

Evotec Modena

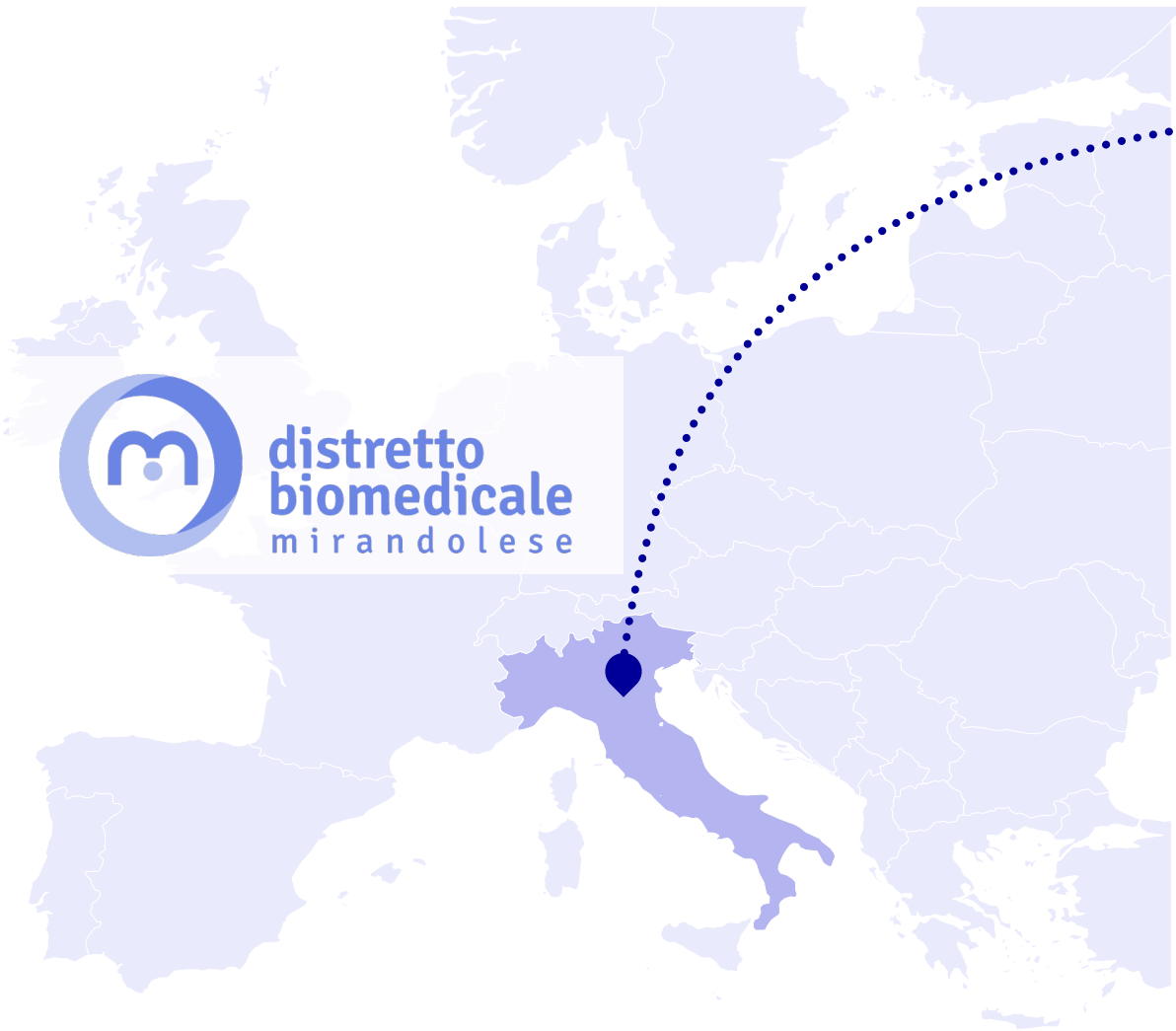
GMP manufacturing site for
iPSC-based cell therapies





Where We Are

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



The most important Biomedical District in Europe and the 2nd globally
> 100 companies specialized in biomedical devices

<i>Baxter</i>	OLYMPUS [®]	 FRESENIUS
LivaNova <small>Health innovation that matters</small>	 Medtronic	B BRAUN
 evotec		



Centre of excellence for cell therapeutics manufacturing

Evotec Modena



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#RESEARCHNEVERSTOPS

NEWS RELEASE, 30 MAY 2022

EVOTEC ADDS CELL THERAPY MANUFACTURING FACILITY WITH ACQUISITION OF RIGENERAND

► EVOTEC'S EVOCELLS PLATFORM INTEGRATES INNOVATIVE OFF-THE-SHELF IPSC CELL THERAPY DISCOVERY WITH DEVELOPMENT AND MANUFACTURING



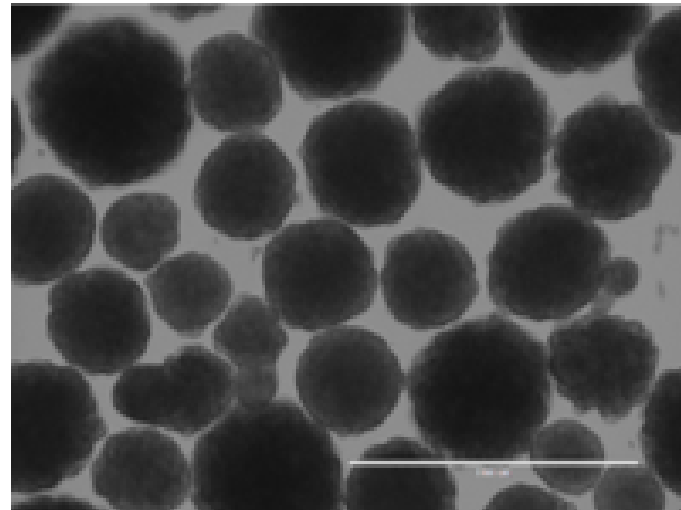
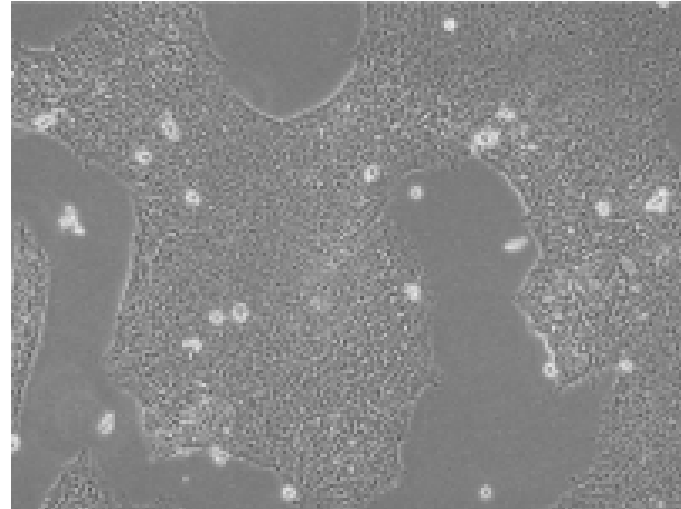
- Founded in 2009 as spin-off of the University of Modena and Reggio Emilia
- Scientific founder Prof. Massimo Dominici is one of the pioneers in clinical cell therapy
- State-of-the art GMP manufacturing facility (5 clean rooms, 1,200 m²) with room for significant expansion
- ~ 25 FTEs
- cGMP facility accredited by Italian Authority for the manufacturing of clinical stage cell therapies
- Experienced to manufacture complex cell therapies including pre-GMP optimization steps
- Experience with MSCs, TILs, CAR-T, dendritic cells and exosomes
- Tech transfer for manufacturing of iPSC-based therapeutics on-going



iPSC-based cell therapeutics manufacturing

From iPSC cells to patients

- Pre-GMP lab and GMP cleanroom design to develop and optimize robust and reliable manufacturing strategy for iPSC-based therapeutics
- iPSC expansion and scale-up
- GMP-compatible bioreactor platform
- Tox study and clinical supply
- Analytical development and QC
- GMP-compatible gene editing
- Smooth transition from GMP development to manufacturing





Quality Control Laboratory

Authorized tests & next implementations

The quality control laboratory is equipped to perform microbiologic tests to monitor the classified rooms and to execute quality and safety controls on intermediate and final products



Actual test authorized

- Cell viability with 7AAD (in house FACS)
- Cell identity and purity (in house FACS surface)
- % transduced cells (in house FACS intracellular marker)
- Cytotoxicity (in house flow cytometry direct method)
- Total cell count (trypan blue)
- ELISA tests
- Karyotype (NO G-banding)
- DNA extraction and quantification
- Senescence (beta galactosidase staining)

New test already in house

- Automated count and viability with Nucleocounter
- Microscopic evaluation, size and morphology
- PCR

Currently in outsourcing (qualified providers)

- STR DNA profiling (Identity)
- Karyotype (Genetic Integrity)
- Array CGH (Genomic Integrity)
- WGS (Genetic suitability of Product)
- NAT qPCR (Human Viruses)
- Sterility
- Sanger Sequencing

Next implementations

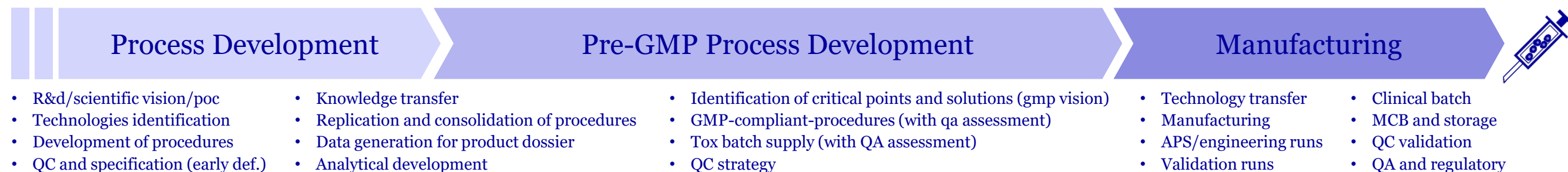
- Soft agar colony assay
- Pluripotent stem plate assay
- qPCR
- Safety test (mycoplasma, endotoxin, sterility)
- Identification of microbiological contaminant
- Fertility and sterility on media and reagent (mediafill)



From Process Development to GMP manufacturing

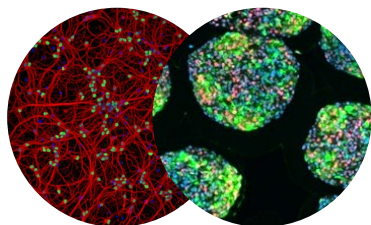
A path-in-stages to facilitate a reliable transition towards manufacturing

Tailored integration of knowledge, skills, capabilities, staff and equipment for effectively and reliable development towards clinical goal

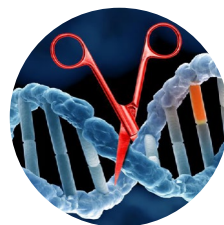


Regulatory support

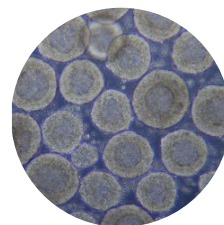
iPSC-derived cell type



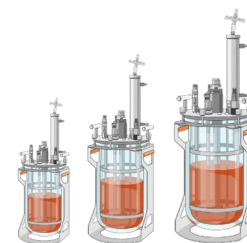
Gene editing



3D expansion



Upscaling



Analytical development
Quality control



GMP
manufacturing



Name
Position

Phone
Mail
