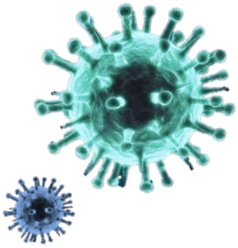
Creatio | Production and validation center of advanced therapies
UNIVERSITAT DE BARCELONA

Clinical production of gene therapies



Gene-based Advanced Therapy Medicinal Products (ATMPs) represent a groundbreaking advance that transforms patients' lives, offering curative and personalized solutions and opening up new frontiers in modern medicine.

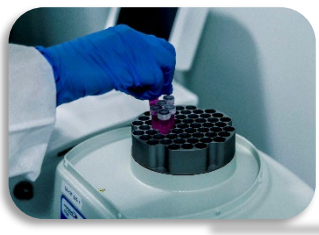
Creatio's clinical production services

Our skilled professionals provide you with tailored support and solutions in:

- ✓ GMP (Good Manufacturing Practice) translation of gene therapies.
- ✓ GMP production of gene-based ATMPs: e.g., lentiviruses (LV) for CAR-T/NK cells.
- ✓ Quality controls and validations.
- ✓ Support for regulatory affairs and compliance.

Expertise

- ✓ 10 years of experience producing ATMPs for clinical applications.
- ✓ Over 800 patients treated with gene-based ATMPs produced at Creatio.
- ✓ Successful production of more than10 different types of LV for clinical use.
- ✓ Tailored protocol for researchers' gene therapy.
- ✓ Suppliers of more than 10 public hospitals across Spain.



1. PLANNING
2. SET-UP & SCALE-UP
3. PRODUCT MASTER DOCUMENTATION
4. VALIDATION
5. PRODUCTION
6. MONITORING & CONTROL

Applications of LVs

- ✓ Gene therapy
- ✓ Vaccination
- ✓ Cancer immunotherapy
- ✓ Cellular reprogramming
- ✓ Stem cell modifications
- ✓ Cell-type differentiation
- ✓ Site-directed Integration

Safety and regulation

- ✓ Creatio ensures that all projects comply with applicable UNE-EN-ISO 9001:2015, and/or GMP guidelines, and the Creatio Quality System.
- ✓ Gene-based ATMPs are subject to rigorous quality controls by regulatory agencies ensuring their effectiveness and safety for patients..

Characteristics and key benefits of gene-based ATMPs

- ✓ Introduction, removal or modification of genetic material within a patient's DNA to correct/enhance their function.
- ✓ Effective solutions to treat and potentially cure currently incurable human conditions or diseases.
- ✓ Personalized treatments tailored to the specific genetic needs of each patient that increase efficacy and reduce side effects.
- ✓ Broad therapeutic applications.

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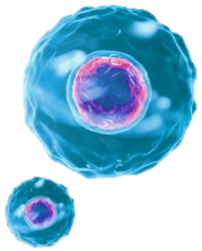
Clinical production of cell therapies



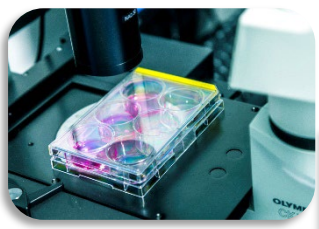
Cell-based Advanced Therapy Medicinal Products (ATMPs) hold great promise for revolutionizing the treatment of human diseases by harnessing the regenerative and therapeutic capabilities of living cells.

Creatio's clinical production services

Our skilled professionals provide you with tailored support and solutions in:

- ✓ GMP (Good Manufacturing Practice) translation of gene therapies.
- ✓ GMP production of cell-based AMPs, e.g. human mesenchymal stem cells (hMSC).
- ✓ Quality controls and validations.
- ✓ Support for regulatory affairs and compliance.

Expertise



- ✓ 10 years of experience producing ATMPs for clinical applications.
- ✓ Over 60 patients treated with cell-based AMPs produced at Creatio
- ✓ Expertise in manipulating and expanding hMSC, human pluripotent stem cells, and primary cultures.
- ✓ Optimized, reproducible and standardized cell manipulation protocols.
- ✓ Collaboration with public and private entities across Europe.

1 PLANNING → 2 SET-UP & SCALE-UP → 3 PRODUCT MASTER DOCUMENTATION → 4 VALIDATION → 5 PRODUCTION → 6 MONITORING & CONTROL

Applications of cell-based ATMPs

- ✓ Regenerative medicine
- ✓ Tissue repair
- ✓ Vaccination
- ✓ Gene therapy
- ✓ Cancer treatment
- ✓ Autoimmune diseases
- ✓ Neurological disorders
- ✓ Inflammatory diseases
- ✓ Drug delivery

Safety and regulation

- ✓ Creatio ensures all projects comply with applicable UNE-EN-ISO 9001:2015, and/or GMP guidelines, and the Creatio Quality System.
- ✓ Cell-based ATMPs are subject to rigorous quality controls by regulatory agencies ensuring their effectiveness and safety for patients.

Characteristics and key benefits of cell-based ATMPs

- ✓ Use of living and manipulated cells or tissues to treat, prevent, or diagnose diseases by to restore/ enhance biological function.
- ✓ Effective solutions to treat and/or modify incurable human conditions or diseases.
- ✓ Personalized treatments tailored to individual patients and/or specific tissues, increasing efficacy and reducing side effects.
- ✓ Regenerative potential and low immunogenicity.
- ✓ Diverse cell sources and therapeutic applications.

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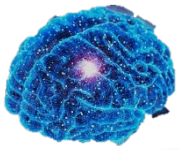
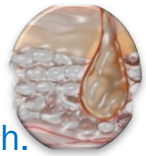
Clinical production of 3D-bioprinted therapies



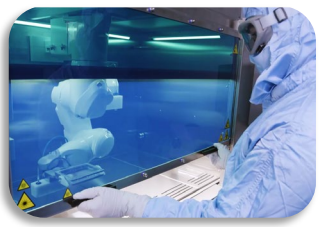
Tissue Engineering-based Advanced Therapy Medicinal Products (ATMPs) enable the creation of functional and complex 3D tissue/organ substitutes to cover unmet needs in regenerative medicine, tissue engineering, and research.



Creatio's clinical production services

Our skilled professionals provide you with tailored support and solutions in:

- ✓ GMP (Good Manufacturing Practice) translation of Tissue Engineered ATMPs.
- ✓ GMP production of Tissue Engineered- ATMPs, e.g., skin substitutes.
- ✓ Quality controls and validations.
- ✓ Support for regulatory affairs and compliance.



Expertise

- ✓ 10 years of experience in producing ATMPs for clinical applications.
- ✓ Expertise in translating research protocols to GMP-compliant procedures.
- ✓ Experience in manipulating and differentiating diverse human cell types.
- ✓ Engagement in ongoing European and domestic publicly-funded 3D-bioprinted projects.
- ✓ Collaboration with public and private entities across Europe.

1 PLANNING
2 DIGITAL FILE DESIGN (CAD)
3 CELLS, BIOINKS SELECTION
4 VALIDATION
5 3D BIOPRINTING
6 MONITORING & CONTROL

Applications of Tissue-Engineered ATMPs

- ✓ Regenerative medicine
- ✓ Tissue repair
- ✓ Disease modeling
- ✓ Drug screening
- ✓ Cosmetic and other consumer tests

Safety and regulation

- ✓ Creatio ensures that all projects comply with applicable UNE-EN-ISO 9001:2015, and/or GMP guidelines, and the Creatio Quality System.
- ✓ Tissue-Engineered ATMPs are subject to rigorous safety and approval controls by regulatory agencies to ensure their effectiveness and safety for patients.

Key advantages of our cutting-edge 3D-bioprinter

- **GMP** CLINICAL USE
- **> 95%** CELL VIABILITY
- **10 µm** RESOLUTION
- **10,000 drops/s** PRINT SPEED
- **100 M cells/mL** CELL CONC.
- **HIGH VISCOSITY** BIOINK

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