The GMP Unit
Mission

Concurrent with the launch of the SCI-TReCS (Spinal Cord Injury and Tissue Regeneration Center Salzburg) project in 2011, a GMP Unit was designed that currently operates and maintains four cGMP-compliant clean-rooms to accommodate the clinical production of human mesenchymal stem cells (MSCs) and MSC-derived exosomes as well as aseptic filling of final liquid products, such as pooled human platelet lysate (pHPL).

The laboratory is accredited for the production of MSC therapeutics for clinical testing and holds a GMP license according to § 63 AMG. Obligation of the unit is the maintenance of a certified manufacturing site with an attached R&D and quality control laboratory for the production, storage and distribution of human stem cells and stem cell products under GMP-compliant conditions for clinical evaluation in patients.

Design & features

- GMP lab of 7,200 ft² total area including quality control, storage and receiving areas
- Additional areas for waste management and -30°C storage
- Cryogenic area for storage of cells and cell products in liquid nitrogen
- Independent two-tier air condition system (plenum concept) and three-tier filter systems
- Coherently closed clean room area

Reference study
MESEMS Austria; EudraCT Nr.: 2015-000137-78
Services

Manufacturing of cell-based therapeutics

- Manufacturing of clinical doses of autologous bone marrow (BM) MSCs (up to $800 \times 10^6$ cells), MSC exosomes and placebo products following validated processes and established SOPs, employing qualified equipment
- cGMP-conform documentation of quality-control tests
- Monitoring of equipment and personnel
- Product labeling
- Separate quarantine product storage until final release
- Options for product delivery or pickup

Aseptic filling and packaging

- Aseptic filling (A-in-B) by experienced and trained personnel (up to 25 L)
- Quality control and documentation according to cGMP
- Monitoring of equipment and personnel
- Product labeling
- Separate quarantine product storage until final release
- Options for product delivery or pickup
Special features

Quality control
Product testing and comprehensive documentation according to cGMP standards.

Quarantine storage
at -40, -80 und -196°C

Advice & feasibility check
We recognize the uniqueness of every project and support our clients and sponsors of clinical studies in the translation of scientific workflows into GMP-compliant processes, including the preparation of specific SOPs. Feasibility checks to assist the implementation of novel work processes are established individually with each assignment.

Training & education
At the GMP Unit all relevant processes of clean room gowning and routine cell culture work under class B / ISO 5 conditions can be executed with the guidance of experienced and qualified personnel.
How to reach us

The GMP Unit at the Paracelsus Medical University in Salzburg is a mere 15 minutes away from the central train station and Salzburg airport. For visitors arriving by car the University provides a convenient park.
Contact

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