Regenerative Medicine Technologies

Certified state-of-the-art technology platform to support Wyss Zurich projects to meet regulatory standards
The Regenerative Medicine Technologies Platform of Wyss Zurich is a fully certified state-of-the-art technical and scientific platform dedicated to manufacturing clinical grade products. The Platform provides the expertise to respond to the unique and diverse challenges of Wyss Zurich projects in the field of Regenerative Medicine. It aims to support Wyss Zurich projects in the efficient translation of basic biomedical research to applied regenerative therapies, and to accelerate entry of their innovative treatments into clinical trials.

In addition, Wyss Zurich has recently established product development processes in alignment with the international standard ISO 13485 to support and accelerate the growing number of medical device projects. Support is provided through the following departments, infrastructure and services:

**Production**
- 800 sqm total footprint; thereof a total area of about 200 sqm with grade A, B, C, D and E pharmaceutical clean room
- Qualified equipment for the production of drugs and ATMPs
- Continuous monitoring of critical parameters (particle, differential pressure, temperature, CO₂ concentration)
- Swissmedic manufacturing license (GMP) and distribution license (GDP)

**Quality Management**
- Certified Quality Management System (e.g. Master Standard Operating Procedures, Deviation Management, Change Control Management, Risk Management, etc.)
- Review and approval of documents for development, production, quality control and shipment
- Initial and continuous training of personnel

**Quality Control**
- QC lab with qualified equipment
- Microbiological monitoring of surfaces, airborne particles and airborne microorganisms

**Biobank**
- Qualified storage tanks for storing cells in liquid nitrogen
- -80°C freezers for sample storage
- Cryogenic workbench
- Validated database for sample management

**ISO 13485 for Medical Devices**
- Quality Management processes according to ISO 13485 for development of medical devices
- Training and support in Quality Management and regulatory issues

**Entrepreneurship**
- Product and process development
- Providing regulatory expertise to enable early clinical trials