT-PCR Applied Biosystems QuantStudio 5
- Nucleic acid extractor Maxwell AS6000
- Quantus Fluorometer E6150

- Microscopes Leica Mateo TL and DM IL Led Fluo
- Cell counter Luna II
- Ultrapure water purifier Wasserlab Plus 1+2 GRUF.5L/H
- Autoclave Raypa AHS-75-B
- Liquid nitrogen tanks Telstar CBS V -1500 AB
- Ramp freezer Telstar Planer Kryo 560
  CO2 incubators Thermo Scientific Steri-cycle i160 CR

Where we are

Address:

Centro de Fabricación de Terapias Avanzadas de Galicia
Edificio Monte da Condesa, Campus Vida
15782, Santiago de Compostela, A Coruña

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8:00 to 15:00

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