

**Finding the right PARTNER for
First-in-Human production for
Advanced Therapies can be challenging**



**Next Generation CDMO Offering Phase-Adjusted
CMC Expertise at an Attractive Cost**

**STEM CELL
THERAPIES**

**GENE-MODIFIED
CELL THERAPIES**

**EXOSOME
THERAPIES**

At **ENABLE Biotech**,

We are redefining the CDMO experience for early-stage biotech innovators.

Our mission is to deliver **flexible, cutting-edge solutions tailored to your unique needs**, driven by four key pillars:

Expertise

- Phase-appropriate tailored support with specific focus on advanced therapies
- We provide expert CMC guidance and deliver optimal solutions and results

Speed

- Ensure timely FIH with smooth shipment between European patients and the facility
- Our next-gen technologies accelerate path from concept to clinic, focusing on scalability & efficiency

Flexibility

- Prioritize transparent collaboration, adapting our strategies & services to meet each client's needs
- We create bespoke solutions that adapt to your development and manufacturing challenges

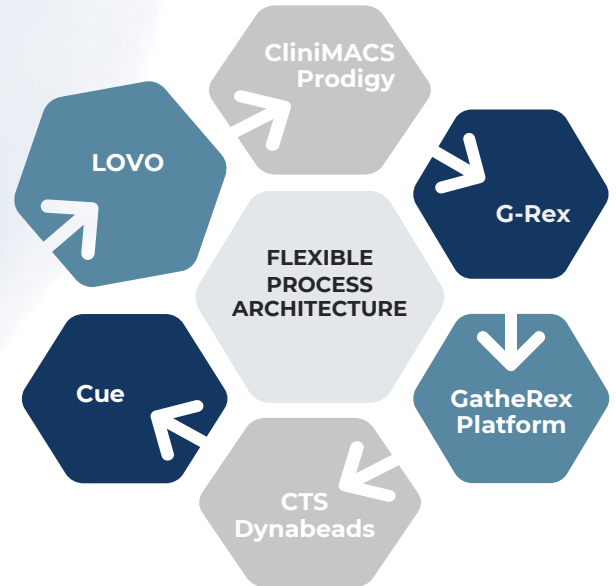
Affordability

- Minimize costs while maintaining timelines through efficient resource use
- We reduce manufacturing costs through use of existing SwissMedic accredited GMP facility

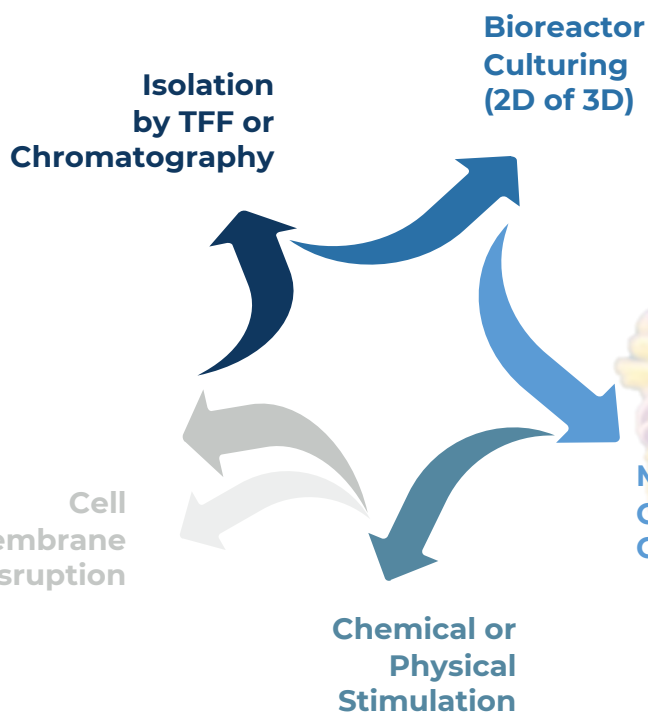
We address **specific** challenges of manufacturing **Advanced Therapies**

CELL THERAPY MANUFACTURING

Process Development & Manufacturing of Autologous & Allogeneic Gene-Modified Cell Therapies, including cell types such as PBMC (T Cells, NK cells, Invariant NK Cells) iPSC, MSC, HLSC



EXOSOME THERAPY MANUFACTURING



Stimulation, production, and isolation of Exosomes following sponsor's manufacturing processes, including selection & optimization of stimulation methods

Chemistry, Manufacturing, Controls Expertise

Team with specific expertise and capabilities in the field of CGT manufacturing, ensuring a smooth transition of manufacturing processes

- ✓ Scalable Manufacturing Processes
- ✓ Robust QMS
- ✓ Stability Studies
- ✓ PD and AD Expertise
- ✓ Regulatory Compliance (EMA, FDA, SwissMedic)
- ✓ DS & DP Development
- ✓ Supply Chain Management
- ✓ Validated Processes

Processes and Equipment can be adjusted based on sponsor's technologies, experience and budget

MANUFACTURING OF MCB AND WCB

Cell Banking Process for Your RCB

Cell line characterization and selection from sponsor RCB
MCB production & release testing
WCB production & release testing
Cryopreservation



Cell Types

All types of **mammalian cells**, including both primary and immortalized cell lines



Closed-System Banking

Expand, test, and cryopreserve Monoclonal Stable Cell Line in a closed-system, **mitigating risks of cross-contamination** and complying with regulatory requirements



Hand Filling

Ensure even the most sensitive cell lines are **processed with care** through hand-filling

Development & Manufacturing Facility Located In Vacallo, Switzerland

- **SwissMedic Accredited** Manufacturing Facility
- **Grade C GMP** production room equipped with 3x **Grade A isolators**
- Process Development & Industrialization Lab
- **QC Lab on-site** for In-Process Controls & environmental monitoring

ENABLING HIGH QUALITY AFFORDABLE ADVANCED THERAPIES



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