evotec

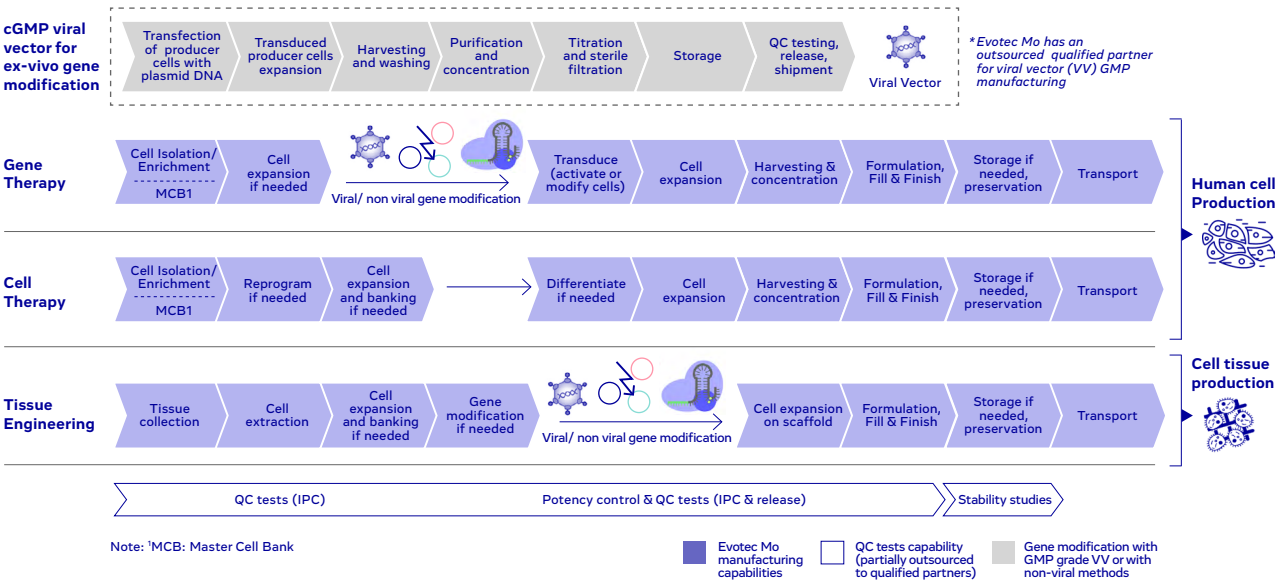
#RESEARCHNEVERSTOPS

Cell and gene therapy manufacturing @Evotec Modena

- State-of-the-art BSL2 facility dedicated to cell and gene therapy development and production
- Expertise spanning from pre-GMP process optimization to large scale manufacturing with up-to-date internal regulatory support
- Ability to support the development of projects for a variety of ATMP: mesenchymal stromal cells, iPSC, dendritic cells, CAR-T and tumor infiltrating lymphocytes (TILs)
- Ability to support the development of projects for Extracellular Vesicles (EV) manufacturing from primary cells

- Competences in both autologous and allogeneic settings, including gene modified ATMP by viral vectors (retro/lentiviruses and others) and non-viral methods

Integrated Platforms Supporting All Stages Of Drug Development



EVOTEC MODENA cell factory can perform all production steps of ATMP manufacturing, from development to production, cold temperature storage and quality control.

Various steps take place in dedicated zones within the facility, in compliance with the highest GMP requirements based on regulatory agency approval.

EVOTEC MO Cell Factory

The GMP manufacturing facility is designed with clean classified areas from grade A to D, surrounded by unclassified technical areas. It is composed of:

- **The cell factory:** equipped with 5 sterile cleanroom/manufacturing suites, suitable for aseptic manipulation of sterile medicinal products (Grade A/B cleanroom) according to EU and US cGMP rules
- **A class cGMP warehouse with ambient and +4°/-20°C storage,** with a dedicated airlocks and a Grade D transfer material zone
- **Cryogenic space:** for qualified controlled storage at -80°C to -196°C with vapor phase liquid nitrogen under 24-h monitoring system and back-up power
- **A QC laboratory:** equipped to perform microbiologic tests to monitor the classified rooms and to execute quality and safety controls on intermediate and final products
- **A R&D laboratory:** for pre-GMP manufacturing development and product optimization
- **Control room:** enabling monitoring of all the critical parameters via SCADA

Rooms 1 and 2: cell factory and GMP warehouse are cleanroom spaces of 450m²

Evotec Modena Capabilities

- **Know-how and facilities for pre-GMP ATMP & EV optimization and development**
  - regulatory support since the early phase
  - tissue procurement: logistics and shipment starting from raw material to the facility
  - tissue processing with cells isolation and early characterization
  - cell expansion in non-cGMP classified environment for *in vitro* functional assays: differentiation, gene expression by RNAsec, mirnome, secretome/ multiplex analyses, ddPCR assay and within 3D *in vitro* (spheroids, 3D matrix) models
  - key reagents optimization for the subsequent cGMP phase
  - cell modification in non-cGMP classified environment
  - cell expansion in non-cGMP classified environment for *in vivo* R&D functional assays accordingly GLP
  - extracellular vesicles (EV) isolation and characterization
  - stability studies
- **Significant experience on ATMP & EV manufacturing**
  - early gap analysis and regulatory support for the manufacturing process
  - tissue procurement: logistics and shipment starting from raw material to the facility
  - tissue processing with cells isolation and expansion in cGMP classified environment
  - cell modification by viral vectors
  - MCB creation
  - formulation, fill and finish
  - extracellular vesicles (EV) isolation
  - delivering fresh (4°C) or N2 frozen product to final destination
  - QC testing: identity, potency, purity (impurities), microbiology, genomic stability & cariology
  - stability studies

ELEVATING IDEAS TO CELL THERAPEUTICS