
FRAUNHOFER INSTITUTE FOR CELL THERAPY AND IMMUNOLOGY

Fraunhofer IZI at a glance



The Fraunhofer-Gesellschaft (FhG) – Europe's Largest Organisation for Applied Research



Headquarters in Munich

- FhG is the largest society for applied research in Europe
 - > 60 Institutes in Germany
 - > 20,000 employees
 - > 1.95 billion € total annual financing
- Focused on applied research projects with industry partners
 - Fraunhofer supports development efforts of its partners by providing them with new technologies, product candidates, problem solutions etc.
 - Main part of the research revenue is derived from contracts with industry and from publicly funded research projects with the industry

The Fraunhofer IZI: Facts

- Staff: 284
- Scientific staff: 89%
- Location: Leipzig, Rostock and Halle
- Finance volume: € 13 million (2013)
- Direct industry projects: 40%
- Focus:
 - Cell therapies, stem cell technologies, regenerative medicine,
 - Immunology, immunological diseases, vaccine technologies
 - Drug discovery, target validation and preclinical development
 - Diagnostics, biomarkers and biobanks



The Fraunhofer IZI: Infrastructure

■ Main Building

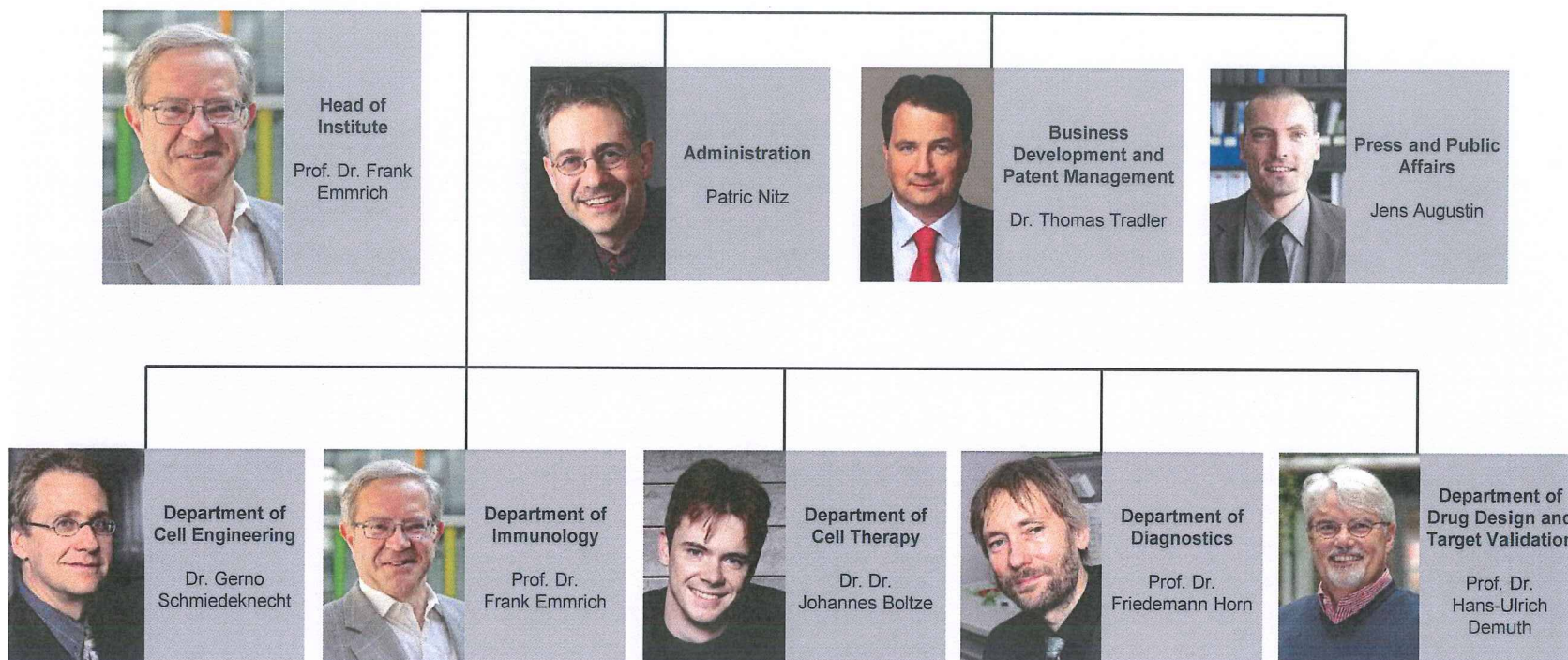
- Space for 200 employees
- 2,300 m² laboratory area
- 450 m² GMP area for all technologies
- Cell and molecular biological laboratories

■ First Extension Building

- 1,400 m² additional space
- 450 m² additional cell tech GMP area
- Special imaging unit
- Special laboratories for preclinical therapy and diagnostics development



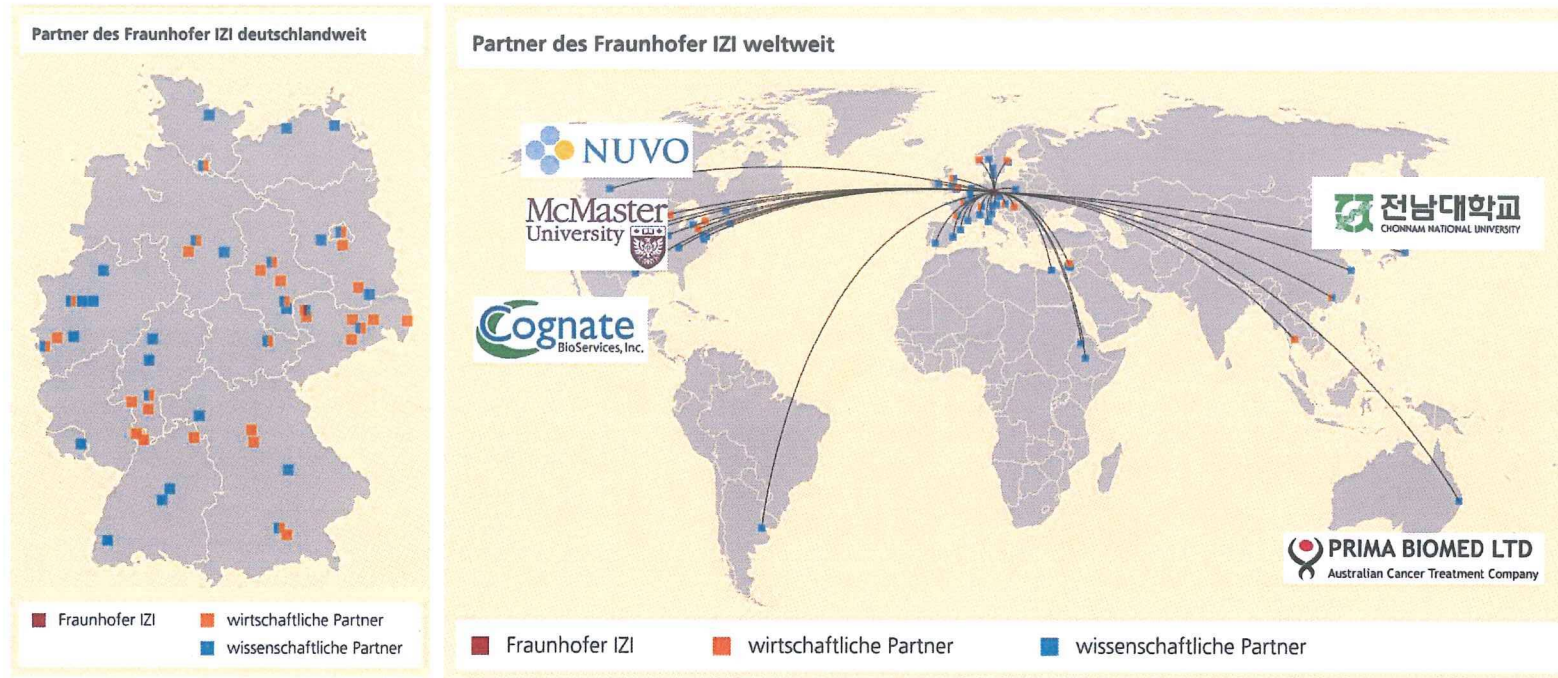
The Fraunhofer IZI: Structure



The Fraunhofer IZI: Business opportunities

- We offer innovative solutions for our partners focusing on innovations at the interface of medicine, biological sciences and engineering sciences
- Partners: pharmaceutical and biotechnology industry, diagnostic laboratories, hospitals and research institutes
- We are your partner for:
 - **Contract research** using our innovative approaches (e. g. development of and testing in a broad range of assays, animal models as well as finding and validation of biomarkers)
 - **Partnerships** in development (e. g. technologies, drug candidates and innovative therapies, diagnostic products)
 - **GMP Manufacturing** (e. g. ATMPs)
 - **Application for public funding** and coordination of funded projects
 - **Scientific consulting** and **staff training**

National and international partners



■ 109 clients from the industry

■ 53 non-university partners

■ 95 academic partners

■ 25 clinical partners

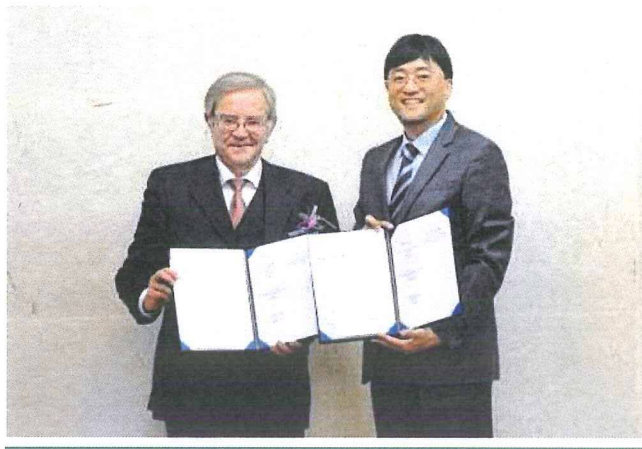
Collaboration with McMaster University

- 09/2013: Fraunhofer IZI and McMaster University (Hamilton/Ontario) signed collaboration agreement
- Collaboration covers first joint research projects in several R&D areas (diagnostics, immunotherapies, vaccines) and will be expanded towards other areas very soon
- Moreover, Fraunhofer IZI and McMaster University intend to establish, in close collaboration with the City of Hamilton, a Fraunhofer Project Center in Hamilton

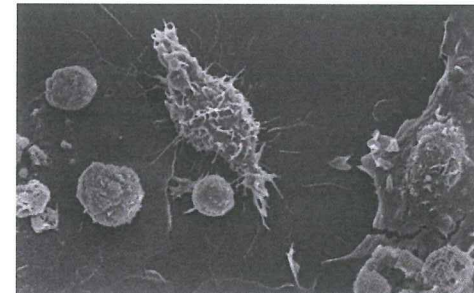
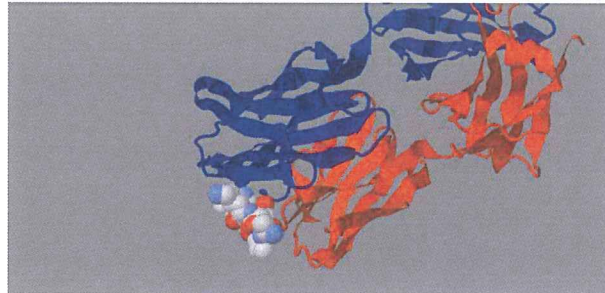
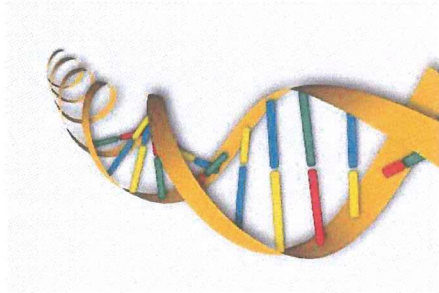


Collaboration with Chonnam National University

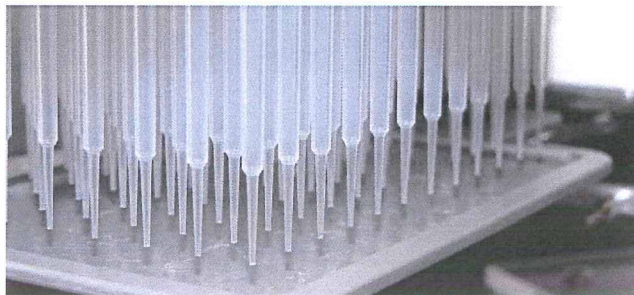
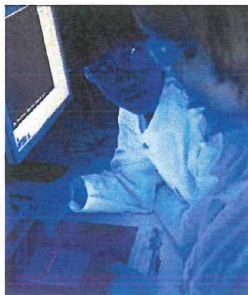
- 03/2013: Opening ceremony for the Joint Laboratory of Chonnam National University Hospital Hwasun and Fraunhofer IZI in Hwasun (South Korea)
- Funded by the south corean Ministry for Education, Science and Technology (Global R&D Centers Program, GRDC)
- Joint research in the areas of stem cells, vaccine development and oncology



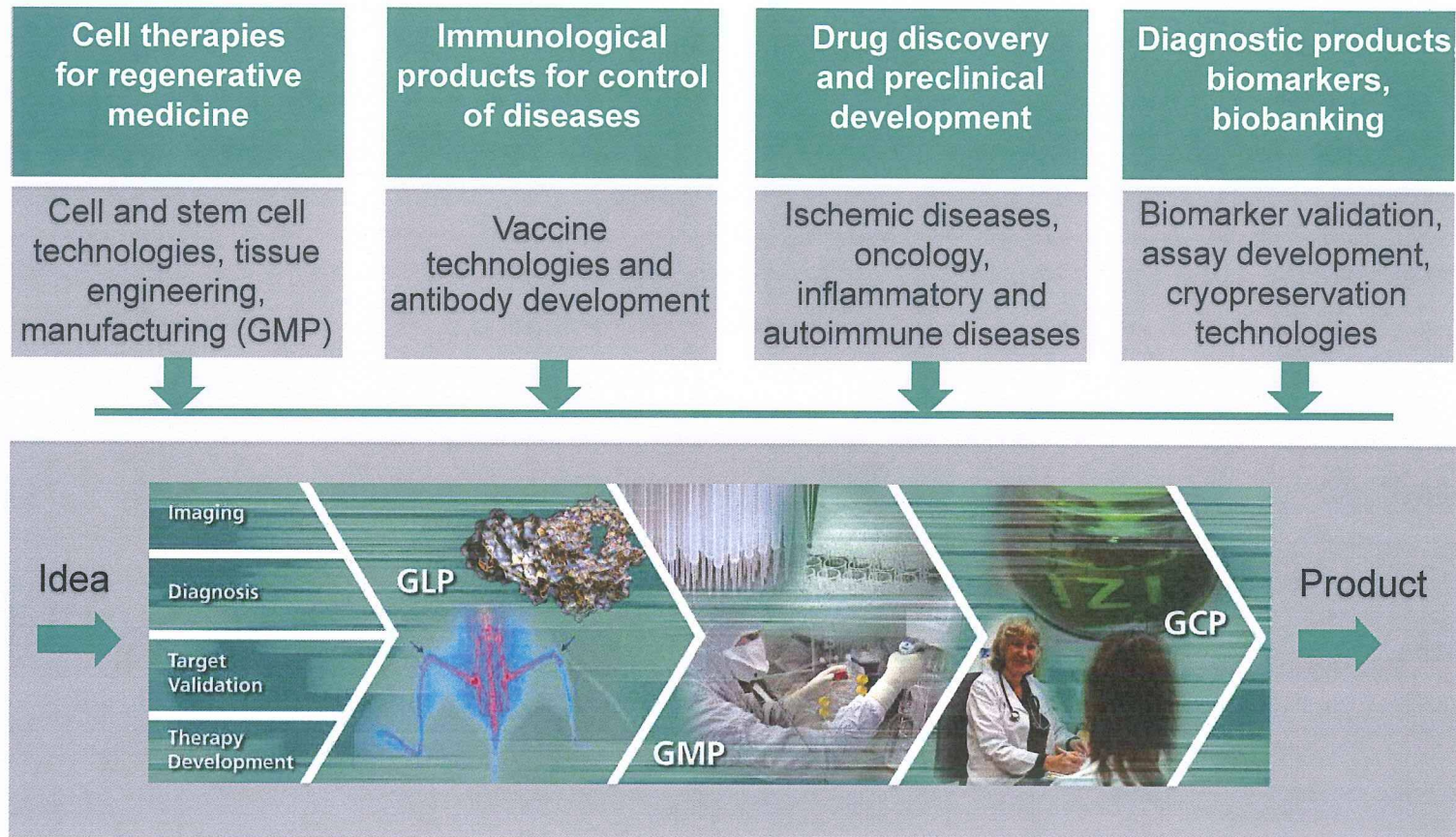
The Fraunhofer IZI: Mission



Our mission is to provide our partners from industry with innovative solutions and technologies, thereby strengthening their competitive situation and supporting their efforts to develop and market innovative products.



The Fraunhofer IZI: Core competencies



Department of Cell Engineering

- **GMP Manufacturing of ATMPs** (cell and tissue products) including application for manufacturing authorization according to §13 AMG
- **Safety & Toxicology studies** for ATMPs and biopharmaceuticals (GLP)
- Development and manufacturing of polyclonal and **monoclonal antibodies**



Project examples in 2013



DCVax® L - process-transfer, application for a manufacturing authorization according to §13 German Drug Act and subsequent manufacturing of investigational medicinal products for clinical trials and hospital exemption



Cvac™ - process-transfer, application for a manufacturing authorization according to §13 German Drug Act and subsequent manufacturing of investigational medicinal products for clinical trials



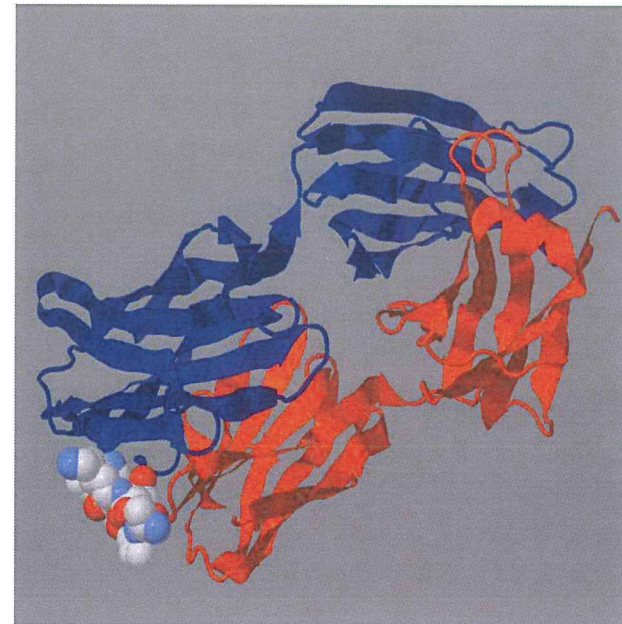
Manufacturing of autologous skin grafts from hair roots (EpiDex™) for treatment of chronic wounds



Manufacturing of cord blood stem cells "InnovaCB" for autologous storage, set-up of GMP-compliant stem-cell banking processes for mesenchymal stem cells from fat

Department of Immunology

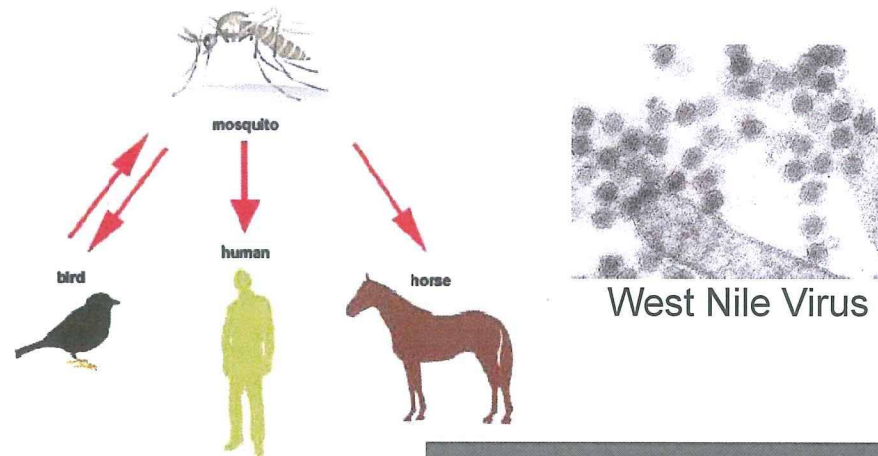
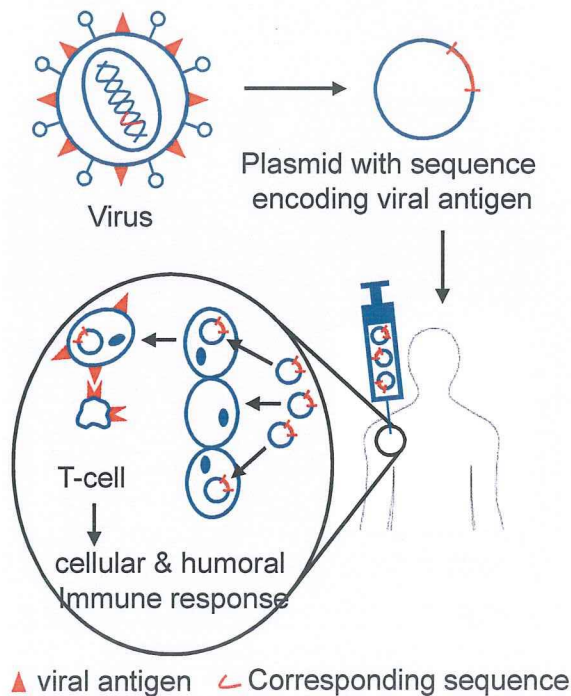
- Development of **cell therapies and biopharmaceuticals for prevention and treatment of complications after stem cell transplantation (GvHD)**
- Development of **innovative vaccines** and of diagnostic test systems for human and veterinary use
- **Ligand development** (e.g. **antimicrobial peptides**), peptide and antibody phage display, epitope mapping, *in vitro* selection of antibodies





WINGS = West Nile Shield Project: Epidemiology, Diagnosis and Prevention of West Nile Virus in Europe

DNA Vaccination technology



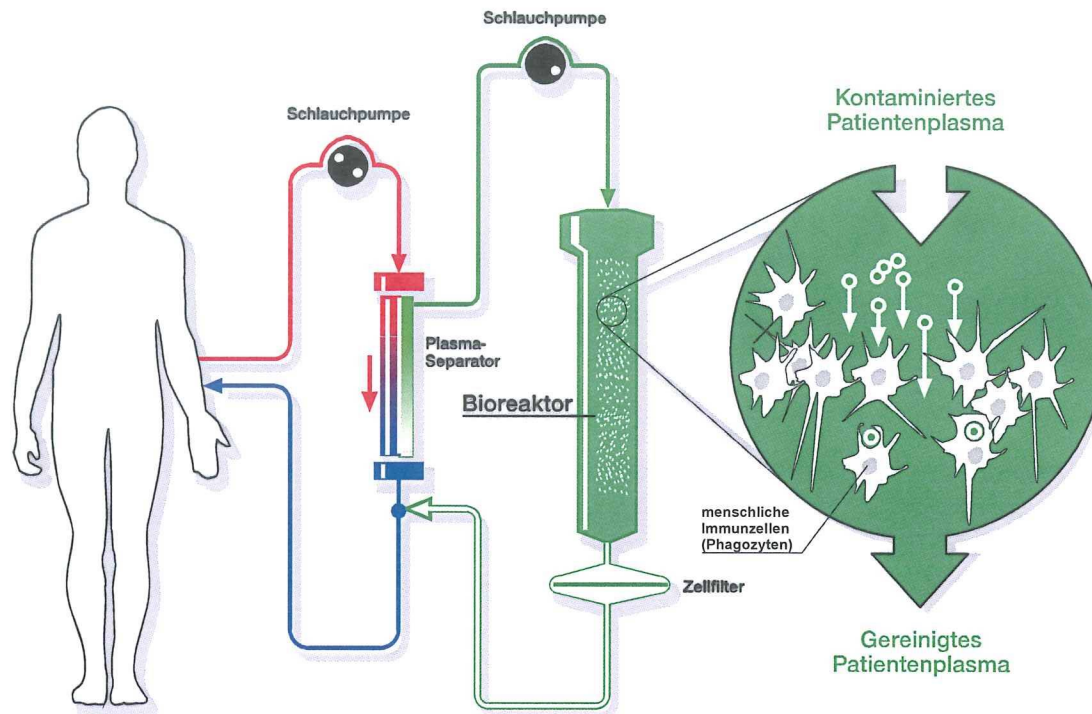
Innovative Vaccines (Vaccine Inductors)

- Effective immunization
- Long lasting protection
- Safety (no replication)
- High stability

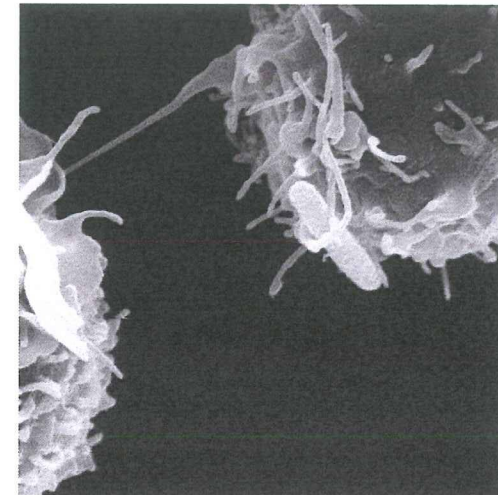


Sebastian
Ulbert
Coordinator

Extracorporeal Immune Support System - EISS



IZI project group Rostock



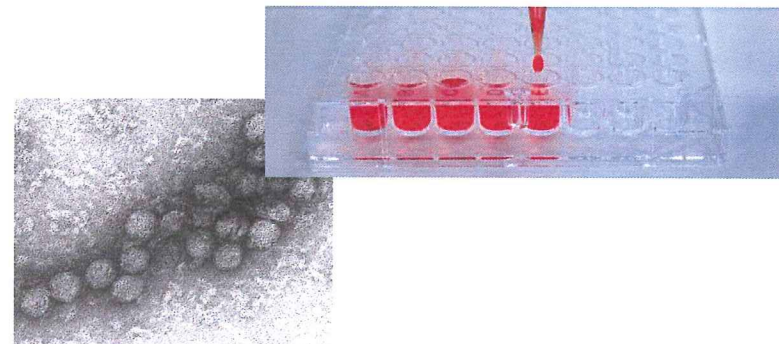
MedTech Device + Living Cells

Biological particle cleaning for treatment of sepsis

New diagnostic assay receives approval by authorities

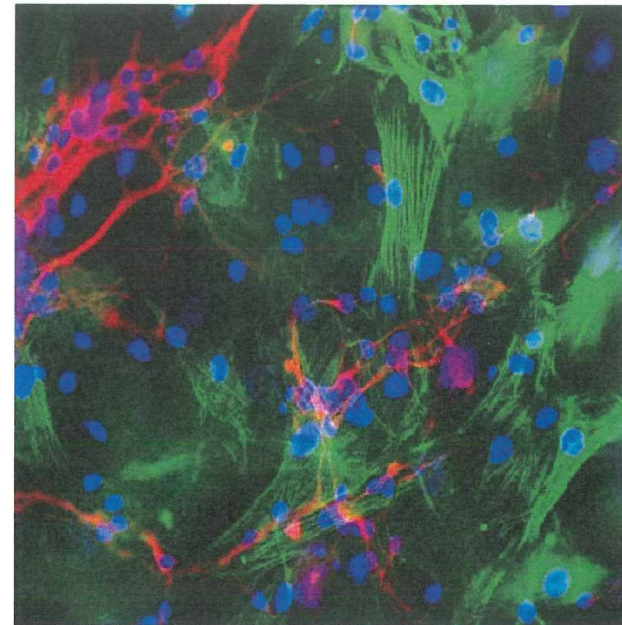
- **07/2013:** Fraunhofer IZI has successfully developed (in close collaboration with industry partners) an ELISA-based assay for detection of Porcine Respiratory and Reproductive Failure Syndrome Virus (PRRSV)
- The diagnostic assay received now approval by federal authorities and marketing will start soon
- Assay is based on antigen „cocktail“ of different recombinant proteins, discriminates virus strains and features a minimal number of false positives/negatives

analytikjena



Department of Cell Therapy

- Development of **new treatment strategies for ischemic diseases (e.g. myocardial infarct, stroke), inflammatory diseases, age-related diseases and oncology**
 - Broad range of small and large animal ischemic disease models and **comprehensive imaging capabilities**
- **Innovative stem cell technologies and R&D on cell and tissue preserving techniques**



Project SIRIUS

■ Cooperation project

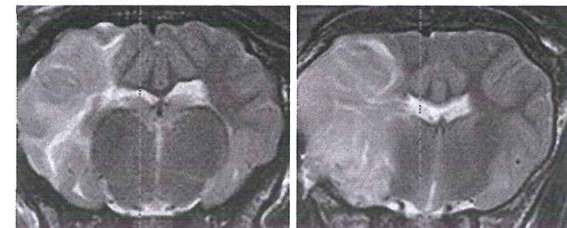
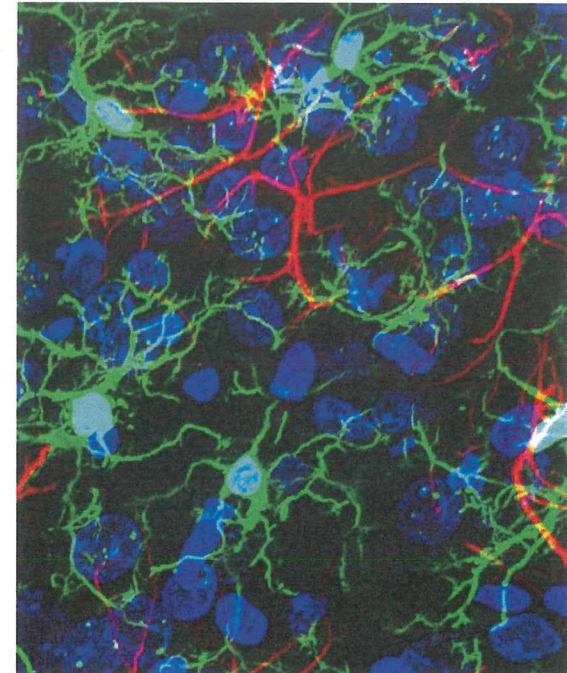
Universität Leipzig (TRM)
Fraunhofer-Gesellschaft (IZI)
Stanford University, CA (CIRM)

■ Stem cell derived neuronal precursor cells for treatment of stroke in a sheep MCAO model



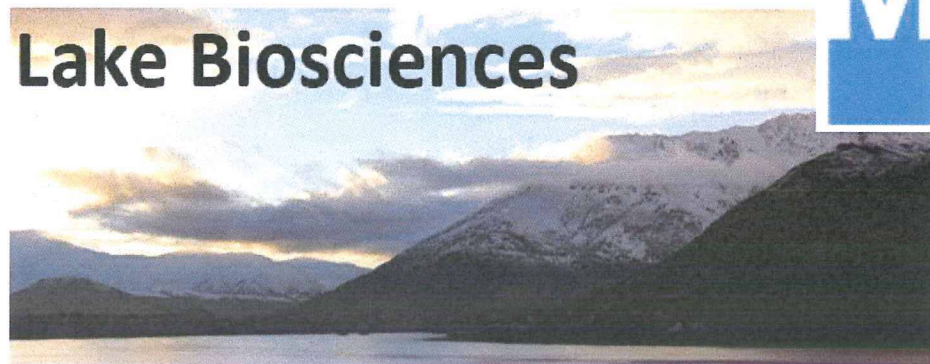
Johannes Boltze
Project Coordinator

UNIVERSITÄT LEIPZIG



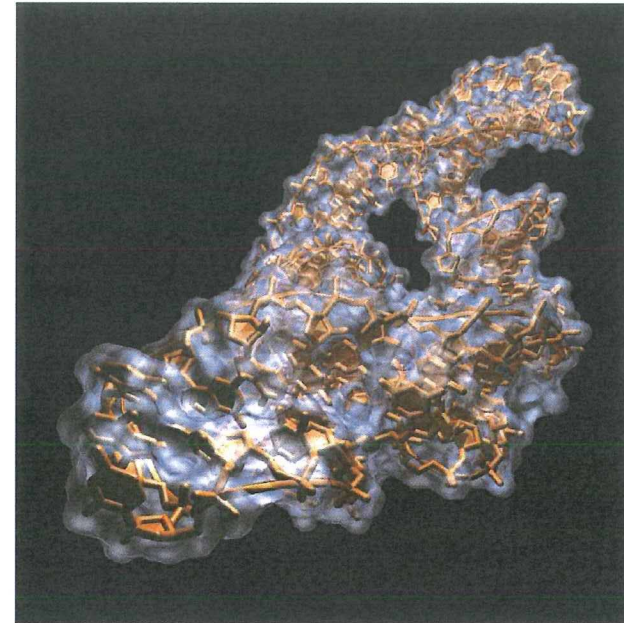
Joint R&D project with MD-5 GmbH

- **03/2013:** Start of a joint R&D project focusing on the development of a medical device for treatment of acute stroke, based on transcranial magnet stimulation
- Fraunhofer IZI successfully supported establishment of MD-5 GmbH (a subsidiary of US-based Lake Biosciences LLC) in Leipzig
- Partners succeeded in acquiring > 1,5 Mio. € from Saxon Development Bank (SAB)



Department of Diagnostics and New Technologies

- Research and development of **diagnostic markers and therapeutic targets based on ncRNA and miRNA** (RNomics)
- Development and optimization of **diagnostic platforms for individualized therapies**
- **Drug R&D** for inflammatory diseases and oncology
- **Cancer stem cell biobanks** and use for development of CSC-targeted therapies, tumor therapy optimization and for diagnostic purposes

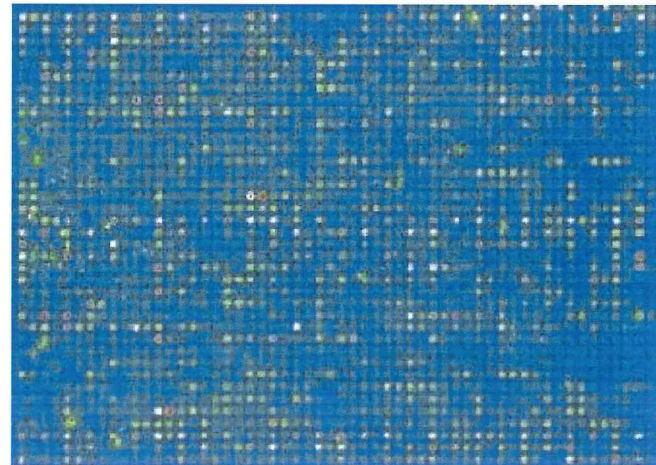
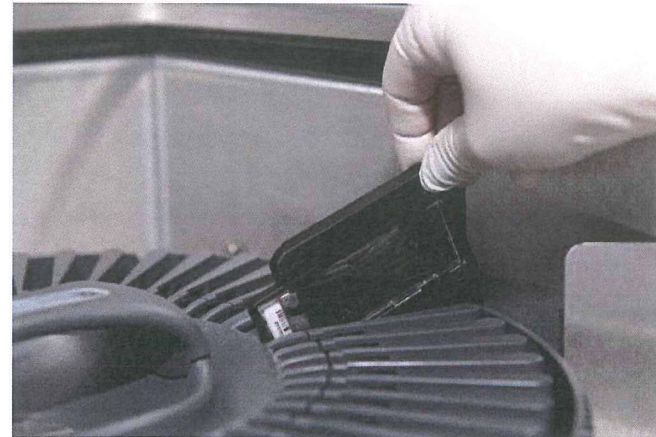


RIBOLUTION

- Project supported by Fraunhofer Future Foundation
- Identification of new targets for diagnosis and therapy based on ncRNA

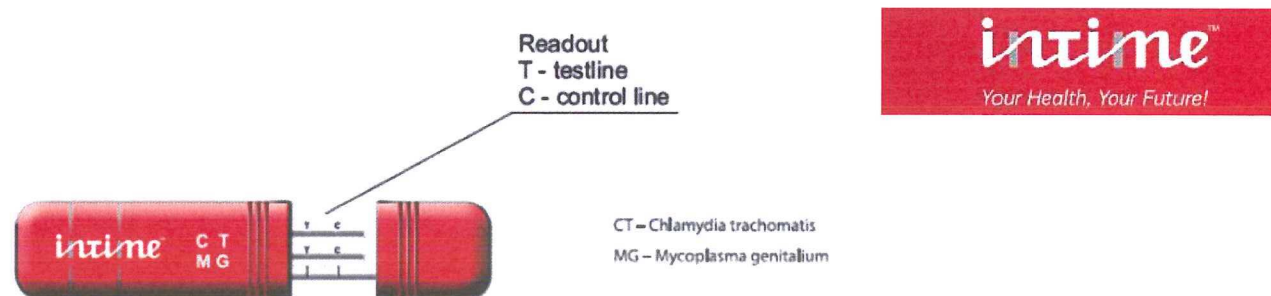


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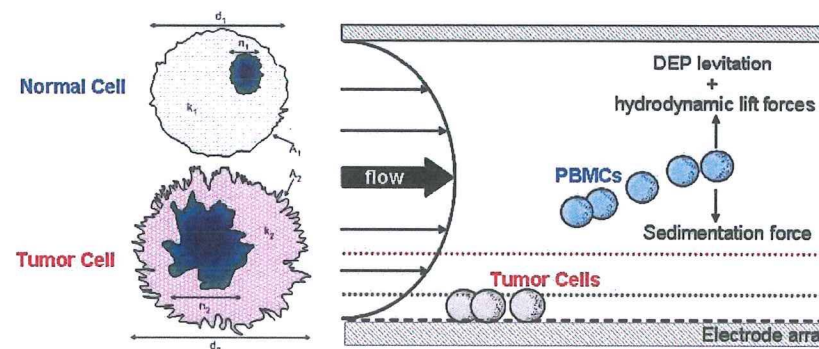
Joint R&D project with SelfD Technologie GmbH

- **05/2013:** Start of a joint R&D project focusing on the development of a „point of care“ diagnostic device for detection of sexually transmitted diseases infections based on innovative PCR technologies and microfluidic systems
- Fraunhofer IZI successfully supported establishment of SelfD Technologie GmbH (a subsidiary of Estonia-based Selfdiagnostics OÜ) in Leipzig
- Partners succeeded in acquiring > 2 Mio. € from Saxon Development Bank (SAB)



Joint R&D project with Apocell Europe GmbH

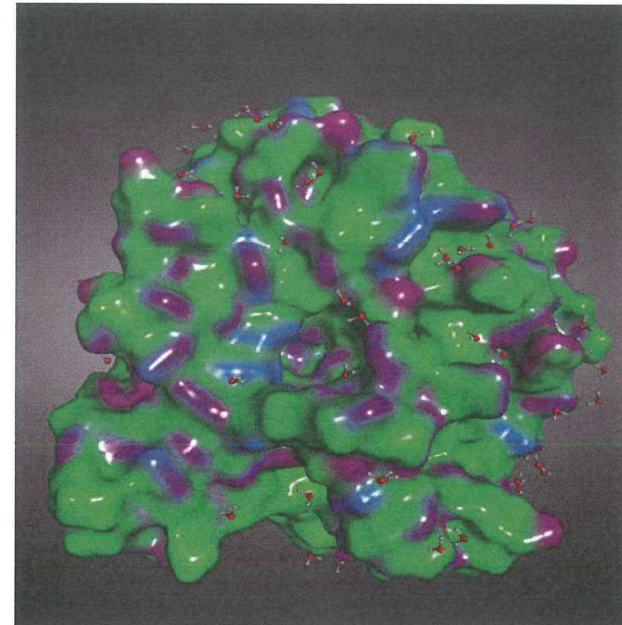
- **07/2013:** Start of a joint R&D project focusing on the further development of a method/device for isolation and characterization of circulating tumor cells and discovery of new cancer biomarkers (ApoStream™)
- Fraunhofer IZI successfully supported establishment of Apocell Europe GmbH (a subsidiary of US-based Apocell, Inc.) in Leipzig
- Partners succeeded in acquiring 4 Mio. € from Saxon Development Bank (SAB)



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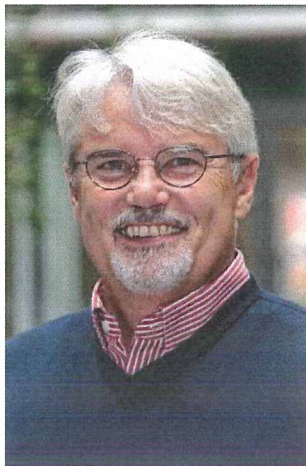
Department of Drug Design and Target Validation

- **Target validation** (*in vitro* and *in vivo*), cell and animal models
- Drug Design (*in silico*) and Computational Chemistry
- **Discovery and development of small molecules and biologics**
- Assay development (biomarkers)
- (GLP-) Analytics for pre-clinical and clinical studies of small molecules
- **Medicinal and Peptide Chemistry**



New project group of Fraunhofer IZI

- **07/2013:** Establishment of the new project group „Molecular Drug Design & Discovery“ in Halle
- Focus on the development of innovative small molecule drugs and biopharmaceuticals for diseases with a high medical need (in particular neurodegenerative diseases, e.g. AD)
- Within the 5 years initial phase funded by grants from the State of Saxony-Anhalt and from the European Union



Prof. Dr. Hans-Ulrich Demuth, Head of the new department „Molecular drug design“

Biozentrum at the Martin-Luther-University Halle-Wittenberg



New companies established by the Fraunhofer IZI

Spin-offs from IZI or subsidiaries of international partner companies

- Cognate Bioservices GmbH
- Northwest Biotherapeutics GmbH
- Prima Biomed GmbH
- Magna Diagnostics GmbH
- Sonovum AG
- Nuvo Research GmbH
- Oncotriton GmbH
- SelfD Technologie GmbH
- MD-5 GmbH
- ApoCell Europe GmbH
- Tutelacell GmbH i.G.



Innovative tumor vaccines

In vitro diagnostics

Diagnostic devices

Drug R&D

Dietary supplements

In vitro diagnostics

Medical devices

In vitro diagnostics

Consulting

The Fraunhofer IZI: Selected Partners



Thank you for your attention