
FRAUNHOFER INSTITUTE FOR CELL THERAPY AND IMMUNOLOGY

Fraunhofer IZI at a glance



The Fraunhofer-Gesellschaft (FhG)

Europe's Largest Organisation for Applied Research



- FhG is a German non-University research organization, largest society for applied research in Europe
 - 69 Institutes / 25.000 employees
 - 2.1 billion € annual research volume
- Governmentally owned & non-profit
- Applied research for industry partners
- Worldwide presence
- Business models*/**:
 - Contract research, testing, manufacturing
 - Joint development
 - Licensing
 - Consulting

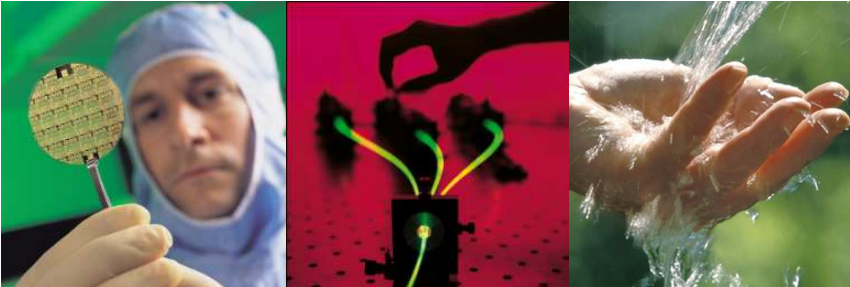
* Fraunhofer grants licenses to industry partners for commercialization

© Fraunhofer IZI ** May also involve public funding

The Profile of the Fraunhofer-Gesellschaft

We undertake applied research in:

- Life Sciences
- Information & Communication Technology
- Microelectronics
- Light & Surfaces
- Production & Energy
- Materials & Components
- Defense & Security



The Fraunhofer Institute for Cell Therapy and Immunology (IZI)

- Staff: 588+
- HQ: Leipzig (Free State of Saxony)
 - Rostock, Halle, Potsdam, Erfurt
 - Hamilton (Canada), Hwasun (ROK), Melbourne (Australia)
- Budget: € 30 million (2016)
- Business Units:
 - Cell Therapy & Regenerative Medicine
 - Drug & Vaccine R&D
 - Diagnostics & Biomarkers
 - Biosystems Technology
- Since 2005:
 - 185 Industrial Partners
 - 192 Academic Partners



Fraunhofer IZI: International Locations



Fraunhofer Project Center BEAM*

Main R&D topics:

- Cell therapies
- Diagnostics
- Biomaterials

Partner: McMaster University, Hamilton, Ontario

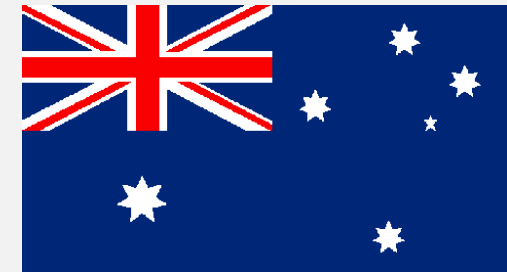


Joint Laboratory

Main R&D topics

- Cancer therapies

Partner: Chonnam National University Hospital, Hwasun



Joint Research Group

Main R&D topics

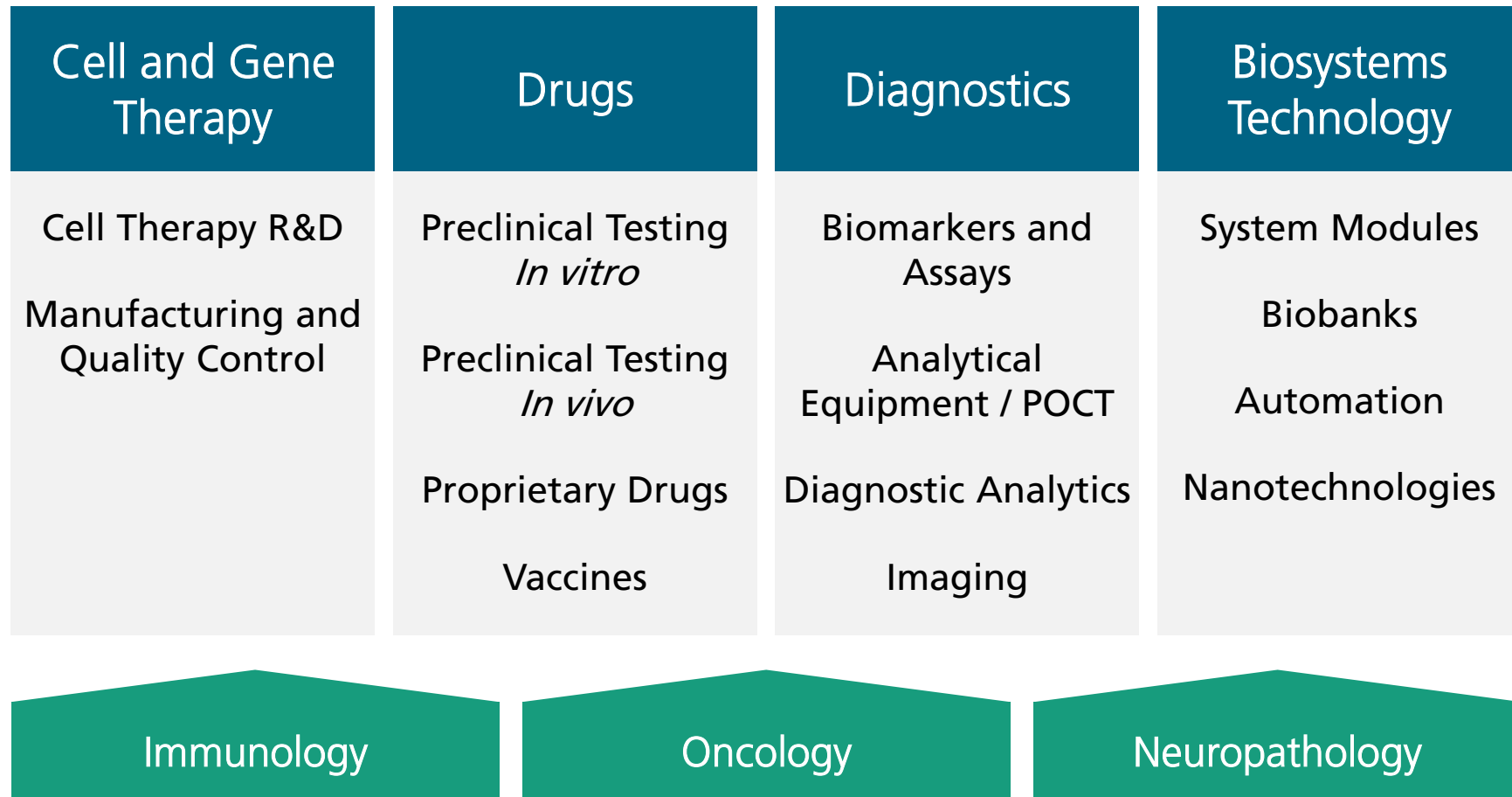
- Imaging
- Immunology

Partner: Monash University, Melbourne, Victoria, Australia



* Fraunhofer Project Centre for Biomedical Engineering and Advanced Manufacturing (BEAM)

Business Units



Business Unit Cell and Gene Therapy

- **GMP Manufacturing of ATMPs** (cell and tissue products) including application for manufacturing authorization according to §13 AMG
- **Safety & Toxicology studies** for ATMPs
- **Development & manufacturing of cell-based therapies** for multiple indications
- **Accompanying technology and product developments** (e.g. induced pluripotent stem cells)



Business Unit Cell and Gene Therapy

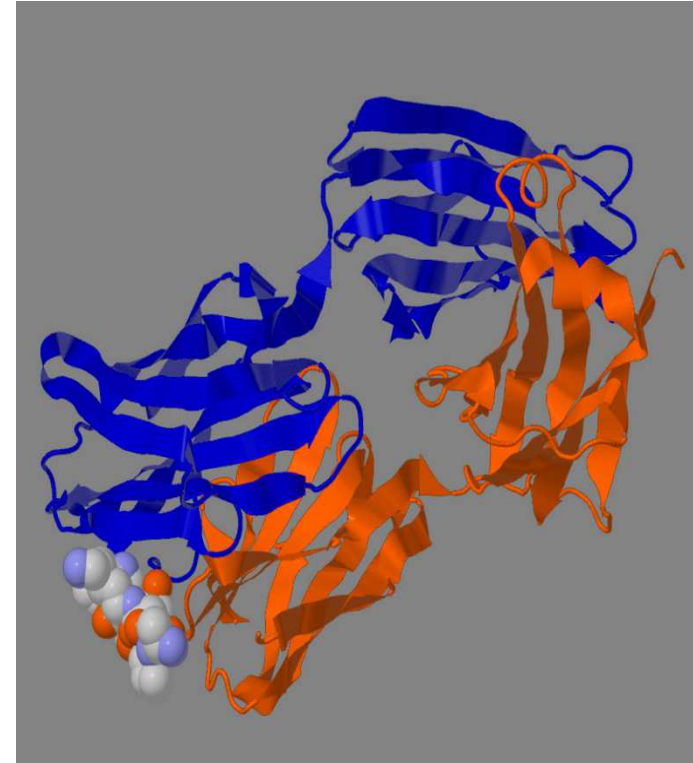
Reference Projects

- CTL019[®], Process transfer, Application for a manufacturing authorization according to §13 German Drug Act
- DCVax[®] L, Process transfer, Manufacturing of investigational medicinal products for clinical trials and hospital exemption
- Placenta-derived mesenchymal stem cells for neurodegenerative diseases
- Adipose tissue derived regenerative cells (ADRC)
- Stem cell derived neuronal precursor cells for treatment of stroke in a sheep MCAO model



Business Unit Drugs

- Development of small molecule drugs and biopharmaceuticals for neurodegenerative, infectious, autoimmune, cancer and other diseases
- GMP manufacturing and GLP Safety, Toxicology and Efficacy for biopharmaceuticals (and small molecule drugs)
- Innovative vaccines and companion diagnostics for human and veterinary applications
- Ligand development – peptide/Ab phage display, epitope mapping
- Innovative *in vitro* and *in vivo* models for safety and efficacy testing



Business Unit Drugs

Project and Partner Examples

- West Nile Virus Vaccine
- Lead candidates for fibrosis
- New therapeutic approaches for stroke
- Antibodies for treatment of Alzheimer's disease
- New antibiotic SM lead candidates, currently under development for periodontitis
- Clay minerals as toxin adsorber
- Unique animal models for inflammatory bowel disease (IBD)
- Low Energy Electron Irradiation (LEEI) for Pathogen Inactivation → Vaccine manufacturing



Business Unit Diagnostics

- Identification and clinical validation of ncRNA-based biomarkers
- Development of ncRNA-based diagnostic procedures
- Development of diagnostics platforms for individualized medicine (point-of-care diagnostics)
- Identification of new epitopes for the diagnosis of infectious pathogens (e.g. flaviviruses)
- Assays and biomarkers for veterinary medical diagnostics and the food industry



Business Unit Diagnostics

Reference Projects

- ncRNA-based IVDs for diagnosis and prognosis of prostate carcinoma
- Development of an ELISA-based assay for the detection of Porcine Respiratory and Reproductive Failure Syndrome Virus (PRRSV)
- Point of care diagnostic device for the detection of sexually transmitted diseases infections



analytikjena



**SelfD
Technologie
GmbH**

Business Unit Biosystems Technology

- Innovative cell-free biosynthesis platform
 - High yield expression of receptors, ion channels, aquaporins, toxins, etc.
- Cell-based technologies and device for extracorporeal immunomodulation/sepsis treatment
- New and improved dialysis devices



Business Unit Diagnostics

Reference Projects (Medical product testing and device R&D for extracorporeal therapies)

- Fibron GmbH, now: Allmed Medical Industries GmbH, Germany



- CytoSorbents Europe GmbH, Germany



- Clearum GmbH, Germany



- Nipro Corporation, Japan



Thank you for your attention