Histocell

Our GMP iPSC and MSC Manufacturing Partner



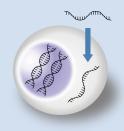
Located in Bilbao, Spain, Histocell is a CDMO and a clinical-stage biopharmaceutical company that specializes in developing cell therapy products for regenerative medicine.

Histocell's highly reliable and qualified scientific team has more than 20 years of experience. They will take care of your iPSC or MSC cell therapy needs with a flexible and scalable manufacturing process.

Our GMP stem cell services provide:

- Investigational medicinal products for human use for European, US, and Japanese customers
- All safety and quality controls specified by regulatory authorities.





Services We Offer In Partnership With Histocell

Clinical iPSC production service 🔗

REPROCELL can provide you with clinical induced pluripotent stem cells (iPSCs) for your therapeutic project, created with our state-of-the-art RNA reprogramming technology. You can test our clonal lines for suitability before scaling up to a GMP Master Cell Bank.

Clinical MSC production service 📀

Whatever the source of mesenchymal stem cells (MSCs) or derivatives thereof you need, REPROCELL can help you drive your next clinical MSC project to success and ensure compliancy with regulatory agencies.

Authorized GMP facility for Manufacturing Clinical Grade Products

Histocell's newly built 600 m² GMP facility is already authorized and registered by the European Medicines Agency (EMA) for the manufacturing of clinical grade cells in compliance with the GMP guidelines of EMA Regulation (EU) 2017/1569.

Advanced Therapy Medicinal Products (ATMPs) manufacturing

Since 2011, Histocell has been an authorized provider of GMP ATMP manufacturing services to clients around the world.

Around 300 patients have already been treated with ATMPs manufactured by Histocell, and more than 350 batches have been manufactured under GMP.

Advanced Therapy Cell Production facilities

Histocell's new Advanced Therapies GMP cell production unit has more than $600 \ m^2$ of capacity.

- GMP manufacturing suites and associate infrastructure
- Fully equipped to manufacture both autologous and allogenic therapies
- Manufacturing and storage for cell therapy and large cell stocks, MCB, WCB
- Production and characterization of cell-derived biologics such as secretomes and exosomes
- · Manufacturing capability: approx 1200 batches/year
- Designed to support both pre-clinical and clinical phases
- Histocell is also gearing up to support commercial manufacturing







