



CORE FACILITY

# Cell and Tissue Engineering Facility - cGMP



HEAD OF CORE FACILITY



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EDUCATION

- ▲ 2001: Ph.D. in Molecular Biology and Genetics, Masaryk University, Brno, Czech Republic
- ▲ 2001: RNDr./MSc. in Molecular Biology, University of South Bohemia, České Budějovice, Czech Republic
- ▲ 1997: Mgr./MSc. in Biochemistry, Masaryk University, Brno, Czech Republic

KEY INTERESTS

Cell-Based Medicinal Products • Advanced Therapy Products • Tissue Engineered Products • Adult Stem Cells • Human Embryonic Stem Cells • Human Induced Pluripotent Stem Cells • Gene Therapy

RESEARCH FOCUS

The Cell and Tissue Engineering Facility (CTEF-cGMP) represents a unit for Cell-based Medicinal Products (CBMPs) or Advanced Therapy Products (ATPs) including cell therapy and tissue engineered products. These products are manufactured from viable autologous, allogeneic or xenogeneic cells and they can also contain non cellular components (chemical/biological compounds, matrices, scaffold etc.). All manufacturing and production control activities in CTEF are carried out in accordance with the principles of cGMP quality, 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.

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 and quality control of releasing clinical-grade products.

CREATING THE FUTURE OF MEDICINE



CLINICAL RESEARCH



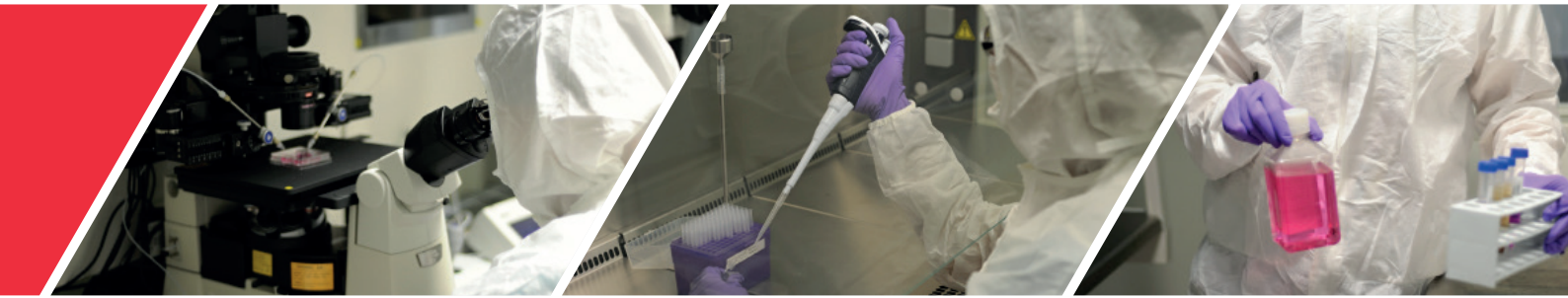
TRANSLATIONAL RESEARCH



BASIC RESEARCH



CORE FACILITIES



## TOP PUBLICATIONS

- ▲ SIMARA P, TESAROVA L, REHAKOVA D, MATULA P, STEJSKAL S, HAMPL A, KOUTNA I. DNA double-strand breaks in human induced pluripotent stem cell reprogramming and long-term in vitro culturing. *Stem Cell Research and Therapy*. 2017, 8(1):73
- ▲ TESAROVA L, SIMARA P, STEJSKAL S, KOUTNA I. Hematopoietic Developmental Potential of Human Pluripotent Stem Cell Lines Is Accompanied by the Morphology of Embryoid Bodies and the Expression of Endodermal and Hematopoietic Markers. *Cell Reprogramming*. 2017, 19 (4), 270-284.
- ▲ TESAROVA, L., SIMARA, P., STEJSKAL, S., KOUTNA, I. The Aberrant DNA Methylation Profile of Human Induced Pluripotent Stem Cells Is Connected to the Reprogramming Process and Is Normalized During In Vitro Culture. *PLoS One*. 2016, 11(6), e0157974.
- ▲ STEJSKAL, S., STEPKA, K., TESAROVA, L., STEJSKAL, K., MATEJKOVA, M., SIMARA, P., ZDRAHAL, Z., KOUTNA, I. Cell cycle-dependent changes in H3K56ac in human cells. *Cell Cycle*. 2015, 14(24), 3851-63.
- ▲ TESAROVA, L., STEJSKAL, S., KOUTNA, I. Driven hematopoietic differentiation of embryonic stem cells: epigenetic perspectives. *Current Pharmaceutical Design*. 2014, 20(11), 1674-86.

## TECHNOLOGICAL EQUIPMENT

- ▲ 4 clean room units grade A, inside grade B rooms and multifunctional C grade laboratory.
- ▲ Independent systems for cell expansion: CliniMACS Prodigy® System; Terumo Quantum® Cell Expansion System.
- ▲ Inverted Fluorescence Microscope with micromanipulators and injectors for applications such as Confocal, FRET, High Content Analysis (HCS), and Photobleaching/Photo Activation to study interaction of fluorescence protein molecules in living cells and tissues.
- ▲ Independent Quality Control Unit.

## OFFERED SERVICES AND EXPERTISE

- ▲ The facility provides licensed manufacturing and testing of cGMP grade cell-based medical products for pre-clinical and clinical trials and is available to academic and private sector scientists.
- ▲ Ensure preclinical and clinical trials, authorization process.

## MAIN PARTNERS AND COLLABORATING INSTITUTIONS

- ▲ **Institute of Hematology and Blood Transfusion**, Prague, Czech Republic
- ▲ **Masaryk University**, Brno, Czech Republic
- ▲ **Institute of Genetic Medicine**, Newcastle, United Kingdom