



# Histocell Regenerative Medicine Contract Development & Manufacturing Services (CDMO)

# About us

Histocell S.L. is a regenerative medicine biopharmaceutical CDMO with extensive experience in developing and manufacturing cell-based therapies

- Spain-based clinical stage CDMO (Basque Country)
- Authorized GMP ATMP manufacturer since 2011
- Highly experienced in handling MSC and biological products
- Rich experience and robust track-record in GMP Manufacturing



## Business model

- **ATMPs Development**
- **CDMO Services**
  - Autologous and allogenic mesenchymal stem cells (MSC)
  - Other types of cells: epithelial cells, chondrocytes, blood cells
  - Induced pluripotent stem cells (iPSCs)
  - Secretomes from cell culture
  - Exosomes (R&D)
  - CAR-T and NK cells (R&D)

## Facilities

- Currently designed to support **pre-clinical** and **clinical** phases
- Setting them to support **comercial** manufacturing



## Our mission

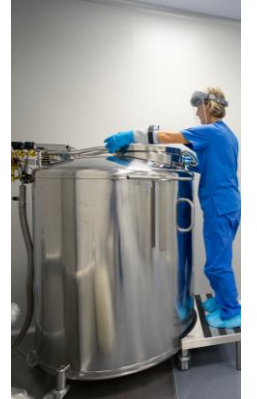


Provide global customers cell production services (ATMPs) to growth therapies from pre-clinical to clinical and commercialization.



### Research and Development services

- Process development and optimization
- Analytical method development and validation
- Allogenic and autologous process scale up



### Cell Banking (MCB, WCB & cGMP)



### GMP Manufacturing

#### PRE-CLINICAL

- Engineering batches
- Pilot scale
- GMP-like batches

#### CLINICAL

- Phase I, II, III
- GMP compliant
- Process authorization

Manufacturer's Authorization **MIA:4269E**

**GMP Certificate** ES/0051/18

Spanish Medicines agency (**EMA**)

**GMP process validation & GMP certification**



Certificado Nº / Certificate No: ES/0051/18\*\*

CERTIFICADO DE CUMPLIMIENTO DE NCF<sup>21</sup> /  
CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER<sup>22</sup>



### Quality control

- Qualification of rooms and equipment
- Testing laboratories (close to manufacturing suites)
- Validation of assays and processes



# Histocell Regenerative Medicine

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