

EVOTEC MODENA

*ATMP Development
and Manufacturing*

*In the Heart of the
Italian Biomed Valley*



EVOTEC Modena: Overview

From laboratory discoveries to novel technological platforms for patients

Overview of EVOTEC MODENA

Website www.rigenerand-biotech.com

Founded 2009

HQ Medolla (Modena), Italy

Employees ~20

Overview Founded as spin-off of the University of Modena and Reggio Emilia, EVT MO (formerly Rigenerand srl) is a venture between Rand, a biomedical company producing bioreactors for liver support and chemo-hyperthermic technology for cancer and researchers of the University of Modena e Reggio Emilia with a lasting expertise in cell and gene therapy.

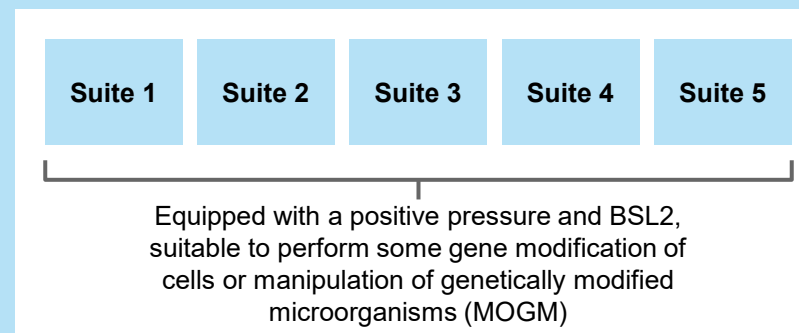
Key Capabilities Cell & gene therapy for solid tumors. Contract manufacturing of ATMPs. Advanced Medical Devices.

Certifications ISO 9001:2015. GMP (AIFA).



EVOTEC MODENA Facility

- EVT MO cGMP cell factory includes five segregated ISO 5/Grade B suites



- Each ISO5/Grade B suite is equipped with an ISO 4.8/Grade A cabinet for aseptic manufacturing of sterile medicinal product and with two CO₂ incubators, a microscope, and a centrifuge

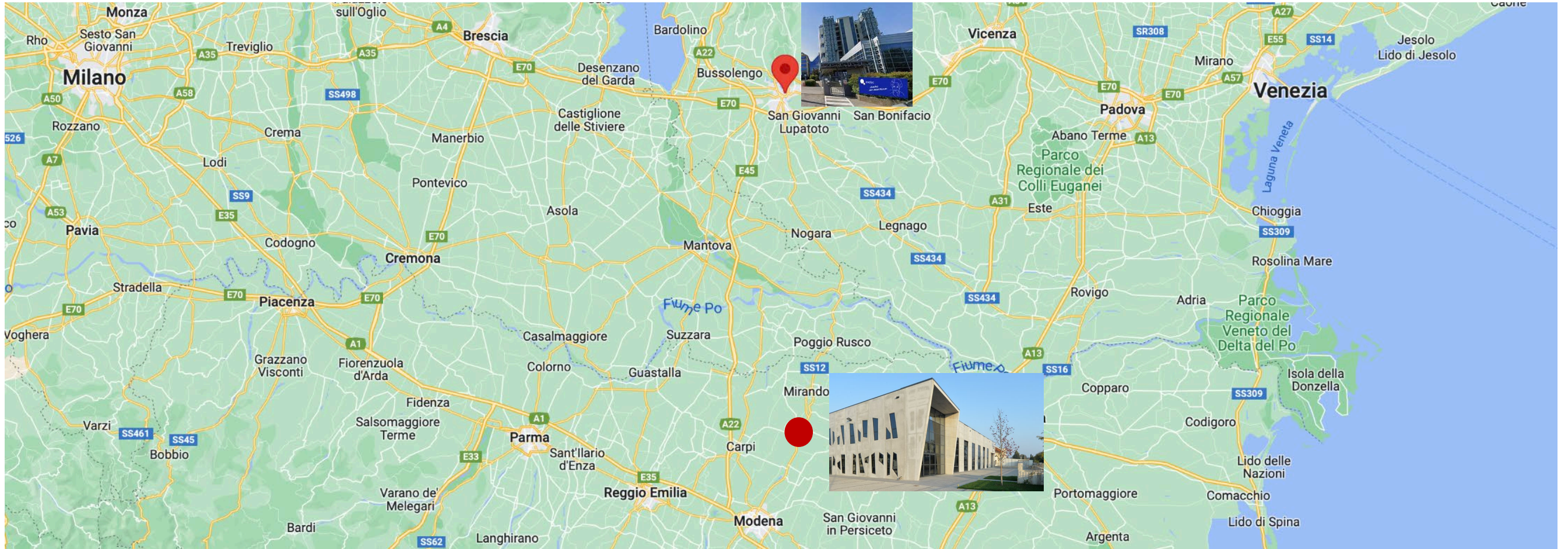
EVOTEC MODENA Location

- Evotec Modena has its facility in Medolla, Italy
- The facility includes a 1200 m2 premises with development and manufacturing teams for R&D and GMP manufacturing of Cell & Gene therapy medicinal products, as well as independent Quality Control (QC) and Quality Assurance (QA) departments.



Where We Are

Modena area: a district rich in excellence with a strong industrial culture



EVOTEC Modena: The Company

1,200 square meters building with advanced technologies and highly qualified staff

R&D and Process Development Spaces

Cell factory (GMP)

Quality Controls Laboratories

Cryo Lab

Warehouses and Offices

Personnel: QP, QC, QA, manufacturing, maintenance



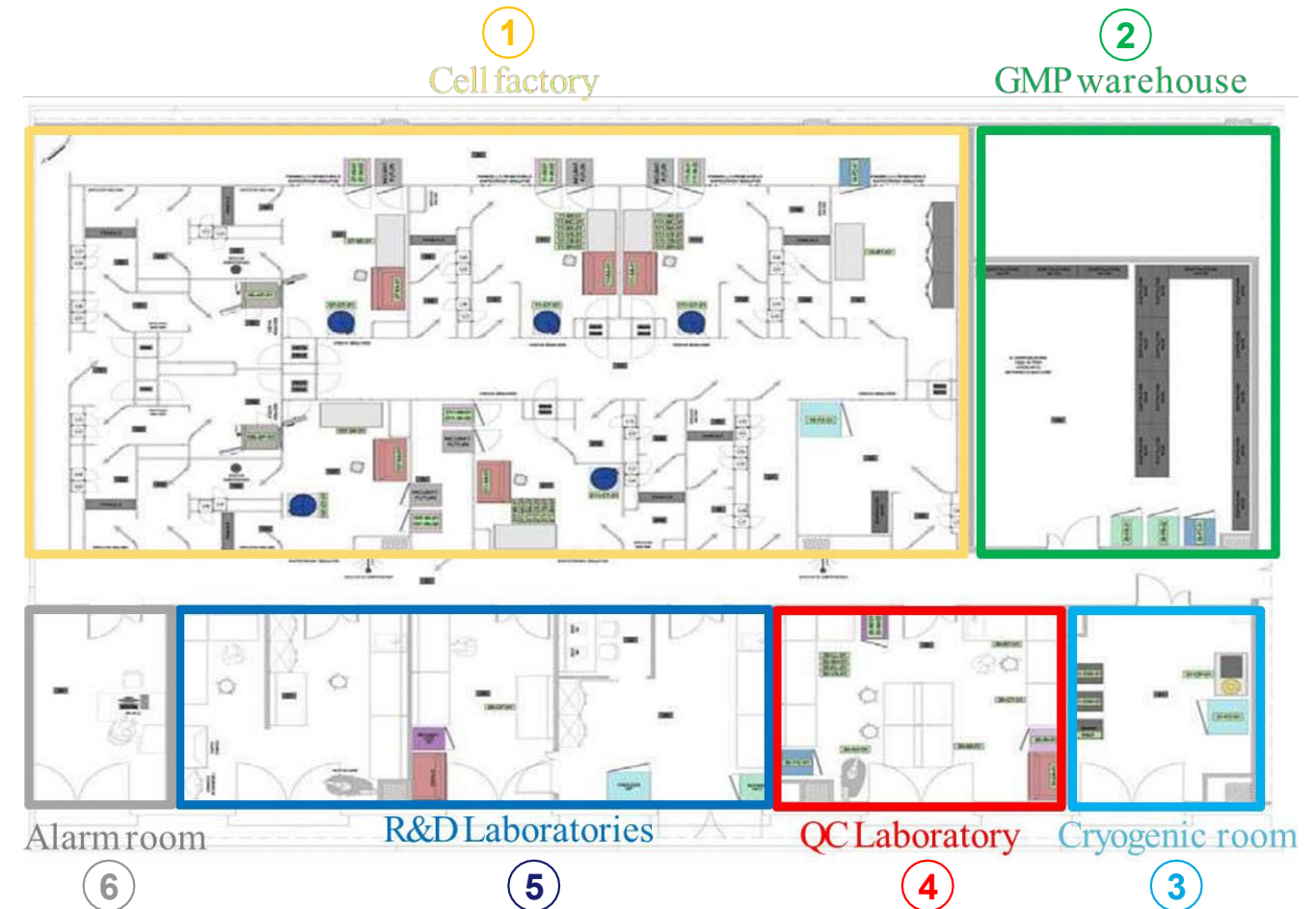
The EVOTEC Modena Cell Factory

EVT MO covers all steps of ATMP manufacturing, in compliance with GMP requirements

EVOTEC MO Cell Factory

- The GMP manufacturing facility is designed with unidirectional flow. It is composed of:
 - 1) A cell factory:** equipped with 5 sterile cleanroom / manufacturing suites, suitable for aseptic manipulation of sterile medicinal products (Grade A/B cleanroom) according to EU cGMP rules
 - 2) A class C GMP warehouse with ambient storage:** with a dedicated airlocks and a Grade D transfer material zone
 - 3) A cryogenic room:** for qualified controlled storage at -80°C to -196°C with vapor phase liquid nitrogen under 24-h remote control & back-up power
 - 4) 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
 - 5) A R&D laboratory:** for ATMP research purposes
 - 6) An alarm room:** for continuous monitoring by SCADA

cleanroom space $\approx 450\text{m}^2$



Manufacturing Suites

EVT MO has 5 class B manufacturing suites with 24/7 monitoring



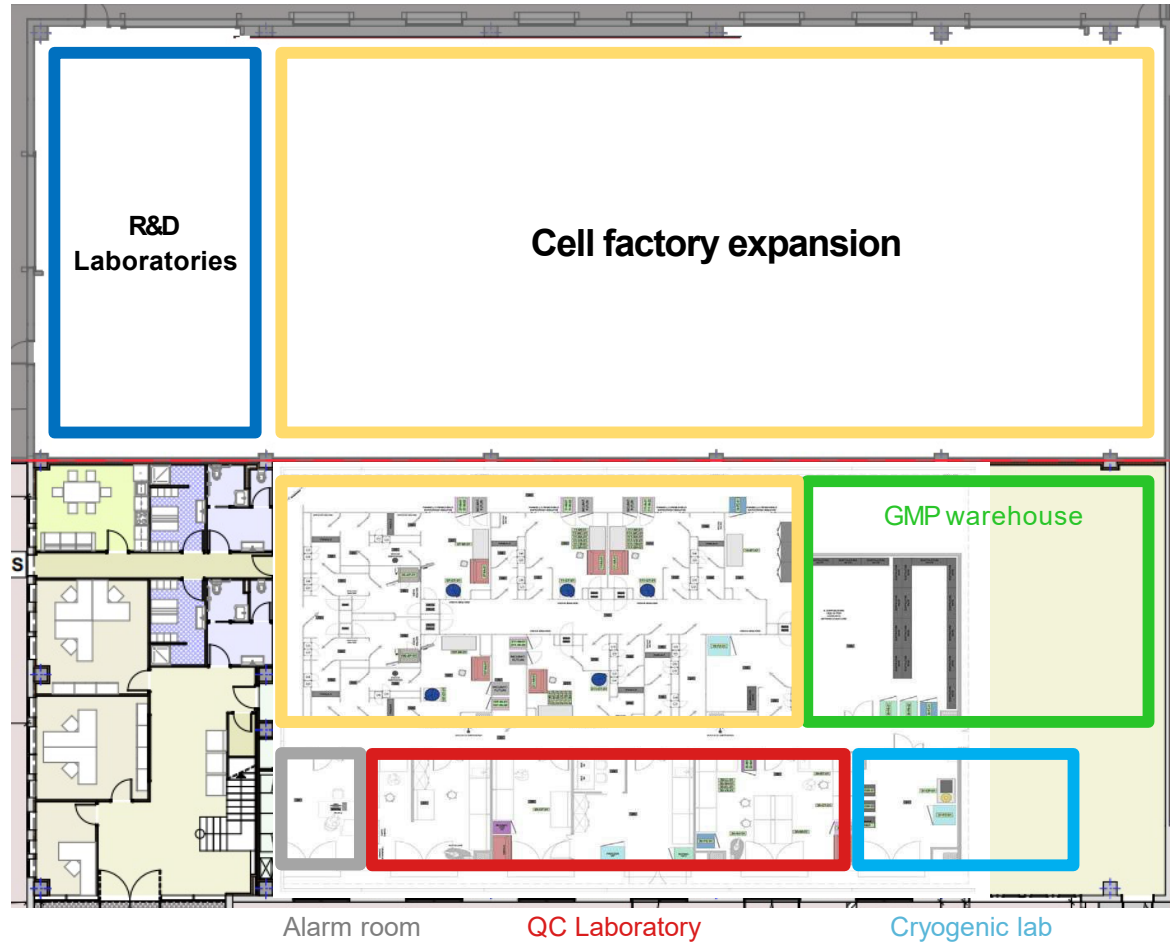
Cryo rooms and GMP warehouses

EVT MO nitrogen vapour freezing & storage spaces. Classified/not-classified warehouses.



Expansion Plan to Accelerate Your Cell and Gene Therapy (2023)

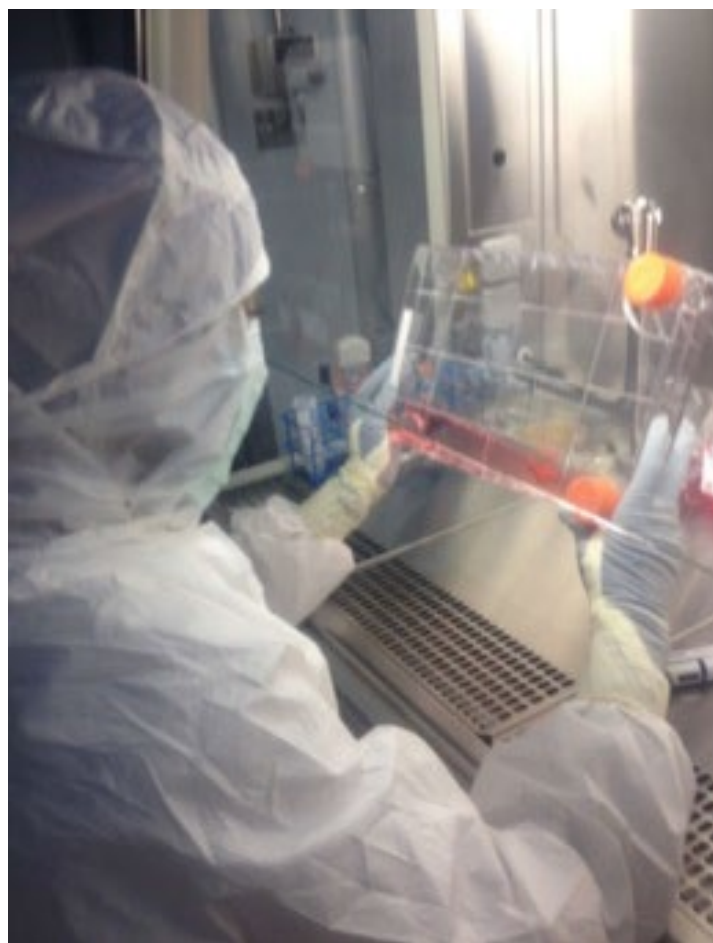
Creating a centre of excellence for ATMP manufacturing



- New additional 700 m² of classified areas
- Additional 300 m² of R&D lab
- New and extended QC laboratory
- Larger GMP warehouse and cryo room
- New staff acquisition
- Integration with EVOTEC facilities and infrastructures

Cell and gene therapy experience

Expertise and flexibility for ATMPs development and manufacturing



MSC

Isolation from different sources (auto, allo)

Ex-vivo expansion using different support and methods

Characterization

Gene modification

& More

A team of expert allows isolation, amplification and manipulation of additional cells types: **dendritic cells, TILs and CAR- T**

Interactions with Regulatory Body for Facility Certifications

Profitable relationship with regulators for new products development and manufacturing

2019	Regulatory (AIFA) Inspection
2020	1 st Certification for MSC-based Gene Therapy products
2021	2 nd Certification for MSC-based Cellular Therapy products
2021	3 rd Certification for therapeutic use of MSC-based Cellular Therapy products



EVOTEC Modena Manufacturing Capacity

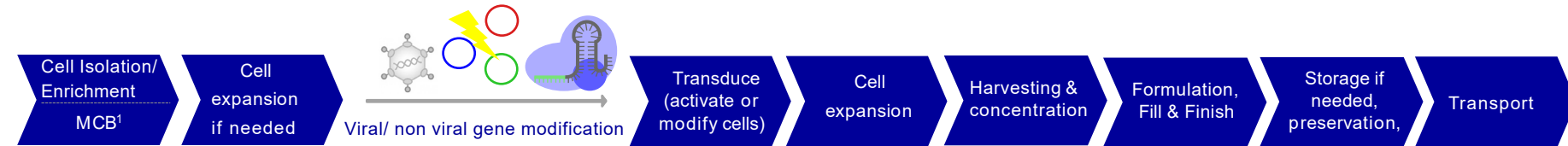
EVOTEC MO produces cell & gene therapies from procurement to patients

cGMP viral vector for ex-vivo gene modification



**Evotec Mo has an outsourced qualified partner for viral vector (VV) GMP manufacturing*

Gene Therapy



Human cell production



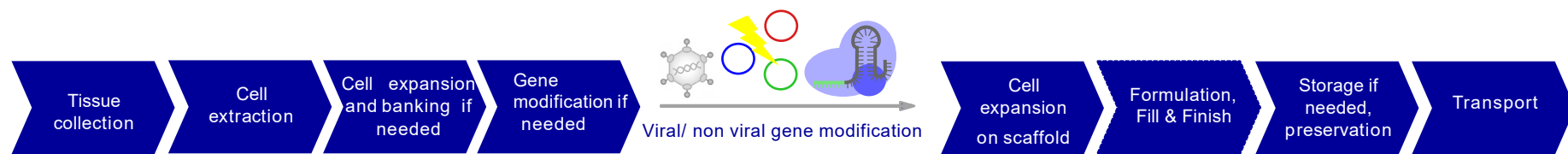
Cell Therapy



Cell tissue production



Tissue Engineering

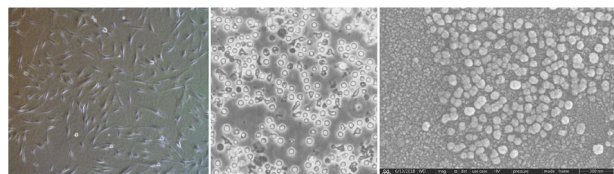


Note: ¹MCB: Master Cell Bank.

Evotec Mo manufacturing capabilities
 QC tests capability (partially outsourced to qualified partners)
 Gene modification with GMP grade VV or with non-viral methods

EVOTEC Modena Services for Cell/Gene Therapy Acceleration

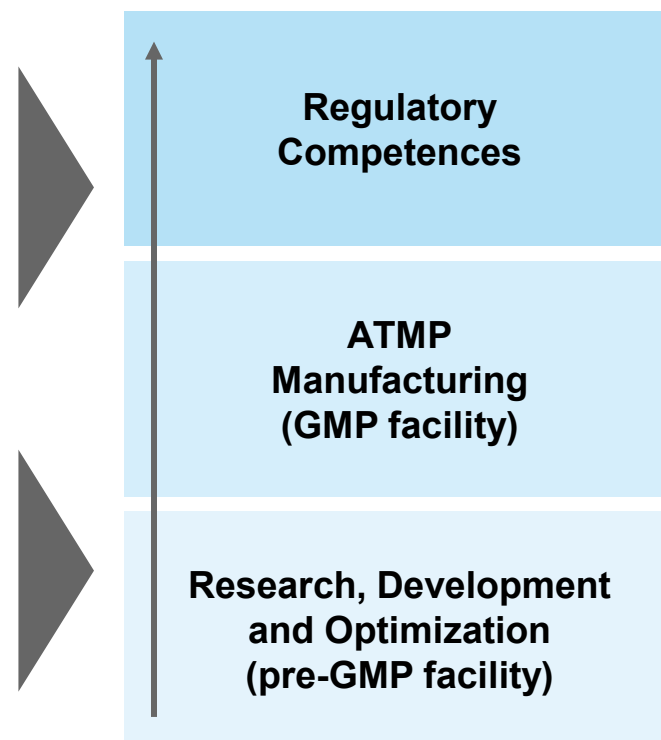
Elevating ideas to cell therapy products



Pharma/Biotech



SME/ Academia



Invited to Evotec Modena!

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