Fraunhofer
IZI

FRAUNHOFER INSTITUTE FOR CELL THERAPY AND IMMUNOLOGY IZI

ANNUAL REPORT 2016
SHORT VERSION

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This is the abridged version of the Fraunhofer IZI Annual Report 2016.

The full version can be found at 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.

PREFACE

DIRECTOR PROF. DR. FRANK EMMRICH

Readers of our annual reports will notice that this year's print version is much more streamlined than in the past. The increasing number of projects has recently led to ever bulkier reports. This year's report has therefore been noticeably shortened. All of the usual, more extensive information previously found in the print version is now available on the Fraunhofer IZI homepage at www.izi.fraunhofer.de. Use the QR code found in the report to retrieve this additional information at the click of a button. This includes detailed project examples from the various departments besides a detailed account of the year's publications.

Eleven years in, Fraunhofer IZI once again stepped things up a notch last year – just as it has done every year since being founded. The institute now employs 588 members of staff across six sites, 395 of whom are based at the headquarters in Leipzig. The annual balance sheet saw the institute's financial value surpass the €30 million threshold last year. From an economic perspective, this makes it one of the most successful institutes within the Fraunhofer-Gesellschaft. The increased demand for our research and development services attests to the strategically successful structure of our internationally visible competences.

The small selection of example projects presented in the annual report should by no means detract from our thanks and respect for the hard work put in by all responsible members of staff. That having been said, we would like to specifically highlight several developments. The Fraunhofer IZI was granted an official pharmaceutical manufacturing license for the development of an innovative leukemia therapy on behalf of an international partner. This involves implanting a genetically designed receptor in the patient's own T-lymphocytes, enabling the immune system to more effectively manage its tumor defense.

We are also handling another major project in the field of oncology supported by the Fraunhofer Future Foundation. Novel biomarkers are being identified here that can detect prostate cancer at an early stage and can even give an indication of malignancy when combined.

At the Fraunhofer IZI, we are especially proud of a grant received from the Bill & Melinda Gates Foundation in the US after the foundation had invited tenders for a program aimed at developing new vaccine production technologies. Working as part of a consortium comprising several Fraunhofer Institutes (IZI, FEP, IPA, IGB) and coordinated by our institute, we have succeeded in developing an innovative process for inactivating vaccines using low-energetic electron irradiation. This, in turn, is able to considerably increase the safety and also quality of vaccines. The funds awarded by the Bill & Melinda Gates Foundation will be used to construct a pilot plant in the second extension building of the Leipzig institute.

Thank you for your interest and have an enjoyable read!

Best wishes
Yours

Prof. Dr. Frank Emmrich

STRUCTURES AND FIGURES 2016

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.

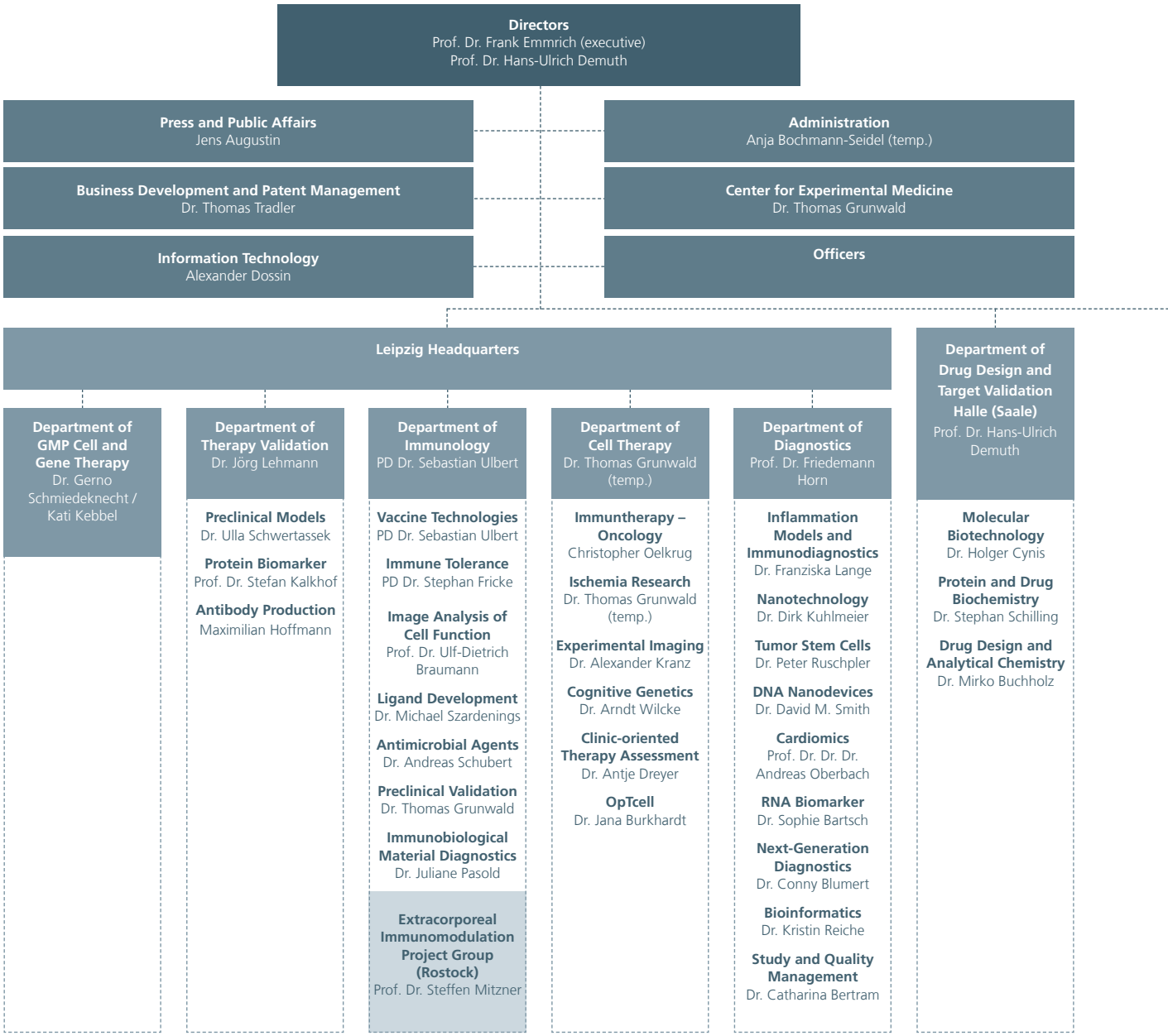
The institute's tasks

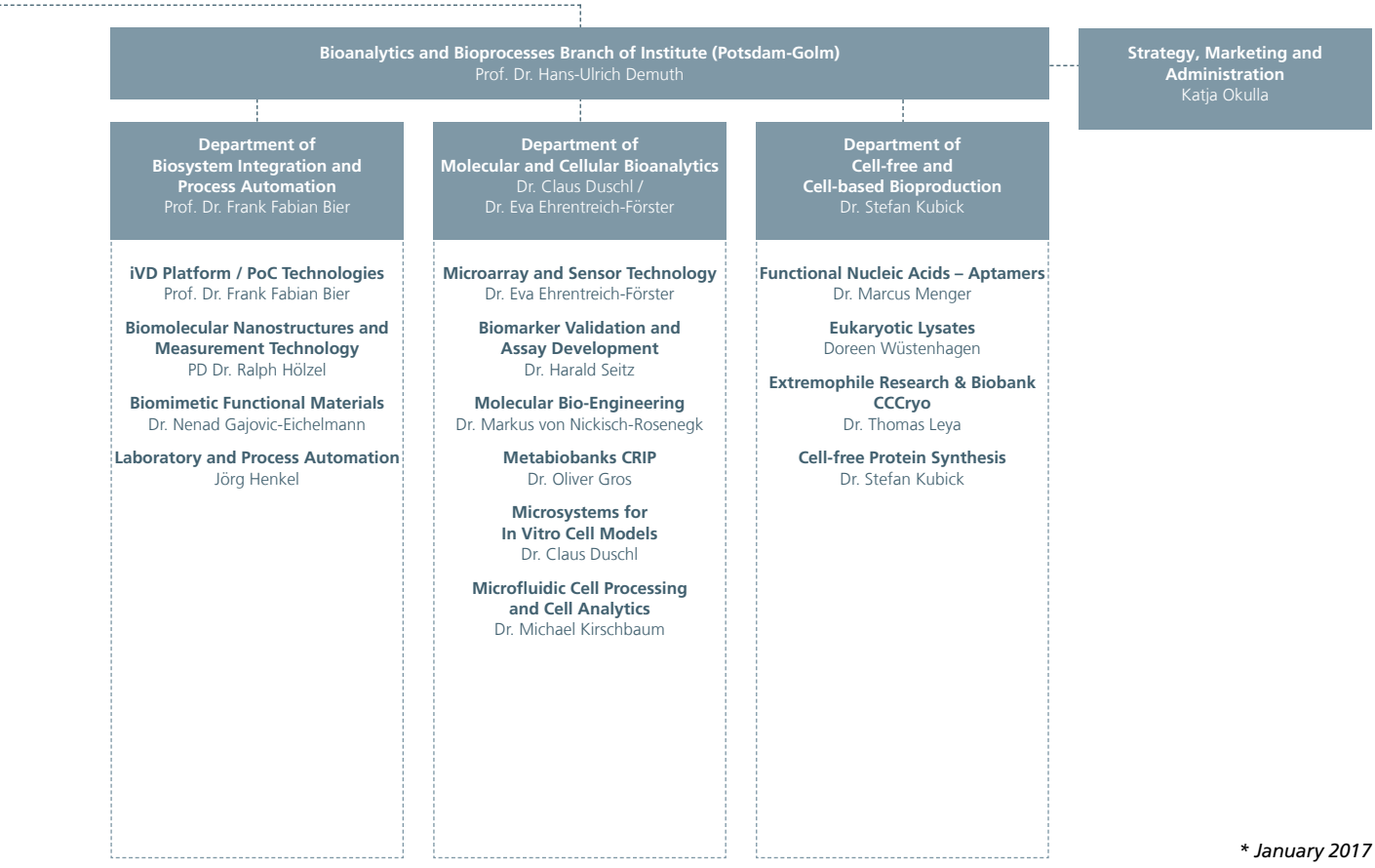
The institute operates four sites. The departments GMP Cell and Gene Therapy, Therapy Validation, Immunology, Cell Therapy and Diagnostics are based at the Leipzig head-quarters. The Potsdam-Golm branch is home to the departments Biosystem Integration and Process Automation, Cellular Biotechnology, Molecular and Cellular Bioanalytics as well as Cell-free and Cell-based Bioproduction. Two additional off-site departments are located in Halle (Saale) and Rostock. 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 2017*

BUSINESS UNITS

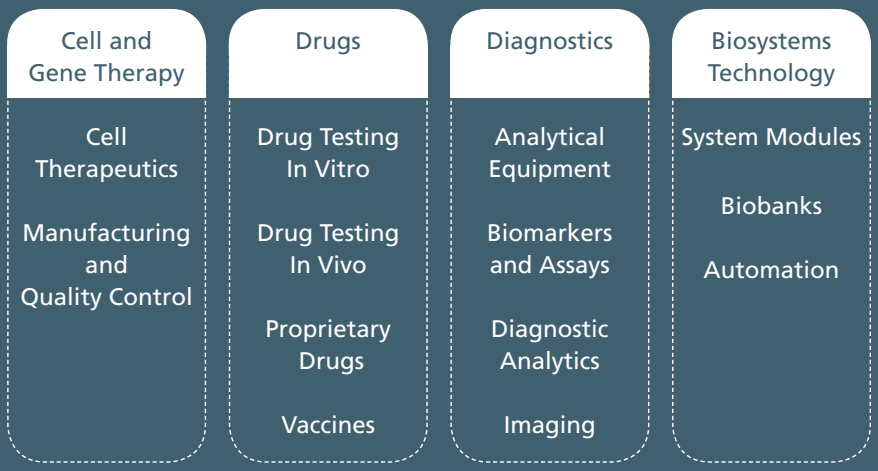
From a market perspective, a business unit is defined as a compilation of services rendered for specific groups of customers within a defined technological area which gives rise to customer value. Business units therefore form a basis for strategic planning within the context of market development and 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

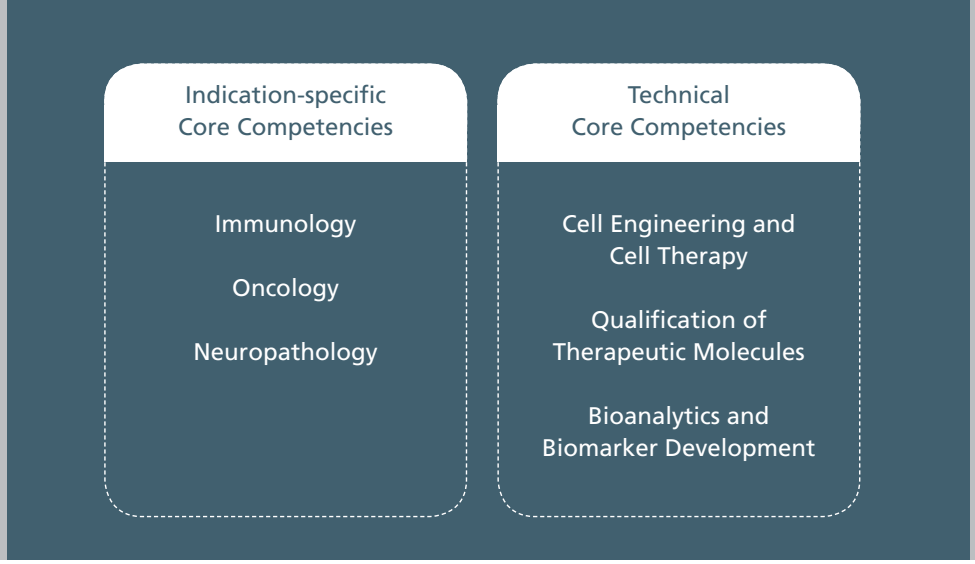
Specific skills and resources at Fraunhofer IZI are defined as core competencies; as such they are of key importance to the development of attractive technologies and product candidates and form the basis of the long-term economic and scientific success achieved by the institute's business units. At 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.



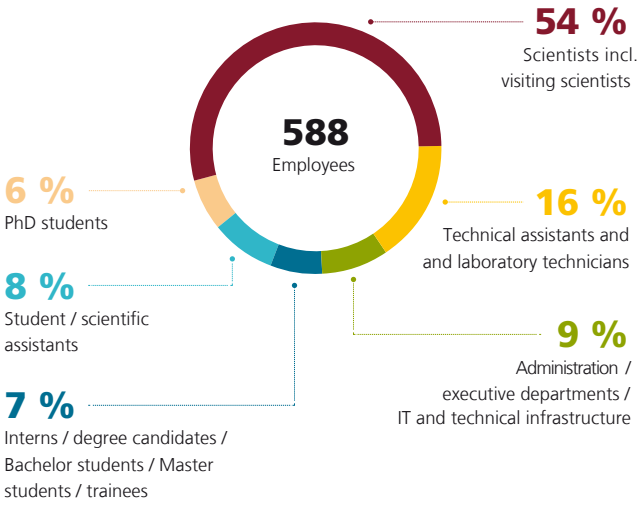
Technical core competencies

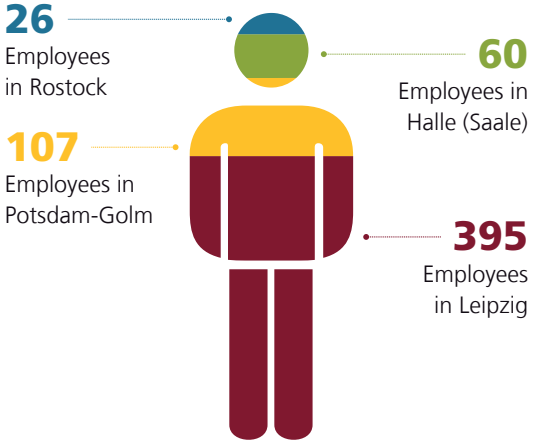
The core competence **Cell Engineering and Cell Therapy** is one of the institute's most important core competencies and has been ever since Fraunhofer IZI was established, as clearly expressed in the institute's name. Comprehensive expertise and an extensive special infrastructure have been established 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.

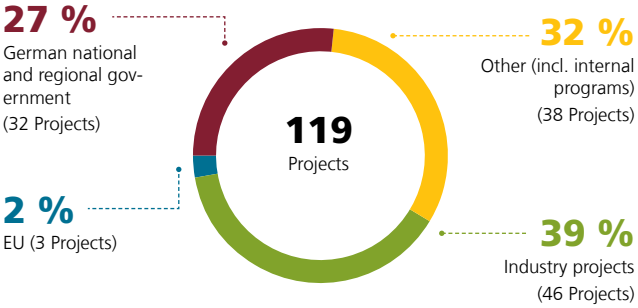
The core competence **Qualification of Therapeutic Molecules** pools together all of the competencies available at Fraunhofer IZI in close connection with drug development. The classes of therapeutic molecules addressed here include small, organic molecules and peptides as well as therapeutic macromolecules 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.

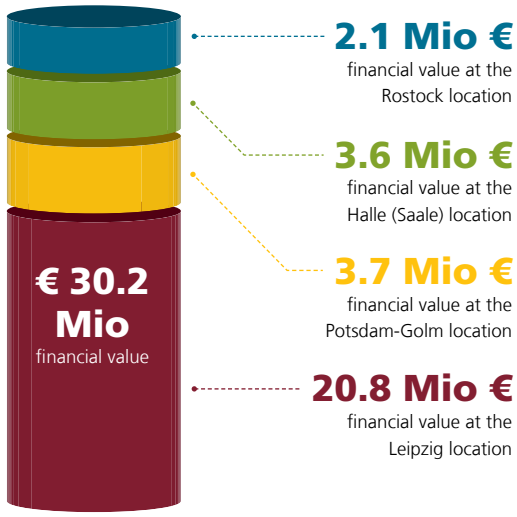
The final technical core competence, **Bioanalytics and Biomarker Development,** addresses all of the available capabilities and resources for the development of biomarkers, assays and detection technologies / solutions for the application area of medicine and food analysis. The biomarkers identified 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 2016









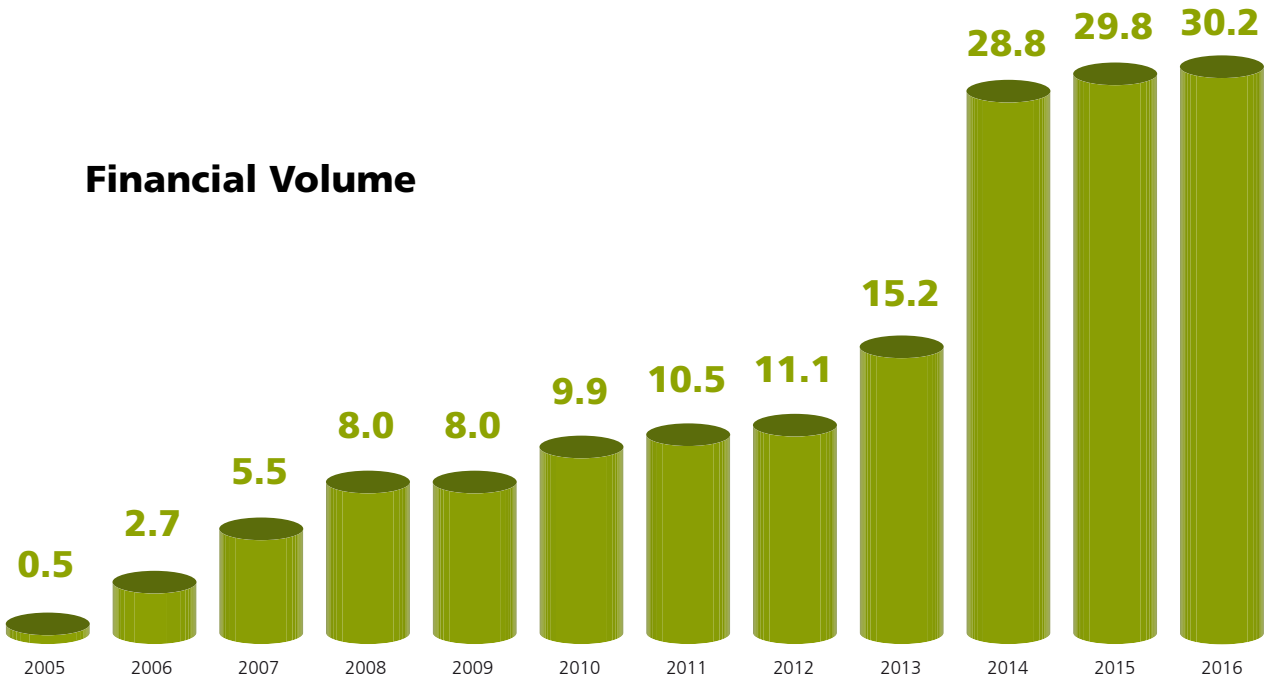
Project revenue 2016 in kEUR

	Leipzig	Halle	Potsdam	Rostock	Total
German national and regional government	1 250	3 140	1 220	1 420	7 030
EU	0	110	250	0	360
Industry projects	10 350	210	540	560	11 660
Other (incl. internal programs)	5 160	110	1 070	0	6 340
Total	16 760	3 570	3 080	1 980	25 390

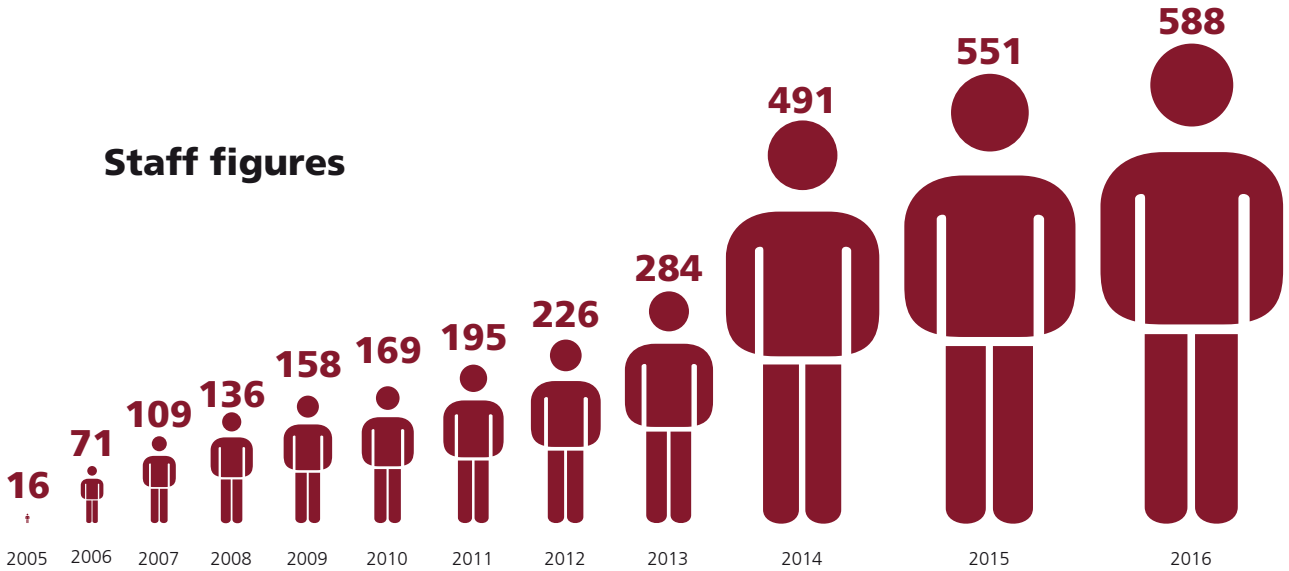
** 31.12.2016*

GROWTH AND PERFORMANCE

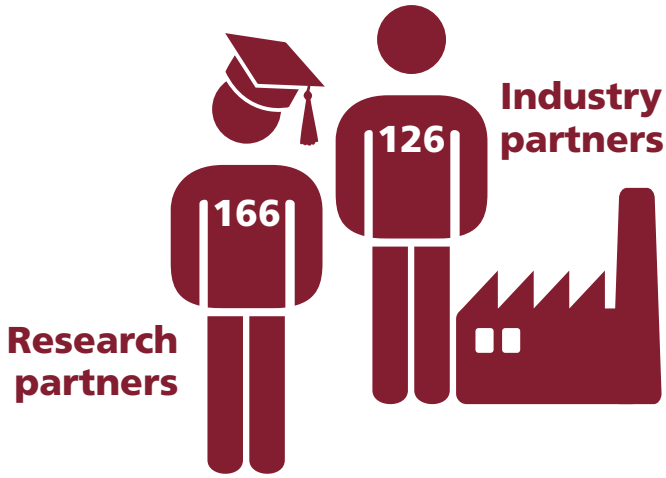
Financial Volume

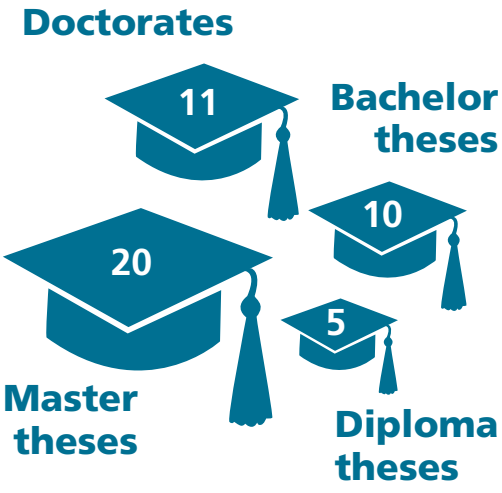


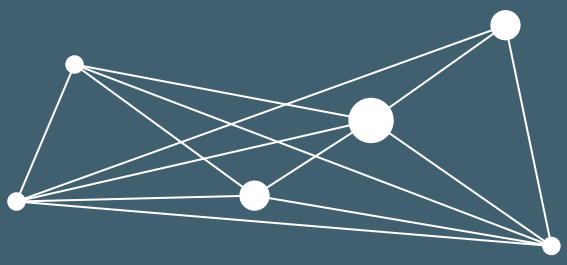
Staff figures



SCIENTIFIC PRESENCE AND NETWORK 2016

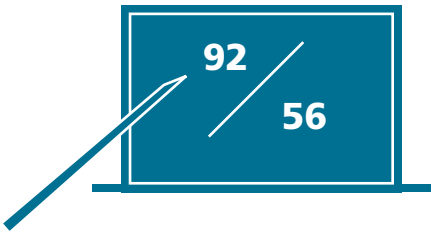






SCIENTIFIC EXCELLENCE
DIVERSITY
NETWORK

Advanced vocational training



Teaching activities

Evaluator activities

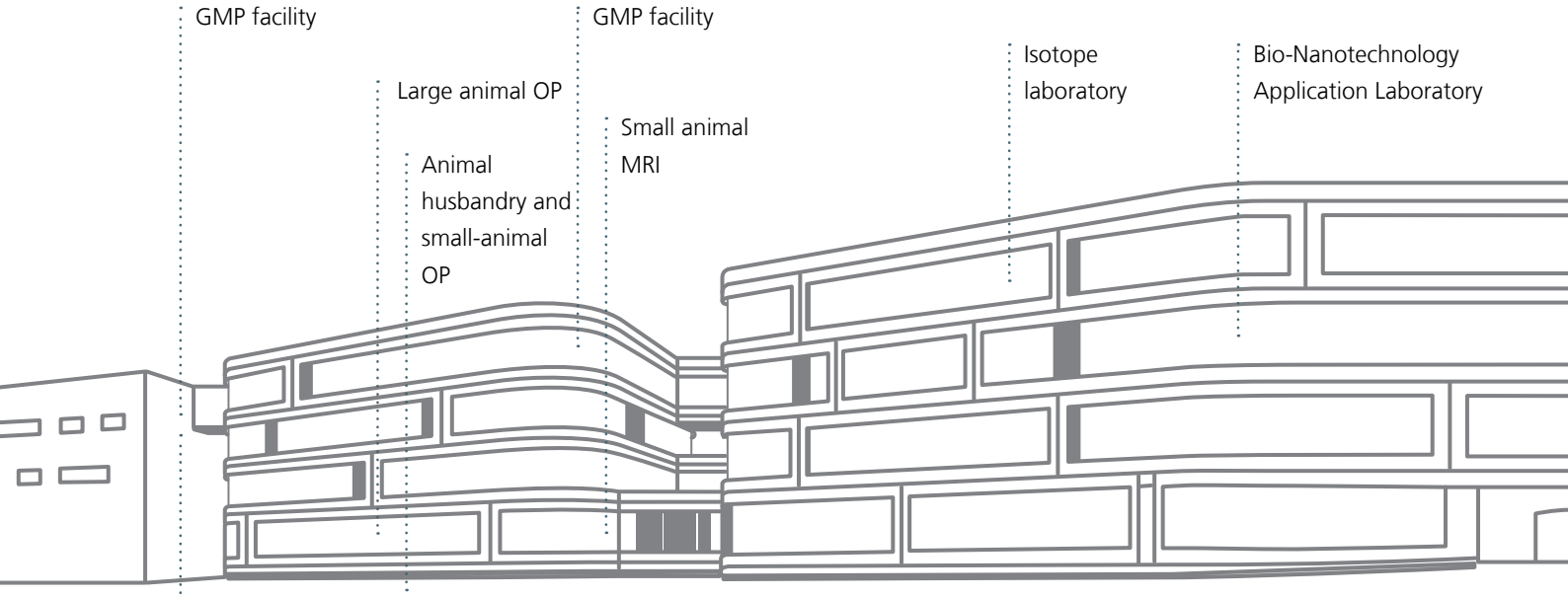
Association memberships

Patent families with 127 Patents

Detailed information on key figures and publications can be found in the full version of the annual report on pages 118–157.

http://s.fhg.de/5iE

RESEARCH INFRASTRUCTURE AT THE LEIPZIG SITE

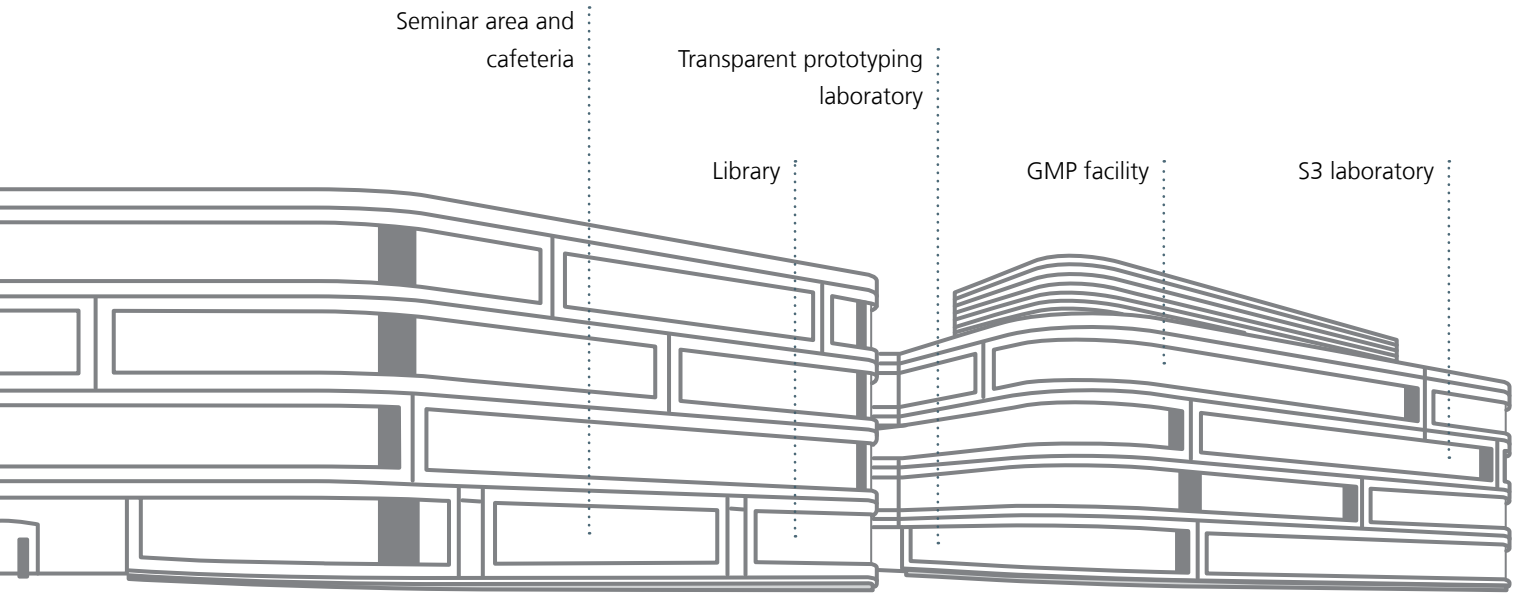


First extension building
Start-up operations: 2012 | Usable area: 1 568 m² | Lab space: 470 m² | Offices: 142 m² | Clean rooms: 377 m²

Main building
Start-up operations: 2008 | Usable area: 4 131 m² | Lab space: 1 867 m² | Offices: 1 615 m² | Seminar area: 276 m²

Rental area at BIO CITY Leipzig
Start-up operations: 2006 | Clean rooms: 450 m²

OUTSTANDING INFRASTRUCTURE



Second extension building
Start-up operations: 2015 | Usable area: 3050 m² | Lab space: 1171 m² | Offices: 881 m² | Clean rooms: 408 m²

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 seventeen 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)

Drugs R&D

- Nuvo Research GmbH (Settlement 2009)*

Natural remedies R&D

- Oncotrition GmbH (Spin-Off 2012)*

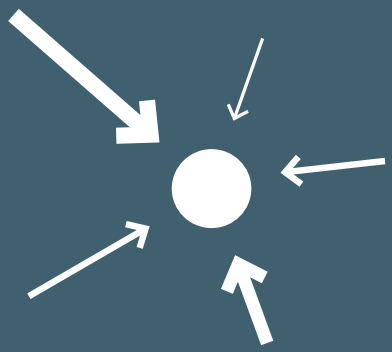
Stem cell bank

- InnovaStem GmbH (Settlement 2009)*

Therapy devices

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

*Spin-off and settlement projects overseen by the Fraunhofer IZI were supported by the SMILE start-up network.



INDUSTRY ATTRACTIVENESS

APOCELL
molecular profiling & diagnostics

BIOVILLE

Cell Pro Tec

Cognate BioServices, Inc.

EPITOPIC

InnovaStem
Innovation for Life

magna DIAGNOSTICS

MD5

Northwest Biotherapeutics

NUVO

oncotrition

PRIMA BIOMED LTD
Australian Cancer Treatment Company

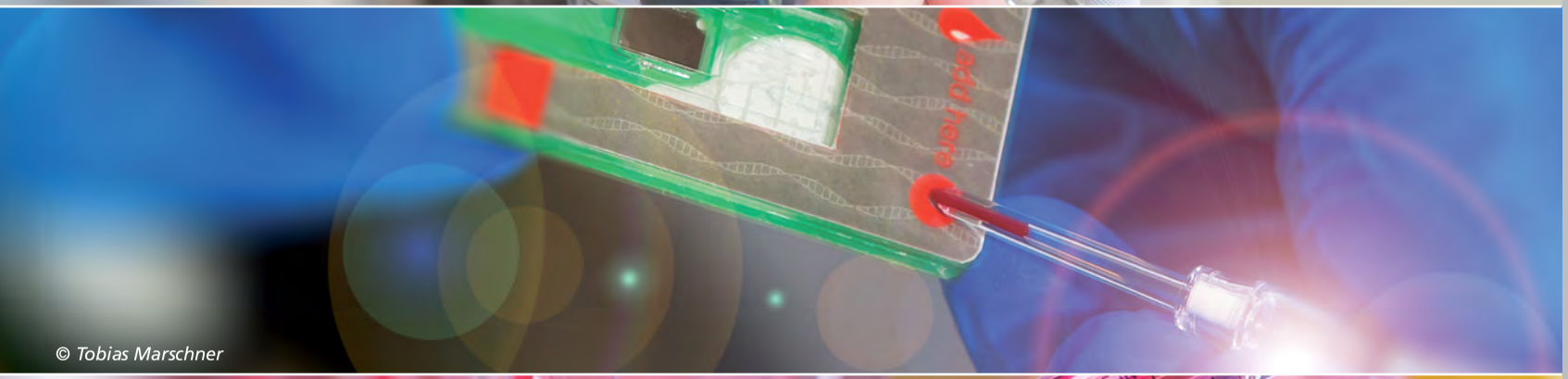
RIBOLUTION

SelfD Technologie GmbH

SoNovum
Cerebrum protego

Tutelacell

DEPARTMENTS



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DEPARTMENT OF GMP CELL AND GENE THERAPY

The 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 therapy area.

Contact

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PROJECT EXAMPLE

autoCard study

Cardiovascular diseases remain the main cause of death in Europe. In Germany alone, over 50,000 people die from myocardial insufficiency every year. At the Fraunhofer IZI, the manufacturing process for a new, cell-based therapeutic procedure is being established, enabling the procedure to then be tested in clinical trials. Developed by the Charité University Hospital in Berlin, the therapy draws on the patient's own heart cells, which are taken during a biopsy and cultivated in the laboratory. The aim of the project is to be granted a manufacturing permit in accordance with Section 13 of the German Drug Act (Arzneimittelgesetz) that will allow the first patients to be treated as part of a clinical trial.

Further information on the department and its projects can be found in the full version of the annual report on pages 24–26.

http://s.fhg.de/5zw

DEPARTMENT OF THERAPY VALIDATION

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.
5) Small-scale GMP manufacturing of therapeutic monoclonal antibodies for preclinical animal studies or clinical trials (Phase I and II).

- GLP-certified since 2009
- Immunotoxicity / immunogenicity in vitro / in vivo
- Safety tests for ATMPs – biodistribution, tumorigenicity and immunogenicity / immunotoxicity

Units

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

Contact

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Head of Department
Phone +49 341 35536-1205
joerg.lehmann@izi.fraunhofer.de

PROJECT EXAMPLES

Preclinical safety testing of a human stem cell therapeutic agent

Evaluation of the biodistribution and tumorigenicity of a human stem cell therapeutic agent for cartilage regeneration. Based on the patient's mesenchymal stem cells, the safety of the procedure is tested in the mouse model as part of a GLP study to rule out potential risks for patients.

FoodAllergen

Development of test systems based on monoclonal antibodies to facilitate the safe detection of allergenic ingredients in food. The aim of the overall project is to develop food technology processes that will reduce the allergenic potential of various types of food.

GMP facility for manufacturing therapeutic antibodies

In 2016, a 180m² clean-room facility was set up for the GMP-compliant production of antibodies. The facility is designed for the batch production of test samples for preclinical and clinical trials (phases I and II).

Further information on the department and its projects can be found in the full version of the annual report on pages 27–33.

http://s.fhg.de/6QW

DEPARTMENT OF IMMUNOLOGY

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 EXIM in Rostock.

Units and Heads of Department

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

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PROJECT EXAMPLES

Process enabling the safe manufacture of vaccines

Development of a new manufacturing process for vaccines based on low-energetic electron irradiation.

Preventing immunological complications following stem cell transplantation

Development of anti-human CD4 antibodies to prevent graft-versus-host disease following stem cell transplantations in leukemia patients while retaining the anti-tumor effect.

Test and advice center for health apps

The clinical study center belonging to the Rostock EXIM off-site department is expanding its competences to include the field of eHeath. As part of a sponsored project, a facility is to be set up where health app developers can seek advice, for instance on quality criteria.

Mapping antibodies in patient sera

Peptide phage display, next-generation sequencing and a new evaluation method allow detailed mapping of antibody epitopes even from sera in indications like allergies, infections or for vaccine development.

Plant antimicrobial peptides for the treatment of infections

Development of alternative therapeutic strategies to buck the trend of growing resistance to antibiotics.

Development of a modular light sheet microscope

The light sheet microscope achieves a higher resolution than other fluorescence microscopy procedures. The imaging procedure is especially gentle on samples and facilitates the examination of living, biological samples. This enables, for instance, the growth of organoids or the fine-tissue architecture of organotypic cultures to be monitored as a long-term process over the course of days or even weeks using 3D imaging.

Further information on the department and its projects can be found in the full version of the annual report on pages 34–45.

http://s.fhg.de/R75

DEPARTMENT OF CELL THERAPY

Cell therapeutic procedures are developed and validated in terms of their safety, feasibility and efficacy in the department. To this end, numerous model systems are maintained which enable the preclinical testing of innovative concepts under the strictest quality criteria. This ensures that the obtained results have a high predictive power with regard to their clinical application. Cell therapeutic procedures in the case of ischemic diseases such as stroke and myocardial infarction form a special focal area, while attention is also given to processes that might prevent cell degeneration and aging. Moreover, the »sleeping« potential of stem cells is also being investigated. The department offers isolation and purification procedures for cells derived from blood and tissue. Furthermore, special treatment procedures are being developed using T cell clones and natural killer cells as well as for tumor treatment.

Units

- Immunotherapy – Oncology, Christopher Oelkrug
- 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

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PROJECT EXAMPLES

3D rendering in modern imaging procedures

The creation of 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.

LEGASCREEN

Development of a multimodal early-screening test to diagnose dyslexia. This involves combining genetic tests and specific brain activity measurements (EEG) 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 46–52.

http://s.fhg.de/9Uu

DEPARTMENT OF DIAGNOSTICS

Within the Department of Diagnostics, the project RIBOLUTION - funded by the Fraunhofer Future Foundation - offers a comprehensive platform for the systematic identification and validation of novel diagnostic or prognostic biomarkers. Here, a particular focus is placed on the novel field of the so far underestimated noncoding RNAs that represent the majority of RNA molecules in human cells and exhibit high biomarker potential. For molecular diagnostics, a variety of state-of-the-art techniques are established, including genome-wide transcriptome, genome, and epigenome analyses (e.g. by next-generation sequencing or microarrays) as well as innovative immunoassays. Furthermore, a strong bioinformatics competency and a proprietary data management system are offered.

A wide variety of cell culture and animal models serve to study novel therapeutic approaches. In this context, the fields of tumor stem cells shows a high perspective for developing and testing novel cancer therapies in vitro or in preclinical models. Animal models for rheumatoid arthritis, asthma, and other chronic -inflammatory diseases allow studying the innovative therapy options. All in-vitro and in-vivo models are adaptable to the individual applications. In addition, xenogenous transplantation models are used to close the gap between model and patient.

The department develops novel molecular -diagnostic assay systems, e.g. on the basis of lab-on-the-chip platforms or strip-based rapid assays. In a market-oriented manner, these systems address companies that intend to simplify and integrate their (bio-)analytical competencies. Furthermore, we offer know-how for the development and approval of point-of-care laboratory diagnostic systems, which allow an autonomously operating health system.

Units and Heads of Department

- 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

Predicting the aggressiveness of prostate cancer

Identifying new biomarkers and developing a molecular diagnostic test to predict the aggressiveness of prostate cancer, aimed at helping support therapy decisions in future.

Programming the mechanical properties of biomaterials using DNA

DNA is primarily known for carrying genetic information. Thanks to its biochemical and biomechanical properties, however, DNA is also an extremely versatile biomaterial applied, among other things, in 3D cell cultures, bioreactor technologies, biosensor technologies, in transporting active agents and in the manufacture of functionalized nanoparticles.

Further information on the department and its projects can be found in the full version of the annual report on pages 53–61.

http://s.fhg.de/fqh

DEPARTMENT OF DRUG DESIGN AND TARGET VALIDATION

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.

Units and Heads of Department

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

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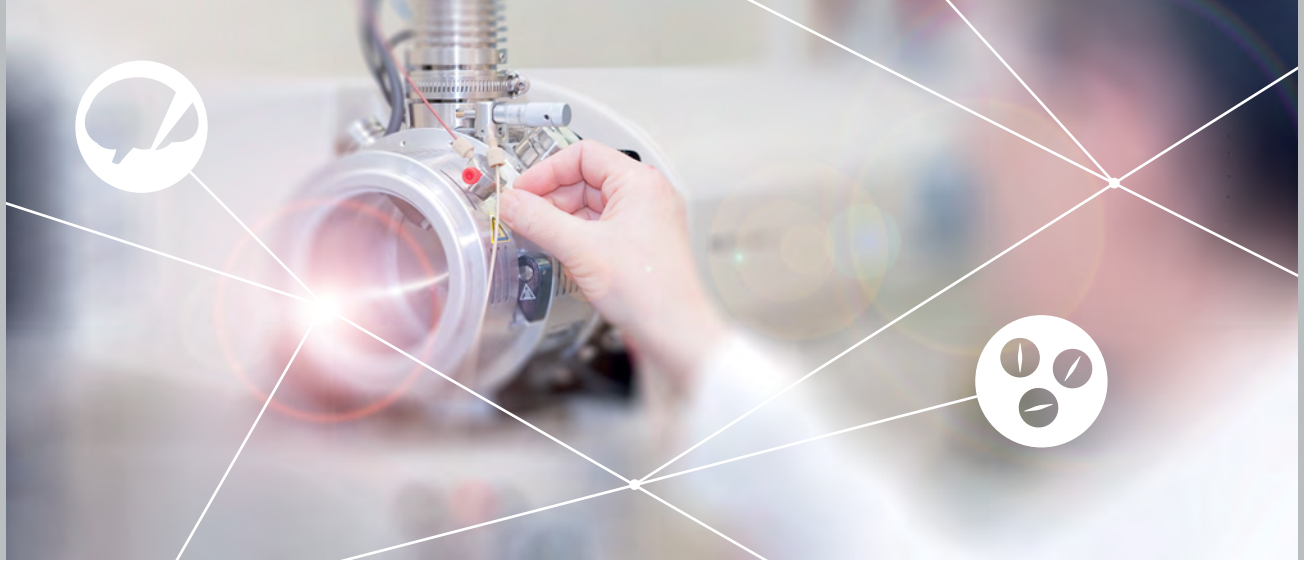

PROJECT EXAMPLES

Viral envelope proteins as new drug discovery targets

Examining the influence of endogenous, retroviral sequences in the genome on the emergence of cancer and autoimmune diseases. A special focus is placed here on the immunological properties of viral envelope proteins and their suitability as therapeutic targets for antibody-based drugs.

Interaction of amyloid peptides in neurodegenerative diseases

The misfolding and depositing of proteins in the brain is a typical feature of Parkinson's and Alzheimer's disease. Although different proteins are primarily responsible here, the underlying processes are similar. In some cases, both types of protein may even emerge in one patient. The project aims to investigate this hybrid form and derive new therapy concepts for both diseases.

Development of small molecules for the treatment of Alzheimer's

Alzheimer's disease is triggered by the accumulation of different proteins in the brain, especially amyloid beta peptide (Aβ). They damage the tissue and cause nerve cells to die off. The objective of this project is the preclinical development of active substances that prevent the formation of Aβ.

Further information on the department and its projects can be found in the full version of the annual report on pages 62–68.

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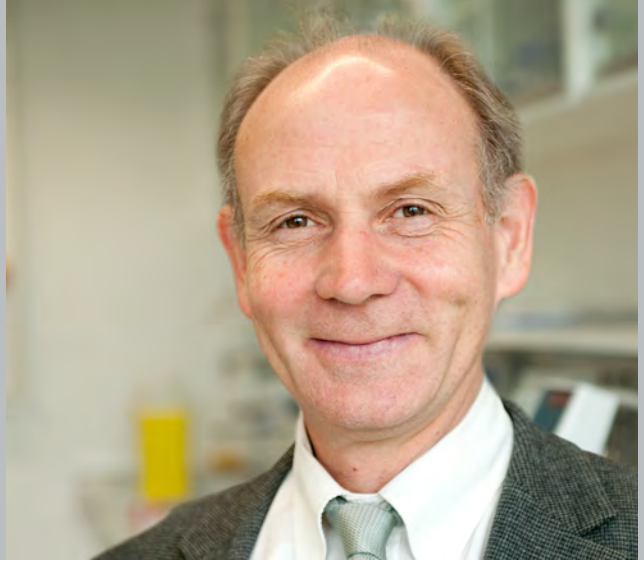

DEPARTMENT OF BIOSYSTEM INTEGRATION AND PROCESS AUTOMATION

The department delivers solutions for complex laboratory automation tasks in biotechnology. Work here focuses on processes related to cell culture, expansion and monitoring and aims at increasing the efficiency, quantity and quality of 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 kinds of ways in diagnostics and analytics.

Units and Heads of Department

- 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

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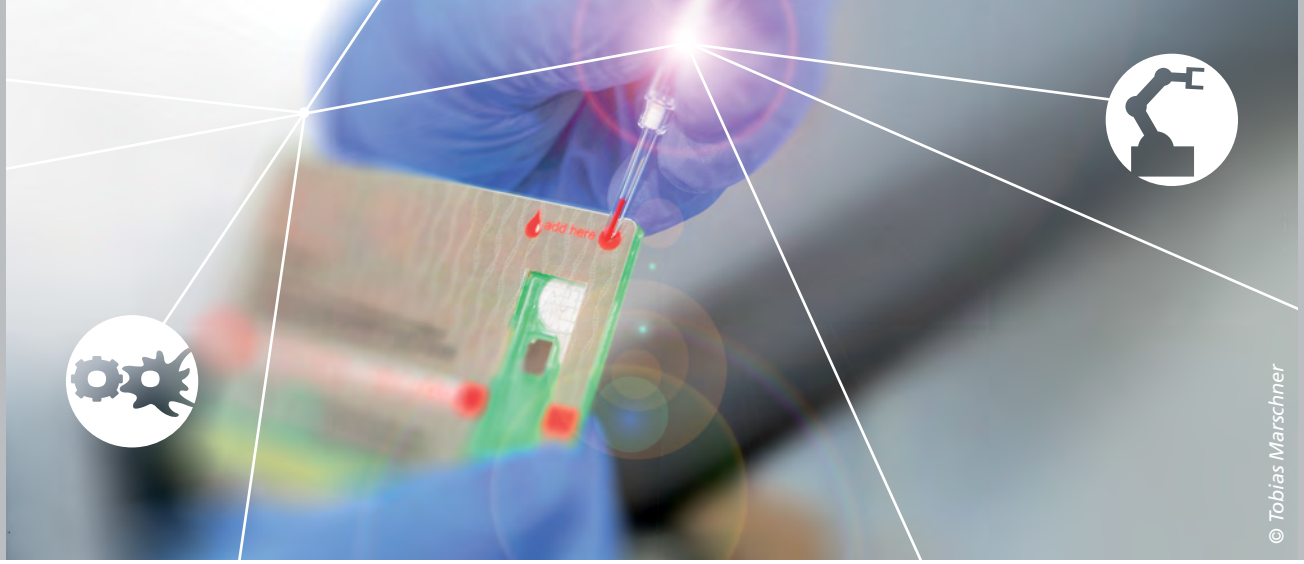

PROJECT EXAMPLES

Peptide-based subtyping of influenza viruses

The influenza virus has been the cause of annual flu epidemics for centuries. The viral strains in circulation around the world have to be recorded quickly and precisely in order for the WHO to give accurate vaccination recommendations. The analysis of viruses taken from patient samples has so far involved complex animal experiments. This project aims to reliably distinguish between the different viral strains using an automatable, molecular testing procedure that dispenses with the need for animal experiments.

Further information on the department and its projects can be found in the full version of the annual report on pages 69–73.

http://s.fhg.de/8rC

DEPARTMENT OF MOLECULAR AND CELLULAR BIOANALYTICS

This department is responsible for developing systems to detect, analyze and process demanding biological samples. These systems address problem areas in the fields of biomedicine, diagnostics, biotechnology, process control as well as environmental analytics, food safety and animal husbandry. The spectrum of 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 duties as establishing assays for the validation of biomarkers. Lab-on-a-Chip systems for cultivating, processing and analyzing cell samples present a further focus. They can be depended upon for carrying out long-term cultivation and toxicity tests on suitable cell clusters and for positioning solitary cells to the micrometer or for sorting heterogeneous cell populations. All of the department's tasks 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. Solid molecular and cell biology expertise enable the targeted use of these technological capacities. 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 also facilitates and supports the web-based case-by-case and sample-by-sample search for human biospecimens and associated data across institutional and national borders.

Units and Heads of Department

- 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

Rapid test for germ load and resistance monitoring

The emergence of bacterial strains that are resistant to almost all known antibiotics is putting patients and consumers at an ever growing risk in the 21st century. The aim of the project is to develop a multiparametric rapid test for germ load and/or resistance monitoring. In doing this, applications are also set to be developed in the areas of health care, animal husbandry and the food sector.

Analyzing post-translational protein modifications

Development of microarrays to analyze post-translational modifications, with the emphasis on kinases and potential inhibitors.

Antimicrobial surfaces in milk production

Development of a rapid test to review germ load on relevant surfaces relevant to 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.

Innovative test stations for dynamic hemocompatibility testing

Development of in-vitro testing systems to assess the hemocompatibility of cardiovascular implants and their coatings under controlled shear and flow conditions.

Further information on the department and its projects can be found in the full version of the annual report on pages 74–83.

http://s.fhg.de/9Yb

DEPARTMENT OF CELL-FREE AND CELL-BASED BIOPRODUCTION

Conservation of resources and creating more efficient material flows are the current challenges facing the economy and technological development. Particularly in the field of health, a sufficient and cost-effective availability of high-quality synthetic products is an important basis for progress. For instance, highly complex proteinogenic active ingredients are the basis for vaccine and antibody development. But in food technology as well as in the agricultural, cosmetics and detergent industries, requirements are continuously increasing on enzymes, complex peptides and proteins or on synthetic biomolecules in general. Currently, these substances are often manufactured with the help of living cells or organisms. However, these systems are subject to considerable limitations. A large material and energy input must be spent to maintain the metabolism of the microorganisms or cell cultures themselves, thus limiting the cost effectiveness of this approach. In addition, many metabolites and final products are toxic, or have a toxic effect on cells or organisms in higher concentrations necessary for economical production . Therefore many important substances cannot be manufactured at all or only in small quantities.

The development of cell-free production of high-quality biomolecules offers completely new possibilities. The exclusive use of subcelluar components of the organisms necessary for the synthesis makes it possible to efficiently produce biomolecules with complex and also completely new characteristics in suitable reaction environments. The technologies established at the Golm site allow an economically efficient use of these processes, thereby creating a new foundation for the economic production of active proteins.

The department's extremophile research is engaged with cold-adapted snow algae. We focus on their use for extracting high-quality substances such as antioxidants or fatty acids. Accompanying product-optimised photobioreactors are also being developed. The culture collection CCCryo is a unique bio-resource that can be used by interested academic and private enterprise groups.

Units and Heads of Department

- 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

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PROJECT EXAMPLES

APTAMASTER

Development of an automated system to monitor wastewater from sewage disposal facilities in terms of drug residues and organic trace elements following the fourth treatment stage. The aim here is to remove drug residues from wastewater, thereby reducing the risks posed to humans and the environment.

CCCryo algae in space

Coordinated by the German Aerospace Center, the BIOMEX (Biology and Mars Experiment) project is researching whether there might be life beyond our planet. To this end, the survival capability of various organisms taken from diverse, extreme environments was examined on the outer skin of the International Space Station, where they were exposed to significant temperature variations, vacuum conditions, aridity and UVs A, B and C besides cosmic radiation. The organisms consisted of various algae strains taken from the Fraunhofer IZI in Potsdam/Golm. And the result? They survived!

Further information on the department and its projects can be found in the full version of the annual report on pages 84–89.

http://s.fhg.de/8Uq

CENTRAL FACILITIES AND SERVICES

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

A


B

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 µm 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)

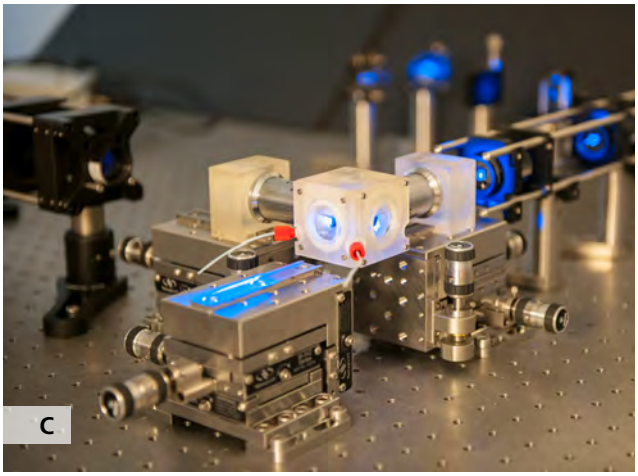
- Label-free methods of depicting the distribution of macro molecules in histological samples based on their degree of ionization and time of flight (TOF) in the electric field; special sample preparation and matrix application required, statistical evaluation of distribution patterns

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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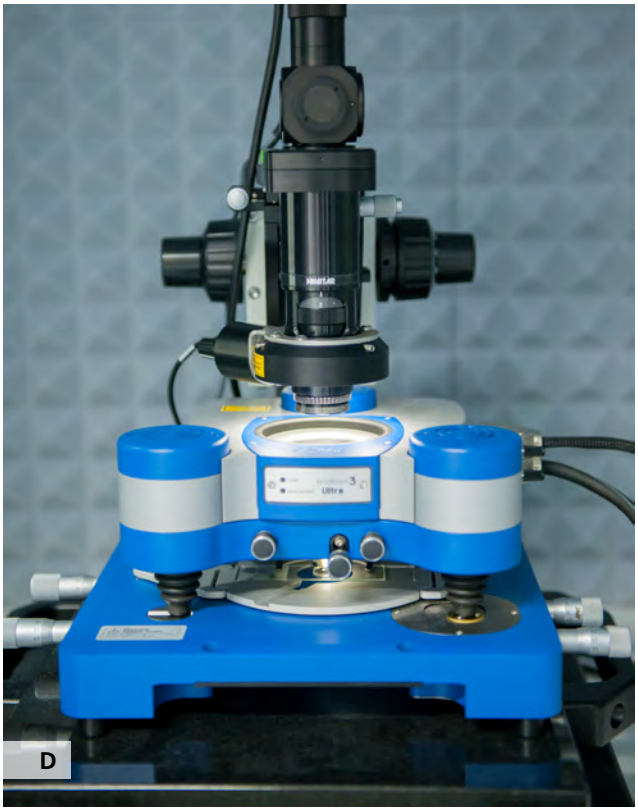
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Individual image evaluation and analysis

With increasing automation and associated quantitative imaging comes a rise in the demand for image analysis which is just as automated and robust. Fraunhofer IZI is highly experienced in the fields of cytometry and histometry (especially using mathematical morphometry), as well as statistical classification procedures in the quantitative microscopy segment. In this regard, our portfolio comprises individually tailored 2D and 3D image analysis methods, shape analyses (eigenshapes, various shape descriptors, topological descriptors), motility / vitality analyses (e. g. by means of fluid registration), topological tissue analyses (speckle pattern statistics) besides biostatistical analyses. Procedures taken from machine learning are used here, for example to detect cells in 3D fluorescent images.

BIO-NANOTECHNOLOGY APPLICATION LABORATORY (BNAL)

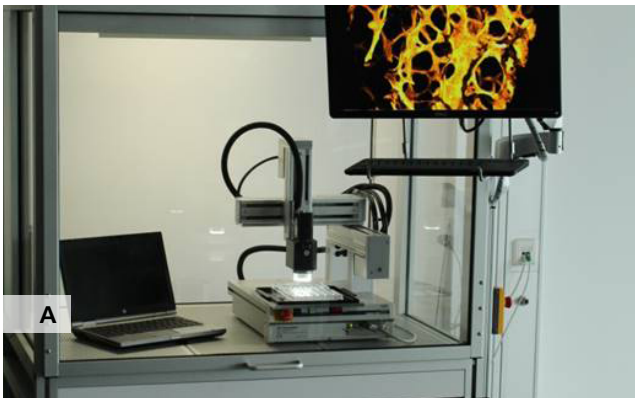
The Bio-Nanotechnology Application Laboratory (BNAL) in Leipzig represents a research infrastructure jointly run by Fraunhofer IZI and Fraunhofer IKTS. With this laboratory, both institutes are opening up new fields of application in biomedicine related to various nanotechnologies.

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 neurodegenerative 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.



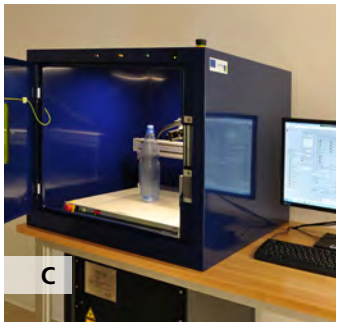
Cell characterization and classification

- 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.

B

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.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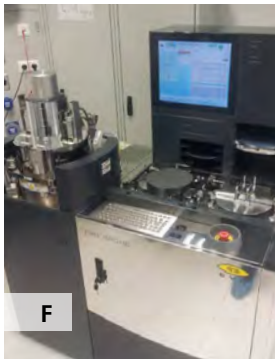
D

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.
- 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.


E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CENTER FOR EXPERIMENTAL MEDICINE (TEZ)

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 stateof-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

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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.


A

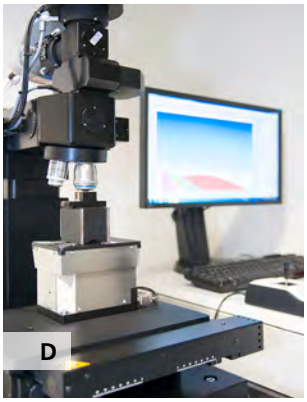

B

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


E

F

- 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

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.

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.

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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.

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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 transport) 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-based therapeutics (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 authorization according to § 13 of the German Drug Act (AMG).

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Why are GMP and GLP 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 Arznei mittel und Medizinprodukte", Federal Institute for Drugs and Medical Devices, Paul-Ehrlich-Institut) and by the responsible ethics commission 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 pre-clinical investigations (e. g. toxicological testing procedures). Furthermore, the quality of manufacture of the investigational medicinal products must be verified by a GMP manufacturing authorization 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 involv ed in the trial including the sponsor, monitor, CRO, primary investigator and ethics committee or intuitional 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.

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LOCATIONS


LEIPZIG
POTSDAM
HALLE
ROSTOCK
GERMANY
HAMILTON
CANADA
GWANGJU
SOUTH
KOREA

THE FRAUNHOFER IZI IN GERMANY AND AROUND THE WORLD

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Extracorporeal Immunomodulation (EXIM) Project Group in Rostock, Mecklenburg-Western Pomerania

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Fraunhofer Project Center for Biomedical Engineering and Advanced Manufacturing (BEAM) at McMaster University, Hamilton, Ontario, Canada

JLCI – Joint Laboratory of Chonnam National University Hospital Hwasun in collaboration with Fraunhofer IZI in Gwangju, Jeollanam-do, South Korea

Please visit our website for directions to the respective sites and for additional contact information
www.izi.fraunhofer.de/en/contact.html

LEIPZIG HEADQUARTERS, SAXONY

Usable area: 8 749 m²
Employees: 395
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 m².

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

Usable area: 4 096 m²
Employees: 107
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 (CCCryo), which serves as a resource for developing production processes for novel, industrial bioproducts.

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

Usable area: 1 300 m²
Employees: 60
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.

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EXTRACORPOREAL IMMUNOMODULATION PROJECT GROUP IN ROSTOCK, MECKLENBURG-WESTERN POMERANIA

Usable area: 700 m²
Employees: 26
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.

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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. On the back of these efforts, initial joint research projects were set up with McMaster University in Hamilton (Ontario, Canada). With approximately 29,000 students, the university is among the leading universities in Canada, with exceptional strengths in health sciences, engineering and natural sciences.

Based on the success of ongoing cooperation projects, the Fraunhofer-Gesellschaft took the decision in 2014 to set up a Fraunhofer Project Center (FPC) at McMaster University. The FPC is jointly managed by McMaster and Fraunhofer senior managers and is devoted to applied research in the business units Diagnostics, Automation, Cell Therapeutics and Biomaterials. In setting up the FPC, both partners aim to collectively develop innovative products and technologies by combining specific technological strengths from both sides. In addition, the FPC helps establish German and Canadian companies and supports the development of business activities in the respective partner country.

Since 2014, the FPC managed to attract significant funding on both the German and Canadian side as well as a series of industry collaboration projects. The total funding acquired from 2014 to 2016 was about 25 million CAD.

This is including FedDev funding in the sum of approx. 12 million CAD for the construction of a joint research building in the McMaster Innovation Park. The building is due to open at the start of 2018. Covering a usable area of approx. 2,000m² it will provide joint German-Canadian research units and research subsidiaries of industrial companies with an outstanding, state-of-the-art research infrastructure.

In the second half of 2016, the FPC successfully passed its mid-term evaluation with excellent results. Subsequently and in a stepwise process, the founding team and BEAM management (Dr. Thomas Tradler and Christopher Oelkrug) handed over responsibility to a new management team.

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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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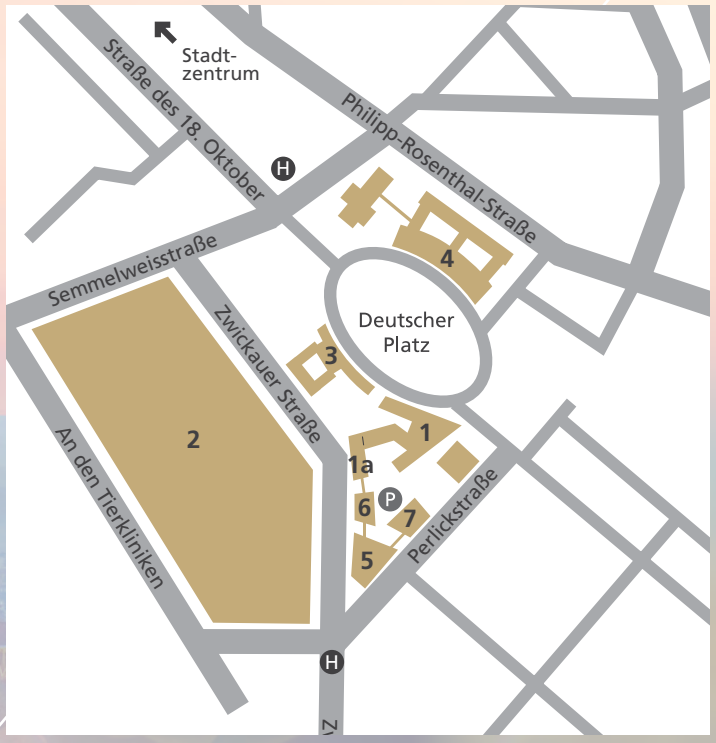
SCIENCE LOCATION LEIPZIG



BIO CITY (1) with hired Fraunhofer IZI area (1a), Faculty of Veterinary Medicine, institutes and hospitals (2), Max Planck Institute for Evolutionary Anthropology (3), German National Library (4), Fraunhofer IZI (5), first extension building Fraunhofer IZI (6), second extension building Fraunhofer IZI (7).

LEIPZIG AND THE FORMER TRADE FAIR

The Fraunhofer Institute for Cell Therapy and Immunology IZI is located on the former trade fair grounds in the south-east of the city of Leipzig. Close cooperation with the nearby facilities of the Leipzig University and the companies of the BIO CITY Leipzig is maintained.

Location: Central for interface partners

The Fraunhofer Institute for Cell Therapy and Immunology IZI is located on the former trade fair grounds in the south-east of the city of Leipzig. The institute's premises are only about a ten-minute drive away from the city center and can easily be reached with public transport. Moreover, many of the already established and potential future cooperation partners are located in the immediate vicinity. Among these are, for example, the BIO CITY Leipzig, the Max Planck Institute for Evolutionary Anthropology, the clinics and institutes of the Medical Faculty, the Chemistry Faculty, the Physics Faculty, the Veterinary Medicine Faculty, as well as the Faculty of Life Sciences, Pharmacy and Psychology.

BIO CITY Leipzig: A potent neighbor

The BIO CITY Leipzig unites university and industry-related research under one roof. It houses, for instance, the Bio technological-Biomedical Center (BBZ) of the Leipzig University and has available space for industrial settlements in the vicinity. More than 25 cell technology companies including VITA34 International AG, Haemabank AG and Curacyte AG are already located there. Cooperations with the Fraunhofer IZI have been established in the fields of cell engineering and applied stem cell biology, bioprocess engineering, protein structure analysis, mass spectroscopy, molecular cell therapy and molecular pathogenesis.

Integrated universities

The academic landscape within Leipzig also benefits from cooperation with the Fraunhofer IZI: The Leipzig University, the Leipzig University of Applied Science (HWTK) and the Graduate School of Management (HHL) have found in the Fraunhofer IZI a strong partner for research cooperations and the development of joint programs for teaching and advanced vocational training, which enhance local attractiveness from an economic and scientific point of view. Thus, for example, students of business administration from the HHL have already been successfully involved in practical scientific projects with their development of business plans or marketing concepts. A particularly intensive cooperation connects the Fraunhofer IZI and the Institute for Clinical Immunology of the University Leipzig.

The outstanding collaboration work with the Faculty of Veterinary Medicine and its institutes and clinics directly opposite the Fraunhofer IZI building deserves special mention. Research involving animal experiments does not only serve the development of new products for human medicine, but also contributes to the development of new diagnostic and therapeutic procedures in veterinary medicine.

The Faculty of Medicine has traditionally been an extremely important partner with many interactions, also in teaching and advanced education. The Fraunhofer IZI has been working closely together with institutional and clinical areas of radiology, nuclear medicine and diagnostics for several years now in order to develop sophisticated imaging procedures for large animal models.

Numerous partners in the immediate vicinity

The neighboring partners of the Leipzig University are, among others, the Medical Faculty, the Veterinary Medicine Faculty, and the University Hospital. Further institutions relevant for cooperation are the Heart Center Leipzig GmbH, the Helmholtz Center for Environmental Research (UFZ), the Leibniz Institute for Surface Modification (IOM), the Interdisciplinary Center for Bioinformatics (IZBI), the Center for Clinical Trials Leipzig GmbH (ZKS), the Institute for Clinical Immunology, the Center for Biotechnology and Biomedicine (BBZ), and the Max Planck Institute for Human Cognitive and Brain Sciences. Moreover, there are numerous interfaces with different special research areas that are located in Leipzig.

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 2016.

January 21, 2016: Leipzig Fraunhofer Institutes' Joint New Year's Reception
Fraunhofer IMW and Fraunhofer IZI welcomed around 100 guests from politics, science and business in Leipzig's Städtisches Kaufhaus.

January 26, 2016: Immunology Workshop together with the University of Potsdam
Scientific exchange between colleagues from Potsdam University and Fraunhofer IZI on various topics within the field of immunology.

April 14–15, 2016: Fraunhofer Life Science Symposium
Around 200 animal care supervisors, experimenters, animal house directors, veterinarians and animal rights campaigners came together at the joint symposium held by Fraunhofer IZI and the Society of Laboratory Animal Science to share their opinions on the topic of animal models in research.

April 19–22, 2016: 9th International Symposium on Neuroprotection and Neurorepair
Around 400 guests from the fields of research, medicine and business discussed the latest findings related to neurodegenerative diseases.
www.neurorepair-2016.de

April 26–27, 2016: German Biotechnology Days (DBT)
The Fraunhofer IZI held a talk to introduce the German biotechnology industry to its major project, RIBOLUTION, and also manned an information stand.
www.biotechnologietage.de

April 28, 2016: Girls' Day at the Fraunhofer IZI
Female scientists from the Fraunhofer IZI gave interested young women a sneak peek into the world of biomedical research.
www.girls-day.de

June 16, 2016: Science Day
Internal symposium where the Fraunhofer IZI's technologies, expertise and projects are presented and discussed among colleagues.

June 24, 2016: Long Night of the Sciences – bringing light into the darkness
Curious visitors were invited to learn about the latest research topics and projects at the Fraunhofer IZI until late into the night.
www.wissenschaftsnacht-leipzig.de

October 1–3, 2016: German Unification Day in Dresden
The Fraunhofer IZI gave interested members of the public a deeper insight into its research topics at a dedicated stand to mark the public celebration.
www.tag-der-deutschen-einheit.sachsen.de

Looking to 2017

- January 19, 2017: New Year reception
- April 27, 2017: Girls'Day 2017, www.girls-day.de
- June 22, 2017: Science Day
- September 8–10, 2017: 18th International Symposium on Albumin Dialysis (ISAD), www.albumin-dialysis.org
- November 8–9, 2017: Fraunhofer Life Science Symposium, www.fs-leipzig.com

Further information on the events can be found in the full version of the annual report on pages 113–117.
http://s.fhg.de/Cqm

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

Freistaat Sachsen

LEIPZIG

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) (President Europe & Immunology Group Nuvo Research Inc.)
- 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, Vice President Bioprocess Sales Europe)
- Klaus Berka (Analytik Jena AG, Chairman)
- 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 (TU Berlin / TissUse GmbH)
- Dr. Kai Pinkernell (Medigene AG)
- Prof. Dr. Andreas Pinkwart (HHL Leipzig Graduate School of Management, Dean)
- 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

At present, the Fraunhofer-Gesellschaft maintains 69 institutes and research units. The majority of the nearly 24,500 staff are qualified scientists and engineers, who work with an annual research budget of more than 2.1 billion euros. Of this sum, more than 1.9 billion euros is generated through contract research. More than 70 percent of the Fraunhofer-Gesellschaft's contract research revenue is derived from contracts with industry and from publicly financed research projects. Almost 30 percent is contributed by the German federal and Länder 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.

Executive board

- Prof. Dr.-Ing. Reimund Neugebauer, President, Corporate Policy and Research Management
- Prof. Dr. Georg Rosenfeld, Technology Marketing and Business Models
- Prof. Dr. Alexander Kurz, Human Resources, Legal Affairs and IP Management
- Prof. (Univ. Stellenbosch) Dr. Alfred Gossner, Finance, Controlling (incl. Business Administration, Purchasing and Real Estate) and Information Systems

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