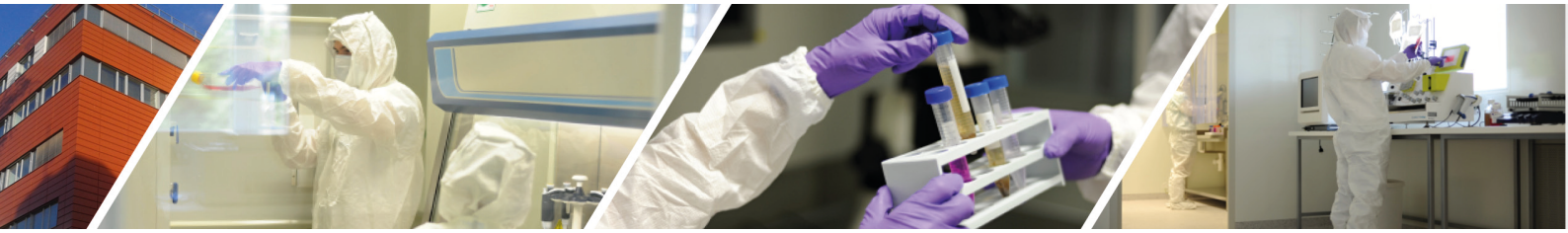
FNUSA ICRC

ST. ANNE'S UNIVERSITY HOSPITAL BRNO
INTERNATIONAL CLINICAL RESEARCH CENTER



RESEARCH GROUP

PRINCIPAL INVESTIGATOR

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KEY WORDS

Advanced Therapy Medicinal Products, Cell and tissue engineering, GMP-production, Gene therapy

RESEARCH FOCUS

CTEF represents a unit manufacturing advanced therapy medicinal products (ATMPs) including cell therapy and tissue engineered products. Products are manufactured from viable autologous or allogeneic cells and they can also contain non cellular components (chemical/biological compounds, matrices, scaffold etc.). All manufacturing and quality control activities at CTEF are carried out in accordance with the principles of cGMP to provide the authorization for the manufacture and investigation of all medical products within the clinical trials. Environmental Monitoring and Assessment is conducted continuously during the production processes.
The facility provides licensed manufacturing and testing of cGMP grade medicinal products for pre-clinical and clinical trials and is available to academic and private sector scientists, taking care of the project license and authorization process. In cooperation with Masaryk University, CTEF also provides support in the translation of research and development outcomes into a manufacturing setting.
CTEF has ISO 9001 certification (quality management system) and GMP manufacture permit from SÚKL.
Specific products: Virus-specific lymphocytes (VSL), peripheral blood mononuclear cells (PBMC), chimeric antigen receptor T-cells (CAR-T cells), human embryonic stem cells (hESC), human induced pluripotent stem cells (hiPSC)
The facility cooperates with many partners, including: Masaryk University, Brno, University Hospital Brno; Olomouc University Hospital; Institute of Hematology and Blood Transfusion, Prague; The Institute of Genetic Medicine, Newcastle, UK; Mayo - Center for Regenerative Medicine, Rochester, USA; Leibniz Research Laboratories for Biotechnology and Artificial Organs, Hannover, Germany

RESEARCH OBJECTIVES

Development of clinical-scale manufacturing processes based on cell and tissue engineering
Development of analytical methods for product characterization and release
GMP manufacturing, quality control and releasing clinical–grade products
Compliance with ISO 9001 and GMP

TECHNOLOGICAL EQUIPMENT

3 clean room units grade A inside grade B, Isolator grade A inside grade C room and multifunctional C grade laboratory

Independent systems for cell expansion: CliniMACS Prodigy® System; Terumo Quantum® Cell Expansion System

Independent Quality Control Unit

Controlled Cryobank

OFFERED SERVICES AND EXPERTISE

- The facility provideslicensedmanufacturing and testing of cGMP grade cell-based medical products for pre-clinical and clinical trialsand is available to academic and private sector scientists.
- Take care of the project license and authorization process.

TOP PUBLICATIONS

0. FARKAS S, SIMARA P, REHAKOVA D, VEVERKOVA L, KOUTNA I. Endothelial Progenitor Cells Produced From Human Pluripotent Stem Cells by a Synergistic Combination of Cytokines, Small Compounds, and Serum-Free Medium. Front Cell Dev Biol. 2020 May

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OTHER SELECTED RESULTS

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Supported by the project no. LQ1605 Translational Medicine from the National Program of Sustainability II (MEYS CR)

Printed 03/2024