



# Fraunhofer

IZI

FRAUNHOFER INSTITUTE FOR CELL THERAPY AND IMMUNOLOGY IZI



ANNUAL REPORT

2017

SHORT VERSION



This is the abridged version of the Fraunhofer IZI Annual Report 2017.

The full version can be found at [www.izi.fraunhofer.de/en/publications](http://www.izi.fraunhofer.de/en/publications)  
The report includes a detailed description of selected projects and a list of this year's publications, besides a number of other features.

Scan the QR codes to go straight to the relevant sections of the annual report.  
We recommend that you use the Mozilla Firefox browser for an optimal page display.

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# PREFACE



# PROF. DR. FRANK EMMRICH

2017 was a resounding success in every way for Fraunhofer IZI and, without doubt, the institute's most prosperous year to date. Never before has it managed to attract so many large-scale and, for the most part, interdisciplinary collaboration projects. For the eighth year running, Fraunhofer IZI was able to round off the year with a positive balance sheet and increased turnover. Over 550 members of staff now work across four German and two international sites. And that's not to mention the additional site in Erfurt, Germany, and the new international collaboration with Monash University in Melbourne, Australia.

The positive outcome of 2017 is reflected in particular in the numerous major and also collaboration projects we were able to attract during the course of the year. The institute flourished in all of the new funding formats offered by the Fraunhofer-Gesellschaft. Special mention here goes to the Chemical and Biosystems Engineering Center (CBS) in Halle/Leipzig, the ImmuVision project cluster and the Microelectronic and Optical Systems for Biomedicine project center in Erfurt, the latter of which is being set up together with Fraunhofer IPMS in Dresden and Fraunhofer IOF in Jena. Together with the Helmholtz Association and University Hospital Leipzig, Fraunhofer is initially funding four proof-of-concept platforms, allocating 3 million euros to each platform. Fraunhofer IZI is involved in two of these projects. Large R&D projects with international pharma and biotech companies have also gotten under way, with the Department of GMP Cell and Gene Therapy having been particularly successful here.

In August 2017, Fraunhofer IZI got to work setting up a research unit at Monash University, Australia, in cooperation with the ARC Centre of Excellence in Advanced Molecular Imaging. The scientific focus of joint research activities in the future will first be placed on molecular imaging and structure determination.

Two working groups have also been evaluated successfully: firstly, the Image Analysis of Cell Function specialist group, which the Fraunhofer IZI has been supporting since 2014 together with Leipzig University of Applied Sciences (HTWK), and secondly the Extracorporeal Immunomodulation Unit (EXIM) in Rostock.

Overall in 2017 we turned over a financial volume of 36 million euros, 45 per cent of which can be ascribed to industry (50 per cent at the Leipzig headquarters). We had 557 members of staff on our books, 366 of whom in Leipzig. What better time to initiate the planned change to the institute's management board, which you can read more about over the next few pages.

This report will also bring you up to date on the institute's competences and projects as well as its research units. Scan the QR codes to open the full, digital version of the report, complete with detailed project descriptions and information on all of the academic papers and publications that appeared in 2017.

My most sincere thanks and respect goes out to all our members of staff and everyone who has supported us on our journey and contributed towards the remarkable success of the institute and its superb form to date. I would like to wish my successor and all my colleagues the very best for the future and I will still be happy to provide advice and support as and when required.

I hope that everyone reading this report will make some interesting discoveries while flicking through its pages. Thank you for your interest in our institute.

Best wishes

Yours



Prof. Dr. Frank Emmrich

# NEW INSTITUTE MANAGEMENT



# NEW INSTITUTE MANAGEMENT

On 15 December 2017, Professor Ulrike Köhl was appointed the new managing director of the Fraunhofer Institute for Cell Therapy and Immunology.

Immuno-oncology is an important and exciting field of cancer research right now. The central question here is how individual immune cells from a patient's immune system can be specifically activated and used in the fight against cancer.

With Professor Ulrike Köhl, who has also been appointed professor of immuno-oncology at Leipzig University and director of the Institute of Clinical Immunology at University Hospital Leipzig, Fraunhofer IZI has placed a highly experienced scientist at the helm of the institute.

Specialized in cellular immunotherapies, the researcher has spent many years working on the interaction between the immune system and cancer. She most recently worked as a professor at Hannover Medical School, where she managed the Institute for Cell Therapeutics from 2012 onwards. Prior to that, the 54-year-old biologist and medical expert held several positions at Frankfurt am Main University Hospital. Her focus on experimental medicine and, most notably, the development of immunotherapies also took her to the MD Anderson Cancer Center in Houston, USA.

With her appointment in Leipzig, the institute expects in particular to strengthen the connection with the University Cancer Center Leipzig (UCCL). This would accelerate the pace at which innovative treatment and diagnosis methods are put into practice to treat cancer patients. The aim here is to continue to establish Leipzig as a leading center for the development and clinical testing of cell and gene therapeutics, aided by the spatial and personal proximity between university and non-university research organizations. By expanding cooperations with further clinical and industrial partners, however, more research can also be carried out on new immune monitoring technologies, functional assays and companion diagnostics in future, while automated manufacturing processes are also to be developed.

The change in the institute's management board was for reasons of age. Professor Frank Emmrich, who set up the institute in 2005 and successfully steered it through its growth period, will stay on at the institute for another year as member of the management board.

## **The new institute management team will be made up as follows in 2018:**

- Prof. Dr. Dr. Ulrike Köhl (Executive Director)  
Management of Leipzig Headquarters and Hanover site (in the process of being set up)
- Prof. Dr. Frank Emmrich  
Management of Erfurt project center and Rostock project group, international locations
- Prof. Dr. Hans-Ulrich Demuth  
Management of Potsdam-Golm branch and Halle (Saale) project group

# STRUCTURES AND FIGURES 2017



# PORTRAIT OF THE INSTITUTE

In light of an aging society and an increasing number of chronic diseases, modern medicine is facing exceptional challenges. The Fraunhofer Institute for Cell Therapy and Immunology IZI is working on meeting the demands of health and quality of life through new developments in the fields of diagnostics and therapy. Our body's immune detection and defense system are of particular interest here, as well as cell-biological assay and treatment methods.

Over the past years, biotechnology and regenerative medicine have taken on greater significance. Of these specialized fields the public expects new therapies for the treatment of diseases which lead to the irreversible damage of tissue and organs; these invariable include chronic, autoimmune and tumor diseases.

The goal is to systematically repair the damages caused by diseases associated with the destruction of cells or tissue and to correct dysfunctions by means of cell therapies, tissue engineering or targeted modulation of the immune system. This goal can be achieved by stimulating the body's own regeneration processes or by means of biological substitutes in form of extracorporeally cultivated tissues.

## General topic: Cell therapy and immunology

In the narrow sense of the word, cell therapy denotes the transfer of cells that provide a substitute for lost functions however are also capable of taking over advanced active functions

This builds a bridge to immunology, which is concerned with cellular defense and control mechanisms. It is expected that cell therapeutic methods for targeted enhancement, suppression or regeneration of the immune system will soon be available, e.g. for stimulating the defense mechanisms of degenerate cells or for suppressing undesired graft-versus-host reactions against grafted tissue. In addition, the further development of immunomodulatory techniques, e.g. vaccination, is of particular importance.

## The institute's tasks

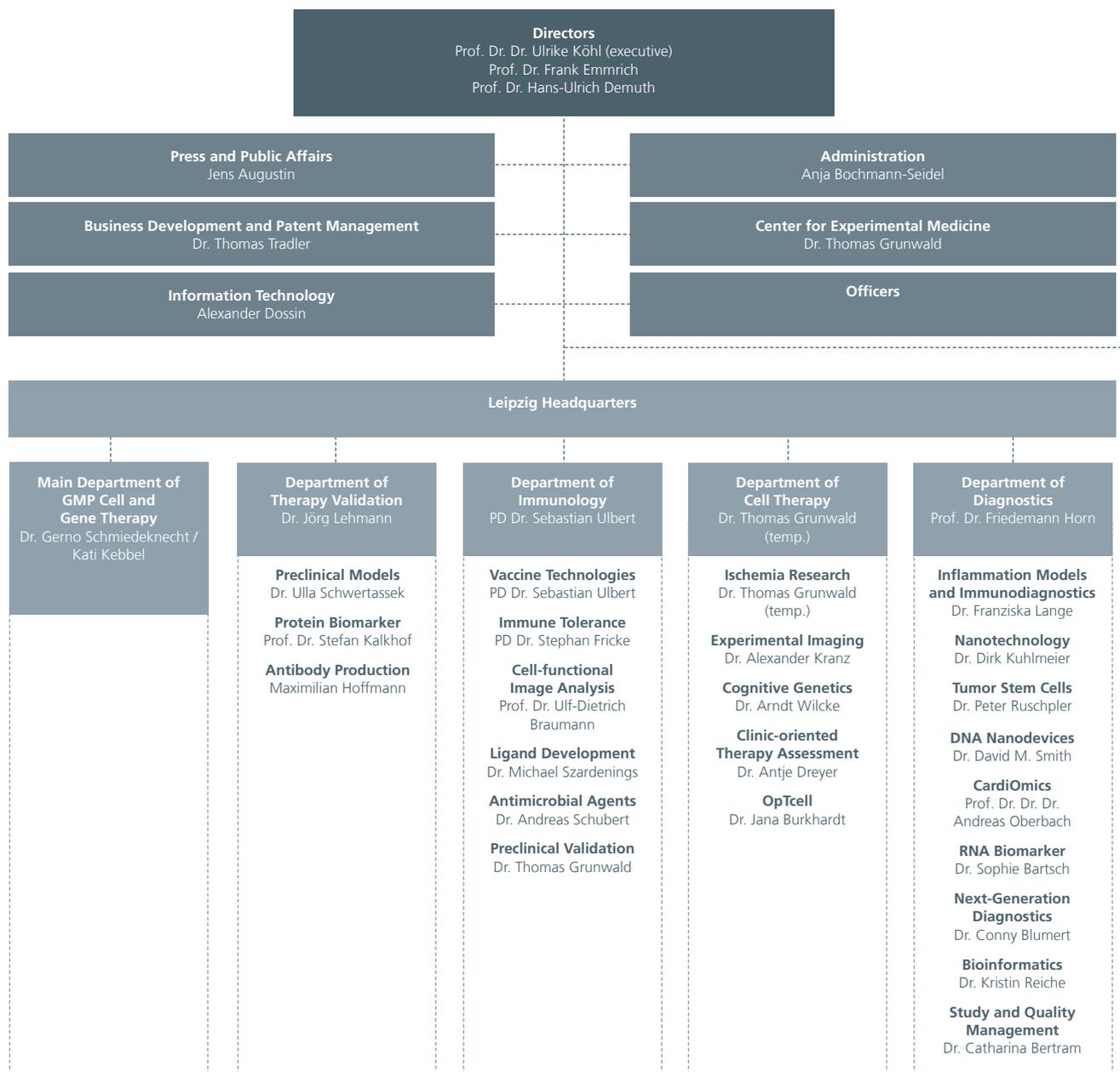
The institute operates five sites. The departments GMP Cell and Gene Therapy, Therapy Validation, Immunology, Cell Therapy and Diagnostics are based at the Leipzig headquarters. The Potsdam-Golm branch is home to the departments Biosystem Integration and Process Automation,

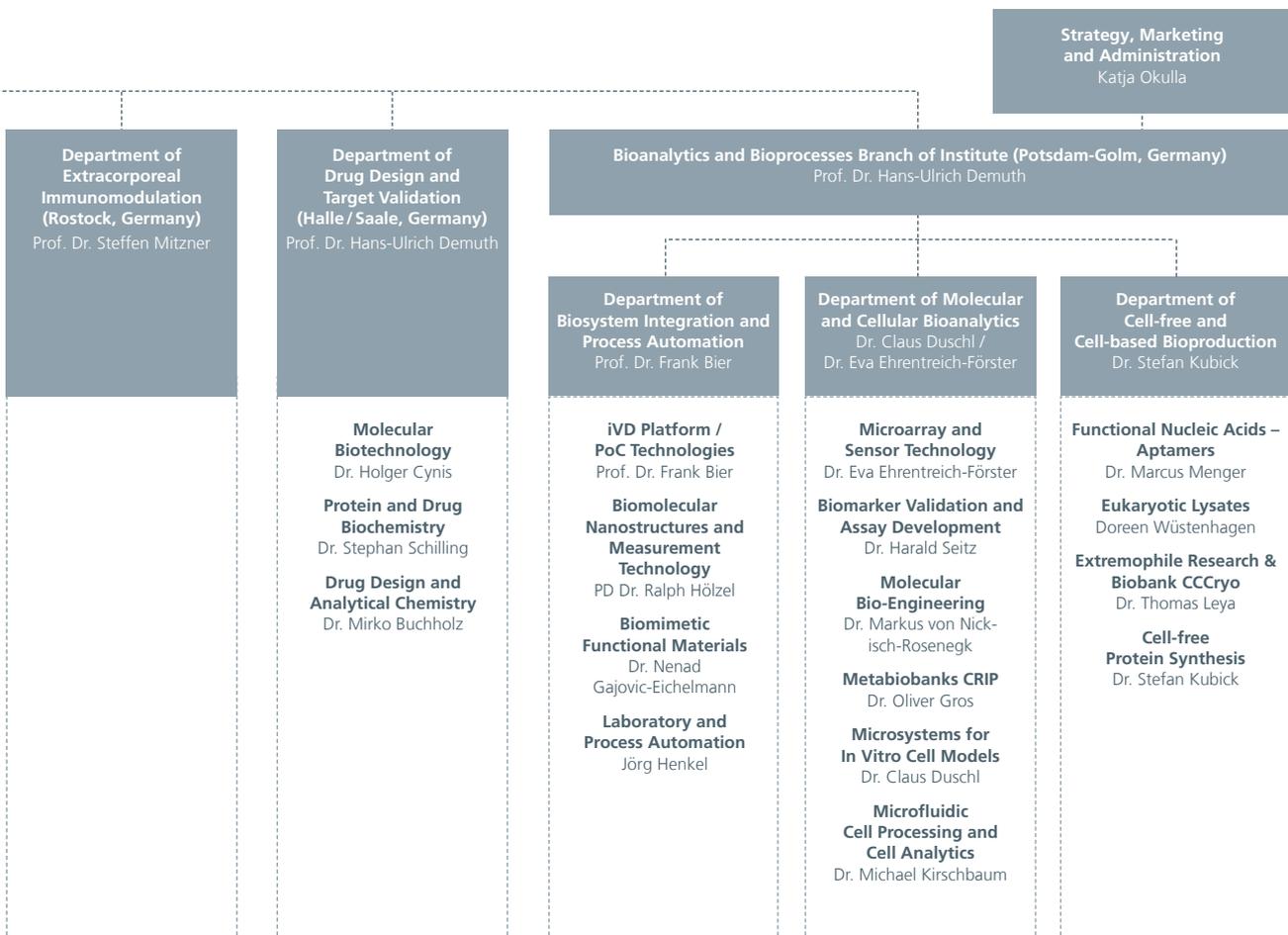
Cellular Biotechnology, Molecular and Cellular Bioanalytics as well as Cell-free and Cell-based Bioproduction. Additional off-site departments are located in Halle (Saale), Rostock and Erfurt. Different units thus represent a broad spectrum of expertise and qualifications.

The institute's spectrum of services is aimed at specific problem solutions at the interfaces of medicine, biosciences and engineering. With this, the Fraunhofer IZI addresses not only the biomedical industry, including pharmaceutical and biotechnological companies and diagnostic laboratories, but also hospitals and research facilities.

The institute's core competences lie in the fields of cell biology, immunology, drug biochemistry, bioanalytics, bioproduction, process development and automation as well as in regenerative medicine. Besides developing and testing new drugs, this also primarily entails cell-therapeutic approaches to restoring dysfunctional tissue and organs right through to biological replacement by means of tissue cultivated in vitro (tissue engineering). For an unproblematic engraftment of these tissues it is necessary to detect cellular and immunological mechanisms of defense and control and to integrate them into the development of methods and products. Around these core competencies a large variety of tasks for new products and methods arises. The institute is strongly oriented towards the hospitals and takes on quality testing, the production of investigational medicinal products according to GMP guidelines and contracted clinical trials. In addition, we support our partners in obtaining manufacturing and marketing authorizations.

# ORGANIZATION\*





\* January 2018

## BUSINESS UNITS

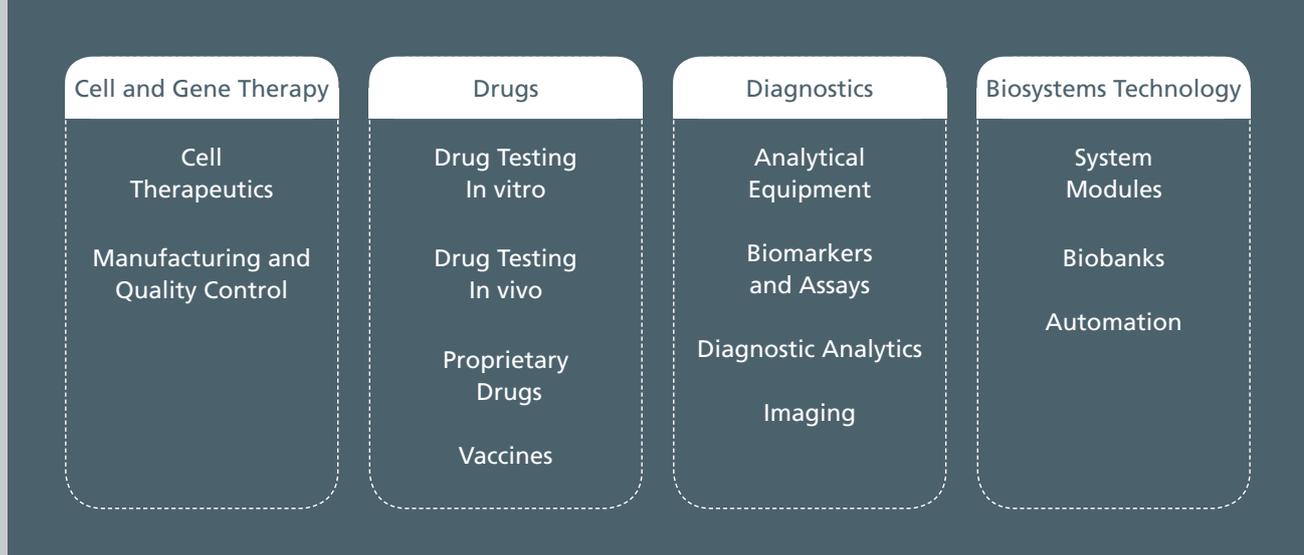
From a market perspective, a business unit is defined as a compilation of services rendered for specific groups of customers within a defined technological area which gives rise to customer value. Business units therefore form a basis for strategic planning within the context of market development and were identified by pooling and analyzing connected services and corresponding development activities as outlined below. As a result, the institute has defined four business units which comprise various areas of competence.

### Cell and Gene Therapy Business Unit

The Cell and Gene Therapy Business Unit is especially important to Fraunhofer IZI and comprises development activities and contract research projects to develop innovative cell and gene therapy concepts as well as their validation, testing and manufacture according to GLP and GMP standards. In this regard, the Cell Therapeutics business field comprises all of the developments relating to proprietary therapeutic concepts, while research and development services for industry partners involving the testing and manufacture of cell and gene therapy agents as commissioned by the customer stand at the fore of the Manufacturing and Quality Control business field. The institute's own future developments will be more heavily devoted to the field of tumor immunology. The Manufacturing and Quality Control business field is currently focused on approaches to fight cancer and treat cardiovascular diseases; the field is, however, generally set up to deal with all indications.

### Drugs Business Unit

Fraunhofer IZI's Drugs Business Unit represents large parts of the preclinical value chain relating to drug and vaccine development and is subdivided into the business fields Drug Testing (in vitro and in vivo), Proprietary Drugs, and Vaccines. With regard to drug testing, development services in the form of in vitro and in vivo models are primarily offered for the detailed characterization and optimization of drug candidates with a view to their efficacy and safety. The models established in this area are adapted in close cooperation with the customer and, in many cases, completely redeveloped and validated. Moreover, Fraunhofer IZI develops proprietary drugs and vaccines for human and veterinary medicine. In this regard, the range of services and parallel proprietary developments should efficiently complement each other. The developed drug and vaccine candidates are licensed to industry partners in line with specific projects at different times, or form the basis of company spin-offs from Fraunhofer IZI.



### Diagnostics Business Unit

At its four sites in Germany and its two sites abroad (Canada, South Korea), Fraunhofer IZI carries out a number of R&D projects in the field of diagnostics that range from finding biomarkers and clinical validation through to assay and test development for the areas of medicine, agricultural economics and food economics right over to the development of respective diagnostic devices and prototype construction. In this regard, the Biomarkers and Assays business field is primarily focused on identifying biomarkers and other marker structures besides using them for diagnosis and prognosis purposes in connection with assays and test systems that have been developed accordingly. By way of contrast, the Analytical Equipment business field looks first and foremost at establishing new analysis and technology platforms for diagnostic applications, which can also be based on publicly accessible, common-knowledge biomarkers or target structures supplied by cooperation partners, alongside biomarkers that the institute has developed itself. Both business fields are closely interrelated, which creates benefits in particular within the context of the demanding biomarker and diagnostics market. Moreover, this business unit includes the development, optimization and diagnostic application of imaging procedures.

### Biosystems Technology Business Unit

In the Biosystems Technology Business Unit, Fraunhofer IZI brings together biomedical, engineering and process engineering expertise in order to develop system solutions in the fields of advanced manufacturing procedures, medical engineering and diagnostics. The components required to design integrative systems are developed in the System Modules business field. Furthermore, R&D activities at Fraunhofer IZI also concentrate on the automation of manufacturing and analytical processes in the business field bearing the same name, whereby the value chain consists of not only drafting, developing and optimizing equipment modules, but also their integration. Particular attention is directed here to the automation of processes that have so far required a high degree of human input and interaction in the laboratory, especially with regard to manufacturing cell therapeutic products. The Biobanks business field, which has also been allocated to the Biosystems Technology Business Unit, is currently under development.

## CORE COMPETENCIES

Specific skills and resources at Fraunhofer IZI are defined as core competencies; as such they are of key importance to the development of attractive technologies and product candidates and form the basis of the long-term economic and scientific success achieved by the institute's business units. At the same time, core competencies not only make an excellent contribution to the value of our services as perceived by the customer, but are primarily distinguished by their unique characteristics. Six core competencies are defined at Fraunhofer IZI, which can be divided into indication-specific and technical core competencies depending on their nature.

### Indication-specific core competencies

The core competence **Immunology** covers special competencies and technologies available at Fraunhofer IZI to develop innovative approaches for the diagnosis, treatment, monitoring and prevention of infectious, inflammatory and hematologic diseases in human and veterinary medicine. A key resource here is the excellent infrastructure at Fraunhofer IZI which features, among other things, a facility for keeping small animals in accordance with the latest standards, comprehensive imaging capabilities and state-of-the-art operating rooms besides specific areas for conducting work in line with BSL-3 and GLP.

The development of new therapeutic strategies and diagnostics platforms for various types of cancer requires special and diverse skills and resources, which are pooled under the core competence of **Oncology**. This includes, for example, special competencies in identifying and validating cellular target structures and signal paths which are of diagnostic and/or therapeutic value, competencies in developing and validating especially predictive animal models, as well as competencies

in developing innovative therapeutic approaches. As a consequence, the competencies available at Fraunhofer IZI allow large parts of the early stages of the value chain to be depicted in this field in terms of diagnostics and therapy development related to oncology.

**Neuropathology** is the third indication-specific core competence and describes pooled expertise in the research of neuropathological and neurodegenerative diseases. A special feature of this core competence is the depth of research established at Fraunhofer IZI which, in several projects, extends to the area of internationally, surpassingly renowned, excellent fundamental research. This research hones in on the areas of stroke and neurodegenerative diseases (Alzheimer's disease). In several projects, the applied research conducted at Fraunhofer IZI into the pathogenesis of various diseases has already enabled promising, new targets to be identified for diagnosing and treating diseases in the described ranges of indication.

### Indication-specific Core Competencies

Immunology  
Oncology  
Neuropathology

### Technical Core Competencies

Cell Engineering and  
Cell Therapy  
Qualification of  
Therapeutic Molecules  
Bioanalytics and  
Biomarker Development

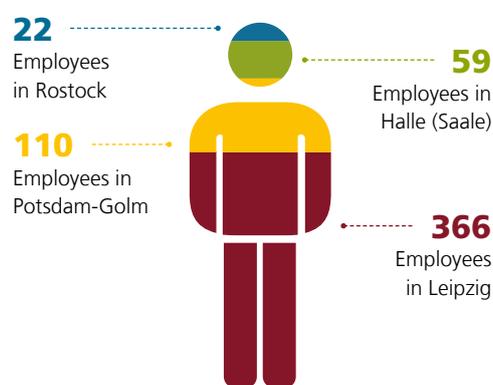
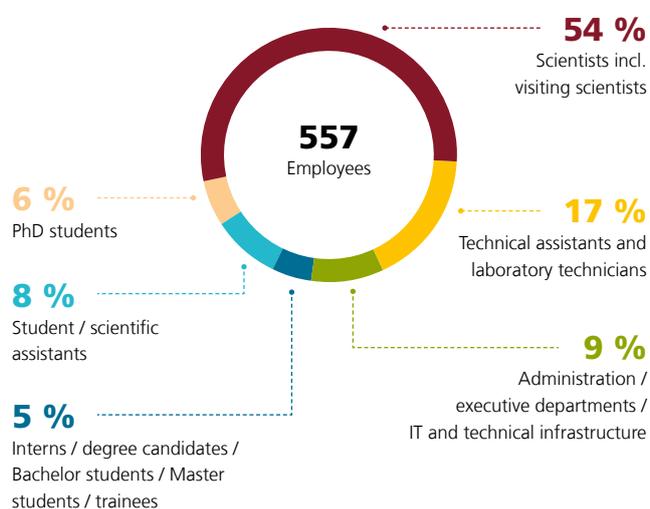
#### Technical core competencies

The core competence **Cell Engineering and Cell Therapy** is one of the institute's most important core competencies and has been ever since Fraunhofer IZI was established, as clearly expressed in the institute's name. Comprehensive expertise and an extensive special infrastructure have been established at the institute for the commissioned testing and manufacturing of cell-based therapeutic agents. The three facilities operated by Fraunhofer IZI for the GMP-compliant manufacture of ATMPs count among the largest and most profiled of their kind in Europe. At the same time, sizeable resources and outstanding regulatory experience have been established at Fraunhofer IZI with regard to reviewing the safety and tolerability of ATMPs and blood products under GLP conditions.

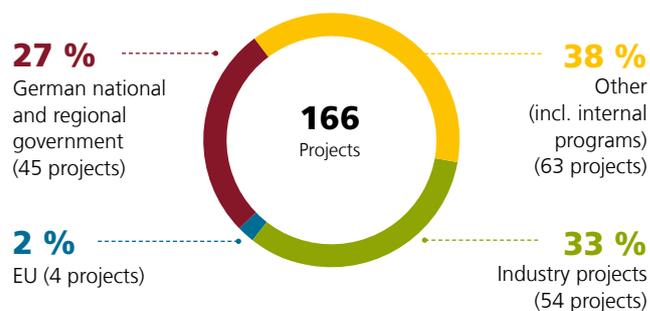
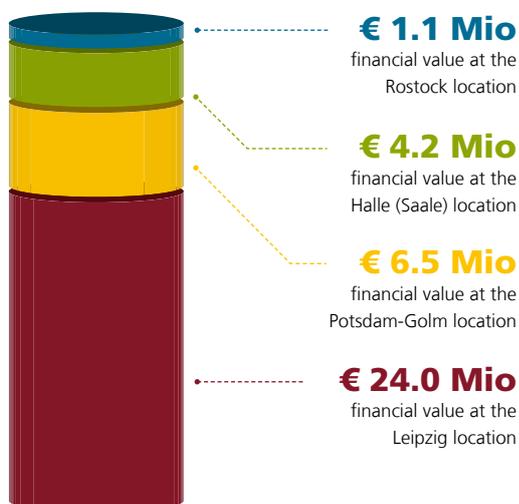
The core competence **Qualification of Therapeutic Molecules** pools together all of the competencies available at Fraunhofer IZI in close connection with drug development. The classes of therapeutic molecules addressed here include small, organic molecules and peptides as well as therapeutic macromolecules such as aptamers and antibodies, besides various kinds of natural products. The Molecular Drug Biochemistry and Therapy Development project group in Halle (Saale) covers a large part of the overall value chain at the preclinical drug development stage, beginning with drug design and the complete spectrum of medicinal chemistry and analytics and extending right through to establishing new animal models for investigating relevant mechanisms of action and conducting in vivo drug candidate tests.

The final technical core competence, **Bioanalytics and Biomarker Development**, addresses all of the available capabilities and resources for the development of biomarkers, assays and detection technologies / solutions for the application area of medicine and food analysis. The biomarkers identified and validated at Fraunhofer IZI often form the basis of a subsequent assay or device development. In this regard, capabilities in the technological areas of analytics, nanotechnology and electrical engineering are what primarily contribute towards the implementation of innovative development concepts.

## KEY INSTITUTE FIGURES 2017\*



**€ 35.8 Mio**  
financial value



### Project revenue 2017 in kEUR

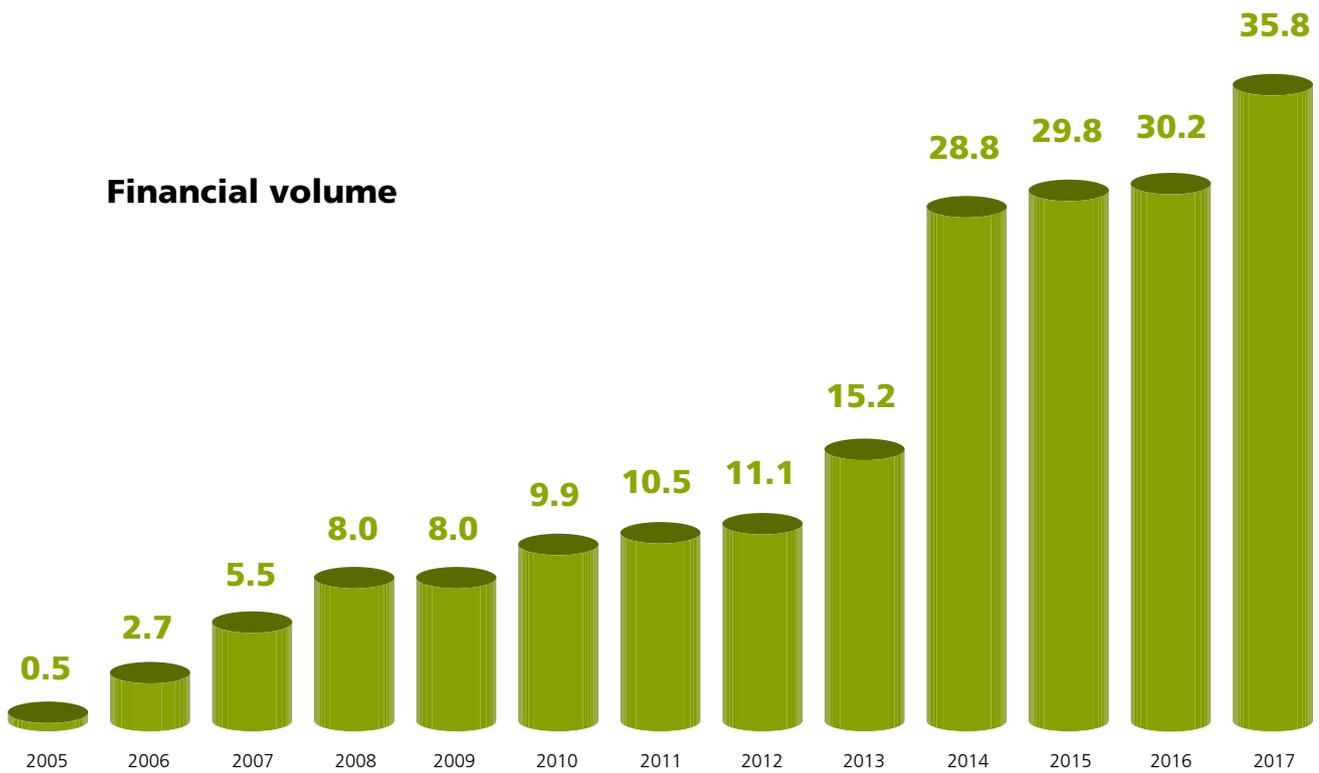
	Leipzig	Halle	Potsdam	Rostock	Total
German national and regional government	1 440	3 200	2 520	950	8 110
EU	50	70	183	0	303
Industry projects	10 900	620	1 130	160	12 810
Other (incl. internal programs)	5 934	310	986	6	7 236
<b>Total</b>	<b>18 324</b>	<b>4 200</b>	<b>4 819</b>	<b>1 116</b>	<b>28 459</b>

\* as at 2017 / 12 / 31

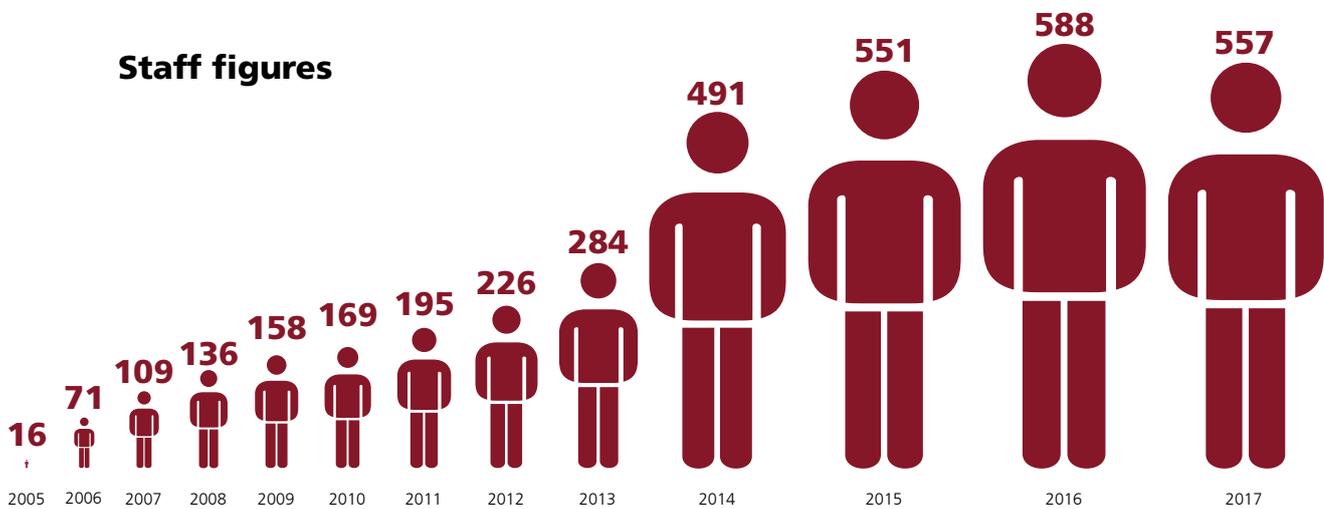


## GROWTH AND PERFORMANCE

### Financial volume



### Staff figures



## SCIENTIFIC PRESENCE AND NETWORK 2017



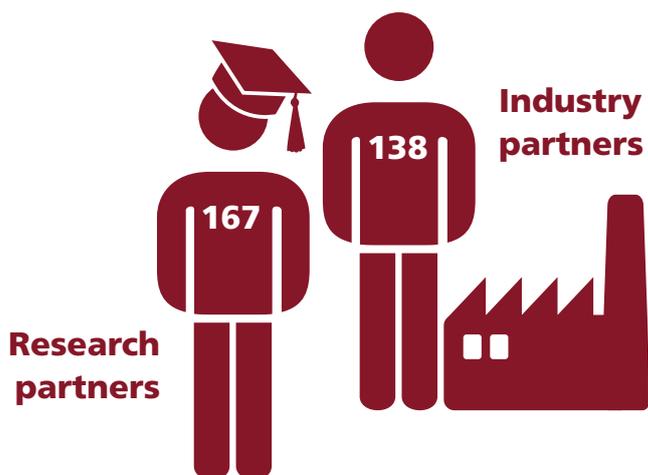
Conventions and  
conferences

Published  
abstracts



Publications

Book  
articles



Research  
partners

Industry  
partners

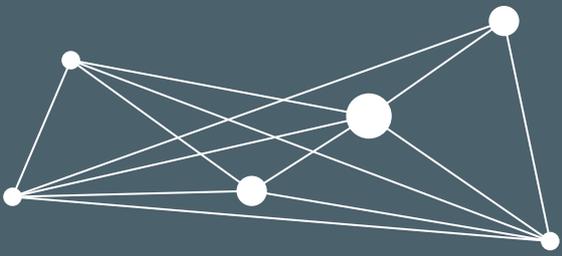
Doctorates



Bachelor  
theses

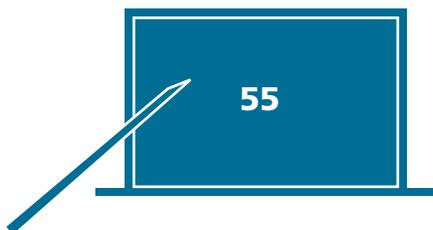
Master  
theses

Diploma  
theses

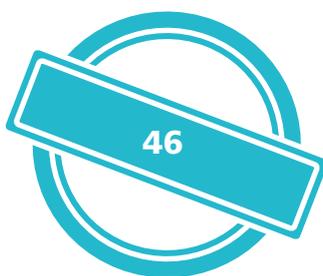


**SCIENTIFIC EXCELLENCE  
DIVERSITY  
NETWORK**

**Teaching activities**



**Evaluator  
activities**



**Patent families with  
146 Patents and  
patent applications**

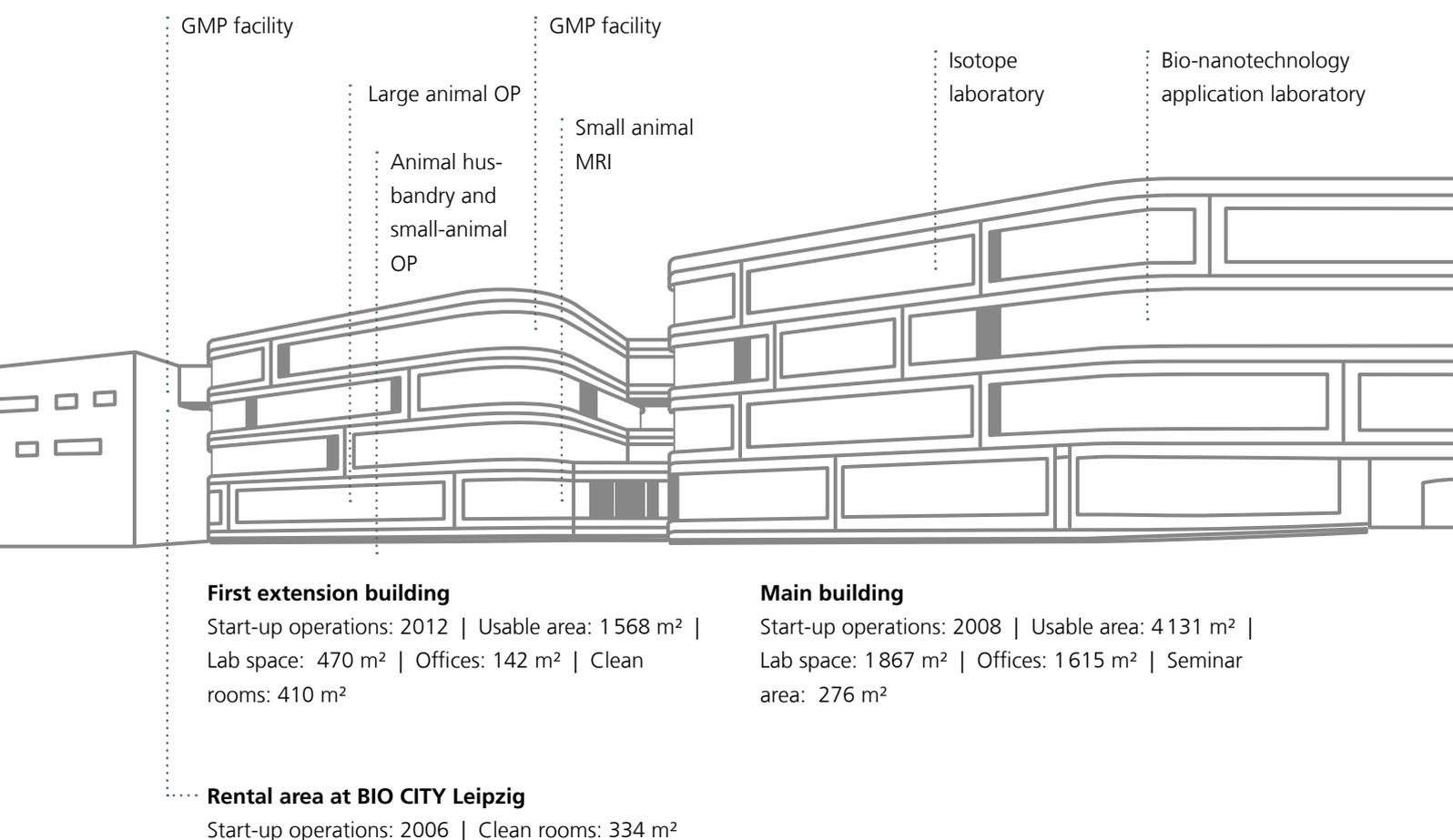


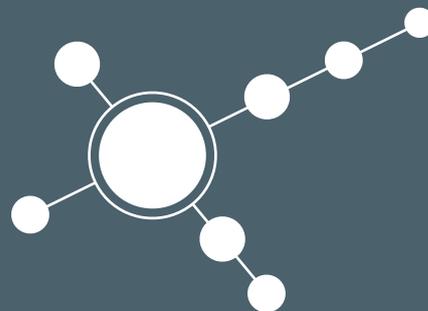
**Association member-  
ships in various expert  
associations**



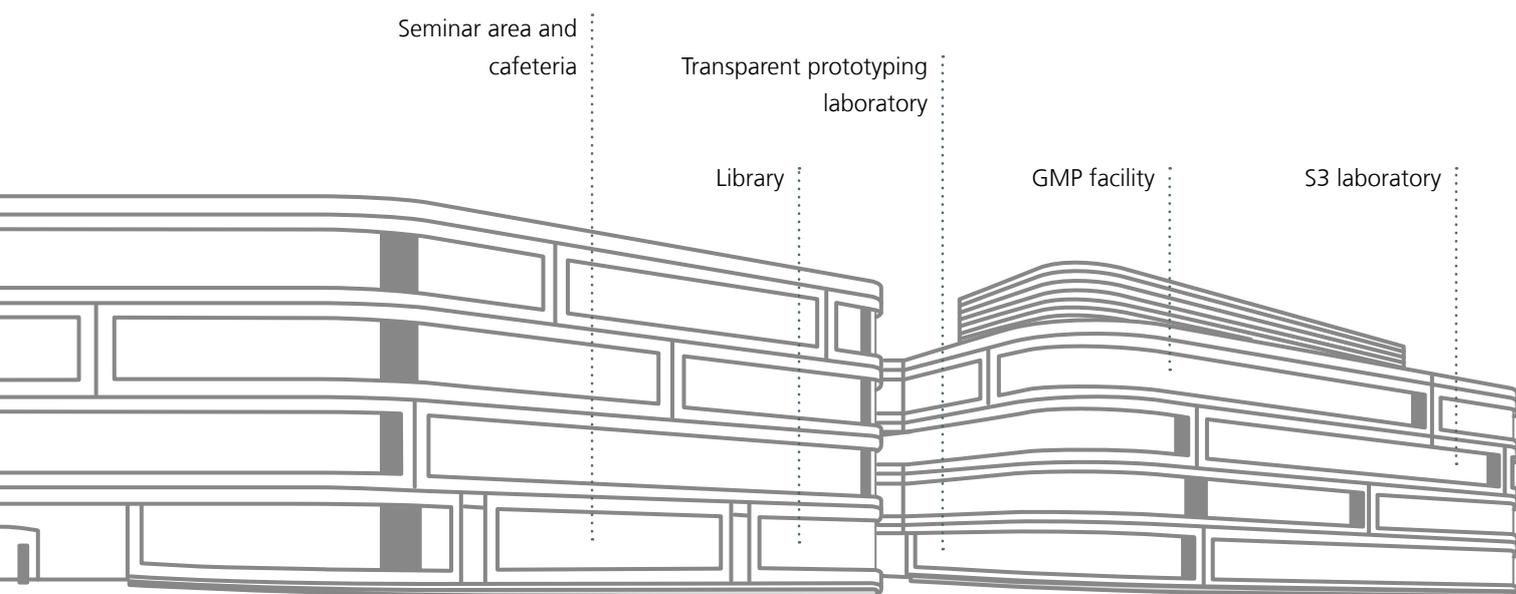
Detailed information on key figures and publications can be found in the full version of the annual report on pages 131–167.  
<http://s.fhg.de/yix>

## RESEARCH INFRASTRUCTURE AT THE LEIPZIG SITE





## OUTSTANDING INFRASTRUCTURE



### **Second extension building**

Start-up operations: 2015 | Usable area: 3 050 m<sup>2</sup>  
| Lab space: 1 171 m<sup>2</sup> | Offices: 881 m<sup>2</sup> | Clean  
rooms: 402 m<sup>2</sup>

## SPIN-OFFS AND COMPANY SETTLEMENTS

The Fraunhofer IZI strengthens the regional economy by helping international and national companies settle in Leipzig and by supporting and encouraging colleagues in starting up their own companies. Since its foundation in 2005, the Fraunhofer IZI has been substantially involved in the settlement and founding of a total of eighteen companies. The site's appeal and its local cooperation with the Fraunhofer IZI were important factors in the partners' decision to settle there.

### Anti-tumor cell vaccines und cell therapeutics

- CellProTec GmbH (Settlement 2015)
- Cognate Bioservices GmbH (Settlement 2011)
- Northwest Biotherapeutics GmbH (Settlement 2011)
- Prima BioMed GmbH (Settlement 2010)

### Developing

- Bioville GmbH (Spin-Off 2010)
- Tutelacell GmbH (Spin-Off 2014)

### Diagnostics

- ApoCell (Settlement 2013)
- epitopic GmbH (Spin-Off 2016)
- Magna Diagnostics GmbH (Spin-Off 2010)
- RIBOLUTION Health GmbH (Spin-Off 2016)
- SelfD Technologie GmbH (Settlement 2012)
- Sonovum AG (Spin-Off 2011)
- Wrig Nanosystems GmbH (Settlement 2016)

### Drugs R&D

- Nuvo Research GmbH (Settlement 2009)

### Natural remedies R&D

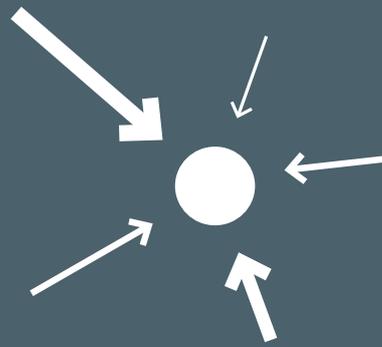
- Oncotriton GmbH (Spin-Off 2012)

### Stem cell bank

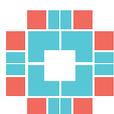
- InnovaStem GmbH (Settlement 2009)

### Therapy devices

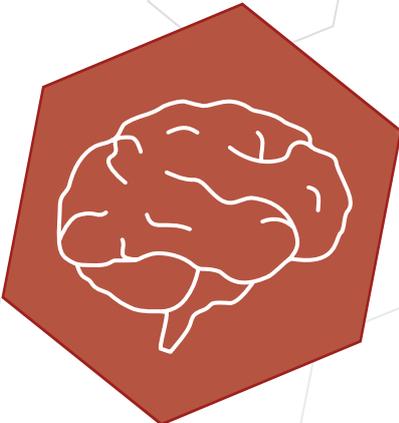
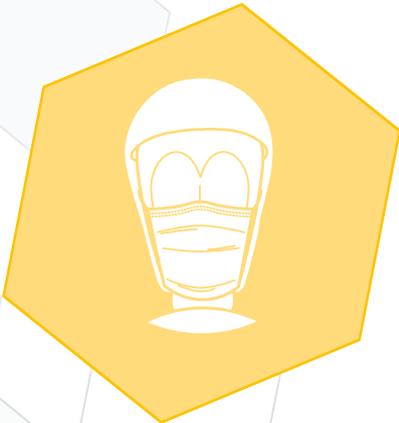
- IPDx Immunoprofiling Diagnostics GmbH (Settlement 2015)
- MD-5 GmbH/Nervive (Settlement 2012)

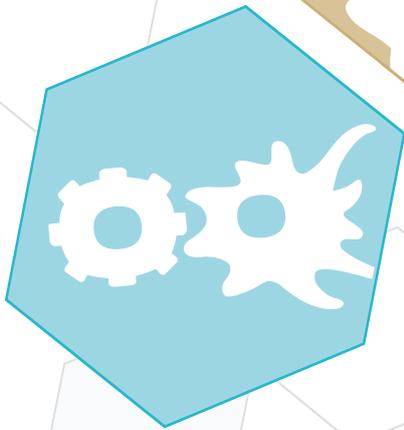
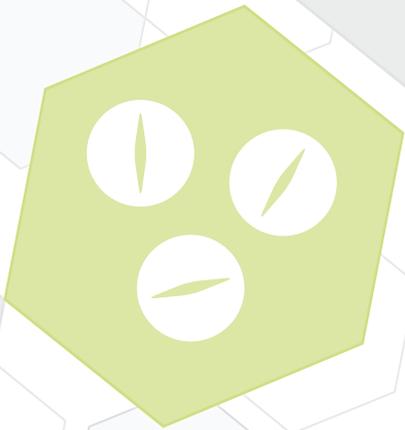
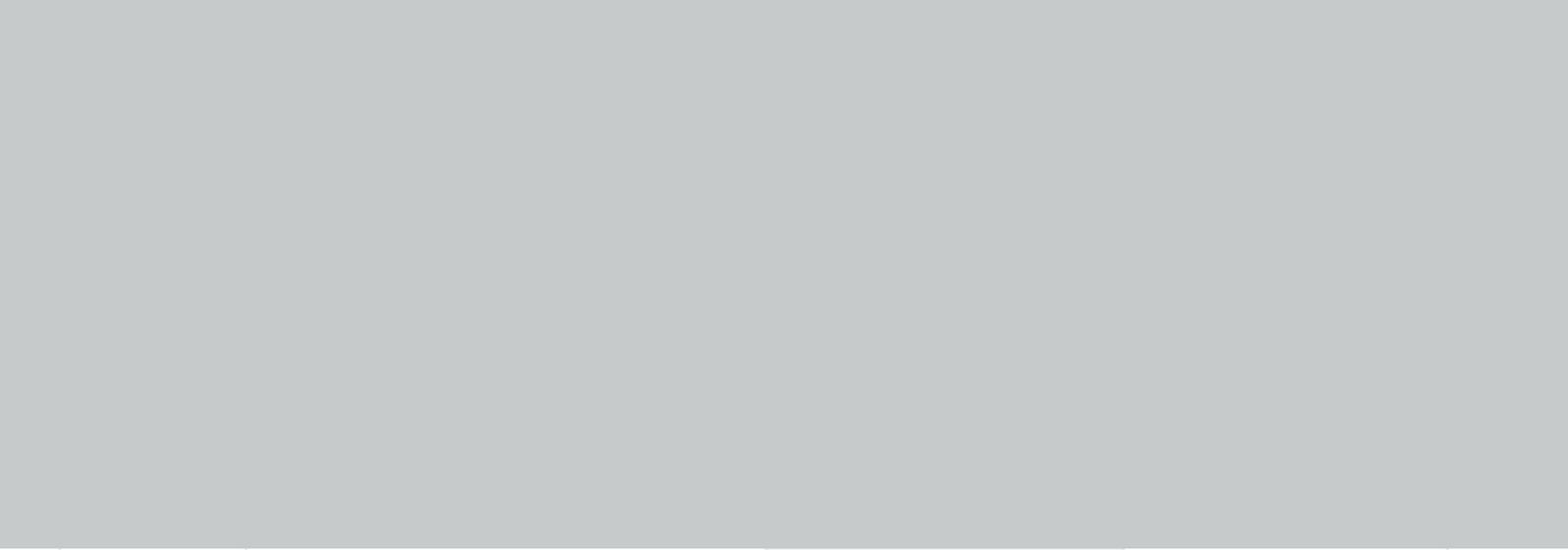


**APPEALING  
TO INDUSTRY**



# DEPARTMENTS





# MAIN DEPARTMENT OF GMP CELL AND GENE THERAPY

## THE DEPARTMENT AT A GLANCE

The main department of GMP Cell and Gene Therapy operates Fraunhofer IZI's three modern GMP facilities consisting of ten separate clean room suites (altogether 21 clean room grade B manufacturing rooms) which have been specially optimized for manufacturing of cell and gene therapy products, so called Advanced Therapy Medicinal Products – ATMP. The particular specialty of the about 90 highly qualified staff members is the GMP-compliant manufacturing and quality control of investigational medicinal products.

GMP-compliant process and quality control development as well as the creation of Standard Operating Procedures (SOPs) are intensively discussed with the project partner before being implemented. The leading staff in charge has many years of experience in designing GMP-processes in the cell and gene therapy area.

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## PROJECT EXAMPLES

### **Manufacture of the immunotherapeutic DCVax®-L for brain tumor patients**

The manufacturing process for the immunotherapeutic DCVax®-L has been optimized and implemented as part of a clinical trial conducted by American biotech company Northwest Biotherapeutics, Inc. The therapeutic approach is based on autologous dendritic cells and aims to improve the treatment of glioblastoma, a particularly aggressive type of brain tumor.

### **autoCard study**

The investigational medicinal products "CardAPcells" (cardiac-derived adherent proliferating cells) will be manufactured at Fraunhofer IZI in future in cooperation with Charité - Universitätsmedizin Berlin. The therapeutic agent contains special heart cells that are isolated from biopsy samples taken from the patient's own heart muscle and expanded over the course of a cultivation process lasting several weeks. Once clinical testing is complete, the new treatment method will be used in patients suffering from chronic myocardial insufficiency.



Further information on the department and its projects can be found in the full version of the annual report on pages 26–29.  
<http://s.fhg.de/X94>

# DEPARTMENT OF THERAPY VALIDATION

## THE DEPARTMENT AT A GLANCE

The department was founded in January 2016 as a direct replacement of the former Cell Engineering/GLP unit. The main goal of the new department is the concentration of expertise for the preclinical validation of novel therapeutic approaches at IZI, to maximize the efficiency in developing new in vitro or in vivo models and their application in preclinical studies. Since the department manages the GLP test facility of Fraunhofer IZI, all preclinical studies (even those in other IZI departments) can be performed under GLP.

### The department covers the following topics:

1) Planning and execution of preclinical efficacy and safety studies for new drug candidates (especially ATMPs) and medical devices (ISO 10993) under GLP or GLP-analogous conditions. This includes the development and validation of suitable in vitro and in vivo models.

2) Developing procedures for the diagnostic analysis of secretory and cellular protein biomarkers, including the development and production of specific monoclonal antibodies for their detection and finally the development and validation of the respective diagnostic assays (e.g. ELISA, Luminex®, flow cytometry).

3) Identifying and validating new protein biomarkers for diagnosis and therapy of chronic-inflammatory and tumor diseases, as well as for the sector of veterinary medicine / farm animal husbandry.

4) Developing human therapeutic monoclonal antibodies for the treatment of tumor and autoimmune diseases, as well as for passive vaccination against bacterial toxins and pathogenic viruses, and their advancement to drug candidates.

### Units

- Preclinical Models, Dr. Ulla Schwertassek
- Protein Biomarker, Prof. Dr. Stefan Kalkhof
- Antibody Production, Maximilian Hoffmann

### Contact



#### Dr. Jörg Lehmann

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## PROJECT EXAMPLES

### **Plant extracts as active agents for the treatment of chronic inflammatory bowel diseases**

The constant rise of chronic inflammatory bowel diseases, such as Crohn's disease and ulcerative colitis, are presenting ever greater challenges to health care systems in industrial and newly industrialized countries. Current treatment options include life-long application of immunosuppressive drugs and biologics, which are both expensive and associated with significant side effects. More suitable animal models are required for the preclinical development of new drugs that can be used to test the efficacy and safety of new therapies. In the Department of Therapy Validation, an improved animal model was developed that features important symptoms of chronic inflammatory bowel disease in humans. The model was already successfully applied to test potential new drugs in several industrial projects. Moreover, the therapeutic effect of a plant extract based on sage and bitter apple could be demonstrated in the frame of an internal research project.

### **Novel bovine biomarkers for monitoring health in dairy cow herds**

In order to be able to establish a simple yet accurate way of monitoring health in herds of livestock (e.g. cattle), new screening tests are needed that can be integrated into everyday farming processes. These tests are based on significant biomarkers, i.e. measurable biological parameters or molecules that can be used to make assertions on the health of individual animals. In the Department of Therapy Validation, various biomarkers have been identified and characterized for health detection in cattle, which will now be validated and developed into a test procedure.



Further information on the department and its projects can be found in the full version of the annual report on pages 30–35.  
<http://s.fhg.de/V8y>

# DEPARTMENT OF IMMUNOLOGY

## THE DEPARTMENT AT A GLANCE

Procedures to stimulate or suppress the immune system are developed in the Department of Immunology. These include vaccines on innovative technology platforms, e.g. novel inactivation methods or plasmid DNA. As such, efficient vaccines can be produced quickly and inexpensively. A further topic is improving the problem-free healing of transplants by the induction of specific tolerance. Furthermore, procedures are being developed to monitor immunoreactivity and to control dysfunctions such as graft-versus-host disease (GvHD). Bacteriostatic peptides and peptide banks for the analysis of immune reactions in food allergies are a further focus. The potential of extracorporeal therapeutic treatments of blood or blood components and of the immune system is investigated by the EXIM project group in Rostock.

### Units

- Vaccine Technologies, PD Dr. Sebastian Ulbert
- Immune Tolerance, PD Dr. Stephan Fricke
- Image Analysis of Cell Function, Prof. Dr. Ulf-Dietrich Braumann
- Extracorporeal Immunomodulation, Prof. Dr. Steffen Mitzner
- Ligand Development, Dr. Michael Szardenings
- Antimicrobial Agents, Dr. Andreas Schubert
- Preclinical Validation, Dr. Thomas Grunwald

### Contact



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## PROJECT EXAMPLES

### Specific detection of viral infections

A particular challenge facing the serological diagnosis of flavivirus infections (e.g. dengue, Zika or West Nile) lies in the structural similarity of the different types of virus. This is why antigens have been developed in the Vaccine Technologies Unit that can diagnose the respective pathogens with greater precision.

### Prevention of immunological complications following stem cell transplants

The main complication following an allogeneic hematopoietic stem cell transplant is acute graft-versus-host-disease (aGvHD). An antibody-based treatment has been developed in the Immune Tolerance Unit that is expected to lessen or prevent this life-threatening immune reaction.

### Non-human papillomaviruses for in-vitro and in-vivo DNA transfer

The application of DNA vaccines still poses a challenge today. In the Preclinical Validation Unit, non-human papillomaviruses are being looked into as a new kind of system for administering DNA vaccines.

### Cytokine adsorber

Investigation to discover the extent to which a cytokine adsorber extracts clinically relevant medicine from the blood.

### Mapping patient antibodies in serums

A new way of identifying antibody binding sites with greater precision has been developed in the Ligand Development Unit. The method is being applied, among other things, in a project aimed at identifying food allergies.

### Non-destructive cell and tissue monitoring

In the Image Analysis of Cell Function unit, an experimental imaging platform has been constructed and established based on light sheet microscopy (Single Plane Illumination Microscopy / SPIM). The imaging procedure is especially gentle on samples and facilitates the examination of living biological samples.

### Antimicrobial agents from plant tissues for the treatment of bacterial infections

The spread of antibiotic-resistant microorganisms poses one of the biggest challenges to modern medicine. The Antimicrobial Agents Unit is looking into the antibiotic potential of plant-based secondary substances that have been isolated from traditional African medicinal plants.



Further information on the department and its projects can be found in the full version of the annual report on pages 36–48.  
<http://s.fhg.de/cmj>

# DEPARTMENT OF CELL THERAPY

## THE DEPARTMENT AT A GLANCE

The Department of Cell Therapy prepares new gene and cell therapy procedures for clinical application. This involves the validation of experimental approaches with an eye to safety, feasibility and efficiency. Numerous model systems that facilitate the preclinical testing of novel concepts under the strictest quality criteria have been and continue to be established by the department. These systems lend the obtained results a high level of predictive power with regard to their future clinical application. Cell therapeutic methods are used, for instance, in the case of ischemic diseases such as stroke and myocardial infarction while attention is also given to processes that could prevent cell degeneration and aging. The "sleeping" potential of stem cells is also investigated. Last but not least, the department focuses on cell therapy methods in the field of immuno-oncology, where genetically modified immune cells (cytotoxic T-cells) or natural killer cells (NK cells) are developed to treat tumors.

### Units

- Ischemia Research, Dr. Thomas Grunwald (temp.)
- Experimental Imaging, Dr. Alexander Kranz
- Cognitive Genetics, Dr. Arndt Wilcke
- Clinic Oriented Therapy Assessment, Dr. Antje Dreyer
- OpTcell, Dr. Jana Burkhardt

### Contact



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## PROJECT EXAMPLES

### **Establishing a rabbit model to investigate propofol infusion syndrome**

Use of the anesthetic propofol is associated with a rare yet fatal adverse effect called propofol infusion syndrome (PRIS), which can emerge in the case of long-term anesthesia and, in particular, in children. In order to optimize and test new anesthetics and formulations, an animal model was established in the rabbit to reliably emulate PRIS. The mode of action of new drugs can be characterized using various criteria thanks to precise monitoring and defined parameters.

### **3D rendering in modern imaging procedures**

This project creates 3D computer models based on imaging datasets (e.g. MRI or microscopy) to visualize biological processes. The procedures enable, among other things, pathological processes to be quantified which, in turn, allows the efficacy of new therapeutic procedures to be evaluated with greater precision.

### **Counteracting the immune-escape mechanisms of cancer cells**

There are various ways in which cancer cells manage to evade the body's own immune defense system. The OpTCell Unit is investigating new drugs that could counteract these immune-escape mechanisms and activate the immune system.

### **LEGASCREEN**

Development of a multimodal early-screening test to diagnose dyslexia. Genetic tests and specific brain activity measurements (EEG) are combined to draw conclusions on the development of poor reading and writing skills as early as preschool age and to recommend suitable support measures.



Further information on the department and its projects can be found in the full version of the annual report on pages 49–57.  
<http://s.fhg.de/HJb>

# DEPARTMENT OF DIAGNOSTICS

## THE DEPARTMENT AT A GLANCE

The Department of Diagnostics offers a value chain that comprises the screening and testing of biomarkers, bioinformatic analysis and interpretation of complex transcriptome and genome data ("big data"), development of in-vitro-diagnostics (IVD) and point-of-care platforms as well as appropriate preclinical animal models.

Within the department, the RIBOLUTION Biomarker Center was established in the course of the Fraunhofer Zukunftstiftung- (Future Foundation-) funded consortium RIBOLUTION (RIBOnucleic acid-based diagnostic soLUTIONs) to systematically identify and validate novel diagnostic or prognostic biomarkers. Noncoding RNAs that possess a promising and long underestimated biomarker potential are a particular focus. The RIBOLUTION Biomarker Center provides experienced bioinformatics for analyzing NGS and other complex data sets. Competencies in study and data management serve to design and conduct clinical cohorts as well as to manage clinical and experimental data. For the development of diagnostic assays, a quality management system following DIN EN ISO13485 rules has been implemented.

The development of innovative molecular diagnostic test systems is offered for medical and food applications and comprises PCR- and NGS-based IVDs, lab-on-a-chip-platforms, and strip-based flash tests. The department aims at diagnostic solutions in many clinical fields, including cancer, infectious and inflammatory diseases.

It also offers the development of companion diagnostics and provides many established cell and animal models in various

areas like tumor stem cells, rheumatoid arthritis and other chronic-inflammatory diseases as well as many more. Furthermore, xenogene transplantation models serve to close the gap between model and patient.

### Units

- Inflammation Models and Immunodiagnostics, Dr. Franziska Lange
- Nanotechnology, Dr. Dirk Kuhlmeier
- Tumor Stem Cells, Dr. Peter Ruschpler
- DNA Nanodevices, Dr. David Smith
- CardioMics, Prof. Dr. Dr. Dr. Andreas Oberbach
- RNA Biomarker, Dr. Sophie Bartsch
- Next Generation Diagnostics, Dr. Conny Blumert
- Bioinformatics, Dr. Kristin Reiche
- Study and Quality Management, Dr. Catharina Bertram

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## PROJECT EXAMPLES

### Non-invasive diagnostics for verifying infecting agents

Modern-day air traffic enables infecting agents to spread at a tearing pace around the globe. The Nanotechnology Unit is involved in the development of a non-invasive diagnostic procedure that can be used to detect bacterial pathogens in the air breathed in by passengers.

### Ways of isolating circulating tumor cells

A procedure is being developed in the Tumor Stem Cells Unit that will be able to separate circulating tumor cells from blood. The diagnostic procedure is expected to facilitate the early detection of recurrences and metastases in blood in the case of advanced ovarian cancer.

### Verifying the virulence profile of organ-specific infections

In order to shed light on the pathomechanisms of infectious diseases affecting the cardiovascular system and to improve respective treatment options, a range of different molecular biological and bioinformatic analyses are being carried out on patient samples in the CardiOmics Unit. This aims to identify the germs involved besides their composition and virulence as well as to transfer the findings into the everyday clinical setting in the long term.



Further information on the department and its projects can be found in the full version of the annual report on pages 58–67.  
<http://s.fhg.de/YnL>

# DEPARTMENT OF DRUG DESIGN AND TARGET VALIDATION

## THE DEPARTMENT AT A GLANCE

The Department of Drug Design and Target Validation in Halle (Saale) boasts considerable expertise in various areas of preclinical drug development, placing a special focus on neurodegenerative and inflammatory diseases. The department's work covers almost the entire range of activities associated with the early stages of drug development, from identifying and characterizing target proteins to identifying initial drug candidates right over to testing substances in the animal model. Members of staff at the Halle (Saale) branch are characterized by their extensive experience in industrial and pharmaceutical-relevant research. This allows scientific issues to be tackled on behalf of industry partners on the one hand, and new drugs and target proteins from the institute's own preliminary research to be identified, patented and subsequently form the basis of industry cooperations on the other.

Small molecules and biologicals will be developed and tested on the back of the department's new treatment concepts. Alongside this, testing procedures will be developed for the identification and diagnostic application of biomarkers, which allow the course of both the disease and therapy to be monitored. Furthermore, the group also houses the expertise required to create pharmacologically relevant in-vitro and in-vivo models.

Besides modern peptide synthesis and protein analytics methods (MALDI-TOF and LC-MS), the department has also developed a broad spectrum of biophysical methods for characterizing therapeutically relevant metabolic pathways, whose key proteins as well as cell-based and pharmacological models are used to characterize innovative chemical and biological agents.

### Units

- Molecular Biotechnology, Dr. Holger Cynis
- Protein and Drug Biochemistry, Dr. Stephan Schilling
- Drug Design and Analytical Chemistry, Dr. Mirko Buchholz

### Contact



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## PROJECT EXAMPLES

### **Peptide aggregates and microparticles for therapeutic applications**

Various neurodegenerative diseases such as Alzheimer's and Parkinson's disease are triggered by misfolded proteins. The body's own proteins form fibrillose structures that are extremely stable in the organism and cause cellular damage to the affected tissue. With a view to opening up new therapeutic applications, processes are being developed in the Molecular Biotechnology Unit that can be used to more precisely examine the binding behavior of antibodies on these structures. Both high-resolution microscopy procedures and chemical-analytical procedures are being used here.

### **Broadening the chemical space of metal binding groups**

By drawing on computational chemistry procedures, the Drug Design and Analytical Chemistry Unit is supporting the development of new drugs whose target structures are metal ions in the catalytic center of enzymes. The procedure helps to identify specially tailored molecules which will then form the basis for manufacturing drugs with as specific an effect as possible.

### **Determining the pharmacokinetic parameters of small molecules**

A vital component when it comes to developing new drugs is their characterization in terms of liberation, absorption, dispersion, metabolism and excretion (L-ADME parameter) in the animal model. This is intended, in particular, to provide information on the overall exposure of the organism, bioavailability following application and the half-life period of the active agent in the circulation. To assist with this, a catheter-based test procedure was established in the Molecular Biotechnology Unit to determine pharmacokinetic properties of small molecules in rats. The procedure is being used in the development of new drugs, for instance to treat neurodegenerative and inflammatory diseases.



Further information on the department and its projects can be found in the full version of the annual report on pages 68–74.  
<http://s.fhg.de/JeM>

# DEPARTMENT OF BIOSYSTEM INTEGRATION AND PROCESS AUTOMATION

## THE DEPARTMENT AT A GLANCE

The department delivers solutions for complex laboratory automation tasks in biotechnology.

Work here focuses on processes related to bioanalysis, diagnostics and cell culture, expansion, preparation and monitoring and aims at increasing the efficiency, quantity and quality of laboratory processes including cell products.

A further focal area is found in developing procedures and devices for a broad range of point-of-care applications. Among other things, an in vitro diagnostics (ivD) platform is available for this purpose, which can be adapted to different diagnostic tests depending on the task at hand.

Furthermore, procedures and devices are also available for analyzing and using molecular interfaces and higher-order electronic effects. Special importance is also assigned to developing procedures to gently dehydrate and fix dry reagents, which are used in all variants in diagnostics and analytics.

### Units

- ivD Platform / PoC Technologies, Prof. Dr. Frank Bier
- Biomolecular Nanostructures and Measurement Technology, Dr. Ralph Hölzel
- Biomimetic Functional Materials, Dr. Nenad Gajovic-Eichelmann
- Laboratory and Process Automation, Jörg Henkel

### Contact



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## PROJECT EXAMPLE

### **AMBIsense – analysis of multivariate binding mechanisms**

A detailed analysis of pathogenic binding patterns on host cells is expected to speed up the detection of these germs, to support differential diagnostics and, in turn, to improve targeted therapy. The resulting findings also serve as a basis for developing new active agents.



Further information on the department and its projects can be found in the full version of the annual report on pages 75–79.  
<http://s.fhg.de/r7x>

# DEPARTMENT OF MOLECULAR AND CELLULAR BIOANALYTICS

## THE DEPARTMENT AT A GLANCE

The department is devoted to developing systems to detect, analyze and process challenging biological samples. These systems address demands in the fields of biomedicine, diagnostics, biotechnology, process control as well as environmental analytics, food safety and animal husbandry. The spectrum of our solutions ranges from stand-alone sensor and fluidic components to integrated analysis systems and comprehensive database tools. The development of point-of-care tests, e.g. for drugs and serum screenings, forms as much a part of the unit's scope of activities as establishing assays for the validation of biomarkers. Lab-on-a-Chip systems for cultivating, processing and analyzing cell samples present a further focus. These chips allow long-term cultivation and toxicity tests on suitable cell clusters and micro-precise positioning of single cells or sorting heterogeneous cell populations. All of the department's activities are based on its profound expertise in sensor technology, spotting and dispensing technologies, surface coatings, microfluidics and the integration of functional units into all-in-one solutions. Its competence in molecular and cell biology allows the department to use its technological abilities in the most purposeful manner. Work can be carried out efficiently using the state-of-the-art instruments and facilities available in the department's well-equipped laboratories. By integrating biobanks into so-called metabiobanks, the department provides solutions that facilitate and support the web-based case-by-case and sample-by-sample search for human biospecimens and associated data across institutional and national borders.

### Units

- Microarray and Sensor Technology, Dr. Eva Ehrentreich-Förster
- Biomarker Validation and Assay Development, Dr. Harald Seitz
- Molecular Bio-Engineering, Dr. Markus von Nickisch-Rosenegk
- Metabiobanks, Dr. Oliver Gros
- Microsystems for In Vitro Cell Models, Dr. Claus Duschl
- Microfluidic Cell Processing and Cell Analytics, Dr. Michael Kirschbaum

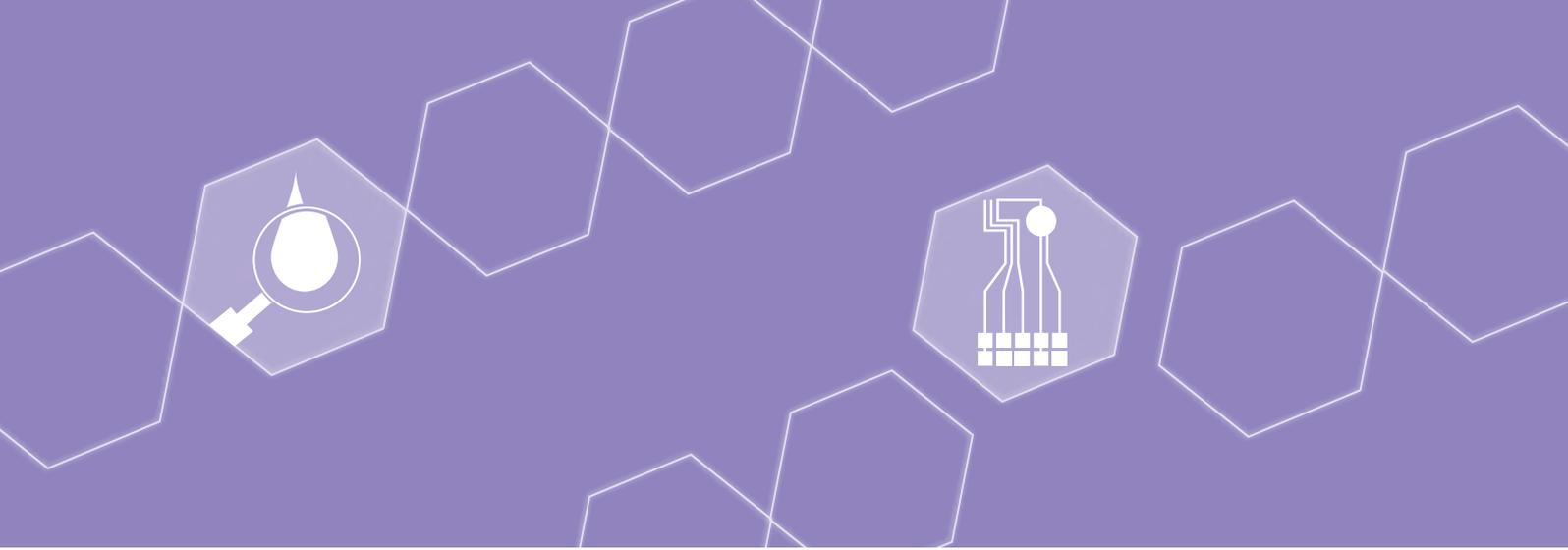
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## PROJECT EXAMPLES

### **Development of a multiparametric rapid test for germ load and/or resistance monitoring**

In the fight against antibiotic-resistant bacterial strains, conventional physical and chemical disinfection procedures have to be supplemented by a robust and fast detection method. The aim of this project is to develop a multiparametric rapid test for germ load and/or resistance monitoring. The test could be used in hospitals, in public areas, in relation to tourism and in food production.

### **Age-dependent liver and endothelial function**

The action and side-effect spectrum of a drug can differ greatly depending on the age of the patient population in question. In order to optimize treatments, a test system has been developed to predict what effects a drug might have on liver and endothelial function on a case-by-case basis.

### **Antimicrobial surfaces in milk production**

Development of a rapid test to review germ load on relevant surfaces in milk production (e.g. milking equipment, lying areas, teat skin). Furthermore, antimicrobial peptides are being developed to reduce this load without simultaneously continuing to foster antibiotic resistances.

### **Knowledge extraction from medical free-text records**

Development of software to extract relevant data from free-text records as well as their user-friendly processing and display, aimed at supporting decision-making process for doctors and researchers.

### **Tools for analyzing post-translational protein modifications**

Analyzing post-translational protein modifications and developing microarrays to analyze post-translational modifications, focusing on kinases and potential inhibitors.

### **Label-free detection and sorting of rare, clinically relevant cells for cellular diagnostics**

Development of a microfluidic procedure for the label-free analysis and separation of living cells from heterogeneous cell samples.



Further information on the department and its projects can be found in the full version of the annual report on pages 80–90.  
<http://s.fhg.de/Dt2>

# DEPARTMENT OF CELL-FREE AND CELL-BASED BIOPRODUCTION

## THE DEPARTMENT AT A GLANCE

Conserving resources and creating efficient material cycles are two challenges currently facing the economy and technology. The sufficient and affordable availability of high-quality synthetic products is an important basis for making progress here, especially in the field of health care. As active agents and analytes, biomolecules such as enzymes, antibodies and aptamers often form the basis of drug development in terms of diagnostics and therapy. But also in food and environmental technology, in the agricultural, cosmetics and detergent industries, the need for synthetic biomolecules is constantly on the rise. At present, many of these substances are manufactured using living cells and organisms. However, this is subject to considerable limitations. A sizable material and energy input has to be made to preserve cell metabolism itself. Beyond this, many metabolites and final products, also in higher concentrations, are toxic to cells or organisms and can impede or even prevent these substances from being manufactured cost-effectively.

The cell-free bioproduction of high-quality proteinogenic biomolecules opens up completely new possibilities here. By using only the subcellular components of the organisms required for synthesis it is possible, in suitable reaction environments, to efficiently manufacture biomolecules with complex and also completely new properties. The technologies established at the Potsdam-Golm site allow these procedures to be used in an economically efficient way, thus creating a new basis for the economic production of active proteins.

The development, synthesis and also transfer of functional nucleic acids such as aptamers into market-relevant applications are just as much a focus as the analysis of cold-adapted snow algae in extremophile research.

The latter of these are being used to extract high-quality substances such as antioxidants or fatty acids and are being manufactured in photobioreactors. The CCCryo culture collection is a unique bioresource that can be used by interested academic and private enterprise groups.

### Units

- Functional Nucleic Acids – Aptamers, Dr. Marcus Menger
- Eukaryotic Lysates, Doreen Wüstenhagen
- Extremophile Research & Biobank CCCryo, Dr. Thomas Leya
- Cell-free Protein Synthesis, Dr. Stefan Kubick

### Contact



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## PROJECT EXAMPLES

### Cell-free synthesis of membrane proteins

Functional membrane proteins play an important role in a number of biological processes. Dysfunctions sometimes lead to serious illnesses such as cystic fibrosis, cancer or chronic pain. Synthesizing functional membrane proteins in a cell-free system provides a versatile, flexible and quick way of manufacturing and modifying these proteins, which are otherwise difficult to express.

Cell-free protein production significantly accelerates structural and functional membrane protein analysis.

### Cell-imaging diagnostics based on functional oligonucleotides

The observation of dynamic transformation processes in specific cell structures or of a disease marker in liquid biopsies in response to a therapeutic agent tends to involve the use of large binding molecules such as antibodies. In both these cases, however, antibodies are not without their limitations: they are too big to penetrate living cells or mark structures and can be unreliable for sensitive diagnostics as they often non-specifically bind to unwanted targets. The programmable properties of RNA and DNA can be harnessed to solve this key problem in cell-based diagnostics with regard to the development and clinical validation of therapies.



Further information on the department and its projects can be found in the full version of the annual report on pages 91–96.  
<http://s.fhg.de/Jn2>

# CENTRAL FACILITIES AND SERVICES



# ANTIBODY PRODUCTION

In recent years, the increasing number of therapeutic monoclonal antibody (mAb) candidates under preclinical and clinical development have required new flexible, efficient, and economic opportunities for GMP production of therapeutic antibody candidates. Small-scale batch production of test samples for late preclinical GLP animal studies or for phase-1 and phase-2 clinical studies is often not appropriate for large-scale manufacturing facilities in the industry.

Since January 2017, the newly constructed GMP antibody production facility of the department of Therapy Validation has been completely qualified. Our facility has a size of 180 m<sup>2</sup> and involves all clean room classes from D to A. The use of single-use equipment and materials enables an easy adaptation to new process requirements. The GMP facility can be used for different contract manufacturing processes for pre-clinical and clinical (Phase 1/2) test samples as well as for process or instrument validation projects under consideration of special customer requests. The standard equipment can be easily adapted for new products.

## In summary the main advantages are:

- high flexibility
- easy switch to different products
- fast implementation of technology changes
- customized production
- ideal batch size for preclinical and early clinical trials
- possibility to obtain ready-to-use GMP-compliant products by integrated sample filling



## Future projects could include:

- transfer of promising biopharmaceutical candidates from research to clinical development
- design of a user-specific processes with single-use materials
- GMP-compliant production of e.g. human monoclonal antibodies in 200-L scale



## Contact



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## IMAGING AND IMAGE EVALUATION

Phenotyping biological samples using multiple imaging methods forms a core competence of preclinical research. This enables thorough depiction, from the smallest structures (cell organelles) right through to entire organ systems, both in spatial and temporal resolution (4D). Fraunhofer IZI has access to a comprehensive, state-of-the-art equipment pool that enables the acquisition and evaluation of various (also correlative) image data. Partners and customers are advised on biological, technical and economic matters and supported in carrying out and evaluating experiments. Furthermore, experimental procedures and equipment can be used, adapted and developed.



### In vivo imaging

Magnetic resonance imaging (7 Tesla high-field small animal MRI) (A)

- Examination of soft tissues and organs, use of contrast agents and cell labeling possible, long-term measurements in single individuals
- Depiction of anatomical changes, MRS, diffusion methods, functional imaging

Computer tomography (CT and X-Ray for small animals) (B)

- Depiction of dense (bone, cartilage) and contrast-enhanced (soft tissue) structures
- Rendered 3D data sets can be used for conformal radiation treatment planning

Fluorescence and bioluminescence imaging for small animals

- Monitoring tumor growth and progression of inflammation, tracking cell movements following transplantation (cell tracking)
- Complex reconstruction of in vivo parameters using Diffuse Light Imaging Tomography (DLIT) and spectral unmixing

Bedside imaging for small animals

- Various ultrasound units with a number of transducers and an implemented Color Doppler
- Flexible miniature cameras for the routine endoscopic examination of small animals and for the development of new lens attachments

## In vitro / ex vivo imaging

Confocal laser scanning microscope with live cell imaging

- Analysis of cell cultures and tissues in 4D, localizing target structures inside cells
- Standard laser lines from blue to red, water immersion lenses, real-time rendering and quantification of results

Light sheet microscopy (C)

- Flexible light sheet microscope with modular sample chamber for sample sizes from just a few  $\mu\text{m}$  to 2cm
- For the study of light-sensitive live-cell samples in high temporal resolution

Atomic force microscopy (D)

- Nanometer-scaled, micro-mechanical sampling of surfaces using a cantilever measuring needle and measurement of the occurring atomic forces

MALDI Mass Spectrometry Imaging (MALDI-MSI)

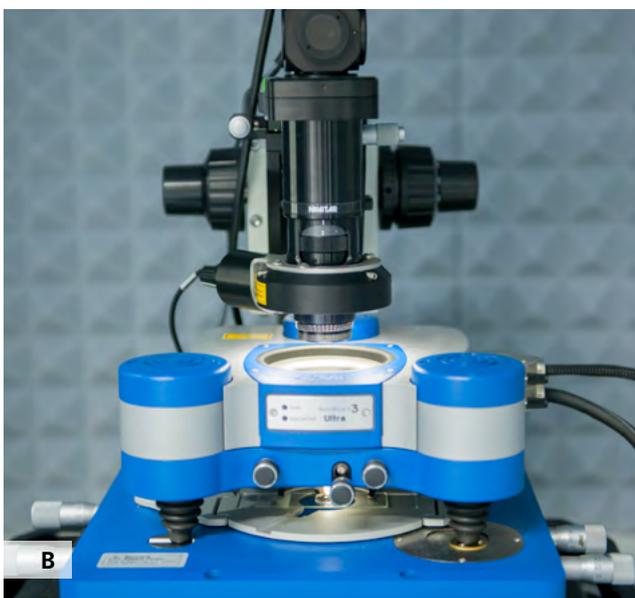
- Label-free methods of depicting the distribution of macro molecules in histological samples based on their degree of ionization and time of flight (TOF) in the electric field; special sample preparation and matrix application required, statistical evaluation of distribution patterns

Laser capture microdissection

- Isolating individual cells or tissue structures by means of microscopic laser cuts, analyzing samples using molecular biology methods (RT-PCR, proteomics)

Hardware-linked evaluation process

- Stereological quantification using the upright fluorescence and reflected-light microscope for unbiased histological evaluations
- Virtual microscopy in order to create completely virtual tissue sections for digital post-processing, high-throughput technique



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## BIO-NANOTECHNOLOGY APPLICATION LABORATORY (BNAL)

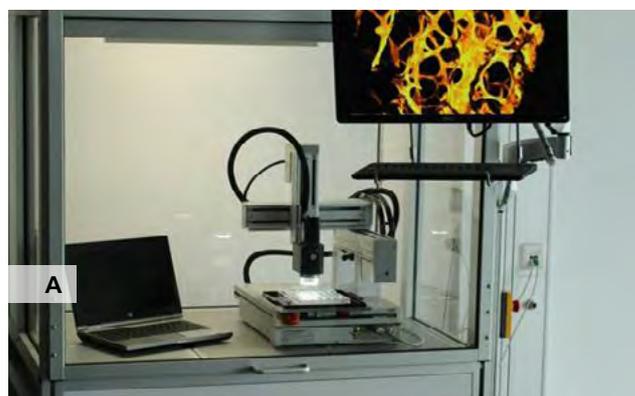
The Bio-Nanotechnology Application Laboratory (BNAL) in Leipzig represents a research infrastructure jointly run by Fraunhofer IZI and Fraunhofer IKTS. With this laboratory, both institutes are opening up new fields of application in biomedicine related to various nanotechnologies.

State-of-the-art equipment allows biological and medical issues to be handled in an interdisciplinary manner. BNAL provides research and development services from fundamental biomedical research by process development up to the development and validation of innovative technologies and system solutions.

Biological and medical expertise at Fraunhofer IZI (e.g. oncology, chronic inflammatory diseases and neuro-degenerative diseases) in combination with established analysis methods for material diagnostics at Fraunhofer IKTS enable the development of new diagnostic and therapeutic technologies and procedures.

### Imaging procedures

- Optical coherence tomography (A): Uses near-infrared light to depict the internal and surface structures of various materials in high resolution.
- Multi-acousto-scope: The combination of three microscopy techniques paves the way to innovative new examination strategies.



### Cell characterization and classification

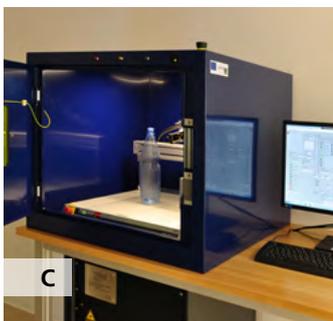
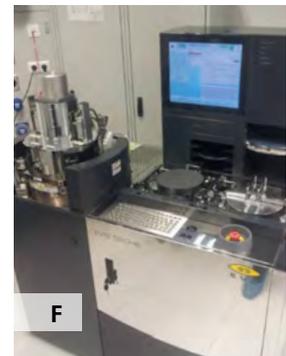
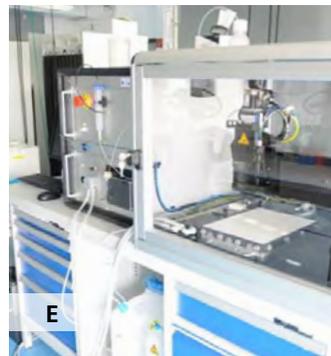
- Diagnosis and mapping for cell biology studies: Non-intrusive way of delivering high-resolution, geometric information from the inside of test objects.
- Spectrometer for time-resolved fluorescence spectroscopy: Procedure to characterize cells based on electromagnetic radiation.
- Ultrasound broadband spectroscopy system: This procedure has long been used in the medical diagnosis of cell tissues, biological materials and in the analysis of fluid media. It mainly identifies acoustic and mechanical properties of substances.
- High-throughput flow cytometry (B): Rapid, multiplex, high-throughput screening of cells and beads in suspension.



- Zetasizer: Determination of particle and molecule sizes, e.g. for characterizing recombinant proteins, micelles and nanoparticles.
- Micro-spotter unit (E): Automated dosing of tiny quantities of liquid (e.g. biological or organic solutions, or solutions containing nanoparticles) on a broad range of different surfaces for the production of microarrays.
- Hot-embossing system (F): Production-relevant manufacturing of nanostructured surfaces on glass and polymer surfaces.

### Surface sterilization and modification

- Electron beam dosimeter (C): Dose measurement of highenergy radiation (e.g. gamma or electron radiation) on even on the different positions of bent 3D free-form surfaces.
- System for electron irradiation of surfaces (D): Sterilization of package / surfaces, inactivation of microorganisms for vaccine production or targeted adjustment of material properties by means of electron irradiation.



### Contact



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### Nanotechnology

- Droplet digital PCR system: PCR-based, absolute quantification of microbial / viral or eukaryotic DNA / RNA as well as precise detection of low genome copy numbers.

## CENTER FOR EXPERIMENTAL MEDICINE

The development of new drugs entails testing using suitable animal models. Animal experiments are therefore an integral component in the development of new drugs, therapies and diagnostic procedures. The institute's Centre for Experimental Medicine (TEZ) is a central unit which facilitates important steps in translating research findings into a clinical application for human subjects.

Moreover, the institute has access to one of the most state-of-the-art animal houses in Germany. The TEZ is distinguished by its highly technical facilities, which are optimized to handle preclinical research projects. These facilities include modern rooms in which the animals are kept, featuring standardized hygiene levels and individually ventilated cage systems that are monitored via the building management system.

The health and care of the animals is of the highest priority. Highly qualified personnel support the scientific staff in daily care, health monitoring and breeding activities, and in administering treatments.

All experimental work can be carried out under practically sterile conditions. Several fully fitted operating suites allow small and large animals to be examined and treated. The comprehensive, state-of-the-art equipment guarantees correct anesthesia, analgesia and species-relevant blood analyses.

An expansive equipment pool for imaging technologies at the institute enables partly non-invasive analysis methods and also contributes towards reducing the need for animal experiments. This means, for example, that in vivo imaging analyses can be carried out using, for instance, 7 Tesla magnetic resonance imaging, bioluminescence imaging or small-animal CT.

In order to work on a range of issues, the TEZ has access to areas approved for genetic engineering safety levels S1 to S3; it may also conduct in vivo studies in line with GLP (Good Laboratory Practice).

The TEZ forms the central interface at the institute for processing preclinical development projects. Furthermore, cooperation projects with external clients and other research institutes are also carried out. At the same time, the TEZ acts as a training facility for animal care supervisors in a research and clinical setting, also offering advanced training courses for experimenters.

Adherence to the animal welfare guidelines is strictly monitored by the institute's animal welfare officer and regularly controlled by the regional animal welfare authority

### Equipment and services:

- Small animals are kept under state-of-the-art standards and permanently monitored
- Animal husbandry under GLP standards
- Animal husbandry with the option to use infecting agents for experimental infection



- Quarantine services
- Standard in-breeding and breeding transgenic lines
- Operation units in various areas including provision of inhalation anesthesia for small and large animals
- Large-animal OP area with intensive care capacity
- C-arm
- Option for individual stereotactic brain surgery
- Autopsy room for large animals
- Intraoperative blood gas analyses
- Small animal endoscope
- Blood cell meter
- Surgical microscope
- Stereotactic manipulation
- Temperature control during operations

- In vivo bioluminescence
- Small animal magnetic resonance imaging
- Small animal computer tomography
- X-ray unit for whole-body irradiation and pinpointed radiation therapy
- Large capacity autoclave
- Sterilization units using hydrogen peroxide fumigation
- Cryopreservation of spermatozoa and embryos
- Tissue bank

#### Contact



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## RIBOLUTION BIOMARKER CENTER

Over the past few years, the Fraunhofer Future Foundation has supported the RIBOLUTION project consortium, which takes an innovative approach to identifying new biomarkers for modern diagnostic solutions. The RIBOLUTION Biomarker Center was set up as part of a close cooperation involving five Fraunhofer institutes and several universities. It was opened on April 26, 2016, at the Fraunhofer Institute for Cell Therapy and Immunology IZI in Leipzig.

At the RIBOLUTION Biomarker Center, novel biomarkers are identified based on ribonucleic acids and developed through to clinical "proof of concept" with the aid of selected patient cohorts. At present, activities are primarily focused on development programs in the areas of prostate cancer, chronic obstructive pulmonary disease (COPD) and infectious diseases.

### Biomarker screening and validation

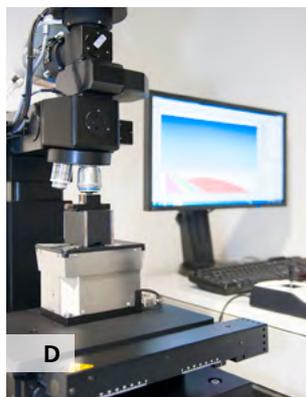
By integrating state-of-the-art genomic analysis methods such as next-generation sequencing (NGS) using our own bioinformatical data analysis methods developed in house, the RIBOLUTION Biomarker Center is able to identify biomarkers and develop new diagnostic tests at the **highest technological level**:

- Illumina HiSeq and Miseq (A): Ultra-high-throughput sequencing platforms
- Hamilton Microlab STARlet/STARplus (B): Fully automated preparation of samples for sequencing and fully automated extraction and purification of nucleic acids





C



D

- Agilent microarray scanner (C)
- EMD (D): Quality and quantity analyses of minimal amounts of nucleic acids with high sensitivity; developed by Fraunhofer FIT
- QIAcube (E): Semi-automated extraction and purification of nucleic acids
- RiBOT (F): Novel procedure for the automated validation of biomarkers in high-throughput based on complex interactions between actuator engineering and media to be dispensed; developed by Fraunhofer IPA



E

The highest quality standards are defined and implemented from start to finish, which increases the intrinsic value of the obtained data and lays the foundations for the implementation of a quality management system pursuant to DIN ISO 13485, which will become necessary as the project progresses.



F

New biomarkers are identified and validated using bioinformatical methods. This includes designing custom expression microarrays and analyzing expression microarray data. A proprietary data management system has been developed to store and supply all clinical and experimental data and is used to manage the extensive biobank which has emerged in the RIBOLUTION project.

### Contact



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## QUALITY MANAGEMENT

With a highly successful quality management the Fraunhofer IZI fulfills its clients' and partners' sophisticated demands and thus guarantees research services at the highest level.

### GLP – "Good Laboratory Practice"

"Good Laboratory Practice" (GLP) is a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. This is the definition of Good Laboratory Practice in the GLP principles of the Organization for Economic Co-operation and Development (OECD) that were devised following the EC-Directive, which was incorporated into German legislation for chemical compounds ("Chemikaliengesetz"). Good Laboratory Practice, as almost no other quality system, has contributed to health, environmental and animal protection through its worldwide implementation and the consequent widely reciprocal recognition of study data.

Fraunhofer IZI holds a separate GLP laboratory and trained personnel. These resources are fully equipped to provide integrated solutions for research and development.

#### Contact



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### GMP – "Good Manufacturing Practice"

The Fraunhofer IZI maintains three GMP-compliant clean room facilities. Through the flexible design, the facilities are especially attractive for new biotechnology companies that seek to bring newly developed medicinal products into clinical application via clinical trials. The facilities are divided into different independent suites. Each has its own grade C clean rooms (preparation), own air locks from grade C to B (personnel and materials transfer) and two grade B rooms (aseptic manufacturing). The clean room grade A is provided via laminar airflow cabinets that are installed in the B-rooms. The available clean room suites are specialized in conducting processes for manufacturing human autologous and / or allogeneic cell and gene therapeutic products (advanced therapy medicinal products). In addition to the clean rooms and the technical infrastructure, the Fraunhofer IZI offers assistance for the set-up and validation of GMP-compliant manufacturing processes as well as for obtaining a manufacturing permit pursuant to section of the German Drug Act (AMG).

#### Contact



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### Why are GLP and GMP important?

The clinical trial of new drug candidates is an essential step on the way to approval. Since the 12th revision of the "Arzneimittelgesetz AMG" (German Drug Act) every clinical drug trial must be approved of by the responsible higher federal authority ("Bundesinstitut für Arzneimittel und Medizinprodukte", Federal Institute for Drugs and Medical Devices, Paul-Ehrlich-Institut) and by the responsible ethics committee prior to the initiation of the clinical study. In order to obtain this authorization, the efficacy and safety of

the investigational medicinal product must first be verified within the framework of GLP-compliant preclinical investigations (e.g. toxicological testing procedures). Furthermore, the quality of manufacture of the investigational medicinal products must be verified by a GMP manufacturing permit pursuant to § 13 AMG. Relevant trial results from GLP-certified trial institutions and a GMP manufacturing authorization are thus absolutely prerequisite when applying for the clinical trial of a new medication.

### GCP – "Good Clinical Practice"

GCP describes internationally accepted regulations which govern the execution of clinical trials. These regulations encompass ethical as well as scientific aspects. Clinical trials are divided into three phases.

- Phase I: Establishment of safety of the new medication / therapeutic
- Phase II: Establishment of the efficacy of the new medication / therapy (Phase IIa) and dose curve (Phase IIb)
- Phase III: Establishment of a significant proof of efficacy (also known as Pivotal-trial).

Only after successful completion of phase III can new substances register for marketing approval. All phases of clinical development must be carried out under the above described GCP-guidelines. The protection of the patient or volunteer must always remain in the foreground. Important aspects of this include the patient consent form, patient trial insurance as well as the exact documentation of the trial results. Additionally GCP regulates the roles of the essential entities involved in the trial including the sponsor, monitor, CRO, primary investigator and ethics committee or institutional review

board and also regulates quality management and adverse event reporting.

The Fraunhofer IZI carries out in co operation with doctors and SMO's (site management organizations) clinical trials as requested by Sponsors. The Fraunhofer IZI is a reliable partner in the area of clinical trial planning, composition of trial protocols and all other necessary documents required for submission to the regulatory authorities including the ethics committee. Private physicians and SMOs carry out on-site patient visits.

### Contact



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# LOCATIONS

**HAMILTON**  
CANADA

**LEIPZIG**  
**POTSDAM**  
**HALLE**  
**ROSTOCK**  
**ERFURT**  
GERMANY

**GWANGJU**  
SOUTH  
KOREA



## LEIPZIG HEADQUARTERS, SAXONY, GERMANY

Perlickstraße 1, 04103 Leipzig, Germany

Usable area: 8 749 m<sup>2</sup>

Employees: 366

Focal areas: Cell engineering, cell therapy, drugs, diagnostics, immunology

Completed in April 2008, the main building boasts extensive laboratory capacities for conducting molecular and cell-biological work. An extensive immunohistochemistry laboratory, an isotope laboratory, a quality control laboratory with qualified equipment, as well as cyro-storage capacities also make up the institute's facilities.

The research infrastructure at the headquarters is complemented by various special facilities found in the extension buildings, which were opened in 2013 and 2015 (e.g. imaging units, laboratories for experimental medicine, a S3 laboratory, and clean-room facilities).

All of the Fraunhofer IZI's laboratories are certified according to S2 standards and therefore suitable for carrying out work in the fields of genetic engineering and infection biology. A flexible cluster structure allows laboratory sections to be adapted and fitted out in line with the specific requirements of a broad range of projects.

The business units Cell and Gene Therapy, Drugs and Diagnostics are primarily based in Leipzig. Biopharmaceutical products for clinical trials are manufactured in line with Good Manufacturing Practice (GMP) in the institute's clean-room facilities, which cover a total area of 1000 m<sup>2</sup>.

### Management



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## BIOANALYTICS AND BIOPROCESSING BRANCH OF INSTITUTE IN POTSDAM-GOLM, BRANDENBURG, GERMANY

Am Mühlberg 13, 14476 Potsdam-Golm, Germany

Usable area: 4 096 m<sup>2</sup>

Employees: 110

Focal areas: Biotechnology, bioproduction, bioanalytics, automation

The Bioanalytics and Bioprocesses Branch in Potsdam-Golm was affiliated with the Fraunhofer Institute for Cell Therapy and Immunology on July 1, 2014. The site was initially founded in 2005 as a branch of the Fraunhofer IBMT and has since worked on technological solutions for biomedicine and diagnostics as well as for biotechnology and bioproduction.

The interdisciplinary team comprising natural scientists, engineers and technicians develops powerful, analytical methods for the detection and validation of pathogens and biological markers besides processes to obtain, handle and manipulate cells and biomolecules. In this context, the team develops applications for personalized medicine, as well as biosensors and detection procedures for the areas of agriculture and the environment, for a broad spectrum of substance classes.

The site has the state-of-the-art infrastructure required for miniaturizing and automating biological processes. This includes various biosensor and biochip technologies, pipetting robots and micro and nano-dispensers, besides many different rapid-prototyping procedures.

A further special feature of the branch's facilities is the life culture collection of cryophilic algae (CCCr<sub>1</sub>), which serves as a resource for developing production processes for novel, industrial bioproducts.

### Management



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**Katja Okulla**

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## DEPARTMENT OF DRUG DESIGN AND TARGET VALIDATION IN HALLE (SAALE), SAXONY-ANHALT, GERMANY

Weinbergweg 22, 06120 Halle (Saale), Germany

Usable area: 1 300 m<sup>2</sup>

Employees: 59

Focal areas: Biochemistry, pharmacology, drug development, analytics

The Department of Drug Design and Target Validation develops new molecular therapies for neurodegenerative and inflammatory diseases. The department's expertise is based on an in depth pharma-like understanding of scientific work and a long-lasting experience in the field of drug development.

This profile encompasses the identification of new target proteins by analyzing putative pathologic post-translational modifications, the misfolding of proteins and the formation of pathological aggregates. Based on these new strategies the department develops and tests small molecules as well as biological agents (biologicals). This research is complemented by the design of new assays for the identification and diagnostic application of biomarkers aiming at monitoring the course of the disease and its therapy.

The department's expertise also expands to the generation of pharmacologically relevant in vitro and in vivo models. Besides state-of-the-art methods for peptide synthesis and protein analytics (MALDI-TOF and LC-MS), the department commands a wide range of biophysical methods to

characterize therapeutically relevant physiological pathways, their key proteins as well as cell-based and pharmacologic models for the characterization of new chemical and biological drug candidates.

### Management



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## EXTRACORPOREAL IMMUNOMODULATION PROJECT GROUP IN ROSTOCK, MECKLENBURG-WESTERN POMERANIA, GERMANY

Schillingallee 68, 18057 Rostock, Germany

Usable area: 700 m<sup>2</sup>

Employees: 22

Focal areas: Organ-supporting technologies, clinical trials

The group focuses on the development and evaluation of extracorporeal (outside the body) organ-supporting technologies with a particular emphasis on supporting the immune system.

The group offers the full range of preclinical and clinical analyses of extracorporeal technologies on the basis of a broad spectrum of in vitro simulations, small and large animal models as well as a powerful clinical study network for in- and outpatients. Moreover, the group offers self-developed unique analytic and diagnostic devices including an ex situ intestine model, a cell sensor and novel protein assays.

### Management



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## PROJECT CENTER MICROELECTRONIC AND OPTICAL SYSTEMS FOR BIOMEDICINE IN ERFURT, THURINGIA, GERMANY

The Microelectronic and Optical Systems for Biomedicine project center in Erfurt brings together the core competencies of three Fraunhofer institutes to span the disciplines of biosciences, microelectronics, microsystems technology, optics and photonics. This combined expertise will be used to develop application-ready systems in the areas of medical engineering, analytics, diagnostics, biotechnology, biophotonics, pharma, health care, ageing and food economics which will then be transferred into industry. Fields of application here include improved medical imaging and visualization as well as technologies for biomarker analysis.

### Involved Fraunhofer Institutes:

- Fraunhofer Institute for Applied Optics and Precision Engineering IOF ([www.iof.fraunhofer.de/en](http://www.iof.fraunhofer.de/en))
- Fraunhofer Institute for Photonic Microsystems IPMS ([www.ipms.fraunhofer.de/en](http://www.ipms.fraunhofer.de/en))
- Fraunhofer Institute for Cell Therapy and Immunology IZI ([www.izi.fraunhofer.de/en](http://www.izi.fraunhofer.de/en))

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## FRAUNHOFER PROJECT CENTER FOR BIO-MEDICAL ENGINEERING AND ADVANCED MANUFACTURING (BEAM) AT MCMASTER UNIVERSITY, HAMILTON, ONTARIO, CANADA

The founding team at Fraunhofer IZI started looking for suitable Canadian cooperation partners back in 2011, a search that led to initial joint research projects being set up with McMaster University in Hamilton (Ontario, Canada). With approximately 29,000 students, the university is one of the most renowned in Canada, with particular strengths in the fields of health sciences, engineering and natural sciences. Over the past four years, McMaster University has attracted the most industry projects of all the universities in Canada.

In 2014, based on the huge success of ongoing cooperation projects, Fraunhofer-Gesellschaft decided to set up a Fraunhofer Project Center (FPC) at McMaster University. Governed by a cooperation agreement, the FPC is jointly run by experienced McMaster and Fraunhofer managers and is devoted to applied research in the business units Diagnostics, Automation, Cell Therapeutics and Biomaterials. Immunologist Professor Jonathan Bramson and materials researcher Professor John Brennan are the center's key partners in terms of scientific cooperation and management on the Canadian side of the cooperation. The FPC also helps to establish German and Canadian companies and supports the development of business activities in the respective partner country.

Within the first few months of being established, the project center was already managing to attract significant funding on both the German and Canadian sides, besides a series of industry cooperation projects including approx. 12 million

Canadian dollars in FedDev funding awarded in December 2015 for the construction of a joint research building in McMaster Innovation Park, set to open in spring 2018. Covering a usable area of approx. 2,000 sqm, it will provide joint German-Canadian research units and also research subsidiaries of industrial companies with an outstanding, state-of-the-art research infrastructure.

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## JLCI – JOINT LABORATORY OF CHONNAM NATIONAL UNIVERSITY HOSPITAL HWASUN IN COLLABORATION WITH FRAUNHOFER IZI IN GWANGJU, JEOLLANAM-DO, SOUTH KOREA

Since 2010, Fraunhofer IZI has maintained a close cooperation with Chonnam National University Hospital Hwasun (CNUHH) in several areas. With 700 beds, the CNUHH is one of the largest university hospitals specialized in the treatment of cancer in South Korea. The hospital is accredited by the Joint Commission International and specializes in cancer and joint diseases.

The JLCI facilitates the collaboration with external partners from academia and industry in Asia. For example the Fraunhofer IZI's ligand development group is using the regular access to fresh tumor materials from patients to identify tumor binding peptides, which already have been validated in tumor models.

The laboratory management is oriented at the standards and rules of the Fraunhofer-Gesellschaft. This shall guarantee a common basis when dealing with patents and contractual matters. The JLCI is financed by the Korean Ministry of Education, Science and Technology (NRF) as part of an initiative to strengthen international cooperation run by the GRDC. Respective funding on the part of the Korean government has been granted to the CNUHH for the collaboration between both institutes since June 2011. Since then, several delegations from Fraunhofer IZI have travelled to Korea for

conferences and scientists have stayed there for up to two months as well as a number of Korean colleagues have also worked at Fraunhofer IZI. Many joint publications have also been written. German-Korean symposiums take place on an annually rotating basis.

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# EVENTS



# THE FRAUNHOFER IZI IN PUBLIC

Events are the key ingredient of the institute's communication strategy. The Fraunhofer IZI once again organized and supported various scientific and public events in 2017.

**January 19, 2017: Leipzig Fraunhofer Institutes' Joint New Year's Reception**

**October 3, 2017: Open Day for Young Scientists: Mouse TV (*Die Sendung mit der Maus*)**

**April 26, 2017: High performance center "Integration of Biological and Physical-Chemical Material Functions" founded in Potsdam-Golm, Germany**

**November 8–9, 2017: Fraunhofer Life Science Symposium – Latest Developments in the Field of Infection Diagnostics**

**April 27, 2017: Girls' Day at Fraunhofer IZI**

**November 16–17, 2017: Workshop on Arthropod-Borne Diseases in Jena, Germany**

**May 12, 2017: Workshop on "Complementary Technologies for Point-of-Care Diagnostics"**

## Looking to 2018

**May 29, 2017: Fraunhofer celebrates 25 years of applied research in the new federal states of Germany**

- January 17, 2018: New Year's Reception
- April 26, 2018: Girls' Day 2018
- May 5, 2018: Potsdam Day of Science
- June 22, 2018: Long Night of Sciences Leipzig
- July 6, 2018: Long Night of Sciences Halle (Saale)
- September 27, 2018: Fraunhofer Life Science Symposium, [www.fs-leipzig.com](http://www.fs-leipzig.com)

**June 15, 2017: Parliamentary academic day at Fraunhofer IZI's Department of Drug Design and Target Validation**

**August 1, 2017: Fraunhofer IZI initiates research unit at Monash University (Melbourne, Australia)**

**August 4, 2017: Specialist group Image Analysis of Cell Function successfully evaluated**



Further information on the events can be found in the full version of the annual report on pages 123–130.

<http://s.fhg.de/sqE>

**August 18, 2017: New Fraunhofer Project Center "Microelectronic and Optical Systems for Biomedicine" in Erfurt, Germany**

**September 8–10, 2017: 18th International Symposium on Albumin Dialysis**

# FURTHERANCE



# SPONSORS AND ADVISORY BOARD OF THE FRAUNHOFER IZI

The support and commitment of active institutions and individuals enable the Fraunhofer IZI to experience continuous and successful development as well as dynamic growth.

## Sponsors

The Fraunhofer IZI would like to thank the European Union, the Federal Ministry of Education and Research, the Free State of Saxony and the City of Leipzig via the Leipzig Foundation for Innovation and Technology Transfer for their financial support.

The European Union sponsors through the programs EFRE and ESF. The building projects of the Fraunhofer IZI are sponsored 60 percent by the European Union and 20 percent each by the Federal Ministry of Education and Research and the Free State of Saxony. The plot of land is provided by the City of Leipzig in hereditary leasehold and free of charge. Furthermore, Fraunhofer IZI would like to thank the Leipzig Foundation for Innovation and Technology Transfer for its support during the institute's construction phase from 2005 to 2010.



European Union



Bundesministerium  
für Bildung  
und Forschung



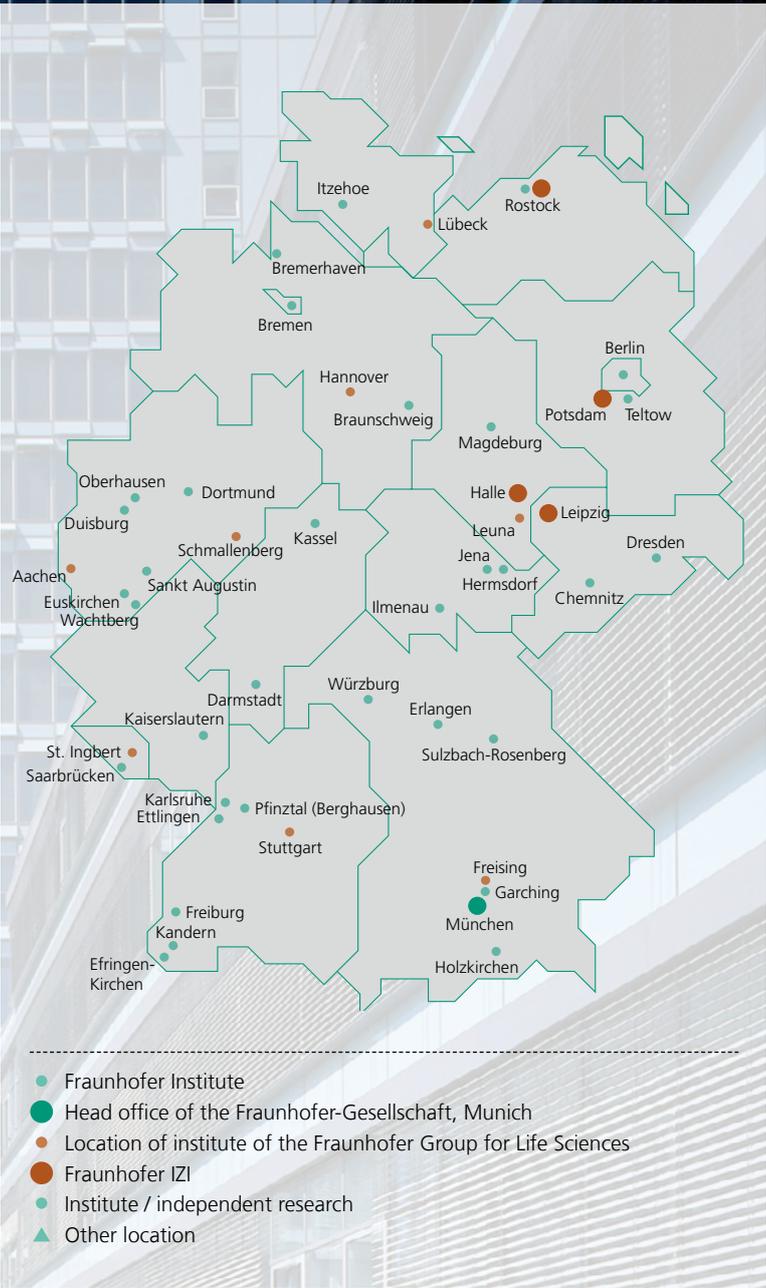
## Advisory board

The advisory board functions as the external expert committee for strategic questions regarding the institutional direction and the Fraunhofer-Gesellschaft. Its members are invited and appointed by the president of the Fraunhofer-Gesellschaft. The advisory board includes representatives from industry and research as well as from authorities, ministries and foundations. The board meets once a year and evaluates the performance and image of the institute.

Members of the advisory board:

- Dr. Henrich Guntermann (Chair) (European Consortium of Technology Transfer S.A.)
- Uwe Albrecht (Mayor and Councillor for Economics and Labour, City of Leipzig)
- MR'in Dr. Annerose Beck Saxon State Ministry of Science and the Arts (SMWK), Head of National-Regional Research Centers Administration)
- Bettina Berendsen (Sartorius Stedim Systems GmbH)
- Klaus Berka (Analytik Jena AG)
- Prof. Dr. Walter Brehm (Veterinary Medicine Faculty, Leipzig University, Dean)
- Prof. Dr. Jörg Gabert (Genolytic GmbH)
- Prof. Dr. Andreas H. Guse (University Hospital Hamburg-Eppendorf, Vice-Dean for Teaching)
- Prof. Dr. Hans-Martin Jäck (University Hospital Erlangen, Head of the Molecular Immunology Department, President of the German Society for Immunology)
- Prof. Dr. Markus Löffler (Leipzig University, Head of the Institute for Medical Informatics, Statistics and Epidemiology)
- Dr. Uwe Marx (Technische Universität Berlin / TissUse GmbH)
- Dr. Kai Pinkernell (Medigene AG)
- Dr. Mark Wolters (Bayer Pharma AG)

# FRAUNHOFER-GESELLSCHAFT



# THE FRAUNHOFER-GESELLSCHAFT IN PROFILE

Research of practical utility lies at the heart of all activities pursued by the Fraunhofer-Gesellschaft. Founded in 1949, the research organization undertakes applied research that drives economic development and serves the wider benefit of society. Its services are solicited by customers and contractual partners in industry, the service sector and public administration.

At present, the Fraunhofer-Gesellschaft maintains 72 institutes and research units. The majority of the more than 25 000 staff are qualified scientists and engineers, who work with an annual research budget of 2.3 billion euros. Of this sum, almost 2 billion euros is generated through contract research. Around 70 percent of the Fraunhofer-Gesellschaft's contract research revenue is derived from contracts with industry and from publicly financed research projects. Around 30 percent is contributed by the German federal and state governments in the form of base funding, enabling the institutes to work ahead on solutions to problems that will not become acutely relevant to industry and society until five or ten years from now.

International collaborations with excellent research partners and innovative companies around the world ensure direct access to regions of the greatest importance to present and future scientific progress and economic development.

With its clearly defined mission of application-oriented research and its focus on key technologies of relevance to the future, the Fraunhofer-Gesellschaft plays a prominent role in the German and European innovation process. Applied research has a knock-on effect that extends beyond the direct benefits perceived by the customer: Through their research and development work, the Fraunhofer Institutes help to reinforce the competitive strength of the economy in their local region, and throughout Germany and Europe.

They do so by promoting innovation, strengthening the technological base, improving the acceptance of new technologies, and helping to train the urgently needed future generation of scientists and engineers.

As an employer, the Fraunhofer-Gesellschaft offers its staff the opportunity to develop the professional and personal skills that will allow them to take up positions of responsibility within their institute, at universities, in industry and in society. Students who choose to work on projects at the Fraunhofer Institutes have excellent prospects of starting and developing a career in industry by virtue of the practical training and experience they have acquired.

The Fraunhofer-Gesellschaft is a recognized non-profit organization that takes its name from Joseph von Fraunhofer (1787–1826), the illustrious Munich researcher, inventor and entrepreneur.

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