



Fraunhofer

IZI

FRAUNHOFER INSTITUTE FOR CELL THERAPY AND IMMUNOLOGY IZI



ANNUAL REPORT
2017

ANNUAL REPORT
2017

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PREFACE



PROF. DR. FRANK EMMRICH

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

In 2017, the Fraunhofer-Gesellschaft was granted additional funding from the government and Länder, enabling it to launch new funding models. These came in the form of large-scale collaboration projects which were put out for tender in the usual way: as part of demanding internal competitions. The institute is proud to have succeeded in the final round of every one of the new funding models. Special mention here goes to the Chemical and Biosystems Engineering Center (CBS) in Halle/Leipzig, the ImmuVision project cluster and the Microelectronic and Optical Systems for Biomedicine project center in Erfurt, the latter of which is being set up together with Fraunhofer IPMS in Dresden and Fraunhofer IOF in Jena and receiving funding in the total value of 35 million euros over a five-year period. Together with the Helmholtz Association and university medical departments, Fraunhofer announced a competition to fund proof-of-concept platforms, with 3 million euros allocated to each platform. After an intensive evaluation period, just four of a total of 82 project proposals were granted funding, two of which involve Fraunhofer IZI.

The institute also surpassed itself in the more traditional competitive project formats announced by the Fraunhofer-Gesellschaft such as MAVO (Market-Driven Prospective Research) and MEF (Internal SME-Oriented Research) and was

able to win three new and innovative collaboration projects in both formats. All these accomplishments are indicative of the high quality, reputation and outstanding networking of the project leaders and their teams.

Colleagues from the Department of GMP Cell and Gene Therapy were especially successful, managing to win huge R&D projects from international pharma and biotech companies. Last year, under the management of Dr Gerno Schmiedeknecht, this division was awarded the status of a main department; it now employs almost 100 members of staff in Leipzig. High-quality cell and tissue products for the clinical testing of innovative cell and tissue therapies are manufactured here at the requisite pharmaceutical quality.

The institute's management team has always placed emphasis on promoting female employees, who now make up 60 per cent of our staff. For many years now, the Fraunhofer-Gesellschaft has run a multi-tiered funding program that provides for a pro-rata subsidy applicable to the personnel costs of particularly qualified and high-performing female research staff. At present across the entire institute, 25 young women are receiving support through one of the three TALENTA formats START, SPEED UP and EXCELLENCE.

In August 2017, Fraunhofer IZI got to work setting up a research unit at Monash University, Australia, in cooperation with the ARC Centre of Excellence in Advanced Molecular Imaging. The scientific focus of joint research activities in the future will first be placed on molecular imaging and structure determination. Alternating extended stays for visiting German and Australian researchers, joint workshops and also symposiums are planned to be held over the next few months and years with an eye to boosting scientific exchange and getting cooperation projects off the ground.

Furthermore, existing working groups were successfully evaluated, securing not only their funding for the next two years but also their long-term prospects. This was the case, for instance, for the Image Analysis of Cell Function specialist group, which the Fraunhofer IZI has been supporting since 2014 together with Leipzig University of Applied Sciences (HTWK). The evaluation committee, made up of representatives from science, business and politics, attested to the outstanding work carried out by the team headed up by Professor Ulf-Dietrich Braumann during this early phase and unanimously recommended that the specialist group continue in its work. The group's outstanding commitment to the teaching and training of young scientists also received special mention.

Similarly, the successful outcome of an external evaluation of the EXIM (Extracorporeal Immunomodulation) Unit in Rostock means it will receive bridge financing from the state of Mecklenburg-Western Pomerania and the University of Rostock for the next two years until its permanent affiliation with the Fraunhofer Institute is clarified.

Besides all of this, the next few pages will also highlight a number of interesting projects involving the institute's various sites in the reporting year. Follow the links to our homepage

(www.izi.fraunhofer.de/en) to find more information on other projects and services offered by the various research departments.

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

My most sincere thanks and respect goes out to all our members of staff and everyone who has supported us on our journey and contributed towards the remarkable success of the institute and its superb form to date. I would like to wish my successor and all my colleagues the very best for the future and I will still be happy to provide advice and support as and when required. I hope that everyone reading this report will make some interesting discoveries while flicking through its pages. Thank you for your interest in our institute.

Best wishes

Yours



Prof. Dr. Frank Emmrich

NEW INSTITUTE MANAGEMENT



NEW INSTITUTE MANAGEMENT

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

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

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

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

With her appointment in Leipzig, the institute expects in particular to strengthen the connection with the University Cancer Center Leipzig (UCCL). This would accelerate the pace at which innovative treatment and diagnosis methods are put into practice to treat cancer patients. The aim here is to continue to establish Leipzig as a leading center for the development and clinical testing of cell and gene therapeutics, aided by the spatial and personal proximity between university and non-university research organizations.

By expanding cooperations with further clinical and industrial partners, however, more research can also be carried out on new immune monitoring technologies, functional assays and companion diagnostics in future, while automated manufacturing processes are also to be developed.

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

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

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

STRUCTURES AND FIGURES 2017



PORTRAIT OF THE INSTITUTE

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

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

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

General topic: Cell therapy and immunology

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

This builds a bridge to immunology, which is concerned with cellular defense and control mechanisms. It is expected that cell therapeutic methods for targeted enhancement, suppression or regeneration of the immune system will soon be available, e. g. for stimulating the defense mechanisms

of degenerate cells or for suppressing undesired graft-versus-host reactions against grafted tissue. In addition, the further development of immunomodulatory techniques, e. g. vaccination, is of particular importance.

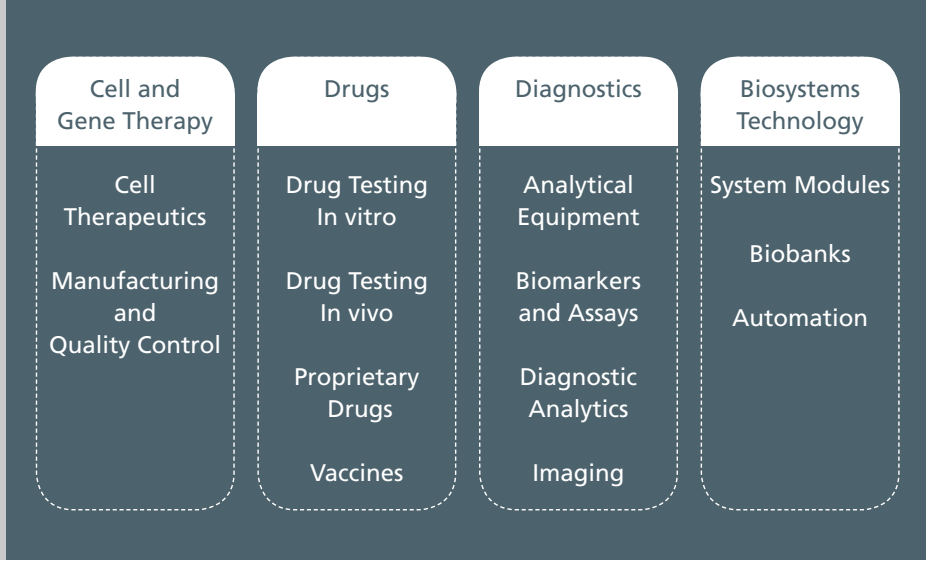
The institute's tasks

The institute operates five sites. The departments GMP Cell and Gene Therapy, Therapy Validation, Immunology, Cell Therapy and Diagnostics are based at the Leipzig headquarters. The Potsdam-Golm branch is home to the departments Biosystem Integration and Process Automation, Cellular Biotechnology, Molecular and Cellular Bioanalytics as well as Cell-free and Cell-based Bioproduction. Additional off-site departments are located in Halle (Saale), Rostock and Erfurt. Different units thus represent a broad spectrum of expertise and qualifications.

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

The institute's core competences lie in the fields of cell biology, immunology, drug biochemistry, bioanalytics,

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



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

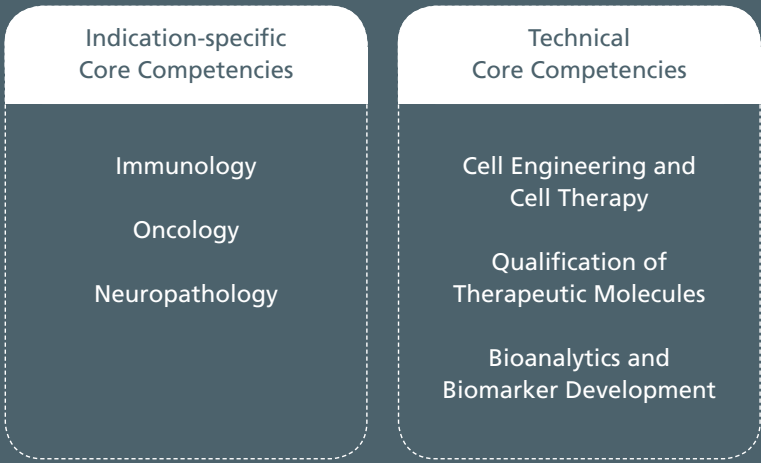
Fraunhofer IZI's Drugs Business Unit represents large parts of the preclinical value chain relating to drug and vaccine development and is subdivided into the business fields Drug Testing (in vitro and in vivo), Proprietary Drugs, and Vaccines. With regard to drug testing, development services in the 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 conse-

quence, 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.

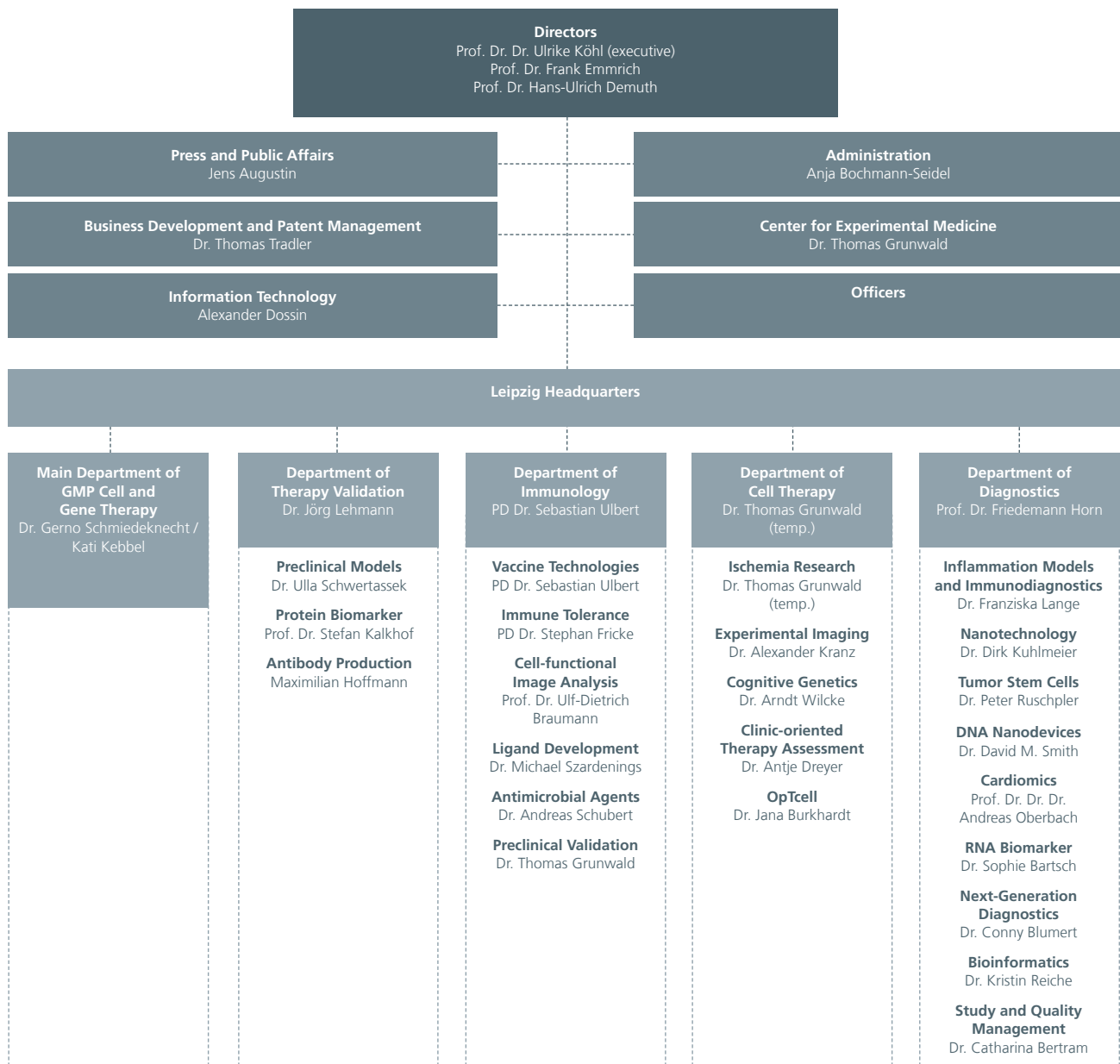
The core competence **Qualification of Therapeutic Molecules** pools together all of the competencies available at Fraunhofer IZI in close connection with drug development. The classes of therapeutic molecules addressed here include small, organic molecules and peptides as well as therapeutic macromolecules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



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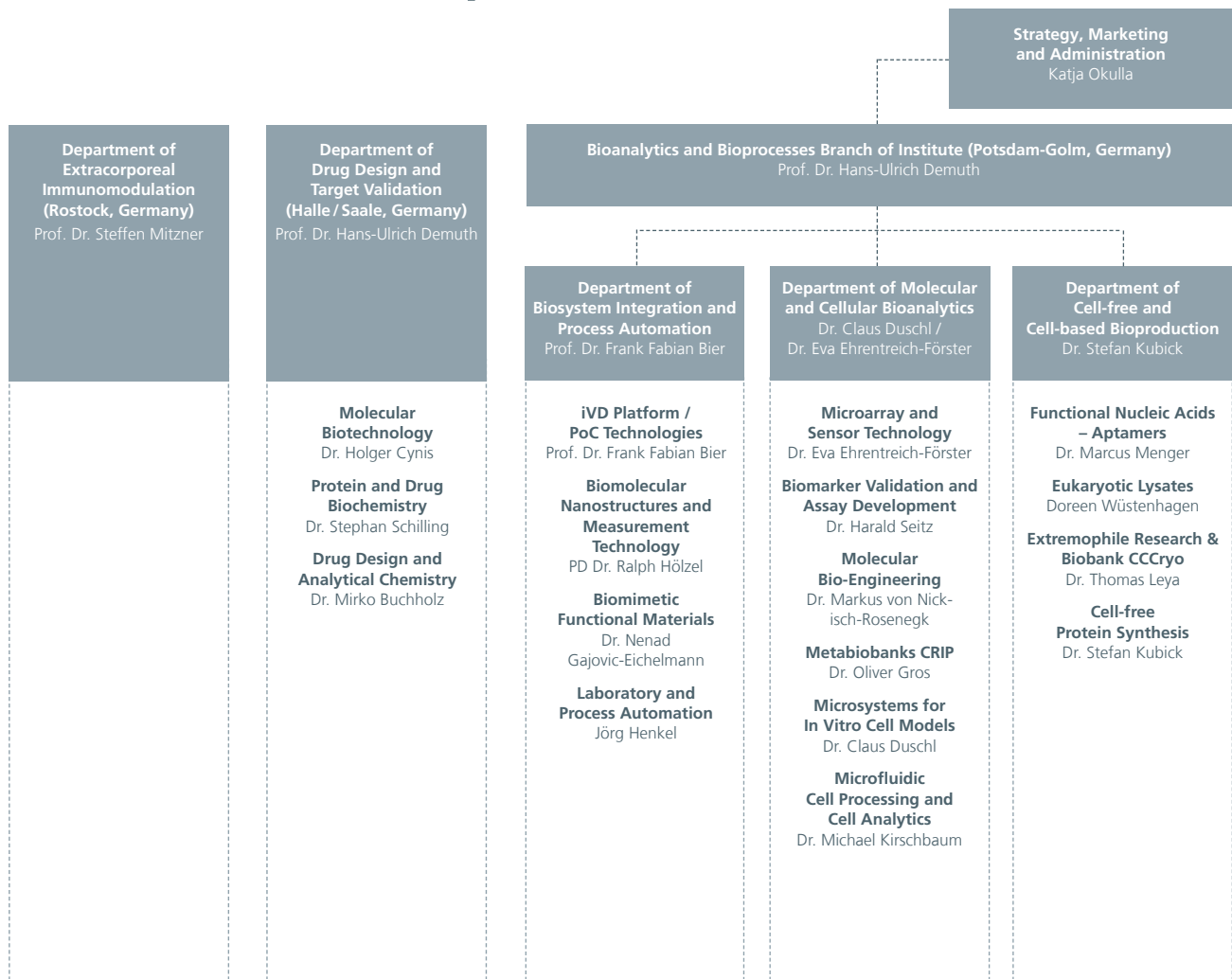
ORGANIZATION LEIPZIG*, GERMANY



* January 2018



ORGANIZATION BRANCHES* ROSTOCK / HALLE (SAALE) / POTSDAM-GOLM, GERMANY



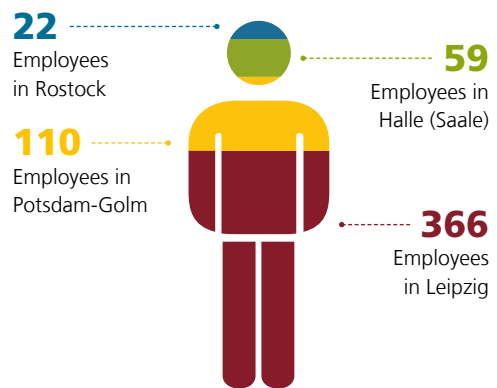
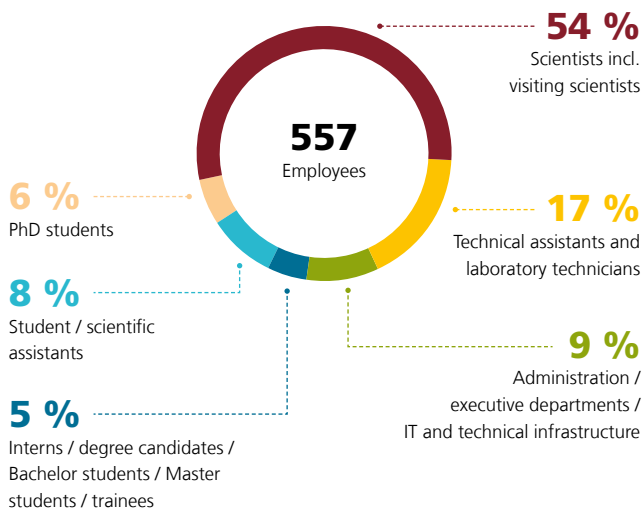
* January 2018

- 1 Rostock, Germany
- 2 Halle (Saale), Germany
- 3 Potsdam-Golm, Germany

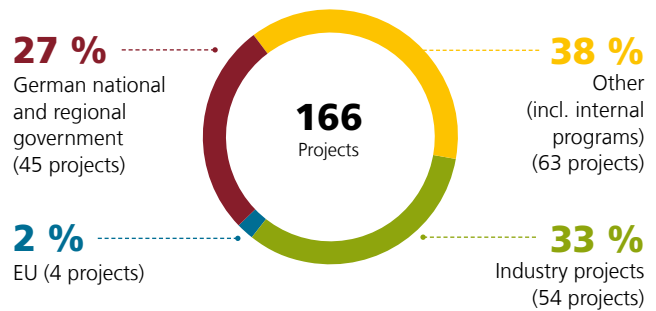
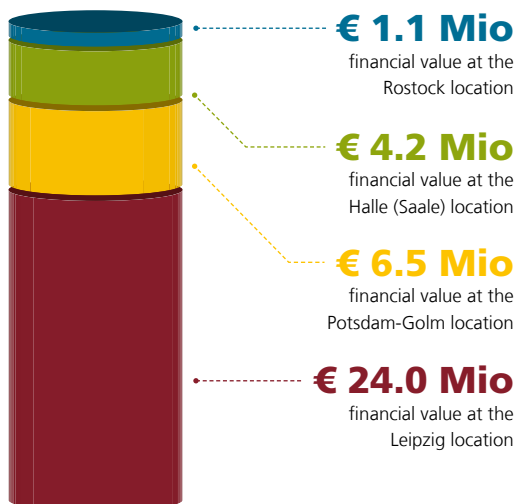


GROWTH AND PERFORMANCE

KEY INSTITUTE FIGURES 2017*



€ 35.8 Mio
financial value

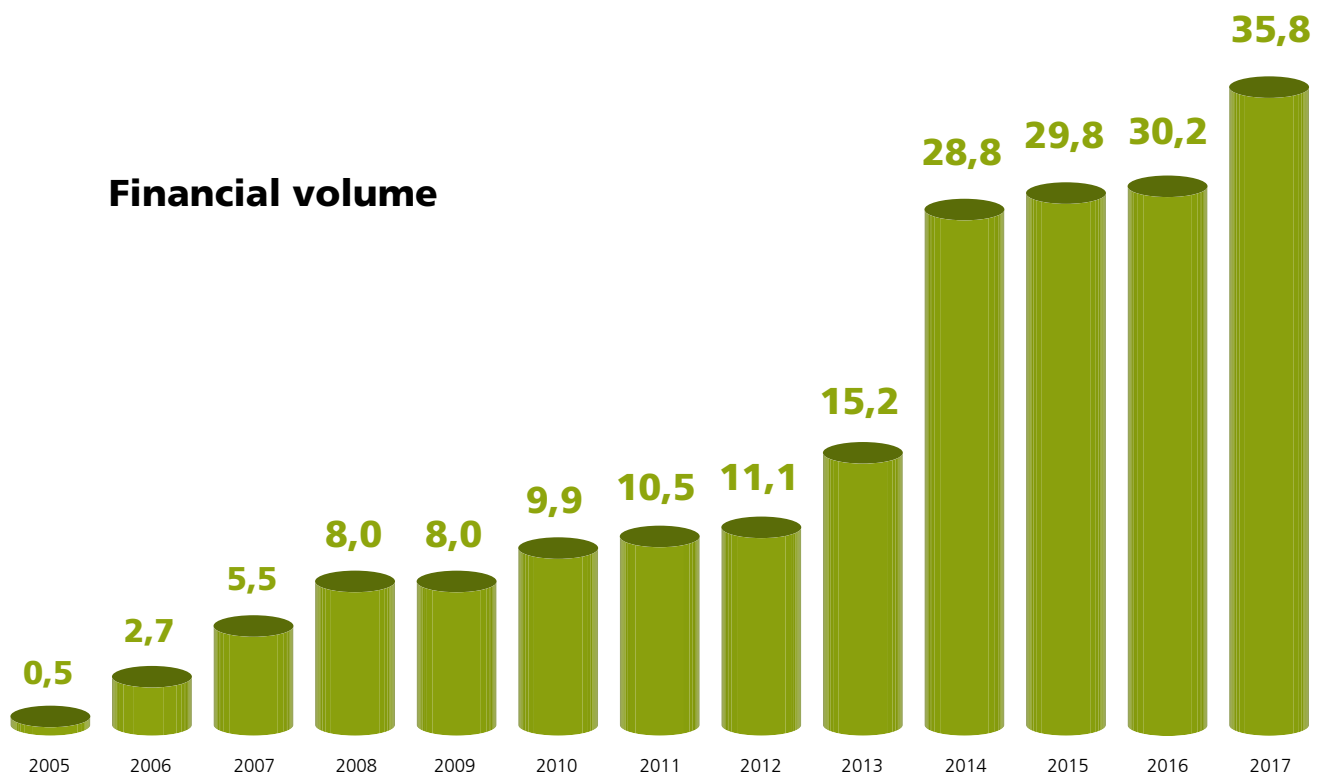


Project revenue 2017 in kEUR

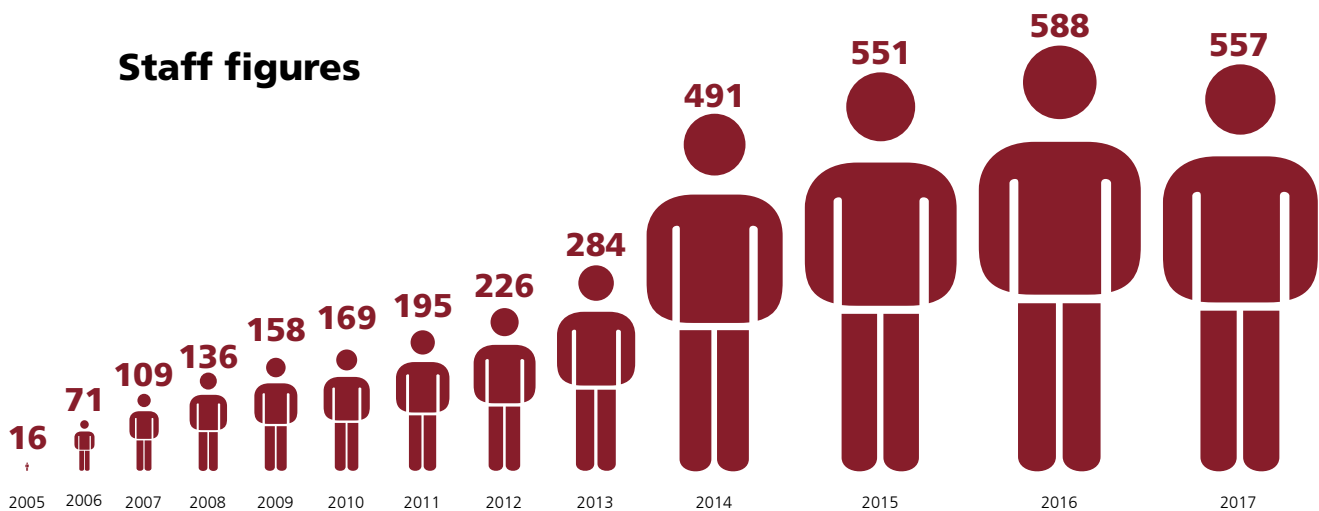
	Leipzig	Halle	Potsdam	Rostock	Total
German national and regional government	1 440	3 200	2 520	950	8 110
EU	50	70	183	0	303
Industry projects	10 900	620	1 130	160	12 810
Other (incl. internal programs)	5 934	310	986	6	7 236
Total	18 324	4 200	4 819	1 116	28 459

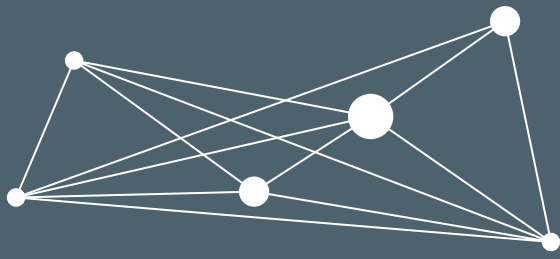
* as at 2017 / 12 / 31

Financial volume



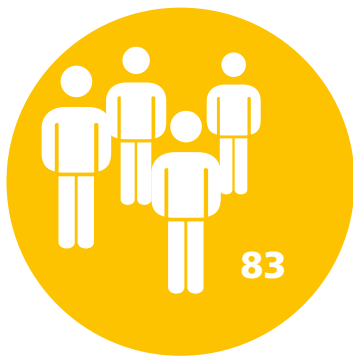
Staff figures





SCIENTIFIC EXCELLENCE
DIVERSITY
NETWORK

SCIENTIFIC PRESENCE AND NETWORK 2017



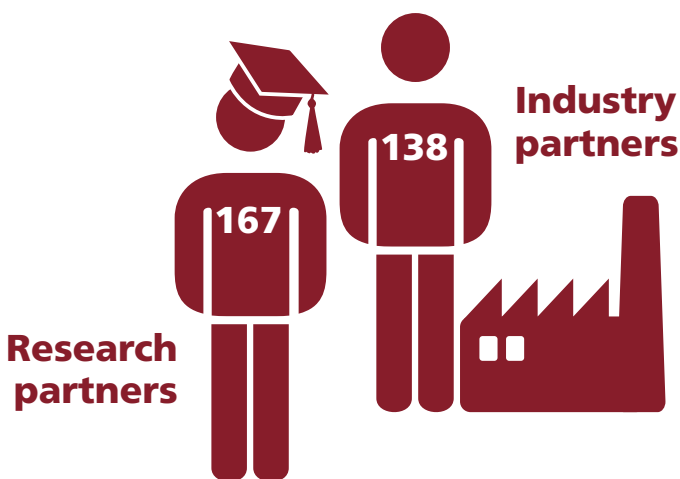
Conventions and
conferences

Published
abstracts



Publications

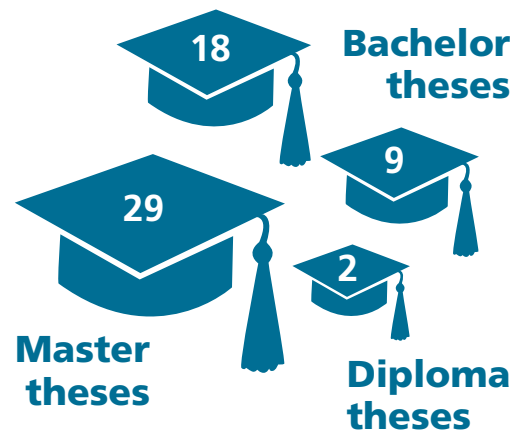
Book
articles



Research
partners

Industry
partners

Doctorates

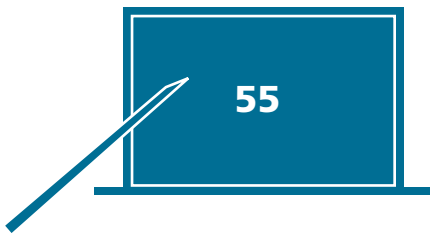


Master
theses

Bachelor
theses

Diploma
theses

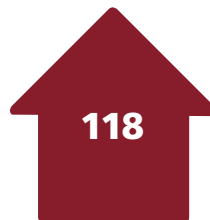
Teaching activities



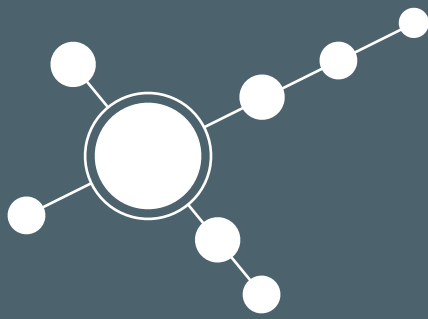
Evaluator activities



Patent families with 146 Patents and patent applications

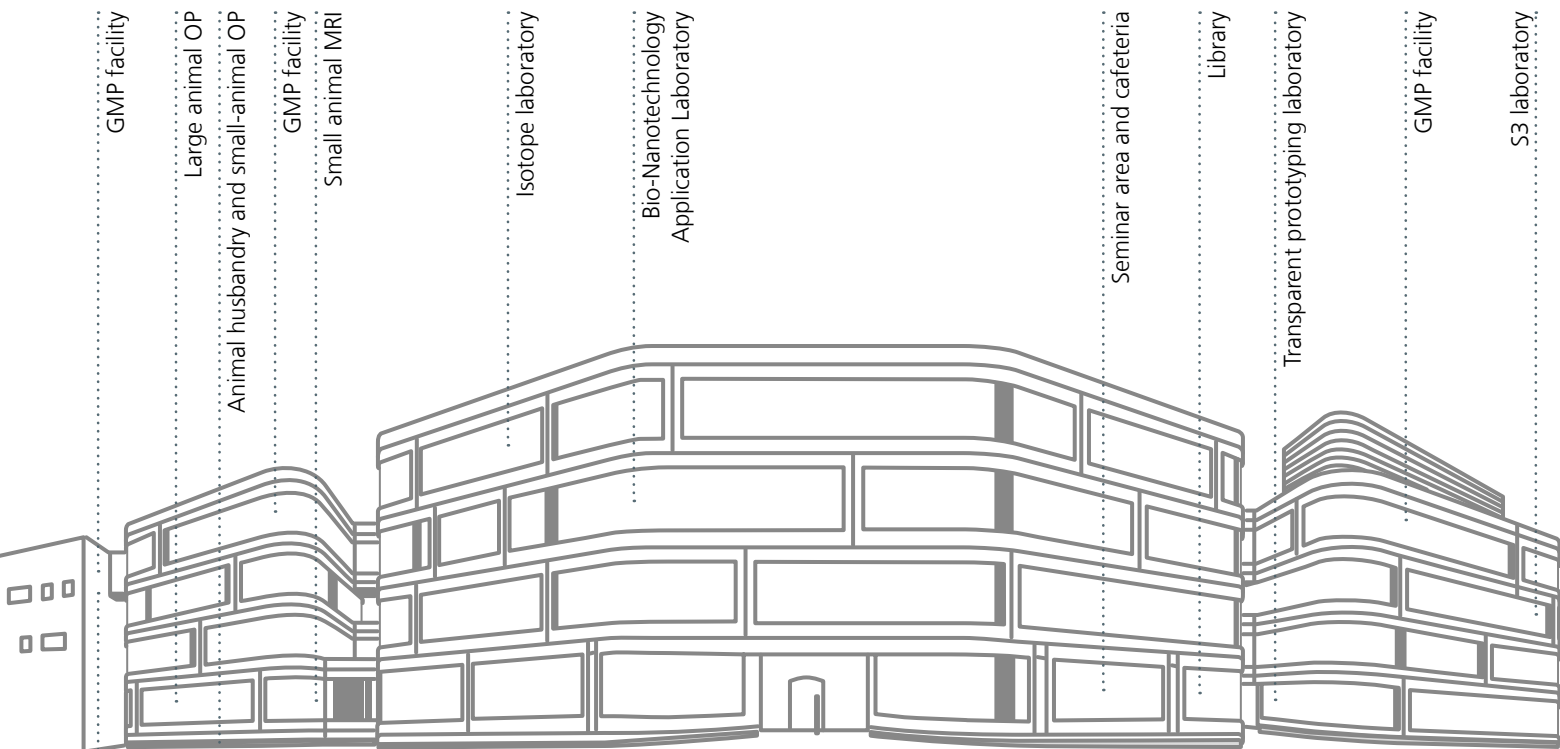


Association memberships in various expert associa- tions



**OUTSTANDING
INFRASTRUCTURE**

**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: 410 m²

Rental area at Bio City Leipzig

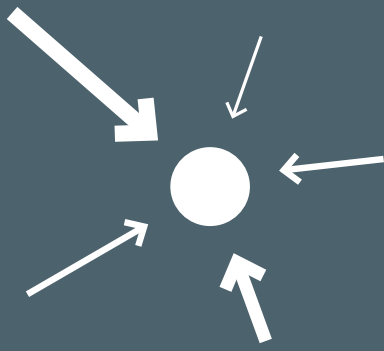
- Start-up operations: 2006
- Clean rooms: 334 m²

Main building

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

Second extension building

- Start-up operations: 2015
- Usable area: 3 050 m²
- Lab space: 1 171 m²
- Offices: 881 m²
- Clean rooms: 402 m²

**APPEALING TO
INDUSTRY**

SPIN-OFFS AND COMPANY SETTLEMENTS

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

Anti-tumor cell vaccines und cell therapeutics

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

Developing

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

Diagnostics

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

Drugs R&D

- Nuvo Research GmbH (Settlement 2009)

Natural remedies R&D

- Oncotriton GmbH (Spin-Off 2012)

Stem cell bank

- InnovaStem GmbH (Settlement 2009)

Therapy devices

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



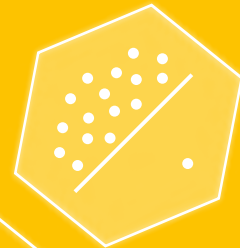
BIOVILLE



Location Leipzig, Germany

MAIN DEPARTMENT OF GMP CELL AND GENE THERAPY

Quality assurance | 1000 m² Clean rooms | ATMPs
Process transfer and development | Manufacturing
authorization according to §13 AMG | Investigational
Medicinal Drug Dossiers (IMPD) | Good Manufacturing
Practice (GMP)





THE DEPARTMENT AT A GLANCE

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

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

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PROJECT EXAMPLES

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

Until recently, Fraunhofer IZI spent several years manufacturing an investigational medicinal product for clinical trial in Germany and the UK, the efficacy of which is still being monitored as part of a phase III clinical trial.

American biotechnology company Northwest Biotherapeutics Inc. had previously succeeded in using the immunotherapeutic DCVax®-L in smaller clinical trials in the USA. This advanced therapy medicinal product (ATMP) is based on autologous dendritic cells and intended for the treatment of glioblastomas, a particularly aggressive type of brain tumor.

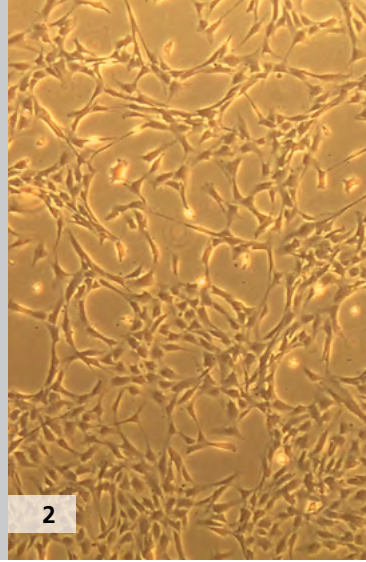
In order to manufacture DCVax®-L for each individual patient, tumor tissue and a blood product first had to be taken from the patient before the cell-based therapeutic agent could then be manufactured in a complex, multi-stage process. The number of patients that had to be recruited for the trial from a statistical perspective was reached back in 2015, marking the successful completion of the manufacturing and testing activities at Fraunhofer IZI.

However, as the therapeutic agent is being administered to the trial participants in several different doses over a three-year period, cryopreserved clinical doses had to be sent to the participating clinical trial sites in 2017 for subsequent administration to the patients. This will also be the case in 2018, until the last scheduled dose is sent. We will then look forward to receiving the evaluation of the clinical trial from sponsor Northwest Biotherapeutics Inc.

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- 1 *Filling the ready-made product DCVax®-L in a class A clean room environment*
- 2 *DCVax®-L undergoes quality control testing in the lab*



autoCard study

Cardiovascular diseases are still the main cause of death in Europe. In Germany, around 60,000 people die from myocardial insufficiency every year. High hopes are being pinned on the field of regenerative medicine to come up with new therapeutic approaches.

With this in mind, Fraunhofer IZI is helping Berlin's Charité University Hospital conduct a clinical trial that will test a novel kind of cell therapy. The new therapy is based on special heart cells taken from patients by means of a heart biopsy. Fraunhofer IZI has the job of manufacturing investigational medicinal products in the institute's clean rooms. In order to do this, the cells will first be cultivated and expanded in a process lasting several weeks. Once the required cell concentrations have been reached (usually after four to six weeks), the cells will then be applied as a suspension in their final formulation – intravenously (IV) through a drip on the one hand and intramyocardially, i.e. directly into the heart muscle, using the MYOSTAR™NOGA system on the other. The aim here is to establish the "CardAPcells" (cardiac-derived adherent proliferating cells) investigational product as routine patient treatment, giving patients the opportunity to enjoy a better quality of life. The risk of rejection is minimal as the study uses the patient's own heart cells. The random formation of scar tissue (fibrosis) is also reduced.

Test batches were first produced in the project at the technology transfer stage; these batches were used to optimize the process with an eye to the stringent production requirements under GMP conditions. The suitability of newly introduced GMP-compliant materials and reagents was also reviewed here and the respective specifications compiled in order to guarantee the consistent quality of these base substances and materials. The process, which is set to be conducted in Fraunhofer IZI's clean room, was then validated. Using sam-

ples taken from the three validation batches produced, the analytical methods used in the so-called safety parameters (checking for mycoplasma, sterility and bacterial endotoxins) were also successfully validated. The application for a manufacturing permit pursuant to Section 13 of the German Drug Act (Arzneimittelgesetz, AMG) was sent in parallel to the responsible state authority, Landesdirektion Sachsen (Saxony Land authorities), which is expected to conduct the acceptance inspection at the start of 2018. Furthermore, a permit authorizing the removal of tissue samples pursuant to Section 20b of the AMG is also being prepared for submission to Berlin State Office for Health and Social Affairs.

The first "CardAPcells" product cannot be manufactured for patient treatment until the manufacturing permit pursuant to Section 13 AMG and the tissue removal permit pursuant to Section 20b AMG has been received, a favorable opinion has been issued by the competent ethics committee and the autoCard study has received official approval from the Paul-Ehrlich-Institute.

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1 A member of staff examines the cells through the microscope.

2 Adherent CardAPcells in culture.

Location Leipzig, Germany

DEPARTMENT OF THERAPY VALIDATION

Preclinical studies | Good laboratory practice
Immunotoxicology (study design and implementation)
Protein biomarker (identification and validation)
Antibody development (therapy and diagnostics)
Antibody development and production (therapy)





THE DEPARTMENT AT A GLANCE

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

The department covers the following topics:

- 1) Planning and execution of preclinical efficacy and safety studies for new drug candidates (especially ATMPs) and medical devices (ISO 10993) under GLP or GLP-analogous conditions. This includes the development and validation of suitable in vitro and in vivo models.
- 2) Developing procedures for the diagnostic analysis of secretory and cellular protein biomarkers, including the development and production of specific monoclonal antibodies for their detection and finally the development and validation of the respective diagnostic assays (e.g. ELISA, Luminex®, flow cytometry).
- 3) Identifying and validating new protein biomarkers for diagnosis and therapy of chronic-inflammatory and tumor diseases, as well as for the sector of veterinary medicine / farm animal husbandry.
- 4) Developing human therapeutic monoclonal antibodies for the treatment of tumor and autoimmune diseases, as well as for passive vaccination against bacterial toxins and pathogenic viruses, and their advancement to drug candidates.

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UNITS

Preclinical Models Unit

The Preclinical Models Unit is concerned with the design and implementation of preclinical efficacy and safety studies for new drug candidates under GLP or GLP-analogous conditions. This includes the development, establishment and validation of in vitro and in vivo models for inflammatory and tumorigenic diseases. The main focus of research is on the development and optimization of humanized mouse models for developing and testing patient-specific therapies.

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[Click here](#) for further information about the unit.

Protein Biomarker Unit

The Protein Biomarker Unit focuses on the identification and validation of proteins to be used as diagnostic biomarkers or representing therapeutic targets. Moreover, the unit aims at the development of single and multiplex assays for biomarker detection. Multi-omics strategies (especially LC-MS based proteomics) are applied for identification. ELISA, western blot, and peptide or bead arrays (Luminex) are utilized for validation. High-affinity monoclonal antibodies, which are usually developed in the group, are key tools for these immunochemical assays.

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Antibody Production Unit

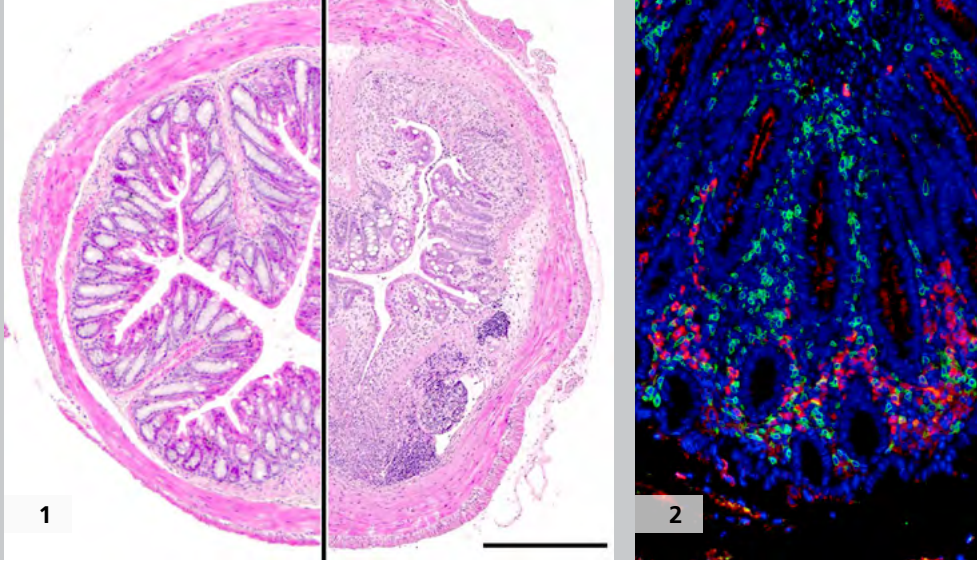
The Antibody Production Unit operates a state-of-the-art clean room facility for the GMP-compliant manufacturing of monoclonal antibodies based on, for example, CHO cell lines. The modular production facility covers clean room categories D to A and stands out due to its high level of flexibility achieved, amongst others, by using single-use disposables. The range of services includes the planning, development and implementation of manufacturing processes for preclinical and clinical test samples (up to phase II). Test samples can be produced either in bulk or in individual doses.

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[Click here](#) for further information about the unit.



PROJECT EXAMPLES

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

Inflammatory bowel diseases (IBD), such as Crohn's disease and Ulcerative Colitis, are multifactorial disorders of the gastrointestinal tract. The incidence and prevalence of these diseases have been rising constantly in industrial and newly industrialized countries for several decades. Although the diseases show a low mortality rate, patients suffer lifelong from episodes of severe pain and bloody diarrhea. The etiology of IBD is unknown but is assumed to be a combination of genetic predisposition, environmental factors and a dysregulated immune response to the gut microbiota. Hence, current therapies mainly focus on inhibiting the chronic immune response in the gut using immunosuppressive drugs and biologics. Since these therapies are often associated with strong side effects, pharmaceutical companies are pursuing the development of new IBD therapies with less side effects.

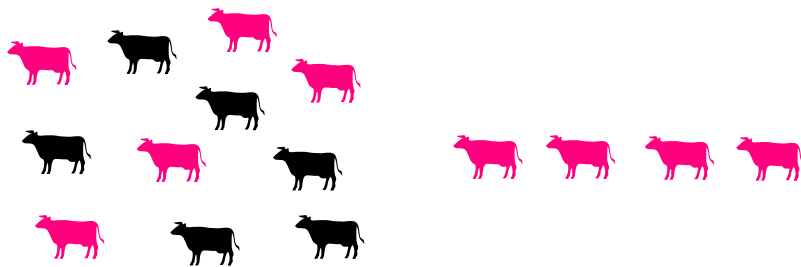
The model often used for such developments - the acute dextran sulfate sodium (DSS)-induced colitis - cannot adequately represent the chronic course of the diseases. Therefore, the Preclinical Models Unit has developed a chronic model that better represents the course of disease and reduces animal burden. Due to its high reproducibility, the model is very well suited for the preclinical evaluation of therapeutic agents. The model of chronic DSS colitis has already been successfully applied in several industrial projects. Moreover, the therapeutic effect of a plant extract based on sage and bitter apple could be demonstrated in the frame of an internal research project. As a next step, the active components of the extract will be identified and tested for their therapeutic efficacy. The use of phytopharmaceuticals could result in a reduction of the dosis and hence the side effects of classical therapeutics. Fur-

thermore, such therapies could be used in phases of remission and thereby prevent the development of resistance to classical therapeutics. The goal is to make the lifelong therapy needed by IBD patients as effective and tolerable as possible and thus improve the quality of life for these patients.

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- 1** Tissue structure of the distal colon in a healthy animal (left) and in chronic DSS colitis (right). Scale bar: 500 μ m
- 2** Detection of immunoglobulin A (red) and T-helper cells (CD4; green) in the distal colon of an animal with chronic DSS colitis. Scale bar: 100 μ m

**Screening**

Test result: sick / healthy

Clinical examination

Diagnosis, Therapy, Prognosis

1

Novel bovine biomarkers for health control in dairy herds

In diagnostics, biomarkers either serve for differential diagnostic stratification or the early detection of diseases even before characteristic clinical symptoms coin the disease patterns. Screening tests verifying biomarkers are particularly appropriate for distinguishing sick from healthy animals, especially in large and hard-to-monitor animal stocks. This method enables farms to detect sick animals and to provide positively diagnosed animals with a veterinary examination and treatment in a targeted manner.

In this way, the stock's health can be further controlled and optimized. Moreover, acute inflammations can be prevented by early treatments. Potentially, this approach could result in a medium-term increase in economic efficiency.

In the project "On-Farm-Recording" supported by the Federal Ministry of Food and Agriculture, the Department of Therapy Validation has identified and characterized different biomarkers for the detection of health in bovines. A patent application submitted in 2015 is aimed at an international patent protection. For the four most promising biomarkers, biomarker diagnostic tests will be developed and brought to market maturity together with the industry partners. Within the frame of the current and proposed projects, diagnostic enzyme immunoassays on the basis of the ELISA technology will be developed, which will allow for the detection of bovine biomarkers Haptoglobin, PIGR, Lactotransferrin and VEGF in milk and blood samples. The methods involve the extraction process and the production of species-specific, monoclonal antibodies, as well as the development and analytical validation of an ELISA at laboratory scale. Furthermore, the methods comprise the diagnostic validation to assess the diagnostic significance of the test system in practice.

At the current stage, two projects have been identified:

- 1) A diagnostic validation trial of the biomarker Haptoglobin in a joint project with partners of industry, agriculture and academic veterinary hospitals.
- 2) The development of another three biomarker diagnostic tests to detect the biomarkers PIGR, Lactotransferrin and VEGF.

As the health and well-being of animals are closely interconnected, the development of biomarker tests has contributed considerably to the principles of animal and consumer welfare. Farmers and veterinarians are responsible for animal welfare implementation. Perhaps biomarkers can be utilized as appropriate animal welfare indicators in the future?

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1 *Large-scale biomarker screening in herds to identify conspicuous animals (magenta).*

Locations Leipzig und Rostock, Germany

DEPARTMENT OF IMMUNOLOGY

Antimicrobial peptides | Cellular adsorbers
Immunome mapping | Vaccine development
Immunological models | Tolerance induction





THE DEPARTMENT AT A GLANCE

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

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UNITS

Vaccine Technologies Unit

The unit develops diagnostic techniques and prevention strategies for infectious diseases in human and veterinary medicine. The main research focus is on viral infections affecting livestock and zoonotic diseases. Pathogens up to biosafety level 3 can also be processed. Marker vaccines are developed which enable differentiation between infected and vaccinated animals (DIVA strategy). All state-of-the-art methods in virology, microbiology, molecular biology and immunology are well established in the unit. Viruses currently being focussed on include West Nile Virus, influenza, and PRRS Virus (Porcine Reproductive and Respiratory Syndrome). Besides this, strategies are being developed to combat ectoparasites. In addition, large-animal models can be provided through the collaboration with the Faculty of Veterinary Medicine at the Leipzig University.

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[Click here](#) for further information about the unit.

Ligand Development Unit

The unit focuses on the interaction of biomolecules, in particular the identification of peptides for tumor targeting and antibody characterization. A new peptide phage display method is combined with modern devices and measurement methods. This allows in silico data evaluation for epitope mapping as well as the immunome of patient sera (e. g. allergy research) and the identification of peptide ligands for characterizing complex structures (e. g. cell surfaces) as an alternative to antibodies. These applications range from the labeling of cancer cells / tissues to the characterization of (stem) cells in different culture and storage conditions.

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Antimicrobial Agents Unit

The aim of this unit is to develop peptides which have an antimicrobial effect to fight multiresistant germs, such as staphylococcus aureus, vancomycin-resistant enterococci, candida albicans, etc., as well as their evaluation in respective animal models. The main focus here is on applications in the field of dentistry and oral hygiene. A further key focus is placed on identifying and evaluating plant compounds for applications in the fields of immunomodulation, inflammation inhibition, concomitant tumor therapy and antibiosis.

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Immune Tolerance Unit

The goal of this unit is to develop cell- and antibody-based therapeutic strategies to treat complications following hematopoietic stem cell transplantation. Novel concepts of immunological tolerance which take into account immunological and therapy-associated complications (e. g. GvHD) are being tested in new, in-house developed models.

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Preclinical Validation Unit

This unit develops and examines new vaccines and drugs in preclinical trials. Drugs and vaccine candidates are tested in vitro in cell culture systems and in vivo in preclinical trails involving different animal species, also under GLP conditions. This research is focused in part on the development and efficacy testing of innovative vaccines for humans and animals.

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Image Analysis of Cell Function Unit

This unit develops new methods for the non-destructive, microscopy-based quantification of physiological and pathological processes. The aim is to support research into fundamental biological connections and to test new therapy procedures by analyzing cells and tissue without their modification or destruction. As this objective requires interdisciplinary cooperation in the fields of electrical engineering, optics, imaging, software development and biology, the specialist group has close ties to the Chair for Biotronic Systems at Leipzig University of Applied Sciences.

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Extracorporeal Immunomodulation Project Group

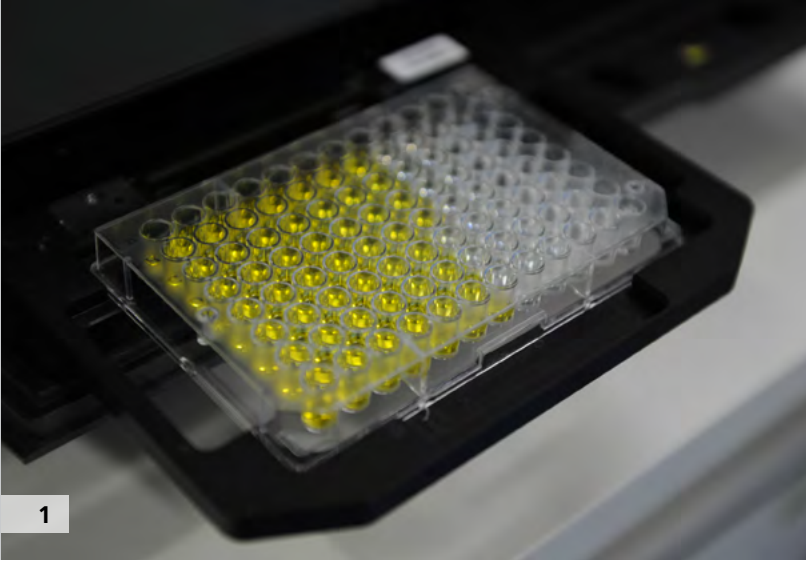
The project group focuses on the development and evaluation of extracorporeal (outside the body), organsupporting technologies with a particular emphasis on supporting the immune system. We offer the full range of preclinical and clinical analyses of extracorporeal technologies based on a broad spectrum of in vitro simulations, animal models, as well as a powerful clinical study network for in and out-patients. Moreover, we offer self-developed unique analytic and diagnostic devices including an ex situ intestinal model, a cell sensor and novel protein assays.

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1

PROJECT EXAMPLES

Specific detection of viral infections

Viral infections tend to be detected using direct diagnostic methods (generally by measuring the viral DNA/RNA) or indirect tests (generally by measuring the virus-induced antibodies).

As viruses can often only be detected in the blood or other bodily fluids for a limited period of time, immunological antibody detection forms an important part of routine diagnostics: this applies both for acute infections and epidemiological studies on the spread of a pathogen or testing of stored blood.

The ELISA test (Enzyme-linked Immunosorbent Assay) is the most common way of detecting antibodies all around the world. Antibodies in serum can be specifically detected here from the way they bind to virus proteins (antigens) on microtiter plates.

In the Department of Immunology (Vaccine Technologies Unit) at Fraunhofer IZI, various procedures are employed to develop and manufacture recombinant viral antigens that can then be used in diagnostic tests. Insect-borne infections, especially flaviviruses such as dengue, Zika or West Nile Virus, are being focused on here.

Global warming, globalization and increased human mobility are causing these infecting agents to spread further and further afield. Some of these flaviviruses have also become endemic in subtropical and even temperate regions of the world in recent years. In 2017, for example, locally acquired West Nile viral infections were recorded in Austria and northern Italy. In 2012, Madeira was plagued by a dengue epi-

dem with thousands of cases recorded. The Zika virus even led to the declaration of a global public health emergency in 2016.

A particular challenge facing the serological diagnosis of flavivirus infections lies in the structural similarity between the different types of virus, which results in a significant amount of cross-reactivity and false positive results with the tests available at present. This means, for instance, that antibodies acting against dengue can barely be distinguished from those against Zika infections.

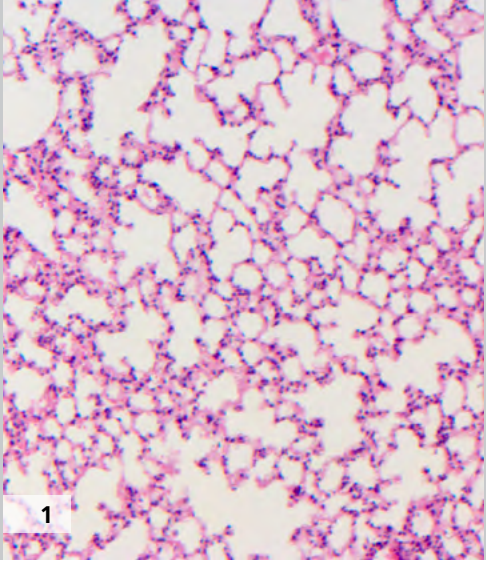
Researchers at Fraunhofer IZI have developed and patented antigens which demonstrate modifications in areas that usually result in the binding of cross-reactive antibodies, leading to a much more specific diagnosis. The institute is now working together with partner companies from the diagnostics industry to further develop these antigens into marketable products for global use.

References: PMID [29116222](#), [26565964](#)

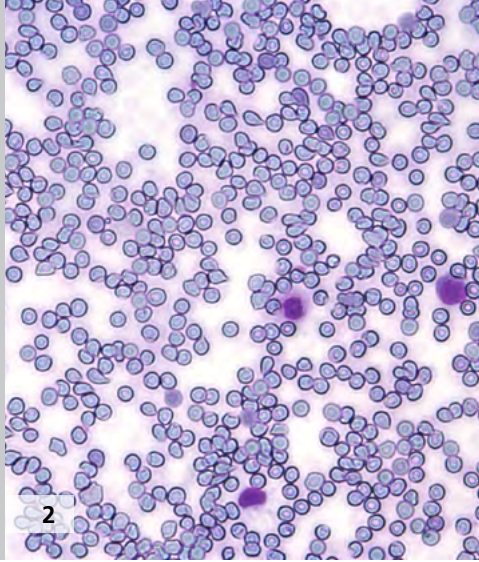
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1 ELISA-Test



1



2

Prevention of adverse immunological complications while retaining the anti-tumor effect following stem cell transplantation using anti-human CD4 antibodies

The main complication following an allogeneic hematopoietic stem cell transplantation is acute graft-versus-host -disease (aGvHD). The conventional treatment methods are frequently associated with low long-term success and toxicities. This necessitates the development of treatment alternatives which are less burdensome.

A new approach involves the use of a specific anti-human CD4 antibody. The antibody specifically reduces adverse immune reactions, thus minimizing the chances of a GvHD emerging following stem cell transplantation. The influence of this anti-human CD4 antibody with regard to the prevention of GvHD and under consideration of the graft-versus-leukemia (GvL) effect in a clinically relevant, humanized leukemia model is currently being investigated.

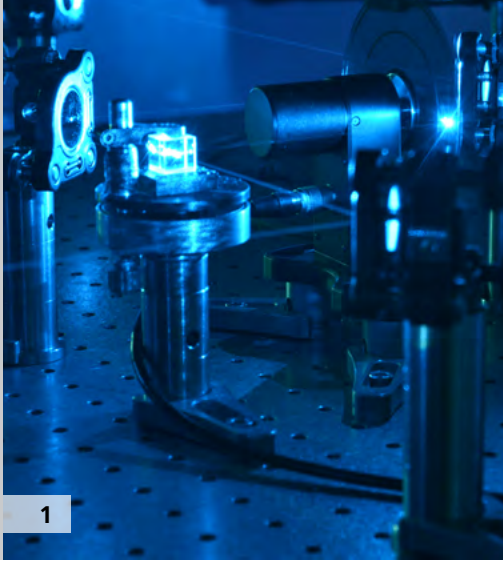
For this purpose models are being used which are particularly well suited to the transplantation of human hematopoietic stem cells and human leukemia cells. The findings are essential in applying the antibody and other new drugs in a hospital environment. Existing leukemia models are being further developed and the anti-human CD4 antibody and other drugs are being evaluated.

By using humanized models it may be possible to achieve new findings concerning immunological processes in the emergence of GvHD and regarding the GvL effect. The models and findings are not only extremely valuable for hematopoietic stem cell transplantation and leukemia treatment, but also for stem cell transplantation in other indications (e. g. autoimmune diseases).

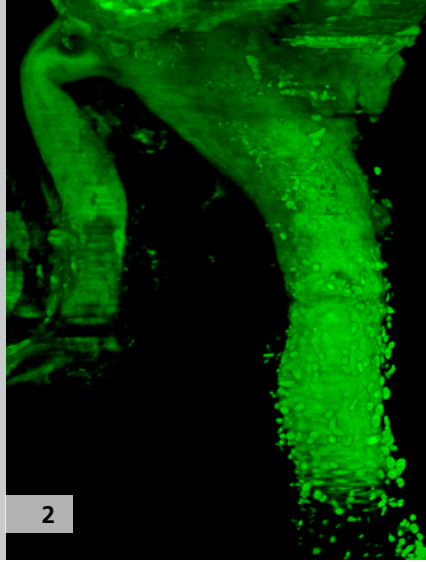
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- 1 Lung tissue,
magnification x10 (HE)
2 Blood smear, magnification
x100 (Pappenheim)



1



2

Non-destructive cell and tissue monitoring

Last year, the joint specialist group comprising Fraunhofer IZI and Leipzig University of Applied Sciences (HTWK) was able to successfully set up a new experimental imaging platform based on light sheet microscopy (SPIM).

So-called Single Plane Illumination Microscopy (SPIM) is a fluorescence microscopic procedure which illuminates just a thin layer of the sample (usually only a couple of micrometers). Compared with other fluorescence microscopy procedures, the microscope is therefore able to achieve a much greater penetration depth and reduce the number of artifacts in the image background. This places biological samples under far less light-induced stress which, in turn, enables live samples to be monitored over a long period of time without the fluorescent dyes fading as quickly.

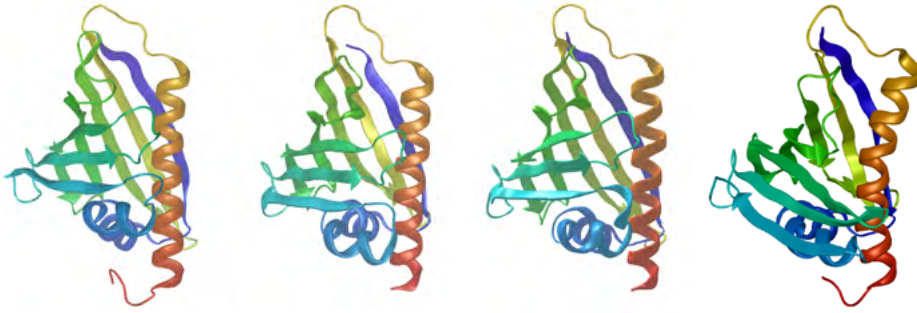
Based on its current operational stage of development, the experimental platform is set to be expanded to include other special applications in the future with a view to offering an extensive range of analytical methods both in-house and to external customers. This also includes SPIM for fixed tissue samples that have been rendered transparent (clearing).

The 3D fluorescence microscopy platform is particularly gentle on samples and can be applied, among other things, to analyze the growth of organoids. It is complemented by image-guided analysis routines which have been adapted to the 3D image data, such as the statistical analysis of spatial point patterns.

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- 1** Part of the SPIM experimental setup. The beam splitter and chopper wheel can be seen here alongside different mirrors.
- 2** Kidney sample following a clearing protocol. A blood vessel is also depicted on the image due to its autofluorescence



1

Mapping of patient antibodies in sera

The ligand development group has developed a new method for precisely identifying the binding sites of antibodies, which are meanwhile being used in diverse applications. The binding sites of antibodies can be determined readily from serum samples, allowing new approaches for research and therapy in many indications like (auto)immune and infectious disease.

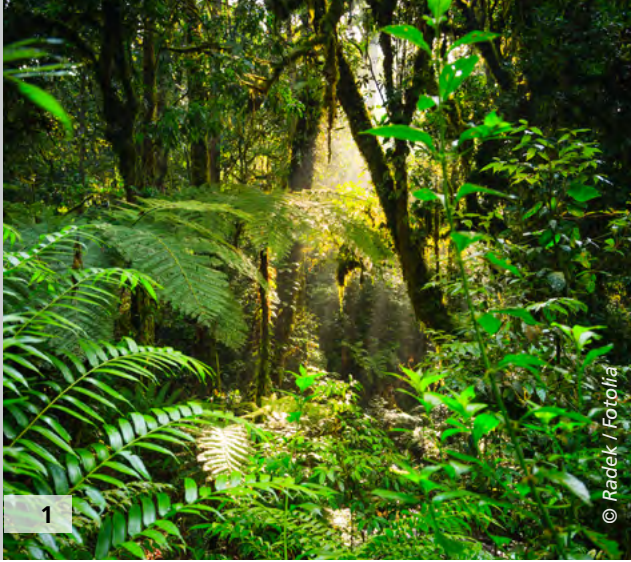
A particularly large-scale project is being funded by the Fraunhofer Zukunftsstiftung. In cooperation with several other Fraunhofer Institutes and clinics, the FoodAllergen project follows a holistic approach to deal with food allergy. The group creates the basis for this by accurately determining the sites in the allergens recognized by the patient antibodies. This can be used to create significantly more differentiated diagnostics for the differentiation of individual allergies. Their recognition and assignment is often complicated by cross reactivity of closely related plant proteins or is even almost impossible (see picture of PR10 proteins). For many patients it is difficult to find an efficient diagnosis, appropriate treatment and adaptation of nutrition.

In addition to mere patient diagnostics, this also provides valuable information for the project partners in the application areas of food analysis and even in the determination of the allergenic potential of processed food ingredients. The project is now being watched with great interest nationally and in the EU, as it aims to improve patient diagnostics, to set new standards for allergens in food analysis and to monitor their reduction by processing selected food ingredients.

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1 Structures of the allergenic protein (PR10) from birch, celery, soy and carrot. Their identical structural folds show how difficult it is for the immune system as well as diagnostic approaches to distinguish between these. Within the project epitopes were identified, which allow to differentiate (between the different species).



Evaluation of effective antimicrobial compounds taken from plant tissues for the treatment of bacterial infections in preclinical immunotoxicological models

Nowadays, the treatment of nosocomial infections, especially those comprising multidrug-resistant bacteria and fungi, presents one of the greatest challenges to modern medicine. Hygiene measures that are in place yet not consistently observed in hospitals, the overuse of antibiotics and lack of strict regime on the part of patients taking them as well as the exorbitant use of antibiotics in large-scale, industrial livestock farming have all led to a situation that can barely be kept under control. The problem of multidrug resistance will only get worse in the long term due to increasing average life expectancy and the associated decrease in the strength of the immune system in older people.

This project was initiated to test the effect of antimicrobial peptides and active substances isolated from plants on typical human pathogenic germs. These include Methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE), bacteria that could produce extended-spectrum beta-lactamases (ESBL) and several human pathogenic fungi from the candida and aspergillus genera. The focus here was placed in particular on plants from tropical parts of Africa, as plants growing under these climatic conditions often form highly efficient, antimicrobial active substances during the course of their co-evolutionary adaptation.

The antibiotic effect of plant-based secondary substances (AMPS) was first examined on attenuated laboratory strains of the respective human pathogenic bacteria and/or fungi species. Moreover, toxicity tests were conducted on the plant-based active substances with regard to different cells from the immune system. This is necessary in order to detect immunomodulatory effects at an early stage. A mouse model was set up to evaluate the effect of the AMPS in vivo.

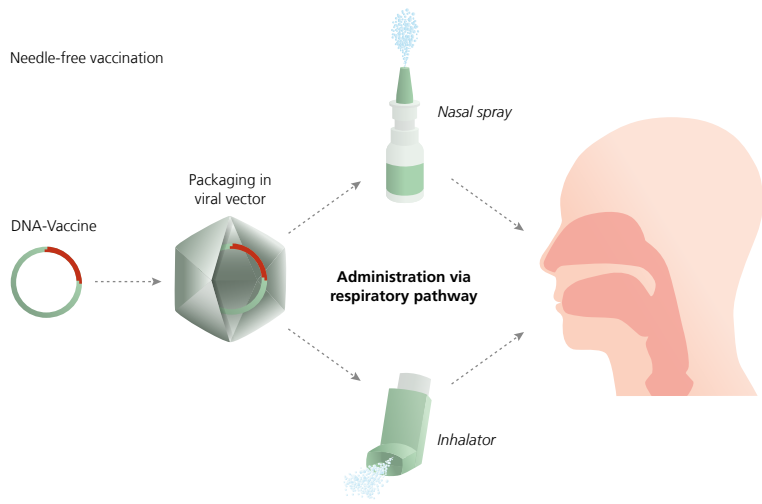
The efficacy of the AMPS in vivo was determined using several clinical parameters (e.g. survival rates, release of specific immune and activation markers, improvement in clinical score, etc.). An extensive histological organ analysis was carried out alongside these investigations.

In all, active substances were isolated from several plants which could, in future, be utilized for a broad range of applications such as antibiotics, wound dressings and nutraceuticals

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1 *Traditional medicinal plants from Africa's rain forests constitute a largely untapped source for new active substances.*



1

Non-human papilloma pseudoviruses for DNA delivery in vitro and in vivo

DNA vaccines are gaining popularity due to their inexpensive production and good stability even at room temperature. While it was possible to overcome the initially unsatisfyingly low antigen-specific antibody response in larger animals and humans by use of electroporation, which greatly increases the cellular uptake of the DNA, this method is comparatively laborious and painful for the vaccinee. Novel delivery methods are thus necessary. Being the DNA delivery specialists that viruses are, pseudoviruses (PsVs), which package the vaccine-plasmid inside their capsid, can mediate the delivery of the vaccine and ensure the efficient shuttling of the DNA vaccine into the cells.

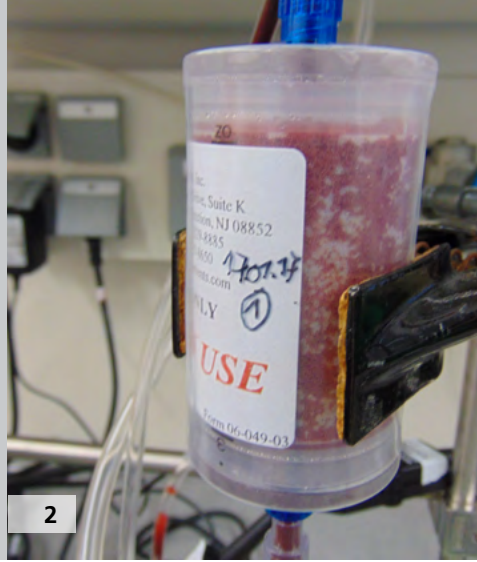
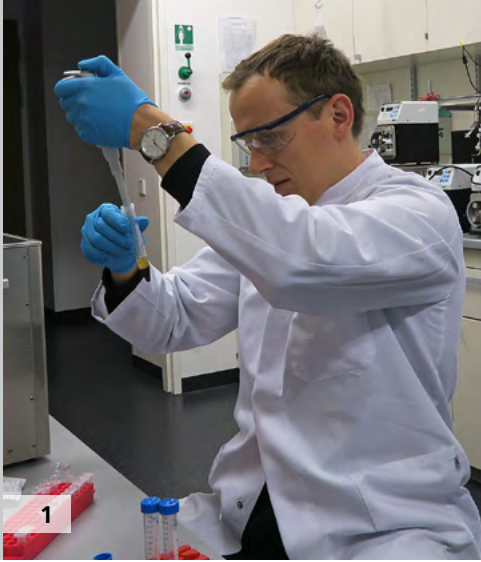
Different animal papilloma viruses were detected and analyzed for their ability to form PsV particles, package DNA in form of a reporter plasmid and transduce cells in vitro. While most of the tested non-human papilloma viruses barely showed a transfer of DNA in vitro, two candidates – papillomaviruses that normally infect the puma (PcPV1) and the macaque (MfPV11) – transduced especially effectively. PcPV1 and MfPV11 PsVs were therefore studied further in in-vivo experiments. Both candidates mediated the transduction of a luciferase reporter plasmid after intramuscular application in mice, leading to the expression of firefly luciferase. This expression lasted several weeks after injecting PcPV1 PsVs. Further, in a vaccination including intramuscular and intranasal application, it was tested whether the papilloma PsV mediated the delivery of a DNA vaccine against the respiratory syncytial virus (RSV) in mice. Finally, the mice were infected with infectious RSV and the viral load was quantified. The application of PcPV1 and MfPV11 PsVs carrying a plasmid coding for RSV-F led to a significantly reduced viral load in the lungs of the vaccinated mice upon challenge.

Human papilloma PsVs have successfully been used for gene delivery in the past, but have limitations due to vector immunity, which would occur in all individuals that have previously been exposed to these viruses. The project results show that non-human papilloma viruses have the potential of being promising gene delivery vectors and present a vaccine platform for intramuscular or mucosal application.

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1 Needle-free, mucosal vaccine administration of virally packaged DNA.



Cytokine adsorber

Sepsis, also commonly referred to as blood poisoning, is a complex systemic inflammatory response produced by the body. It is usually triggered by bacteria and their toxins when they manage to enter the bloodstream and results in a powerful immune response which is also directed in part against the patient's own body. In severe cases, the patient becomes highly susceptible to secondary infections and multiple organ failure.

Sepsis and its serious forms of progression is becoming more and more prevalent around the world. This explains why severe cases of sepsis still prove fatal in over 50 per cent of cases today, in spite of the various state-of-the-art intensive care options available. It is essential that the disease is diagnosed and effective antibiotic treatment initiated as quickly as possible: this can mean the difference between life and death.

In order to improve a patient's prognosis, various therapeutic approaches such as renal replacement therapy or adsorptive procedures can be introduced in addition to standard treatment. Hemoperfusion is an important adsorptive procedure, whereby the patient's blood passes extracorporeally through a cartridge containing an adsorbent.

The various commercially available adsorbers target either the removal of toxins (lipopolysaccharides) or of inflammatory mediators (cytokines / chemokines), which are increasingly released during the overreaction of the immune system. This type of cytokine adsorber (CytoSorb) was examined in collaboration with the company CytoSorbents Europe GmbH. CytoSorb adsorption columns are approved in Europe as an auxiliary extracorporeal treatment for sepsis. The columns aim to remove pro- and anti-inflammatory messenger substances from the blood during the immediate defense response

where possible. As, however, this adsorption is a non-specific process, investigations were carried out into whether and to what extent different medications used in intensive care such as antibiotics and also other substances such as painkillers, sedatives, cardiovascular drugs and anticoagulants are similarly retained by the adsorber.

In in-vitro studies it could be shown that the investigated adsorber removes a significant amount of an anticoagulant-inhibitor (rivaroxaban) from the blood. This finding is of direct clinical relevance: patients who take this anticoagulant-inhibitor and require emergency surgery cannot be subjected to surgery before the active agent has been completely excreted from the body – a process that can take up to eight hours. The adsorber could notably reduce this waiting time, thereby gaining valuable therapy time. Further investigations into the removal of various other interesting substance classes are scheduled for 2018.

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- 1 *Preparation of experiments*
- 2 *Laboratory sample of a Cytokine adsorber*

Location Leipzig, Germany

DEPARTMENT OF CELL THERAPY

Experimental imaging | Stroke models
Cell therapeutics | Preclinical study design
Experimental neurosurgery | Histology





THE DEPARTMENT AT A GLANCE

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

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UNITS

Experimental Imaging Unit

Experimental imaging stands at the interface between engineering and life sciences. It is dedicated to research activities where the acquisition and processing of images are required before implementation is possible. This draws on different technical devices and software. As the methods used in the applied procedures are constantly being developed, the field of work is always adjusting to reflect the latest developments. The focus here lies on applying state-of-the-art imaging techniques as part of the task assigned to us by our respective project partners.

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[Click here](#) for further information about the unit.

Cognitive Genetics Unit

The Cognitive Genetics Unit investigates the foundations and application possibilities for the genetics involved in cognitive processes. The main focus of our work is on the genetics of dyslexia. Our main aim is to develop an early screening test which will effectively facilitate the functional regeneration of dyslexia-related cellular deficits in the future.

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Clinic-oriented Therapy Assessment Unit

The unit tests and develops innovative diagnosis and therapy procedures for ischemic stroke. As the possibility of being able to transfer findings from current laboratory rodent models to human patients is sometimes only very limited, a globally unique large-animal model was established for the translational approach. Tests can be carried out using this model under clinically relevant and patient relevant conditions. Both the gyrencephalic brain structure and the size of the brain much more closely resemble the human situation in the sheep model as opposed to in the small animal.

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OpTcell Unit

The OpTcell Unit is primarily focused on cancer immunotherapy. Both patients and science have high hopes for this field in terms of modern cancer therapies. Particularly relevant aspects of cancer immunotherapy are dealt with under three core areas of activity. The aim is to create technological innovations which will potentially increase the efficacy of cancer immunotherapeutics and which may also be used to treat solid tumors.

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Ischemia Research Unit

The common conditions stroke, myocardial infarction and vascular dementia are caused by an acute or chronic lack of supply of blood and oxygen. This ischemic tissue damage results in an inflammatory response which is important for the healing process, but may also exacerbate the initial damage. Comorbidities such as hypertension, hyperlipidemia and chronic inflammation especially determine the relationship between protective and damaging influences.

The unit explores the foundations of these correlations with the aim of identifying and preclinically validating novel therapy options.

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PROJECT EXAMPLES

Establishment of a rabbit model for the propofol infusion syndrome

The use of anesthetics can lead to unwanted and sometimes life-threatening side effects. One of the most commonly used anesthetics is propofol. During the use of propofol for long-term anesthesia and during the anesthesia of children, propofol can cause a rare but fatal side effect, the propofol infusion syndrome (PRIS). PRIS is a symptom complex that can lead to severe disorders of the cardiovascular system, kidney failure, a drastic reduction in blood pH (lactic acidosis) as well as the resolution of striated muscles (rhabdomyolysis). In most cases these disorders lead to fatal multi-organ failure. In cooperation with a large industrial partner, a model system in the rabbit was established to investigate PRIS.

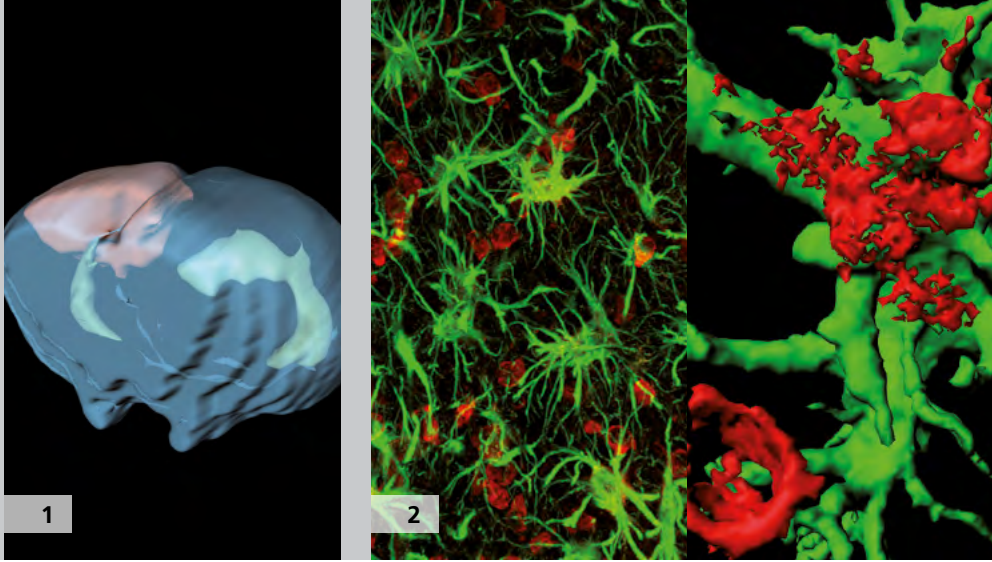
Based on a publication from 2007 (Ypsilantis et al., 2007), a pilot study was carried out at the Fraunhofer IZI to adapt the described model to the questions. After intubation and successful initiation of propofol anesthesia, it was possible to keep the animals stable under anesthesia for a period of up to 48 hours. Meanwhile, the oxygen and carbon dioxide levels as well as the acid-base balance of the animals were closely monitored. In addition, reflex tests were carried out to ensure a safe depth of anesthesia and the heart functions as well as the temperature were monitored at regular intervals. The successful development of PRIS resulted in an irreversible lethal multiple organ failure. After each experiment, all organs of the animals were removed, fixated and stained for histological examinations. Furthermore, mass spectroscopic analyses of the bile fluid and detailed examinations of the blood work were performed.

The pathological findings of most animals were normal. However, a new biomarker could already be identified in this pilot study, which may be of possible use for monitoring anesthetized patients. This biomarker will be validated in human blood samples over the next few months.

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1 *The use of anesthetics may cause undesirable side effects.*



PROJECT EXAMPLES

Use of 3D rendering in modern imaging procedures

The field of life sciences presents us with a variety of diagnostic options. The procedures applied in this field harness the entire span of the electromagnetic spectrum, ranging from short-wave x-ray (computer tomography) and light which is visible to humans (microscopy) right over to magnetic resonance imaging in the radio frequency range. Each one of these procedures pinpoints and visually illustrates structures or biological processes in the living organism. Thanks to the increased resolution of devices, sufficient data can now be gathered to create a virtual reproduction of the examined structures. Calculations can be made and biological processes visualized based on the computer models rendered from these devices. This is made possible due to the use of sophisticated computer systems and special software applications.

Pathological processes which emerge, for example, in the case of the widespread condition stroke can thus be precisely quantified. It is not possible to depict the affected structures directly without surgery as they are shielded in the cranium. With the aid of MRI scanners with extremely high field strengths (up to 140,000 times the strength of the earth's magnetic field) and special algorithms which are used to segment these structures, the damaged region can simply be depicted "in vivo". By using different contrast methods, macroscopic pathologies are made visible on the screen as 3D objects (image 1).

Far-reaching microscopic reconstruction processes take place in the affected areas of the brain following brain tissue damage caused by trauma or hypoxia, which cannot be seen using MRI scanners. The brain's connective and supportive tissue (glial cells) reacts to this by enlarging the cells (hyper-

trophy) and increasing the number of cells (hyperplasia). In order to be able to depict regeneration the affected region is immunohistochemically stained and scanned using a confocal laser scanning microscope. The resulting data record is processed and transformed into a 3D structure. This makes it possible to precisely describe the number and morphology of cells, their interaction with other cells, and their changes over the course of time (image 2).

Both processes facilitate the evaluation of pathological changes following brain damage and are therefore suitable for verifying the effectiveness of new therapeutic procedures. The methods used to segment, evaluate, and assure quality are hugely similar here in spite of the different processes. Combining these competencies into one unit thus facilitates various synergies.

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1 Visualization of a stroke in a 3D model of a rat's brain

2 3D model of astrocytes based on immunohistochemical staining



LEGASCREEN - Development of an early screening test for dyslexia

Dyslexia is a severe disorder of reading and writing, affecting about 5% of all German schoolchildren. It is one of the most common developmental disorders in childhood and youth. Dyslexia is unrelated to the child’s intelligence. It results in tremendous problems in school, education and at work.

One of the main problems hampering successful therapy is late diagnosis: With current methodology, dyslexia can be reliably diagnosed at the earliest at the end of the second grade. By this time, a large part of speech development has already passed, and a lot of precious time for early therapy is inevitably lost.

Benefiting from previous research on the genetics of dyslexia, this project aims to overcome these limitations. The earlier that a risk for dyslexia is diagnosed, the earlier therapy can be initiated to reduce later problems. The project is a joint project between the Fraunhofer Society and the Max Planck Society. It integrates different research areas: Genetics as well as specific measures of brain activation (EEG).

Heritability of dyslexia is estimated at between 50% and 70%. Genetic information does not basically change during the life span. Consequently, specific genetic variants can be measured long before reading and writing is taught. The project will leverage known genetic risk variants as well as further optimize those genetic markers.

The other important part of the test is based on electroencephalography (EEG). Here, brain activation is analysed, even without drawing attention to a stimulus. It is known that children with a risk for dyslexia, even as infants, have specifically altered brain activation patterns in response to specific language stimuli.

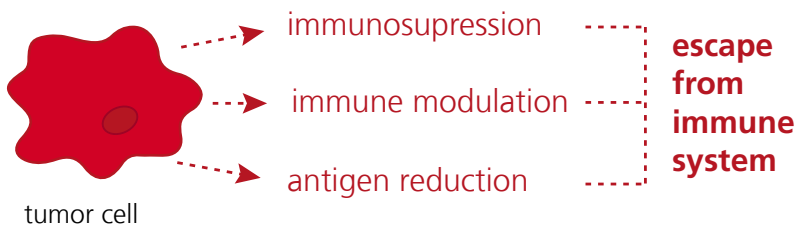
Finally, the project includes magnetic resonance imaging (MRI). MRI assessments will not be part of the final test but are very helpful during assay development. Information about brain structure provided by MRI can hint to connections between genetics and activation patterns seen in the EEG measures.

To summarize, the aim of this project is to develop an early screening test for dyslexia. This test should be applicable long before conventional testing is carried out. It is believed that early testing will improve the access to as well as the success of dyslexia therapy.

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- 1 EEG examination
- 2 MRI examination



1

New approaches in cancer therapy: counteracting the immune-escape mechanisms of cancer cells (BITCAT)

The ability to recognize and destroy degenerative cells forms an inherent part of the human immune system. A person is therefore more likely to develop cancer if their immune system is impaired. Cancer can, however, also emerge in people whose immune systems are fully intact. One cause of this is the development of so-called immune-escape mechanisms, whereby the cancer cells employ various immune suppression mechanisms, for instance, to evade an immune response. One of these mechanisms blocks so-called immune checkpoints, which in turn inhibits the activation of T-cells.

Modern immunotherapies therefore look at counteracting these protection measures or stimulating the body's immune system to fight cancer cells. Most of the immunotherapeutic agents used here are based on proteins (e.g. antibodies) or cells (e.g. cancer vaccines). The BITCAT project pursues the development of a completely new type of immunotherapy based on oligonucleotides, i.e. short DNA or RNA molecules. These oligonucleotides are expected to modulate the expression of receptor genes (e.g. PD-L1, CTLA4) in order to prevent immune checkpoints from being blocked. This in turn facilitates T-cell activation, enabling the immune system to attack the cancer cells once more.

This project will see a number of different drug candidates being investigated and optimized in vitro, i.e. in cell culture, to begin with. The most promising candidates will then be investigated in vivo, i.e. as part of an animal experiment, with an eye to functionality, efficacy and toxicity. Liposomal or polycationic nanoparticles are being used here to ensure the oligonucleotides reach the target cells in the body. Respective studies have already shown they are tolerated and demonstrate good bioavailability in the tissue.

This new method has the advantage that it can also be applied ex vivo, e.g. in the case of stem cell or organ transplants. This improves cell-based cancer therapy while avoiding systemic administration.

The collaboration project overseen by Fraunhofer IZI and McMaster University (Hamilton, Canada) is conducive to developing a new key technology in the field of cancer therapy.

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1 *Immune-escape mechanisms allow cancer cells to evade the body's immune defense system.*

Location Leipzig, Germany

DEPARTMENT OF DIAGNOSTICS

Transcriptome analyses | Next-generation-diagnostics
Bioinformatics | Nanotechnology | Lab-on-chip
Biomarker identification | Tumor models

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THE DEPARTMENT AT A GLANCE

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

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

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

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It also offers the development of companion diagnostics and provides many established cell and animal models in various areas like tumor stem cells, rheumatoid arthritis and other chronic-inflammatory diseases as well as many more. Furthermore, xenogene transplantation models serve to close the gap between model and patient.

UNITS

Inflammation Models and Immunodiagnosics Unit

This unit develops rapid, straightforward, immunological, cell biological and genetic analysis and model systems for the areas of graft rejection, inflammation research and tumor biology, in particular for joint and pulmonary diseases. This involves the use of innovative immunoassays, genetic analyses, complex cell culture models and animal experimental approaches..

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[Click here](#) for further information about the unit.

RNA Biomarker Unit

Our focus is on the identification and validation of new diagnostic and prognostic RNA biomarkers for various diseases. We use a wide range of molecular methods (nextgeneration sequencing, microarrays, PCR-based methods) for the GLP-oriented screening and validation process. We also focus on companion diagnostics, which is an important step towards personalized health care. With the development of specific tests (e. g. cancer diagnostics), we are constantly moving towards the optimal goal.

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Next-Generation Diagnostics Unit

This unit develops and establishes analysis strategies for discovering novel biomarkers to diagnose and anticipate diseases. The focus here is placed on the detection and characterization of RNAs, especially of non-protein-coding RNAs (ncRNAs), which possess a great deal of potential in terms of their use as biomarkers. The latest nucleic acid analysis techniques are employed here based on next-generation sequencing and microarrays. These procedures are being optimized to analyze various base materials (cryo tissue, FFPE tissue, urine, blood).

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Tumor Stem Cells Unit

This unit's objective is to develop therapeutic strategies based on cells and agents for the treatment of neoplastic diseases based on the elimination or modification of tumor stem cells in the relevant malignant tumor. This concept is to be used to describe the tumor stem cells of further tumor entities and to facilitate therapeutic innovations in the field of internal oncology.

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DNA Nanodevices Unit

This unit focuses on exploring and developing DNA-based tools for biomedical research. In doing this, DNA molecules and their characteristics are used to arrange and structure biomaterials on the nanometer scale. This type of technology is applied to develop biosensors and nanocircuitry for biochips, in addition to being used to develop new procedures to specifically transport molecules in vivo and in vitro. To this end, the unit investigates the biochemical and biophysical characteristics of specific DNA molecules and composite materials in order to deduce concrete applications.

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Nanotechnology Unit

This unit develops molecular diagnostic test systems for the food and medicine/clinical practice sectors. A major focus is rapid tools to detect infectious agents or diseases-specific biomarkers including methods for bioanalytical sample preparation. Work is being done with customers to create novel reagent-free cell lysis methods and lab-on-a-chip diagnostics platforms, e. g. to detect sexually transmitted pathogens in a home-testing format. The field of immunomic and oncological exosome analytics form a further focus. The unit has access to hot embossing methods.

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Bioinformatics Unit

The Bioinformatics Unit develops and establishes computer aided ways of identifying and verifying new biomarkers for the personalized diagnosis and prognosis of diseases and for the detection of novel therapeutic targets. The fact that a vast number of RNA molecules are not translated into proteins has only been known for a few years. The latest scientific findings show that these non-coding RNAs (ncRNAs) perform fineregulatory tasks in gene regulation and are therefore suitable as markers for individual disease patterns and progression. The unit develops strategies for efficient processing and (statistical) analyzing molecular biological data gained from extensive clinical cohorts based on next-generation sequencing, microarrays, and DNA, RNA, and epigenetic analytics in order to detect disease-relevant ncRNAs. The gene regulatory mechanisms of ncRNAs are modeled using methods from systems biology and RNA bioinformatics. The objective of the unit is to analyze the potential of these innovative RNA molecules as biomarkers or therapeutic targets and to establish them as appropriate clinical markers or targets.

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Study and Quality Management Unit

The Study and Quality Management Unit develops and implements processes for establishing a quality management system according to DIN EN ISO 13485. The unit's activities here focus in particular on quality assurance in the design and development of in vitro diagnostics (IVDs). A specifically designed and in-house developed data management system supports quality-compliant documentation and sample management. It captures a sample's underlying clinical data and enables every lab processing stage to be recorded in detail. The unit helps plan screening and validation studies, which are then carried out in close consultation with clinical Key Opinion Leaders (KOLs).

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CardiOmics Unit

The unit carries out research into infectious diseases relevant to cardiac surgery using state-of-the-art OMICS technology platforms. Infective endocarditis and the development of molecular biological diagnostic procedures are of particular scientific interest here, as is the translation of such procedures into routine clinical practice. Based on improved diagnostics, alternative treatment methods are evaluated and new interventional procedures taken to clinical maturity.

The unit will concentrate on the connection between infectious diseases and molecular regulatory mechanisms associated with haemostasis. In the interdisciplinary field of intervention strategies relating to cardiac surgery, the diagnosis and therapeutic intervention of the coagulation system play a vital role. The unit primarily develops diagnostic procedures to determine the effect of factor X inhibitors and /or coagulation diagnostics during the final stages of plasma coagulation.

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1

PROJECT EXAMPLES

HyFly – Non-invasive diagnostics for infectious diseases

Modern air traffic is not just useful for the fast transport of passengers or goods. Even infectious agents travel by planes over long distances within a few hours as unwanted passengers. Infectious diseases such as influenza or SARS, which can develop into pandemics, are nowadays spreading rapidly and much faster than years ago.

Steps to effectively control and prevent chains of infection in the field of modern mobility have not yet been effectively established worldwide. Initial approaches using simple questionnaires or non-contact temperature measurement, however, have remained largely ineffective.

The project "HyFly", funded by the German Federal Ministry of Education and Research (BMBF) within the InfectControl 2020 initiative, addresses the sensitive issue of passenger control. Together with partners, a non-invasive method based on ion mobility spectrometry (IMS) is being worked on. Applying this strategy, infected persons should be identified within a few minutes via components of their breathing air. IMS is already routinely used worldwide to detect drugs or explosive remnants in airports providing an established infrastructure. So-called volatile organic substances that are metabolic products of microorganisms are detected. The focus is on bacterial pathogens, which, according to information from the German Robert Koch Institute, have a high relevance for aviation.

Initial results show that the method has great potential for discriminating between different pathogens. In addition to system development, a study is underway to identify microorganisms at various international airports to determine the cleaning efficiency and impact of antimicrobial coatings

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1 *Global air traffic enables pathogens to spread at an increasing rate.*

Development of a method for the insulation of circulating tumor cells (CTC) of ovarian cancer based on the pluriBead® technology

The common objective of this research and development project between the pluri-Select Life Science UG & Co. KG (pluriSelect) and the Tumor Stem Cells work group at the Fraunhofer Institute of Cell Therapy and Immunology (IZI) lies in establishing a specific separation method for detecting circulating tumor cells (CTC) from the blood based on the pluriBead® separation technology for patients with advanced ovarian cancer.

In this project, the CTC pluriBead® separation technology should enable the early detection of recurrences and metastases in the blood in advanced ovarian cancer.

To do so, the Tumor Stem Cells work group carries out in vitro experiments to characterize CTC-specific surface markers as well as attempts to recover labeled CTC in human whole blood (spiking in). pluriSelect Life Science UG & Co.KG develops and establishes polyvalent CTC-specific pluriBeads® based on these results in AP2 and 3b to quantify isolated CTC from whole blood.

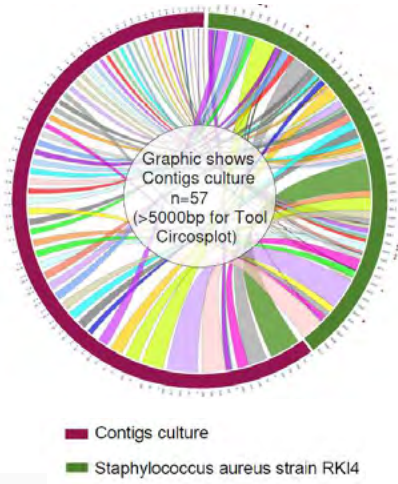
As part of a clinical study in collaboration with the gynecological oncology of the University Hospital Leipzig the validation of the CTCspecific PluriBead® separation technology is planned for test persons.

Furthermore, a tumor initiation model can be established in AP8, which can be used in subsequent experiments to demonstrate the metastatic potential of isolated CTCs and to perform therapeutic studies.

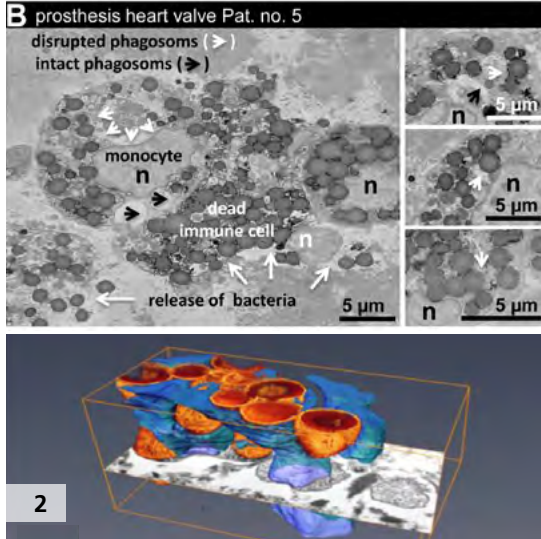
All results will be crucial to characterize CTCs for subpopulations and their biomarkers as well as to enable improved tumor therapy with conclusions about the status of the tumor illness and the observation of the success of patient treatment.

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1



2

Verification of the virulence profil of organ-specific infection

In the past decade, infectious diseases in the cardiovascular sector have been increasingly emerging as a clinical challenge. This is not only to be attributed to an increasing pathogen-specific resistance to chemotherapy but also to an improved therapy landscape, such as implanting cardiac pacemakers, heart valve systems and artificial heart systems. Current research results show that a polymicrobial pathogen infiltration defines the disease status and course.

Previous research efforts focused on identifying pathogen spectra by means of total genome investigations. Further, the goal of the research effort is to identify disease-causing pathomechanisms. To this end, it is necessary to ensure the identification agents up to the root level to allow conclusions on disease mechanisms.

Initially, the microbial community of a patient sample was analyzed via a specifically defined PCR panel. The PCR allows a quick analysis of known pathogenic germs. As unknown bacteria, which may also be pathogenic, remained undetected, the T-RLFP analysis was also used to characterise the diversity of the samples. This non-targeted method is based on the amplification and restriction of 16S RDNA and then uncovers unknown germs via cloning and sequencing. However, the sensitivity of the method is limited by the number of clones analyzed, and in some cases it does not read a differentiation of the species of a genus. A more sensitive process is genome sequencing based on the 16S RDNA or the overall genome. It was possible analyse the microbial composition of a patient sample and also detect bacteria in low concentrations up to the species level.

The main challenge in applying the new analysis methods lies at the level of bioinformatics diagnostic strategies. This ranges from the assignment of pathogen-specific DNA molecules to the identification of the pathogen stem to the classification of virulence factors. These virulence factors must be correlated with the patient outcome in prospective clinical trials and thus their clinical relevance will be developed. The aim of the working group is to develop this clinical molecular biological diagnostic path, to establish necessary bioinformatic tools and to incorporate the findings into the daily routine in clinics.

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1 Whole-genome analysis of a *Staphylococcus aureus* culture
 2 2D and 3D images of a heart valve with bacteria

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DEPARTMENT OF DRUG DESIGN AND TARGET VALIDATION

Medicinal chemistry | Assay and model development
Neurodegenerative diseases | Pharmacology
Drug development | Drug design (in silico)
Drug testing (preclinical) | Synthesis





THE DEPARTMENT AT A GLANCE

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

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

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

UNITS

Molecular Biotechnology Unit

The Molecular Biotechnology Unit develops and establishes analysis and model systems for use in cellular and molecular biology. This involves cell-based assays, gene expression analyses, immunological and protein-chemistry methods, sophisticated cell culture models and animal experiment approaches. In the area of preclinical development, the unit is able to conduct a series of cell-based tests to characterize substances with regard to efficacy, toxicology and transport. Furthermore, in collaboration with the unit's analytical laboratory, pharmacokinetic parameters are determined in vivo and the effectiveness of small molecules and protein drugs are investigated in respective disease models. The unit is also able to establish new animal models to investigate enzyme functions in the organism. Beyond this, it assists with drug development in terms of regulatory preclinical practice.

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Protein and Drug Biochemistry Unit

The Protein and Drug Biochemistry Unit has extensive experience in the purification of target proteins and their enzymatic characterization. Besides traditional protein chromatography procedures, protein chemical methods are also used, e.g. spectroscopic and crystallographic methods for analyzing structure and enzyme-kinetic effect. The unit specializes in the humanization of antibodies to manufacture protein drugs right up to their semi-preparative extraction. The subsequent structure-activity analysis and structure-based molecular optimization round off the unit's portfolio.

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Drug Design and Analytical Chemistry Unit

The service portfolio offered by the Drug Design and Analytical Chemistry Unit covers the entire spectrum of medicinal chemistry and analytics required to identify potential new drug candidates from the field of "small molecules" and develop them into clinical candidates.

By using computational procedures, potential new target molecules are first designed in silico and evaluated as to their efficacy on the target protein. Once this stage is complete, synthesis and real testing on the isolated target protein can then be carried out. The unit is also able to provide analytical assistance to drug development in preclinical and clinical trials. Respective parameters can be pursued using HPLC-coupled mass-spectrometry methods. These investigations can also be conducted in line with regulatory requirements (GLP). Moreover, biophysical methods such as isothermal titration calorimetry and surface plasmon resonance spectroscopy are drawn upon to characterize binding behavior. Biological assays are developed and validated together with the other units, allowing the success of new types of treatment to be monitored using biomarkers.

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PROJECT EXAMPLES

Peptide aggregates and microparticles for therapeutic applications

Countless human diseases, many of which are incurable, can be traced back to the misfolding and depositing of peptides or proteins. Protein misfolding diseases include, for instance, Alzheimer's and Parkinson's disease as well as other neurodegenerative diseases. In these cases, fibrillose structures are formed by the body's own proteins that are extremely stable in the organism and cause cellular damage to the affected tissue.

One therapeutic approach lies in the development of antibodies that mark the stable aggregates and pave the way for alternative degradation processes (phagocytosis). Characterizing the binding behavior to the aggregate is essential in developing these types of substances.

This collaboration project between Fraunhofer IZI-MWT and Fraunhofer IMWS therefore seeks to investigate the structure of fibrillose proteins (e.g. amyloid- α , ADan) using microscopic techniques (TEM, AFM).

In order to do this, the peptides and/or proteins will be synthesized, purified and caused to aggregate in vitro. The binding of monoclonal antibodies to these structures will be characterized by means of immunogold labeling.

To this end, the project partners came together to draw up a protocol for processing and preparing (contrast filling) the respective proteins. Using HAADF-STEM and AFM, accumulations of proteins with ring and globular structures were able to be detected on β -synuclein filaments, for instance, during protein aggregation. Investigations focused on antibody-fibril

interactions demonstrate the binding of gold cluster-labeled antibodies to A β filaments, enabling the antibodies' binding positions to be differentiated on the filaments.

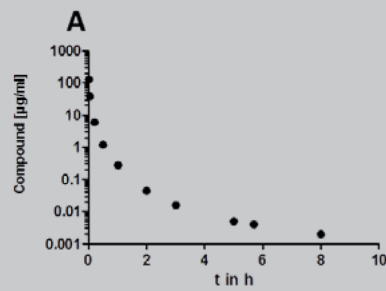
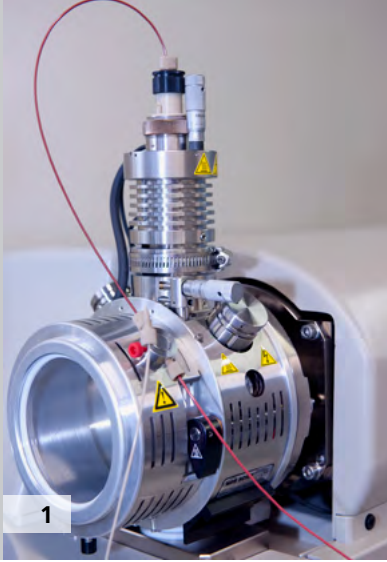
Assisted by surface plasmon resonance (Biacore™) and isothermal titration calorimetry (ITC), these investigations are valuable in developing antibodies and therefore serve as an exemplary model for protein drug development.

The project is being handled by the High Performance Center for Chemistry and Biosystems Engineering.

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1 *Preparative chromatography
for protein purification*



Determination of pharmacokinetic parameters of small molecules

A comprehensive characterization of physico-chemical, cell-biological and pharmacokinetic properties of small molecules are prerequisite for their preclinical development. This process is required for the application of efficacious, safe and well-tolerated molecules in human subjects later during clinical development. Important steps during preclinics are investigations on liberation, absorption, distribution, metabolism and excretion (L-ADME parameters) in animal models. Here, information on exposure, bioavailability and terminal half-life will be collected. These data serve as decision points for selecting preclinical candidates or are used for optimization, e.g. bioavailability of an already selected candidate, by formulation development.

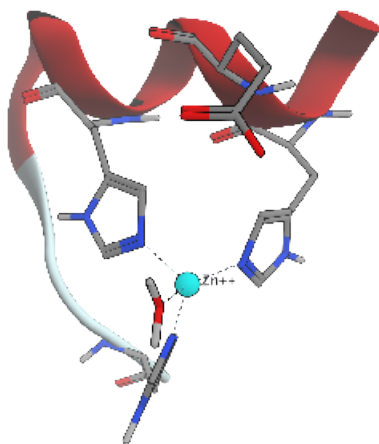
The Department of Drug Design and Target Validation at Fraunhofer IZI develops new molecular therapies for neurodegenerative and inflammatory disorders. The department's strategy includes identifying novel drug target and testing novel therapies. For characterizing new small molecule classes, a catheter-based rat model for analyzing pharmacokinetics of such compounds has been established by the Molecular Biotechnology unit. The model is comprised of surgical application of a catheter in the jugular vein (V. jugularis) and in the carotid artery (A. carotis communis), respectively. Using this method, it is possible to obtain complete compound profiles from a single animal, which avoids inter-individual variations, e.g. when using mice. In addition, a close collaboration with the Drug Design and Analytical Chemistry unit enables rapid determination of compounds concentrations in blood samples by LC-MS.

The applied method is being used successfully within the Department of Drug Design and Target Validation, e.g. for own projects, such as the development of novel inhibitors for alternative beta-secretases or the development of novel inhibitors for the treatment of periodontitis. It is also requested and used by partners from industry and academia.

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1 *Mass spectrometry analysis to determine the concentration of the active ingredient in the organism (A)*



1

Broadening the chemical space of metal binding groups

A whole spectrum of target enzymes seen to be of medical interest contain a metal ion in their active site that is involved in the catalysis of the corresponding reaction. These metal ions usually present a starting point for the development of new drugs as the principal affinity of the respective inhibitor often emerges as the result of the medicinal substance binding to these metals. As however, until now, only very few active metal binding groups have been described in the literature, which then often do not block the actual target enzyme selectively but also other metal-dependent enzymes, the development of highly promising approaches often failed. Due to cross-reactivities within the enzyme class, matrix-metallo-protease inhibitors, for instance, were not pursued further despite years of intensive research.

A new computational chemistry approach has been developed in the Drug Design and Analytical Chemistry Unit that represents a combination of semi-empirical and quantum chemical methods alongside ligand- and structure-based approaches. Based on these complex calculations, it is now possible to significantly expand the chemical space of metal binding groups. Fragments discovered here are adapted for the respective application and constitute completely new chemical classes of molecules for future medicinal-chemical development. In the case of one particular metal-dependent acyltransferase, for example, alongside the four metal binders already known, another six new and just as active compound classes were able to be identified and pursued further.

As they had never been described in the past, they have now expanded the patent portfolio of the Department of Drug Design and Target Validation. The approach depicted here is currently being modified and adapted to the molecular properties of another target protein from the Astazine family. The aim is to avoid the possible adverse effects of potential new drugs described in the literature for the metal binding groups utilized so far.

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1 *View of the active site of Meprin β , a possible target enzyme involved in various fibrotic diseases. The graphic shows catalytically active zinc with the coordinating amino acids and a water molecule as the 4th ligand.*

Location Potsdam-Golm, Germany

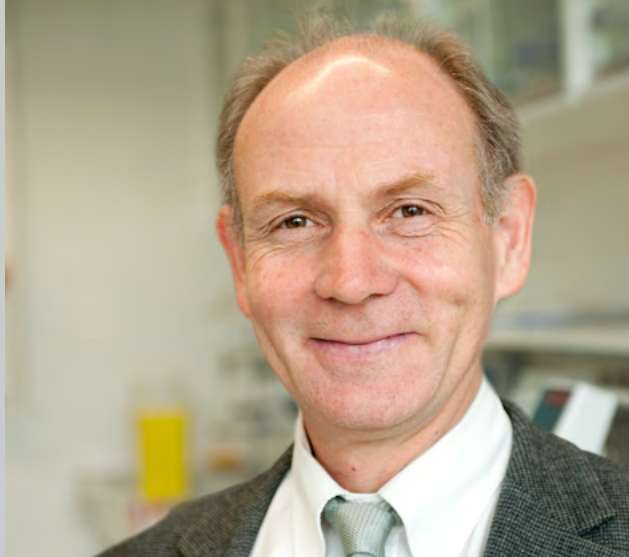
DEPARTMENT OF BIOSYSTEM INTEGRATION AND PROCESS AUTOMATION

Point-of-care | In-vitro-diagnostics

Automation | Assay development | Device development

Processautomation





THE DEPARTMENT AT A GLANCE

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

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

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

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

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UNITS

ivD Platform Unit

The unit develops procedures and devices for various point-of-care applications. Based on miniaturized lab automation using microfluidics and biosensors, application-related, on-site solutions are developed for use in medical and non-medical fields. Among other things, an in vitro diagnostics platform (ivD platform) is available for this purpose, which can be adapted to different diagnostic tests depending on the matter at hand. Besides developing new diagnostic procedures, the unit offers customers and partners the opportunity to transfer existing tests (e. g. ELISAs, DNA microarrays, etc.) to the ivD platform. It also offers test optimization and technical verification, right through to authorization. The platform is open to numerous biomarkers and offers customers a fast way of moving from the biomarker to the actual product.

Current activities are focused around processing and detecting microbial samples (infection diagnostics, hygiene) and characterizing antibiotic resistances besides detecting specific nucleic acids in blood and other bodily fluids.

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Biomolecular Nanostructures and Measurement Technology Unit

The unit carries out research and development for the analysis of biomolecular interfaces and higher-order electronic effects. At the center of our activities are applications for point-of-care testing, however applications in a laboratory environment are also included. The methods used cover a broad range of microscopies including high-resolution optics, electronic and atomic forces microscopy, as well as THz spectroscopy.

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Biomimetic Functional Materials Unit

The unit develops technologies and solutions for fast, homogeneous immunoassays with an affordable electrochemical readout system for point-of-care, food and environmental analytics. "Smart" dry reagents tailored to the customer offer not only a high level of storage stability, but also added functionalities such as adhesion, transparency, slow-release kinetics or desiccation protection. Biomimetic electrochemical sensors, functionalized with artificial binding molecules (MIPs, "plastic antibodies"), offer new analytical options if antibodies are not available or desired.

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Laboratory and Process Automation Unit

This unit provides solutions for the automation of complex processes in biomedicine and biotechnology. The workflow in cell culture, cell expansion and monitoring, as usually done in the lab, forms the basis of analysis. The aim of all automation approaches is to standardize complex workflows and enhance efficiency as well as the quality of cell products.

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PROJECT EXAMPLE

AMBIsense – improving the analysis of viral pathogens

Infectious diseases continue to pose one of the greatest challenges to health care systems all around the world. They have reemerged as an increasingly serious health risk in industrialized societies for a number of reasons in recent years: population growth, increased mobility of people and goods, demographic transition, complacency towards vaccination and even medical advancement have all contributed towards a shift in the appearance of illnesses that were once thought vanquished, e.g. measles and tuberculosis. New viruses and modified germs are, however, also a natural development, as is the emergence of antibiotic resistance as evidenced by avian flu, HIV, Ebola and the Zika virus.

The collaboration project "Analysis of multivariate binding patterns for applications to detect and fight infections using switchSENSE (AMBI-SENSE)" is a cooperation between the company Dynamic Biosensors and the Department of Biosystem Integration and Process Automation which aims to better analyze the binding patterns of viral pathogens. Multiple binding patterns are being looked at in the hope they can then be used to generate novel binding molecules. These types of molecules are of biotechnological, bioanalytical and, in particular, medical interest in terms of specific detection methods and as base substances for new drugs. In order to demonstrate how this analysis will be used, an example will be taken from the field of virus detection to begin with. In the second stage, microbial pathogens will then also be recorded as targets and the differences between the binding patterns will be pinpointed.

Detailed analyses of pathogenic binding patterns on host cells can be used to speed up the detection of these germs, to support differential diagnostics and, in turn, to improve targeted therapy. On the other hand, they will provide the basis for developing new vaccines and drugs.

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Location Potsdam-Golm, Germany

DEPARTMENT OF MOLECULAR AND CELLULAR BIOANALYTICS

Lab-on-chip | Microfluidics and systems
Biobanks | Rapid prototyping | Biosensor technology
Assay development | Functionalized surfaces





THE DEPARTMENT AT A GLANCE

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

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UNITS

Microarray and Biosensor Technology Unit

The unit develops and modifies the surfaces of biological materials with the aim of also analyzing and characterizing the smallest sample quantities in as much detail as possible. The technological implementation takes place both on geometric materials, such as fibers, and as well as on planar carriers, such as plates or chips. The surfaces themselves vary from glass containers and wafer materials through to plastics. The products developed by the unit include independent sensor elements (e. g. test strips) or analysis and database tools (cell and peptide chips) and can be applied to the various issues in the fields of environmental analysis, food control, herd management, process control and diagnostics.

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Biomarker Validation and Assay Development Unit

The main tasks of the research area are the development of specific assays for validating biomarkers as well as developing and adapting assays on various platforms such as microarrays, ELISA, lateral flow systems and beads-based assays in the fields of life science, environmental and food analysis. In addition, physico-chemical parameters such as kinetic constants (KD) can be determined using label-free detection methods (e. g. Biacore, bScreen, Nanotemper) and the composition or modification of surfaces (e. g. contact angle measurements and ellipsometry) can be determined. All techniques are being continuously developed further for (customer) specific applications. Applications include systems biology projects for the validation of potential biomarkers, kinetic analysis of antibodies, the quantification of specific markers in serum samples, and the development of point-of-need applications, e. g. for the determination of microbial contamination in environmental samples.

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Metabiobanks Unit

The unit develops ICT infrastructure for and solutions around networked biomedical research: Based on the CRIP Privacy Regime (which was approved by German data protection authorities in 2006), remote biobanks are integrated into so-called meta-biobanks, facilitating cross-institutional and transnational queries concerning human specimens on a case-by-case and sample-by-sample basis. Thus, material and data originally collected for health care (e. g. blood, serum, tissue) are swiftly made accessible through stratified, statistically relevant "clinical cohorts" to support research in personalized medicine and disease biomarkers.

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Molecular Bio-Engineering Unit

This unit converts natural biological processes into isolated artificial architectures and strategies which utilize new perspectives in applications of cellular structures, mechanisms and metabolisms. In former studies, for example, modified synthetic membrane proteins were used to fix extracellular entities. More recent studies deal with innovative immunodominant antigens taken from cDNA libraries of prokaryotic transcriptomes, which mainly consist of pathogens, besides the development and construction of antimicrobial peptides, especially synthetic and artificial peptides, within the scope of antibiotic resistances.

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Microsystems for In Vitro Cell Models Unit

This unit offers the application-related and customer-specific development of procedures and prototypes for cultivating, characterizing and processing precious cell samples. Our expertise in microreactors, microfluidics, sensor technology and functional polymer coatings forms the basis for innovative solutions, which are complemented by our knowledge in the fields of cell biology, toxicology and bioanalytics. The unit's interdisciplinary orientation enables us to provide well-founded, targeted advice and to address your specific needs. Our work focuses on (i) developing in vitro test procedures for the assessment of the toxicity of drugs and chemicals based on highly functional microbioreactors and relevant cell models, as well as (ii) establishing intelligent polymer coatings which allow the behaviour of adherent cells to be controlled on technical surfaces.

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Microfluidic Cell Processing and Cell Analytics Unit

This unit offers the application-related and customer-specific development of procedures and prototypes to process and manipulate demanding biological samples. It focuses in part on manipulating individual objects, e.g. the gentle and versatile handling of single cells and particularly small cell samples in microfluidic chips. This usually involves the use of electric fields in the radio frequency range. For more complicated tasks, this is combined with complementary manipulation procedures involving optical tweezers or microfluidic processes. In addition, the unit deals with the integration of sensor technology in microfluidic components to record key parameters relating to cells and other complex biological samples.

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1

2

3

PROJECT EXAMPLES

Development of a multiparametric rapid test for germ load and/or 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. This increased threat caused by bacterial pathogens requires innovative solutions that allow a quick and easy analysis to be carried out and the relevant countermeasures to be initiated in good time as necessary. To this end, the physical and chemical antibacterial procedures currently in use have to be supplemented and supported by a robust, rapid detection procedure. A preventive, non-toxic, sensory element coupled with a reduction in germ load and/or antibiotic treatment would significantly raise the efficiency of countermeasures and treatments universally, flexibly and as required.

The aim of the project is to develop a multiparametric rapid test for germ load and/or resistance monitoring. There are a number of different fields of application relevant not only to preventive and general health care but also animal husbandry and exploitation and even the food sector. The procedure described here therefore has an integrative effect, bringing together all fields and topics relevant to health care from across all kinds of departments. The subsequent findings allow new strategies to be developed in the area of bacterial infections that will increase the effectiveness of preventive health care besides promoting fit and healthy living.

The test will potentially be used in hospitals (e.g. in the reception area), in public areas (e.g. in airports) and in the tourism industry (e.g. cruise ships), as well as among livestock populations and at various stages of the manufacturing process. The aim is to create an expanded, faster and more efficient way of detecting the presence of relevant pathogens and resistance genes. Moreover, the test can be used as a second, independent verification method alongside existing procedures.

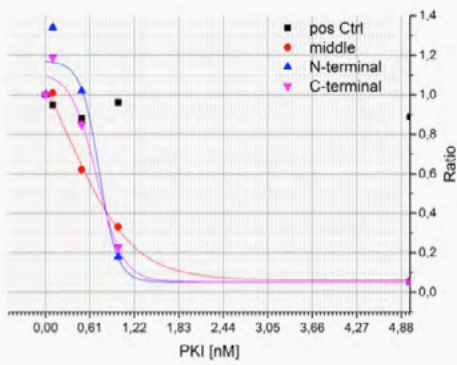
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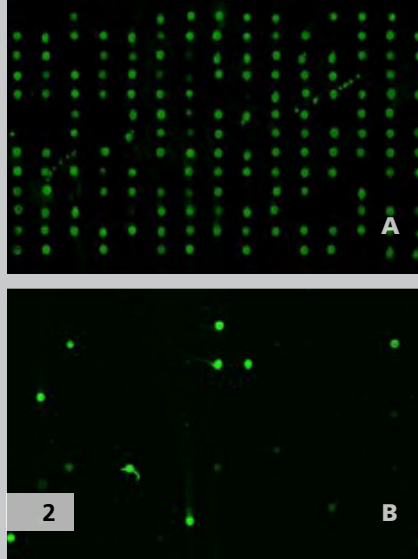


EUROPEAN UNION
European Regional
Development Fund

1/2/3 Possible areas of application for a multiple rapid test for germ load monitoring (hospitals, airports, tourism)



1



2

Tools to study post-translational Modifications (Phosphorylation) of proteins / peptides

In the project, techniques for investigating signal transduction in cells, especially for the analysis of post-translational modifications (phosphorylations), should be developed and tested in a system-biological context for specific questions. These tools should have the potential to screen both potential target molecules (proteins and peptides) as well as to screen chemical compounds to identify specific inhibitors of the enzymes involved. As a model system, kinases and their targets were selected which were involved in the sensitization of pain and supplemented with data derived from in vivo experiments and by modeling the signaling pathways.

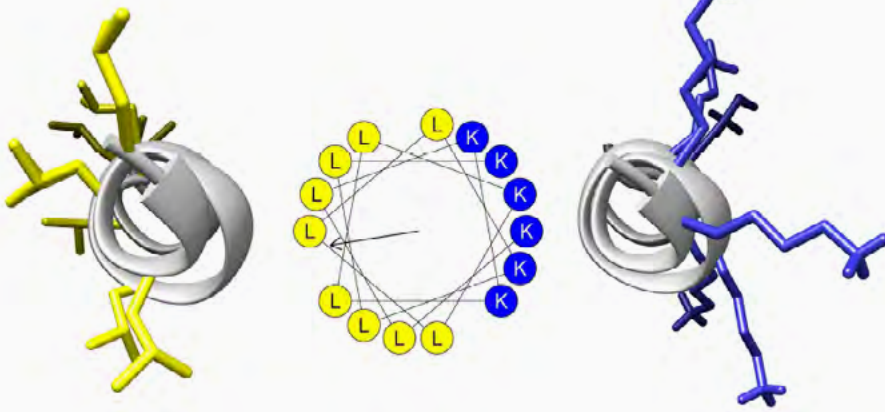
As an experimental approach, peptide microarrays and a beads-based system were used and various specific fluorescence-based detection systems were established. Quality control has been established for all reagents, e.g. allowing a rapid and simple analysis of the enzymatic activity of kinases or tests the specificity of the used antibodies. The standardization of the individual experimental steps allows using the same starting reagents for both techniques. In addition to cost reduction, this leads to a high comparability between the two techniques. The combination of peptide microarrays and a beads-based system allows the parallel screening of several 1000 peptides (peptide microarrays) and a fine analysis of selected peptides (beads-based system). Using the established techniques, two methods for the analysis of phosphorylation are available with which other post-translational modifications can be analyzed. Thus, kinases for instance, whose target sequence already contains a phosphorylation, could be analysed with the method.

In addition to the analysis of post-translational modifications the techniques can be used for characterizing enzymes and compounds which lead to an activation / inhibition of these enzymes, the techniques are suitable for determining the specificity of antibodies and other binders as well as for serum screening for identifying and validating potential biomarkers .

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1 Beads assay. Red circle: the kinetics of phosphorylation of a known peptide through the PKA. Black square: phosphorylated control peptide.
2 Peptide microarray with 189 different peptides. A) Control peptide immobilization B) Following incubation with PKA and detection with a phosphospecific antibody



1

Peptide-based antimicrobial surfaces in dairy production

One of the most important procedures to decrease germ burden at dairy plants is an antimicrobial intervention at the significant surfaces such as dairy equipment, resting areas or skin of dugs.

Currently there is either no reduction of burden or in the case of equipment there is an extensive disinfection by germicides which is finally unsatisfactory, regarding the relevant pathogens.

For an effective reduction it is necessary to identify the germs followed by a targeted and lasting disinfection by appropriate agents. Therefore the consortium of RemuNa seeks two procedures for the identification of bacterial biofilms by using sensor-driven pen-side monitoring and MALDI-TOF for a specific on-site analysis or in the lab. There is no longer a need for laborious screening and cultivation. Thus the consortium of RemuNa is able to elucidate the germ reduction by using these two developed techniques.

The mentioned reduction of germ burden will be facilitated by so-called antimicrobial peptides (AMPs), which are to be developed within this consortial work. AMPs are known to avoid multiple resistances like antibiotics. AMPs represent an effective control measure and do not require any recognition sites on cell membranes. To prevent AMP action, cells have to reconstruct their membrane architecture. This is hard to be permuted and hence the initiation of resistances is implausible. AMPs are presumed an effective alternative to antibiotics and can decrease infections caused by pathogenic bacteria.

To avoid the development of bacterial biofilms, which cause source of germ contamination, the design of new biological germicides based on dissolved AMPs or AMPs immobilized on surfaces is a promising attempt. This is an effective possibility to minimize biofilms and germ burdens by inactivating of bacterial contaminations, which is the focus of the cooperative project.

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1 *Antimicrobial peptides:
Schematic depiction of an am-
phipathic, α -helical peptide.*



Gastric adenocarcinoma → ICD-10: C16
ICD-O-3: 8140/3, C16

1



2

MOLECULAR AND CELLULAR BIOANALYTICS

CRIP.CodEx: Knowledge extraction from free-text medical records

Nowadays, medical research draws on a range of technologies, databases and connected platforms such as Arevir (Roomp et al., 2006), CRIP (Schröder et al., 2011) or p-Bio-SPRE (Weiler et al., 2014) in order to process mounting knowledge and the wide range of measurement data and to use it to improve drug compatibility, decision-making support and statistical analyses. The information contained in free-text records is, however, usually withheld from the fields of research or personalized medicine if the data have not been appropriately processed or displayed in a structured format (Ambert & Cohen, 2009).

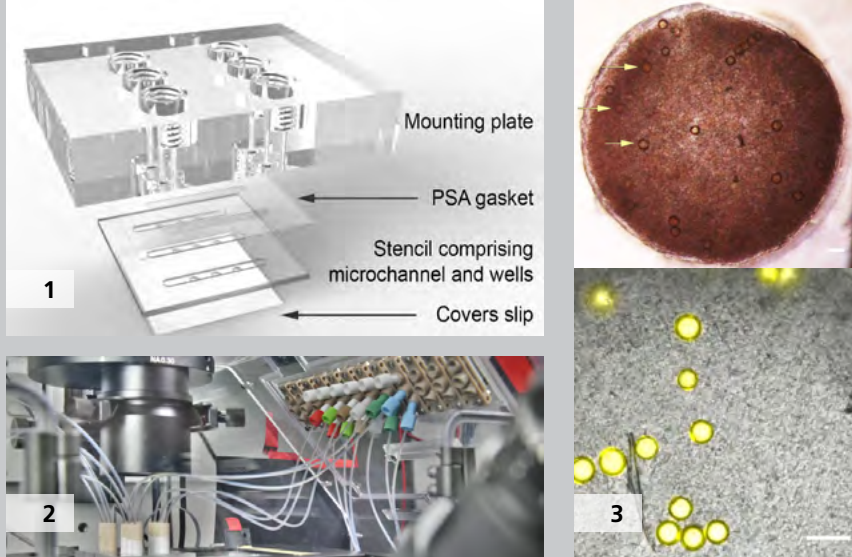
So that it can be integrated and used with different research approaches, the information held in medical free-text records has to be well-structured and also suitably extracted from the text. The CRIP.CodEx process takes care of this extraction in a user-friendly, quick and efficient way and presents the extracted information in a structured format (e.g. ICD codes, TNMSystem). CRIP.CodEx recognizes word relations, negations and their scope within free text (Gros & Stede, 2013) and does not require any access whatsoever to internal or external databases or other resources. The extraction rules are automatically "learned" after a coding guide is imported as a one-off action. This does not require a previously annotated training set or rules to be manually entered. Dictionaries and guidelines can simply be added as and when required. CRIP.CodEx is multilingual (currently in German and English), can be used right away on any Windows computer without prior installation, is intuitive and only takes a few seconds to process each text.

CRIP.CodEx was developed using medical records from the field of pathology and achieves a hit ratio of 97–99 per cent with 94–98 per cent accuracy (German pathological findings; ICD-O-3). The software can, however, also be used with free-text records from other fields of medicine and can also be combined with other systems (e.g. MOTS; Stede & Bieler, 2012).

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- 1 Knowledge extraction from free text using CRIP.CodEx
- 2 CRIP.CodEx online demonstrator website



Age-related liver and endothelial function

The proportion of the population above the age of 60 is increasing at a remarkable rate in highly industrialized countries; in some regions this is propelled even further by socio-logical developments. This scenario is posing some huge challenges to health care. While people are increasingly living longer and longer on the one hand, the suitability and effectiveness of therapeutic measures tend not to be reliably reviewed with an eye to this particular population group on the other.

Issues surrounding age-related pathological processes affecting cell, tissue and organ functions are currently being investigated as part of the cluster "Consequences of age-associated cell and organ function" at Brandenburg Health Campus (Gesundheitscampus Brandenburg). More specifically, the problem of adverse drug reactions (ADRs) is being examined together with colleagues from Brandenburg University of Technology (BTU) Cottbus Senftenberg, the University of Potsdam and Helmholtz Zentrum Geestrich.

The project aims to develop a concept for predicting what effects a drug might have on liver and endothelial function on a case-by-case basis. To this end, in-vitro test systems are being established based on cell systems comprising hepatocytes and endothelial cells. Alongside physiologically relevant cells from cell lines, primary cells from patient biopsies are also being looked at to create the test systems.

A micro-bioreactor recently developed at Fraunhofer IZI-BB is being used for the long-term cultivation of cells. Microsensors for the determination of the concentration of oxygen in the cell medium, which enable an optical readout are the innovative feature of this reactor. They allow the cells' metabolic activity to be continuously measured in real time over a period of several weeks - something that has never been

done before. The dynamic data that can be generated here provide, for example, valuable information on the cellular mechanisms associated with the metabolism of potentially toxic substances. Measurements carried out on modified hepatocytes with an important up-regulated liver enzyme (BTU), which are exposed to various drugs and medication cocktails, demonstrate the usefulness of the pursued approach.

Funded by



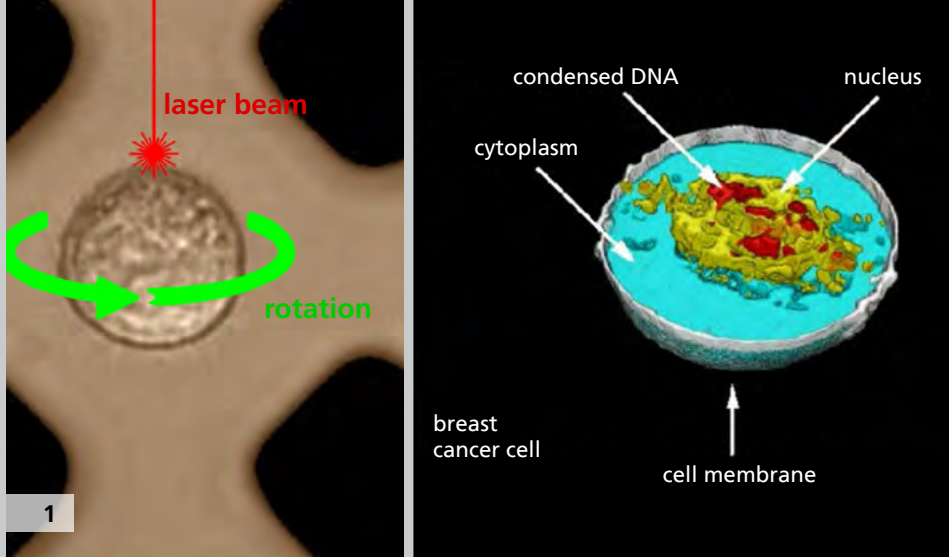
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1 Exploded view of the micro-bioreactor. The three channels, each featuring three wells where the cells are placed, can be operated independently.

2 This photo shows the micro-bioreactor (bottom left) in operation. The array with the control valves can be seen at the very top.

3 Both microscope images show a well in the microchannel containing the cells and sensor particles. Three of the particles in the top image are marked by arrows; the particles are yellow in the bottom image (scale equivalent to 100 µm).



Phase 3D label-free optical nano-sensing and sorting of rare clinically relevant cells on dielectrophoresis-based microfluidic chips for cellular diagnostics

The analysis of rare cells, such as hematopoietic stem cells or circulating tumor cells (CTC), in biological biopsies can yield better diagnosis decisions and empower new therapeutic approaches. However, current strategies for cell separation do not offer the discriminative power needed for an unambiguous identification of these clinically relevant cells. Moreover, most techniques for cell sorting are based on staining with small molecules or antibodies, which impairs the viability of the cells or make them incompatible with further therapeutic use. Therefore, label-free cell separation techniques, which allow for noninvasive and automated cell processing and at the same time offer high discriminative power on the level of the individual cell, are urgently required.

The aim is a microfluidic process line for the label-free analysis and separation of living cells from heterogeneous cell samples. Quantitative phase imaging with sub-nanometric sensing capabilities as well as contact-free, noninvasive dielectrophoretic (DEP) cell handling is employed to non-invasively determine the optical thickness of the cells over different spatial directions. This will help to resolve the three-dimensional distribution of the cell's refractive index and, thus, morphological structures within the cells.

For the first time, it will be possible to quantify multiple biophysical parameters of the cells such as size, structure, shape, dry matter, density and membrane area as well as subcellular structures in real time and during flow. Based on the obtained data, the cells will be precisely characterized and stored individually in standard microtiter plate formats.

If successful, the system will offer an outstanding approach for live-cell sorting that may be used as a powerful device in automated cell processing systems with a great potential for basic cell biology and medical research, cell-based therapeutics and personalized medicine.

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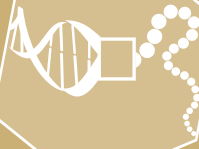
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1 Schematic of the label-free and contact-free analysis and separation of living cells from heterogeneous cell samples. One cell is made to rotate contact-free using high-frequency electric fields and is irradiated with a laser beam. Using a phase optics procedure, the optical thickness of the cells is recorded across all spatial directions and the 3D distribution of the refraction index in the cell is then calculated, providing an insight into morphological details on the inside of the cell.

Standort Potsdam-Golm

DEPARTMENT OF CELL-FREE AND CELL-BASED BIOPRODUCTION

Cell-free protein synthesis | Interaction assays | Protein characterization | "On-chip" synthesis | Antibodies and membrane proteins | Massproduction of algae
Biosynthesis of toxic proteins | Photo bioreactors
Cryophilic algae collection





THE DEPARTMENT AT A GLANCE

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

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

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

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

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UNITS

Functional Nucleic Acids – Aptamers Unit

The Functional Nucleic Acids – Aptamers Unit aims at developing new innovative products on the basis of aptamers. This goal comprises the generation, synthesis and functionalization of aptamers as well as the integration in diverse applications. The unit thereby seeks a close collaboration with the industry and academic institutes. Primarily, aptamers are short, single-stranded DNA and RNA molecules with the particular feature of binding high-affine and high-specific a target molecule such as antibodies. The very broad capabilities of aptamers as binding molecules are used in analytical, diagnostic and therapeutic applications. A focus is on the generation of new aptamers by using an automatic in vitro selection process as well as a monitoring and managing process. Additionally, the unit develops of aptamer-based detection methods such as lateral flow assays or so-called aptasensors.

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[Click here](#) for further information about the unit.

Eukaryotic Lysates Unit

The unit is developing cultivation systems for eukaryotic cell lines in order to obtain translationally active lysates for cell-free protein synthesis. In this respect, testing new cell lines for their in vitro expression capabilities is of highest interest. Furthermore, the unit develops and optimizes eukaryotic cell-free translation systems. The influence of fermentation conditions, cell disruption as well as transcription and translation components are of special interest for the translational productivity of the generated lysates.

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Extremophile Research & Biobank CCCryo Unit

The unit studies the adaptation strategies and industrial usability of cryophilic (= cold-loving) freshwater microalgae. The aim is to characterize these so-called snow and permafrost algae with regard to the various strategies by which they oppose extreme environmental parameters such as cold, UV radiation, drought and osmotic stress, before transferring these natural adaptation strategies into industrial applications. The CCCryo culture collection is unique in its diversity and scope and forms the basis of this work. Furthermore, the unit develops optimized photobioreactors for a sterile mass bioproduction of these autotrophic organisms on an industrial scale

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Cell-free Protein Synthesis Unit

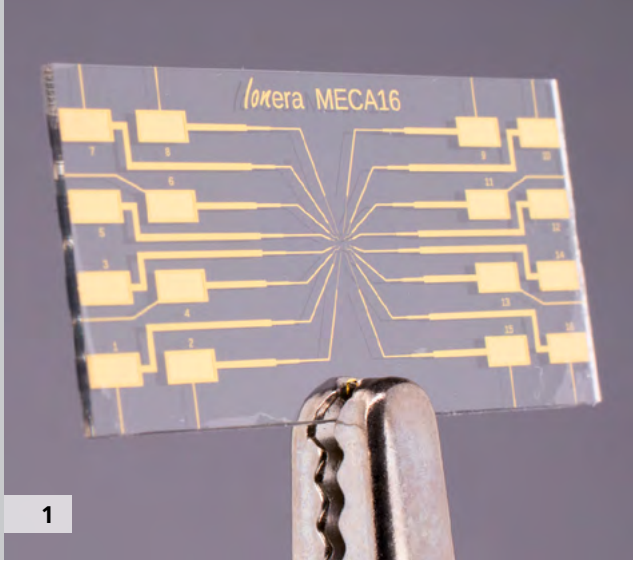
The unit researches and develops systems for the cell-free synthesis of recombinant proteins. A special focus here lies on characterizing, modifying and examining the functions of cell-free manufactured proteins, with particular emphasis on ion channels, glycoproteins and antibody formats. Quick and affordable target-protein synthesis is ensured as only the constituents of the cells are used. The use of eukaryotic cell lysates also allows the synthesis of post-translationally modified proteins. Beyond this, position-specific labeling enables proteins to be specifically modified, changing and optimizing their properties, e.g. through the introduction of polymeric groups. By introducing fluorescent groups at selected positions, membrane proteins in particular can be measured, functionally characterized and analyzed with an eye to identifying new binding molecules.

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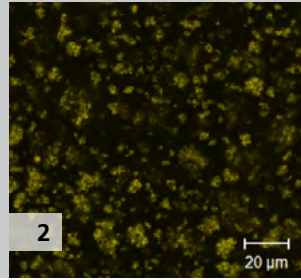
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[Click here](#) for further information about the unit.



1



2

PROJECT EXAMPLES

Cell-free synthesis of membrane proteins

Membrane proteins are essential in a number of biological processes. In humans, they make up around a third of all proteins that are coded by the genome. Ion channels and transporter proteins are of particular importance here; they play pivotal roles, for instance, in processing pain or taking in medication and nutrients.

Dysfunctions in membrane proteins therefore impact on cellular activities and can lead to a number of diseases including cystic fibrosis, different tumor diseases, chronic pain and autoimmune diseases. Furthermore, these types of defects can also result in unexpected toxic effects as well as undesirable drug interactions.

Within the field of research that looks at functional membrane proteins and toxins, cell-free protein synthesis constitutes a versatile, flexible and fast way of manufacturing these difficult to express proteins.

The synthesis reaction can be largely controlled and managed here, while the open system allows the reaction conditions to be directly influenced and enables protein folding, disulphide bridging and the assembly of non-canonical amino acids to be controlled.

The addition of detergents and liposomes as well as the use of endogenously available microsomes support the solubility of functionally active membrane proteins here as well as their correct folding. The efficient use of cell-free protein synthesis systems thus leads to the economic production of functional membrane proteins as target structures for drug development.

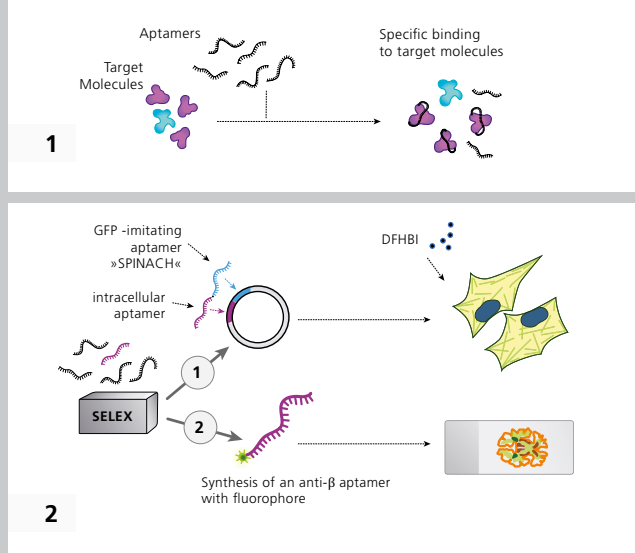
Alongside the synthesis of ion channels and transporter proteins in cell-free systems, the Cell-free Protein Synthesis Unit also pursues the development of specific, functional and pharmacologically relevant test procedures which can be used to analyze clinically relevant proteins

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1 Meca 16 chip with 16 cavities and individually addressable microelectrodes. Following the automated bilayer production, cell-free synthesized ion channels are functionally characterized on the chip surface.

2 Fluorescence microscopic image of cell-free synthesized and fluorescently labeled membrane proteins in lipidic vesicles. These vesicles are fused into planar lipid bilayers to allow analysis of the membrane proteins contained therein.



ZELDON: cell-imaging diagnostics based on functional oligonucleotides

ZELDON draws on the programmable properties of nucleotide-based materials such as RNA and DNA to solve a key problem of cell-based diagnostics concerning the development and clinical validation of therapies. The observation of dynamic transformation processes in specific cell structures or of an indicative disease marker in liquid biopsies in response to a therapeutic agent tends to involve the use of large binding molecules such as antibodies. In both of these cases, however, antibodies are not without their limitations: they are too big to penetrate living cells and mark structures, and they can be too unreliable for sensitive diagnostics as they often non-specifically bind to unwanted targets. The ZELDON project provides attractive market solutions to both cases thanks to its use of highly programmable, synthetic antibody variants known as aptamers.

Aptamers are short DNA or RNA chains (oligonucleotides) which bind to an individual target molecule with high affinity. Exclusive aptamers are to be developed with an eye to cell-imaging diagnostics for structural protein scaffolds in living cells, with the aim of identifying a marker for Alzheimer's in liquid biopsies. This kind of technology would be highly sought after among pharmaceutical developers and in the validation of new drug candidates at the preclinical stage besides as a basis for companion diagnostics in determining efficacy in clinical trials. The necessity of new procedures in cell-imaging diagnostics is highlighted in the following two examples. Firstly, commercially available options for live imaging with regard to internal cell structures and dynamics (LCI – Live Cell Imaging) have not been all that effective so far. Secondly, the visualization of biomarkers for specific illnesses, e.g. the neurodegenerative disease Alzheimer's, is seriously lacking. Tracers used in this area until now do not specifically

detect the post-translationally modified variants of amyloid beta peptides, despite them being decisive for pathogenesis, but often simply identify a handful of non-modified amyloid beta peptides or plaques without being able to make any kind of statement on pathological relevance or health benefit. In both cases – Live Cell Imaging and the specific detection and quantification of biomarkers – non-toxic, small, highly specific binding molecules that are able to cross cell membranes are required for the target molecules and structures being aimed at here. As functional oligonucleotides, aptamers display, among other things, precisely these characteristics and are also patentable.

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- 1 Aptamers as highly specific recognition molecules
- 2 Application goals for the RNA aptamers developed using the SELEX process

CENTRAL FACILITIES AND SERVICES



ANTIBODY PRODUCTION

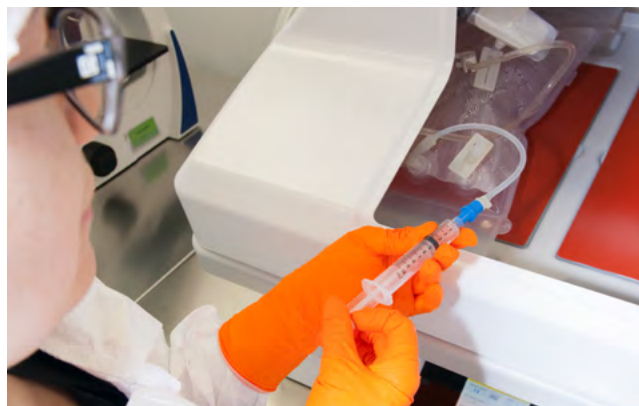
In recent years, the increasing number of therapeutic monoclonal antibody (mAb) candidates under preclinical and clinical development have required new flexible, efficient, and economic opportunities for GMP production of therapeutic antibody candidates. Small-scale batch production of test samples for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

Since January 2017, the newly constructed GMP antibody production facility of the department of Therapy Validation has been completely qualified. Our facility has a size of 180 m² and involves all clean room classes from D to A. The use of single-use equipment and materials enables an easy adaptation to new process requirements. The GMP facility can be used for different contract manufacturing processes for pre-clinical and clinical (Phase 1/2) test samples as well as for process or instrument validation projects under consideration of special customer requests. The standard equipment can be easily adapted for new products.



In summary the main advantages are:

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





Future projects could include:

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

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IMAGING AND IMAGE EVALUATION

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

In vivo imaging

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

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

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

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

Fluorescence and bioluminescence imaging for small animals

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



A



B

Bedside imaging for small animals

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

In vitro / ex vivo imaging

Confocal laser scanning microscope with live cell imaging

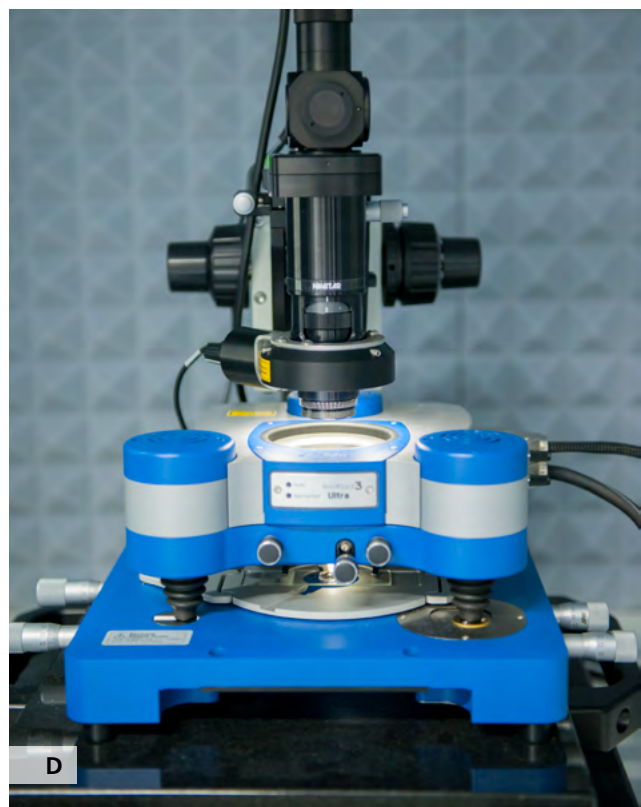
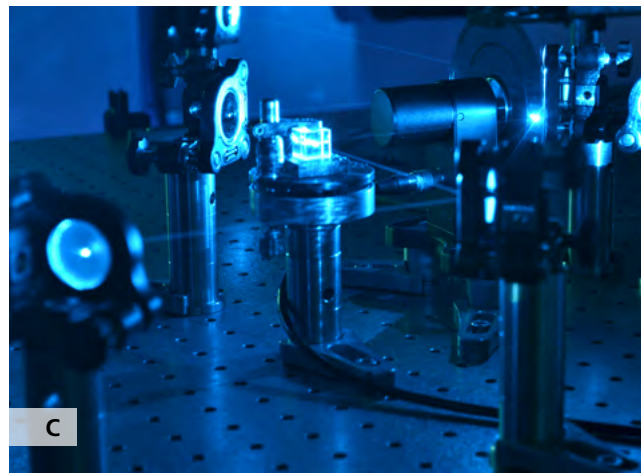
- Analysis of cell cultures and tissues in 4D, localizing target structures inside cells
- Standard laser lines from blue to red, water immersion lenses, real-time rendering and quantification of results

Light sheet microscopy (C)

- Flexible light sheet microscope with modular sample chamber for sample sizes from just a few 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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BIO-NANOTECHNOLOGY APPLICATION LABORATORY (BNAL)

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

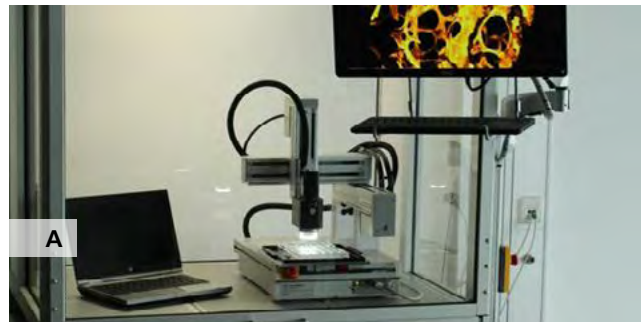
State-of-the-art equipment allows biological and medical issues to be handled in an interdisciplinary manner. BNAL provides research and development services from fundamental biomedical research by process development up to the development and validation of innovative technologies and system solutions.

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

Imaging procedures

Optical coherence tomography (A): Uses near-infrared light to depict the internal and surface structures of various materials in high resolution.

Multi-acousto-scope: The combination of three microscopy techniques paves the way to innovative new examination strategies.



Cell characterization and classification

Diagnosis and mapping for cell biology studies: Non-intrusive way of delivering high-resolution, geometric information from the inside of test objects.

Spectrometer for time-resolved fluorescence spectroscopy: Procedure to characterize cells based on electromagnetic radiation.

Ultrasound broadband spectroscopy system: This procedure has long been used in the medical diagnosis of cell tissues, biological materials and in the analysis of fluid media. It mainly identifies acoustic and mechanical properties of substances.

High-throughput flow cytometry (B): Rapid, multiplex, high-throughput screening of cells and beads in suspension.



Zetasizer: Determination of particle and molecule sizes, e. g. for characterizing recombinant proteins, micelles and nanoparticles.

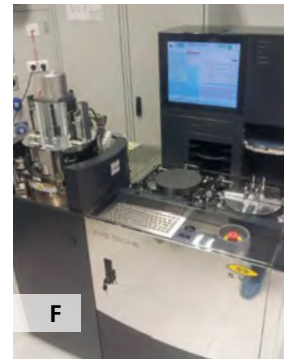
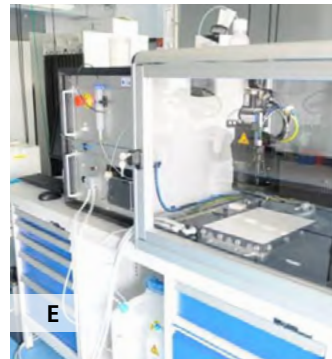
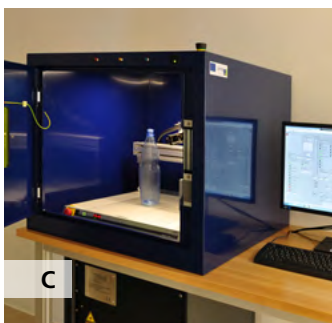
Micro-spotter unit (E): Automated dosing of tiny quantities of liquid (e. g. biological or organic solutions, or solutions containing nanoparticles) on a broad range of different surfaces for the production of microarrays.

Surface sterilization and modification

Electron beam dosimeter (C): Dose measurement of high-energy 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.

Hot-embossing system (F): Production-relevant manufacturing of nanostructured surfaces on glass and polymer surfaces.



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.

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CENTER FOR EXPERIMENTAL MEDICINE

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

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

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

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

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

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

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

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

Equipment and services:

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



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

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

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RIBOLUTION BIOMARKER CENTER

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

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

Biomarker screening and validation

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

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



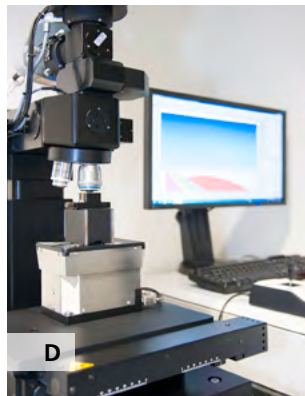
A



B



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

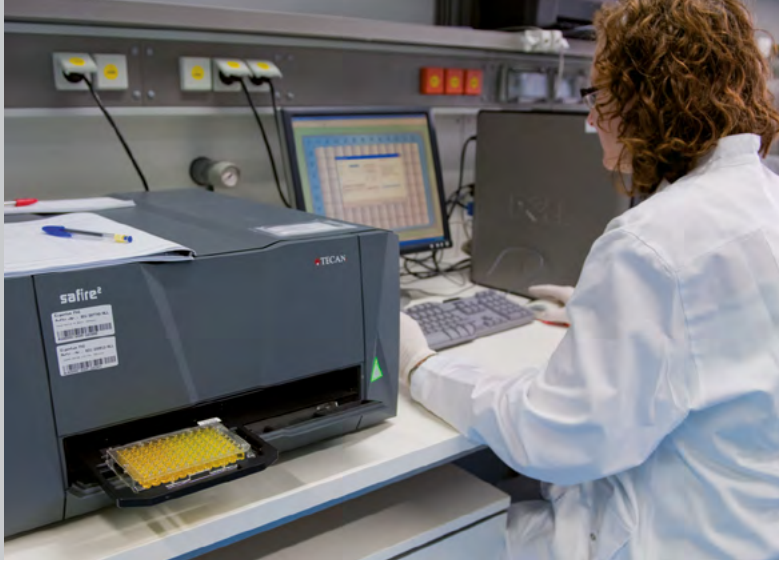
The highest quality standards are defined and implemented from start to finish, which increases the intrinsic value of the obtained data and lays the foundations for the implementation of a quality management system pursuant to DIN ISO 13485, which will become necessary as the project progresses.

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 transfer) and two grade B rooms (aseptic manufacturing). The clean room grade A is provided via laminar airflow cabinets that are installed in the B-rooms. The available clean room suites are specialized in conducting processes for manufacturing human autologous and / or allogeneic cell and gene therapeutic products (advanced therapy medicinal products). In addition to the clean rooms and the technical infrastructure, the Fraunhofer IZI offers assistance for the set-up and validation of GMP-compliant manufacturing processes as well as for obtaining a manufacturing permit pursuant to section of the German Drug Act (AMG).

Contact



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Why are GLP and GMP important?

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

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

GCP – "Good Clinical Practice"

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

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

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

board and also regulates quality management and adverse event reporting.

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

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LOCATIONS



HAMILTON
CANADA

LEIPZIG
POTSDAM
HALLE
ROSTOCK
ERFURT
GERMANY

GWANGJU
SOUTH
KOREA

THE FRAUNHOFER IZI IN GERMANY AND AROUND THE WORLD

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14476 Potsdam-Golm
Germany

Department of Drug Design and Target Validation in Halle (Saale), Saxony-Anhalt

Weinbergweg 22
06120 Halle (Saale)
Germany

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

Schillingallee 68
18057 Rostock
Germany

Project Center Microelectronic Optical System for Biomedicine in Erfurt, Thuringia

Herman-Hollerith-Straße 3
99099 Erfurt
Germany

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



LEIPZIG HEADQUARTERS, SAXONY, GERMANY

Usable area: 8 749 m²

Employees: 366

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

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

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

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

The business units Cell and Gene Therapy, Drugs and Diagnostics are primarily based in Leipzig. Biopharmaceutical products for clinical trials are manufactured in line with Good Manufacturing Practice (GMP) in the institute's clean-room facilities, which cover a total area of 1000 m².

Management



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

Usable area: 4 096 m²

Employees: 110

Focal areas: Biotechnology, bioproduction, bioanalytics, automation

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

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

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

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

Management



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

Usable area: 1 300 m²

Employees: 59

Focal areas: Biochemistry, pharmacology, drug development, analytics

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

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

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

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

Management



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

Usable area: 700 m²

Employees: 22

Focal areas: Organ-supporting technologies, clinical trials

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

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

Management



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PROJECT CENTER MICROELECTRONIC OPTICAL SYSTEM FOR BIOMEDICINE IN ERFURT, THURINGIA, GERMANY

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

Beteiligte Fraunhofer-Institute:

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

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

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

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

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

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

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

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

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

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

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

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SCIENCE LOCATION LEIPZIG



LEIPZIG AND THE FORMER TRADE FAIR GROUNDS

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 Biotechnological-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.

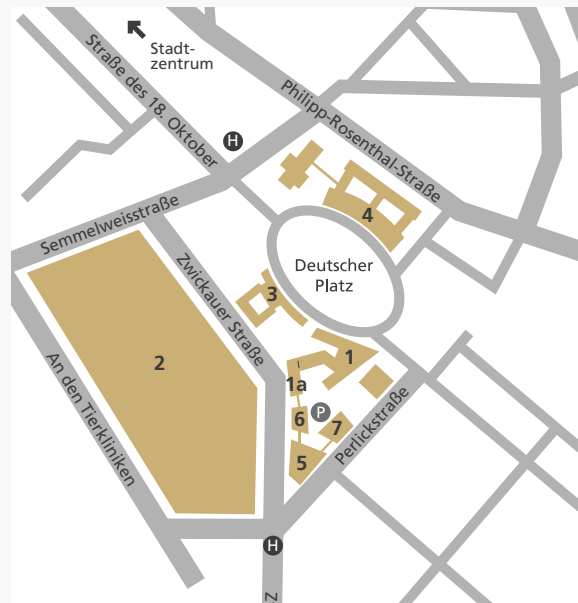
The outstanding collaboration work with the Faculty of Veterinary Medicine and its institutes and clinics directly opposite the Fraunhofer IZI building deserves special mention. Research involving animal experiments does not only serve the development of new products for human medicine, but also contributes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



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).

EVENTS



THE FRAUNHOFER IZI IN PUBLIC

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

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

The new year got off to a good start on 19 January 2017 at the Leipzig Fraunhofer Institutes' New Year's Reception. The event gave around 200 guests from the fields of research, politics and business the opportunity to catch up and network with fellow attendees in a celebratory atmosphere. Besides hearing from the directors of the two institutes, the entertaining guest lecture by Professor Michael Stelter (Fraunhofer IKTS) shed light on the possible applications of ceramics in biomedicine. The event location alternates every year between the Fraunhofer institutes, meaning Fraunhofer IMW will once again host the next traditional New Year's celebration on 17 January 2018.

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

The high performance center "Integration of Biological and Physical-Chemical Material Functions" opened on April 26, 2017. The center aims to manufacture products with integrated material functions in as few process steps as possible. The group is coordinated by the Bioanalytics and Bioprocesses Branch of Fraunhofer IZI and the Fraunhofer Institute for Applied Polymer Research IAP. Additional partners include the University of Potsdam and various players from research and industry. The aim of the cooperation is to combine structural materials which lend a product shape and stability with functional materials. Functionally integrated products such as novel lab-on-a-chip modules for medicine, sensors integrated into lightweight construction materials and smartcards for the security sector offer extraordinary potential for innovation. Another focus here is to make manufacturing processes as efficient as possible. In order to do this, material development and production technology are to be brought together and combined with one another in the new high performance center. The project is being funded by Brandenburg's Ministry of Science, Research and Cultural Affairs (MWFK) and Ministry for Economic Affairs and Energy (MWE) as well as the Fraunhofer-Gesellschaft.



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April 27, 2017: Girls' Day at Fraunhofer IZI

Girls' Day was held all across Germany on April 27, 2017. Fraunhofer IZI took part in the initiative once again, welcoming 17 schoolgirls aged 14 years and above to the institute: After a short presentation on the topic of gene therapy entitled "What can we do, what do we want to do, what are we allowed to do?" Dr Jana Burkhard, Head of the OpTCell Unit, and Susanne Przybylski, doctoral student in the OpTCell Unit, showed the girls around their laboratory. Split into two groups, the girls took turns to isolate genetic makeup from fruit and to analyze dyed healthy and diseased tissue under the microscope. Cornelia Gruhle, Heike Hemmann and Annegret Shaw spoke to the girls about equality, career opportunities and areas of research at Fraunhofer IZI. www.girls-day.de

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

Fraunhofer IZI and the Saxony Economic Development Corporation organized a workshop in Leipzig on May 12, 2017, on "Complementary Technologies for Point-of-Care Diagnostics". Point-of-Care (PoC) diagnostics is also often referred to as bedside testing: rather than rely on a central laboratory, diagnostic procedures can be carried out directly on a ward, in a doctor's surgery or even in an ambulance. Ease of use, reliability and speed are top priorities here. The research trend into these types of biochemical detection technologies is really driving development here. However, developing market-ready products requires partners in complementary technologies such as biotechnology, medicine, engineering, innovative materials, microfluidics, sensor technology and manufacturing technologies. The workshop brought together companies, research institutes and authorities from across Saxony which represented a cross-section of precisely these

technologies. The aim of the event was to connect the different players, prompt cooperations and spark development processes. Just under 20 companies and institutes took advantage of the opportunity to present themselves, their competences and their ideas.

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

At the 2017 Annual Fraunhofer Conference, which was held in Dresden from May 29 to 31, the Fraunhofer-Gesellschaft and its institutes also celebrated 25 years of applied research in the new federal states of Germany. The diverse and interactive exhibition "#real_digital: Creating values together" held to celebrate this anniversary showcased important events and types of technology typically involved in Fraunhofer research. At the International Congress Center Dresden, the 16 Fraunhofer institutes from the new federal states, including Fraunhofer IZI, introduced themselves, their history, their milestones, and the topics and projects they are set to tackle in the future to invited guests and members of the public. Another highlight of the event was the interactive "experience route" around Dresden city center that focused on the topics of research, networking and innovation. The facades of selected buildings provided the perfect backdrops for light and laser projections, through which dramatic artists illustrated the history of the city of Dresden besides relevant research topics and Fraunhofer.

- 1 *Girls' Day at Fraunhofer IZI*
Participants isolate genetic makeup from fruit.
- 2 *Workshop on »Complementary Technologies for Point-of-Care Diagnostics«.*



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

As part of a parliamentary academic day held on June 15, 2017, the Fraunhofer's Department of Drug Design and Target Validation in Halle (Saale) gave a positive recap almost four years since being established. The project group was set up back in 2013 as an off-site department belonging to Fraunhofer IZI supported by the Ministry of Economy, Science and Digitalisation in the State of Saxony-Anhalt and the investment bank Investitionsbank Sachsen-Anhalt. Today, almost 60 members of staff carry out research in the department, focusing on neurodegenerative diseases such as Alzheimer's and Parkinson's disease as well as their treatment strategies. Besides conducting contract research for industry, the department is also involved in numerous national and international research consortia. On occasion of the parliamentary academy day, Professor Armin Willingmann, Minister of the Economy, Science and Digitalisation for the State of Saxony-Anhalt spoke to the 60 guests who had been invited from the fields of politics, science and industry and paid tribute to the accomplishments of the Halle researchers.

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

On August 1, 2017, Fraunhofer IZI and Fraunhofer IZI-BB started setting up their new research unit at Monash University in cooperation with the ARC Centre of Excellence in Advanced Molecular Imaging.

Alternating extended stays for visiting German and Australian researchers, joint workshops and symposiums are also planned with an eye to boosting scientific exchange and getting cooperation projects off the ground. The partners hope that the collaboration will lead to increased access to the Asia-Pacific and European research and economic landscape.

The scientific focus of the joint research activities will initially lie on the area of molecular imaging and structure determination. As part of the cooperation, methods and instruments are to be developed to improve current technologies. Furthermore, molecules that play a significant role in therapy design are to be analyzed in detail and consequently optimized.

The cost of setting up the research unit is initially being supported by the Federal Ministry of Education and Research with EUR 200,000 in funding to cover a two-year period, awarded as part of the Federal Government's Strategy for the Internationalization of Education, Science and Research.

1 *Professor Armin Willingmann, Minister of the Economy, Science and Digitalisation for the German Federal State of Saxony-Anhalt.*

2 *Prof. Dr. Frank Emmrich at the opening event at Monash University*



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

On August 12, 2014, Fraunhofer IZI and Leipzig University of Applied Sciences (HTWK Leipzig) got the ball rolling on a joint specialist group for the "Image Analysis of Cell Function". The scientific focus of this group lies on establishing and further developing non-destructive imaging technology for biomedical research. The group was evaluated after a three-year start-up phase on August 4, 2017, also with an eye to its future viability. The evaluation committee, made up of representatives from science, business and politics, attested to the outstanding work carried out by the team headed up by Professor Ulf-Dietrich Braumann during this early phase and unanimously recommended that the specialist group continue in its work. The group's outstanding commitment to the teaching and training of young scientists also received special mention.

Students from HTWK Leipzig were incorporated into the specialist group located at Fraunhofer IZI and familiarized with competitive research on an international scale. Furthermore, six scientific members of staff from Fraunhofer IZI contributed towards teaching activities at HTWK Leipzig on the topics of bioreactors and microscopic imaging. Through these activities, more and more electrical engineering and information technology students have begun to take an interest in life sciences while engineering skills have been introduced and utilized at Fraunhofer IZI.

This led to four practical research projects and five master's theses being completed within the group during the start-up phase alone. Five further master's theses and a doctoral research project are currently under way. The goals for the coming year are to entrench the group within the Fraunhofer model, to significantly boost personnel and to expand teaching and research activities.

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

On August 18, 2017, the Free State of Thuringia and the Fraunhofer-Gesellschaft signed a joint foundation agreement to create a Fraunhofer project center in Erfurt. Three Fraunhofer Institutes are involved in the project center "Microelectronic and Optical Systems for Biomedicine". Alongside Fraunhofer IZI, these are the Fraunhofer Institute for Photonic Microsystems IPMS, a leading research service provider in the field of microelectronics and microsystem technology, and the Fraunhofer Institute for Applied Optics and Precision Engineering IOF, a recognized competence center for optics and photonics. Research into new biomedical applications linked to the stated technologies is to be carried out at the project center in close collaboration with business partners.

The project center will initially focus on two selected areas of application: improved medical imaging and visualization besides technologies for biomarker analysis. Start-up financing in the amount of 20 million euros spread over five years will be split equally between the Fraunhofer-Gesellschaft and the state of Thuringia.

1 Participants in the evaluation conducted on August 4, 2017, at Fraunhofer IZI

2 The foundation agreement is signed by Professor Reimund Neugebauer, President of the Fraunhofer-Gesellschaft (left) and Wolfgang Tiefensee, Minister for Economic Affairs, Science and Digital Society in the German Free State of Thuringia (right).



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

The 18th International Symposium on Albumin Dialysis (ISAD, www.albumin-dialysis.org) was held from September 8 – 10, 2017, in Rostock-Warnemünde. Organized as a cooperation between the forum for liver dialysis "Forum Leberdialyse e.V.", the University of Rostock and, since 2013, Fraunhofer IZI, the ISAD meeting is the largest regular specialist conference held worldwide in the area of liver support processes. The event once again proved highly popular on a global scale this year with a remarkable level of interest shown by the dialysis and blood purification sector. For instance, the company Vital Therapies, Inc. from San Diego presented its cell bioreactor system ELAD (Extracorporeal Liver Assist Device); Fraunhofer IZI and the University of Rostock's Department of Medicine are both taking part in the company's global authorization trial.

www.albumin-dialysis.org

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

Die Sendung mit der Maus open day was held on October 3, 2017. And we were lucky enough to be part of it! The open day sees companies open their doors to inquisitive young fans of the German children's TV show, revealing interesting projects and products that the general public would not usually get to see. As part of the German BioImaging Society for Microscopy and Image Analysis, Fraunhofer IZI took part in this year's open day under the lead of by Dr Alexander Kranz. After playing games to get an idea of the size of living things and the level of magnification possible with a microscope, the children then looked at microscopy as a concept in itself. Once they had been given some general pointers, prepared samples and samples the children had brought along with them of leaves, toenails, and even insects were dissected and then viewed through different microscopes. The children learned how to correctly mount a sample on a slide and found out how a specimen is prepared to go under the microscope. First with guidance and then by themselves, the children examined the different specimens under the various microscopes.

www.wdrmaus.de/extras/tueren_auf

¹ Dr. Alexander Kranz at the microscope with his young guests at the open day of *Die Sendung mit der Maus*.



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

On November 8 and 9, 2017, the Fraunhofer Life Science Symposium played host to internationally renowned researchers, physicians and companies as well as dedicated up-and-coming scientists, all of whom had gathered to discuss the latest developments in the field of diagnostics.

Infectious diseases, i.e. diseases caused by pathogens such as bacteria, fungi and viruses, still pose one of the most relevant medical challenges in the world today. Around 22% of all deaths worldwide can be directly attributed to infectious diseases. As general living conditions and hygiene improved and medical knowledge advanced in the industrialized countries during the course of the 20th century, many infectious diseases were able to be suppressed and were no longer considered life threatening. They do, however, remain a problem globally. With climate change on the one hand and more and more people traveling farther and wider on the other, tropical and subtropical disease carriers are increasingly spreading around the world. The development of resistance to antibiotics and the adaptive strategies of many pathogens also demand the continuous advancement of medical care and prevention. Being able to rely on accurate, specific diagnostic methods is essential not only to treating but also to researching infectious diseases. It is therefore imperative that diagnostic procedures continue to be developed and new analytical methods are explored. Just under 180 researchers from Germany and ten other countries presented new findings in talks and scientific posters besides discussing how these findings can make their way into broader application and commercialization.

www.fs-leipzig.com

November 16 – 17, 2017: Workshop on Arthropod-Borne Diseases

The "Workshop on Arthropod-Borne Diseases Transmitted by Ticks, Mites, Fleas, and Lice" was held at the Friedrich-Loeffler-Institut (FLI) in Jena on November 16 and 17, 2017. The joint event was organized by Fraunhofer IZI and the National Reference Laboratory for Q Fever at the FLI in Jena. International guest speakers from nine countries as well as representatives from companies, laboratories and research institutes discussed the latest research findings. The event allowed knowledge to be shared on how to successfully combat diseases transferred by arthropods (e.g. insects and arachnids). The workshop focused in particular on diseases carried by ticks. Dr Makert dos Santos from Fraunhofer IZI presented new strategies for fighting red mite as well as a cooperation project (Federal Ministry of Education and Research Q-GAPS consortium project) between Fraunhofer IZI and the FLI.

¹ *Fraunhofer Life Science Symposium – Latest Developments in the Field of Infection Diagnostics*



LOOKING TO 2018

January 17, 2018

New Year reception

April 26, 2018

Girls' Day 2018

www.girls-day.de

May 5, 2018

Potsdam Day of Science

www.potsdamertagderwissenschaften.de

June 22, 2018

Long Night of Sciences Leipzig

www.wissen-in-leipzig.de

July 6, 2018

Long Night of Sciences Halle (Saale)

www.wissenschaftsnacht-halle.de

September 27, 2018

Fraunhofer Life Science Symposium

www.fs-leipzig.com

¹ Long Night of Sciences 2016

SCIENTIFIC PRESENCE



CONVENTIONS AND CONFERENCES

1. Europäisches BioSensor-Symposium (EBS), March 20–23, 2017, Potsdam, Germany

10th General Meeting of the International Proteolysis Society, October 27–28, 2017, Banff, Canada

12th International Symposium on Electrokinetics, September 10–12, 2017, Dresden, Germany

15th B Cell Forum, March 2–4, 2017, Budenheim, Germany

16th workshop of the study group »Immunobiology of Viral Infections« of the Society for Virology (GfV), September 27–29, 2017, Taubertschheim, Germany

19. Bundeskongress Le-gasthenie und Dyskalkulie, March 17–19, 2017, Würzburg, Germany

19th IUPAB congress and 11th EBSA congress, July 16–20, 2017, Edinburgh, UK

1st European / 10th German BioSensor Symposium, March 20–23, 2017, Potsdam, Germany

24. Essener Informationstreffen für Tierschutzbeauftragte, Tierexperimentatoren und mit Tierversuchen befasste Behördenvertreter, March 8, 2017, Essen, Germany

254th ACS National Meeting & Exposition, August 20–24, 2017, Washington DC, USA

27th Annual Meeting of the Society for Virology, March 22–25, 2017, Marburg, Germany

2nd Annual Immuno-Oncology Summit Europe, March 20–24, 2017, London, UK

34th Winter School on Proteases and Inhibitors 2017, March 8–12, 2017, Tiers, Italy

7. Berliner LC–MS/MS Symposium, March 13–14, 2017, Berlin, Germany

8th Annual Symposium »Physics of Cancer«, October 4–6, 2017, Leipzig, Germany

Alzheimer's Association International Conference, July 16–20, 2017, London, UK

American Physical Society March Meeting 2017, March 13–17, 2017, New Orleans, USA

Annual Meeting of the German Society for Matrix Biology, March 9–11, 2017, Cologne, Germany

ARM European Section Meeting, March 23, 2017, Barcelona, Spain

Berlin–Brandenburger Diagnostik–Kolloquium, September 7, 2017, Potsdam, Germany

BIO 2017, June 19–22, 2017, San Diego, USA

BIO–Europe® Spring, March 20–22, 2017, Barcelona, Spain

BioJapan / Regenerative Medicine Japan 2017, October 11–13, 2017, Yokohama, Japan

Bioelectronics Workshop Berlin, November 30, 2017, Berlin, Germany

BIO–Europe®, November 6–8, 2017, Berlin, Germany

bionection, October 17–18, 2017, Jena, Germany

BIONNALE 2017, May 17, 2017, Berlin, Germany

Biotechnica, May 16–18, 2017, Hanover, Germany

Biotechnology Symposium, October 5, 2017, Leipzig, Germany

Cell & Gene Meeting on the Mesa, October 4–6, 2017, La Jolla, USA

Cell Therapy Manufacturing & Gene Therapy Congress, December 5–7, 2017, Amsterdam, The Netherlands

Chance For Science 2017 "Academics on the Flight", September 15, 2017, Leipzig, Germany

Cross–Innovation–Workshop "Bioprozess–Analyse–Technologie", December 14, 2017, Berlin, Germany

Deutsche Biotechnologietage, April 5–6, 2017, Hanover, Germany

DGfI Jahrestagung, September 12–15, 2017, Erlangen, Germany

Diagnostics and the Developing World Conference, January 23–25, 2017, London, UK

DNA Mitteldeutschland, May 18, 2017, Jena, Germany

DPG–Frühjahrstagung 2017, March 19–24, 2017, Dresden, Germany

ECA – GMP für Advanced Therapy Medicinal Products, March 28, 2017, Mörfelden, Germany

EMBO | EMBL Symposium: Mechanisms of Neurodegeneration, June 14–17, 2017, Heidelberg, Germany

European Antibody Congress 2017, October 31– November 2, 2017, Basel, Switzerland

- Festival of Genomics London**, January 31–February 1, 2017, London, UK
- Foundations of Nanoscience**, April 10–13, 2017, Snowbird, USA
- Fraunhofer International Day**, March 29, 2017, Munich, Germany
- Fraunhofer Life Science Symposium 2017 »Latest Developments in Diagnostics«**, November 8–9, 2017, Leipzig, Germany
- Fraunhofer-Symposium »Netzwerk«**, February 21–22, 2017, Munich, Germany
- Future Technologies Science Match**, January 26, 2017, Dresden, Germany
- GSCN-PEI-ATMP-Workshop**, November 6–7, 2017, Berlin, Germany
- Herbstschule Immunologie 2017**, October 8–13, 2017, Merseburg, Germany
- Imaging CoE Summit**, November 20–22, 2017, Melbourne, Australia
- Immuno-Oncology Summit Europe**, March 20–24, 2017, London, UK
- in-cosmetics Global**, April 4–6, 2017, London, UK
- Innovationsforum Optogenetik – Technologien und Potenziale (INOTEP)**, November 28–29, 2017, Hanover, Germany
- Innovative bioanalytics in food and in humans**, December 5, 2017, Potsdam, Germany
- International Congress of Immunology ICI**, February 16–17, 2017, London, UK
- ISCT 2017**, May 3–6, 2017, London, UK
- ISMIRM**, April 22–27, 2017, Honolulu, USA
- Jahrestreffen des Netzwerkes Internationales Business Development der Fraunhofer-Gesellschaft**, September 25–26, 2017, Birlinghofen, Germany
- Lab-on-a-Chip & Microfluidics SELECTBIO conference**, May 10–11, Munich, Germany
- LAB-SUPPLY**, June 22, 2017, Berlin, Germany
- Life-Science-Forum Sachsen**, November 29, 2017, Leipzig, Germany
- LIN Honorary Symposium: Neuroplasticity in Health and Disease**, June 8–9, 2017, Magdeburg, Germany
- MEDICA**, November 13–16, 2017, Dusseldorf, Germany
- Microbiology and Infection – 5th Joint Conference of the DGHM & VAAM**, March 5–8, 2017, Würzburg, Germany
- Natural Killer Cell Symposium 2017**, March 9–11, 2017, Dusseldorf, Germany
- Netzwerktreffen NeZuMed**, September 26, 2017, Coburg, Germany
- New and emerging technologies**, September 11–13, 2017, Potsdam, Germany
- PEGS Europe: Protein & Antibody Engineering Summit**, November 13–17, 2017, Lisbon, Portugal
- Pharma-Kongress 2017**, March 28–29, Dusseldorf, Germany
- Potsdam Days of Bioanalysis**, November 23–24, 2017, Potsdam, Germany
- Preclinical models in immuno-oncology research**, February 1, 2017, Heidelberg, Germany
- Regionaler EU-Förderdialog 2017**, October 26, 2017, Potsdam, Germany
- Research Xchange Forum 2017**, February 22–23, 2017, Göttingen, Germany
- SITC Annual Meeting**, November 8–12, 2017, National Harbor, USA
- Symposium »Joachim R. Kalden – life time achievements and milestones in rheumatology and clinical immunology«**, November 25, 2017, Erlangen, Germany
- Symposium »Medikamente aus Pflanzen für eine neue Welt«**, May 8, 2017, Mainau, Germany
- Symposium on Microscopy Imaging: From Molecules to Organisms**, March 22–23, 2017, Jena, Germany
- Synergy-Boost Review Meeting**, November 23, 2017, Berlin, Germany
- The 13th International Conference on Alzheimer's and Parkinson's Diseases**, March 29–April 2, 2017, Vienna, Austria
- Treffpunkt In-vitro-Diagnostik »Allergien«**, May 11, 2017, Berlin, Germany
- Ulm Meeting. Biophysics of Amyloid Formation**, March 8, 2017, Ulm, Germany
- Workshop »Wege der Kostenerstattung von Medizinprodukten«**, December 14, 2017, Leipzig, Germany

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Rathenower Optik GmbH, Rathenow, Germany

RedHill Biopharma Ltd., Tel Aviv, Israel

ReliaTech Receptor Ligand Technologies GmbH, Wolfenbüttel, Germany

RESprotect GmbH, Dresden, Germany

RIPAC-Labor GmbH, Potsdam, Germany

RS Zelltechnik GmbH, Leipzig, Germany

SanWa Biotech Ltd., Hong Kong, China

Sartorius Stedim Biotech AG, Göttingen, Germany

Schmuhl Faserverbundtechnik (FVT) GmbH & Co. KG, Remptendorf, Germany

SCIENION AG, Berlin / Dortmund, Germany

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Secopta GmbH, Berlin, Germany

Securetec Detektions-Systeme AG, Munich, Germany

SelfDiagnostics Deutschland GmbH, Leipzig, Germany

Seramun Diagnostica GmbH, Heidesee, Germany

Siemens AG, Munich /Erlangen, Germany

SKW Stickstoffwerke Piesteritz GmbH, Lutherstadt Wittenberg, Germany

Sonovum AG, Leipzig, Germany

Surflay Nanotec GmbH, Berlin, Germany

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we love apps, Erfurt, Germany

WISAG AG, Frankfurt, Germany

WRIG Nanosystems GmbH, Leipzig, Germany

Yumab GmbH, Braunschweig, Germany

Zellmechanik Dresden GmbH, Dresden, Germany

TEACHING ACTIVITIES

Beuth University of Applied Sciences Berlin

Selected aspects of biotechnology: cell free protein synthesis (lecture), Dr. Stefan Kubick

University of Applied Sciences Jena

Databases for biotechnology (lecture), Thomas Fritzsche

Fraunhofer IZI

Education and training of persons carrying out animal experiments (Category B / FELASA) (course), Dr. Thomas Grunwald, Dr. Franziska Lange, Dr. Vera Nykiel

Free University of Berlin

Cell-free Synthesis of Membrane Proteins (training), Dr. Stefan Kubick

Cell-free Synthesis of Membrane Proteins (training), Dr. Stefan Kubick

Membrane Proteins: Classification, Structure and Function (lecture), Dr. Stefan Kubick

Coburg University of Applied Sciences

Biochemistry II (lecture), Prof. Dr. Stefan Kalkhof

Instrumental analytics (problem-oriented learning), Prof. Dr. Stefan Kalkhof

Protein analytics (problem-oriented learning), Prof. Dr. Stefan Kalkhof

Protein mass spectrometry (problem-oriented learning),

Prof. Dr. Stefan Kalkhof
Spectroscopy (lecture), Prof. Dr. Stefan Kalkhof

Spectroscopy separation technologies (lecture), Prof. Dr. Stefan Kalkhof

Anhalt University of Applied Sciences

Protein biotechnology (lecture), Prof. Dr. Hans-Ulrich Demuth

Leipzig University of Applied Sciences (HTWK Leipzig)

Image processing (lecture), Prof. Dr. Ulf-Dietrich Braumann

Bioreactors (lecture), Prof. Dr. Ulf-Dietrich Braumann, Claire Fabian

Biostatistics (lecture), Prof. Dr. Ulf-Dietrich Braumann

Microscopic imaging (lecture), Dr. Alexander Kranz, Prof. Dr. Ulf-Dietrich Braumann

Microscopic image processing (lecture), Prof. Dr. Ulf-Dietrich Braumann

Martin Luther University Halle-Wittenberg

Lab Course on Vector Construction (training), Dr. Stephan Schilling

Molecular Biotechnology: Construction of Hosts and Vectors (lecture), Dr. Stephan Schilling

Plant biotechnology (training), Dr. Holger Cynis

Ruhr University Bochum

Virology for natural scientists (lecture), Dr. Thomas Grunwald

Immunotherapy and prophylaxis of infectious diseases (lecture), Dr. Thomas Grunwald

Technical University of Berlin

Membrane proteins: classification, structure and function (lecture), Dr. Stefan Kubick

Cell free synthesis of membrane proteins (training), Dr. Stefan Kubick

TMF Berlin

Harmonization of S3 facilities according to security standards in S3 laboratories (seminar), Dr. Thomas Grunwald

University of Leipzig

Advanced Soft Matter and Biological Physics (lecture), Dr. Jörg Schnauß

Pharmaceutical analytics / Drug monitoring (seminar), Dr. Mirko Buchholz

Pharmaceutical analytics / Drug monitoring (training), Dr. Daniel Ramsbeck

Autoimmunity (seminar), Claudia Müller, Lilly Stahl, Nadja Hilger, Dr. Stephann Fricke

Experimental Physics (lecture), Dr. Jörg Schnauß

History of natural sciences with particular focus on pharmacy (lecture), Dr. Mirko Buchholz

Tissue typing (seminar) Nadja Hilger, Dr. Stephan Fricke

Immunological training for clinicians (training), Nadja Hilger, Dr. Stephan Fricke

Medicinal microbiology (lecture), Dr. Thomas Grunwald

Modern developments in LC-MS (lecture), Prof. Dr. Stefan Kalkhof

Molecular Nanotechnology (seminar), Dr. David Smith

EVALUATOR ACTIVITIES

Molecular medicine (lecture),
Dr. Thomas Grunwald

Molecular medicine (training),
Lea Wierich,
Dr. Thomas Grunwald

Molecular Medicine/Virology
(training),
PD. Dr. Sebastian Ulbert

Pharmaceutical biology /
Immunology (lecture),
Dr. Jörg Lehmann

Pharmaceutical chemistry
(training), Dr. Mirko Buchholz

Pharmaceutical and medical
terminology (seminar),
Dr. Daniel Ramsbeck

QSB 4 / transfusion medicine /
tissue typing (course),
Dr. Peter Ruschpler

QSB 6 / Environmental medicine
(seminar),
Dr. Jana Burkhardt,
Susanne Przybylski

Statistical learning (lecture),
Dr. Kristin Reiche

Environmental medicine
(seminar),
Lilly Stahl,
Dr. Stephan Fricke

Vector-borne virus infection
(lecture),
PD. Dr. Sebastian Ulbert

University of Potsdam

Applied limnology: recent topics
of aquatic ecology (lecture),
Dr. Thomas Leya

Cell-free protein synthesis
(seminar), Dr. Stephan Kubick

Cell-free protein synthesis
(lecture), Dr. Stephan Kubick

Cell-free Synthesis of Membrane
Proteins (training),
Dr. Stephan Kubick

University of Split (Croatia)

Mass Spec in Bioanalysis
(problem-oriented learning)
Prof. Dr. Stefan Kalkhof

Advances in Dairy Research,
Dr. Jörg Lehmann

**Alzheimer Association,
Alzheimer Association
Research Grant (AARG)
Program,** Dr. Holger Cynis

Analytical Chemistry,
Dr. Eva Ehrentreich-Förster

**Applied Biochemistry and
Biotechnology,**
PD Dr. Sebastian Ulbert

Bioengineering,
PD Dr. Sebastian Ulbert

Biosensors/Bioelectronics,
Dr. Eva Ehrentreich-Förster

BMC Bioinformatics,
Dr. Kristin Reiche

BMC Bioinformatics,
Dr. Sven-Holger Puppel

Clinica Chemica Acta,
Dr. Holger Cynis

Cytometry Part A,
Prof. Dr. Attila Tárnok

**Deutsche Forschungs-
gemeinschaft (DFG),**
Dr. Eva Ehrentreich-Förster,
Prof. Dr. Frank Emmrich

**Deutscher Akademischer
Austauschdienst (DAAD),**
Prof. Dr. Frank Emmrich

Engineering in Life Sciences,
Dr. Stefan Kubick

**Emerging Microbes and
Infections,**
PD Dr. Sebastian Ulbert

Faculty 1000 Member,
Dr. Jörg Lehmann

**German Stem Cell Network
(GSCN),** Prof. Dr. Frank Emmrich

**High-Tech Gründerfonds /
Steinbeis Transferzentrum,**
Dr. Mirko Buchholz

Human Genetics,
Dr. Arndt Wilcke

InnoHealth Australia,
PD Dr. Sebastian Ulbert

**IQ Innovationspreis Mittel-
deutschland,**
Prof. Dr. Hans-Ulrich Demuth

**Journal of Alzheimer's
Disease,** Dr. Stephan Schilling

**Journal of Nanomedicine &
Nanotechnology,**
Dr. Eva Ehrentreich-Förster

Journal of Proteomics,
Prof. Dr. Stefan Kalkhof

Journal: Scientific Reports,
Dr. Alexander Kranz

**Medical Microbiology and
Immunology,**
PD Dr. Sebastian Ulbert

Medicine, Dr. Holger Cynis

ASSOCIATION MEMBERSHIPS

PLoS Neglected tropical Diseases,
PD Dr. Sebastian Ulbert

PLOS ONE,
Dr. Jörg Lehmann

Scientific Reports,
Dr. Arndt Wilcke,
Prof. Dr. Stefan Kalkhof

South African Journal of Science, Dr. Thomas Leya

SPIE Medical Imaging: Digital Pathology Conference,
Prof. Dr. Ulf-Dietrich Braumann

The Open Veterinary Science Journal, Dr. Jörg Lehmann

Vaccine, Dr. Thomas Grunwald

Veterinary Immunology and Immunopathology,
Dr. Jörg Lehmann

Virus Disease,
PD Dr. Sebastian Ulbert

Virus Research,
PD Dr. Sebastian Ulbert

Viruses, PD Dr. Sebastian Ulbert

Alliance for Regenerative Medicine, Dr. Thomas Tradler

Alzheimer's Association International Society to Advance Alzheimer's Research and Treatment (ISTAART), Dr. Holger Cynis

American Chemical Society (ACS), Prof. Dr. Hans-Ulrich Demuth, Dr. Mirko Buchholz, Dr. Daniel Ramsbeck

American Diabetes Association (ADA),
Prof. Dr. Hans-Ulrich Demuth

American Physical Society,
Dr. David M Smith

American Society for Mass Spectrometry, Prof. Dr. Stefan Kalkhof

Arbeitskreis experimentelle Stammzelltransplantation,
PD Dr. Stephan Fricke

Ärzte für Madagaskar e. V.,
Prof. Dr. Frank Emmrich

biosaxony e. V.,
Prof. Dr. Frank Emmrich,
Dr. Thomas Tradler

Biotechnologieverbund Berlin-Brandenburg e.V.,
Dr. Thomas Tradler

BMC Bioinformatics,
Dr. Kristin Reiche

CENTER OF APTAMER RESEARCH AND DEVELOPMENT,
Dr. Marcus Menger

DECHEMA - Gesellschaft für Chemische Technik und Biotechnologie e.V.,
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Dr. Mirko Buchholz,
Dr. Stefan Kubick

Deutsche Arbeitsgemeinschaft für Knochenmark- und Blutstammzelltransplantation e. V. (DAG-KBT),
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Section Phycology of the German Botanical Society,
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Deutsche Gesellschaft für Biomedizinische Technik (DGBMT), Thomas Fritzsche

Deutsche Gesellschaft für Geschichte der Pharmazie,
Dr. Mirko Buchholz

Deutsche Gesellschaft für Humangenetik e.V.,
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Deutsche Gesellschaft für Immunologie e. V. (DGfI),
Dr. Andreas Grahner,
Prof. Dr. Frank Emmrich,
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Lea Bayer,
Sina Riemschneider,
PD Dr. Stephan Fricke

Deutsche Gesellschaft für Interdisziplinäre Medizin e. V. (MEDICA),
Prof. Dr. Frank Emmrich

Deutsche Gesellschaft für Massenspektrometrie,
Prof. Dr. Stefan Kalkhof

Deutsche Gesellschaft für Medizinische Physik (DGMP),
Prof. Dr. Ulf-Dietrich Braumann

Deutsche Gesellschaft für Proteomforschung (DGPF),
Dr. Stefan Kubick

Deutsche Gesellschaft für Regenerative Medizin e. V. (GRM), Prof. Dr. Frank Emmrich,
PD Dr. Stephan Fricke

Deutsche Gesellschaft für Stammzellforschung e. V. (DSZ), Prof. Dr. Frank Emmrich

Deutsche Nucleinsäurechemiegesellschaft e.V. (DNG),
Dr. Marcus Menger

Deutsche Pharmazeutische Gesellschaft (DPHG),
Dr. Daniel Ramsbeck,
Dr. Julia Stäker,
Dr. Mirko Buchholz

Deutsche Physikalische Gesellschaft,
Dr. Jörg Schnaus,
Martin Glaser,
PD Dr. Ralph Hölzel

Deutsche Zoologische Gesellschaft e.V. (DZG),
Dr. Gustavo Makert dos Santo

Deutsches Institut für Normung e.V. (DIN),
Dr. Christina Schröder,
Dr. Thomas Leya

Deutsch-Kanadische Gesellschaft,
Dr. Thomas Tradler

Deutsche Gesellschaft für Parasitologie (DGP), Dr.
Markus von Nickisch-Rosenegk

DiagnostikNet Berlin-Brandenburg e.V.,
Dr. Marcus Menger

Dt. Gesellschaft für Virologie,
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PD Dr. Sebastian Ulbert

European QP Association,
Maximilian Hoffmann

European Society for Advances to Study Diabetes (EASD),
Prof. Dr. Hans-Ulrich Demuth

European Society for Virology,
Jasmin Fertey,
PD Dr. Sebastian Ulbert

European, Middle-Asian and African Society for Biopreservation and Biobanking (ESBB), Dr. Oliver Gros

Förderverein für Medizinische Ausbildung e. V. (FörMa),
Prof. Dr. Frank Emmrich

Freunde der Veterinärmedizinischen Fakultät der Universität Leipzig e.V.,
Dr. Anke Hoffmann
Dr. Jörg Lehmann

German QP Association,
Dr. Gerno Schmiedeknecht,
Dr. Jörg Lehmann,
Kati Kebbel,
Ulrike Jehmlich

German Quality Management Association e.V. (GQMA),
Martin Dähne

German Society of Mass Spectrometry (DGMS),
Prof. Dr. Hans-Ulrich Demuth

German Stem Cell Network e. V. (GSCN),
Prof. Dr. Frank Emmrich

Gesellschaft Deutscher Chemiker e.V. (GDCh),
Dr. Daniel Ramsbeck,
Dr. Eva Ehrentreich-Förster,
Dr. Marcus Menger,
Dr. Michael Szardenings,
Dr. Mirko Buchholz,
Dr. Walter Stöcklein

Gesellschaft für Biochemie und Molekularbiologie (GBM),
Prof. Dr. Friedemann Horn,
Prof. Dr. Hans-Ulrich Demuth,
Dr. Holger Cynis,
Dr. Kristin Reiche,
Lilly Stahl,
Dr. Marcus Menger,
Dr. Markus von Nickisch-Rosenegk,
Dr. Michael Szardenings,
Dr. Stephan Schilling,
Dr. Walter Stöcklein

Gesellschaft für biologische Systematik (GfBS), Dr. Markus von Nickisch-Rosenegk

Gesellschaft für Versuchstierkunde e.V. (GV-SOLAS),
Dr. Jörg Lehmann,
Sarah Leitenroth,
Dr. Thomas Grunwald

Gesellschaft für Virologie e.V. (GfV), Dr. Thomas Grunwald

Glyconet Berlin Brandenburg (glyconetBB e.V.),
Dr. Stefan Kubick

InDeKo Innovationszentrum Deutschland Korea - The Korean-German Innovation Hub e. V.,
Prof. Dr. Frank Emmrich

Institute of Electrical and Electronics Engineers (IEEE),
Prof. Dr. Ulf-Dietrich Braumann

International Dyslexia Association,
Dr. Arndt Wilcke

International Proteolysis Society (IPS),
Prof. Dr. Hans-Ulrich Demuth

International Society for Cellular Therapy (ISCT),
Dr. Gerno Schmiedeknecht

International Society for Magnetic Resonance in Medicine (ISMRM),
Dr. Alexander Kranz

International Society for Nanoscale Science, Computation and Engineering,
Dr. David M Smith

International Society for Optics and Photonics (SPIE),
Prof. Dr. Attila Tárnok

International Society on Aptamers (INSOAP),
Dr. Marcus Menger

International Union for the Study of Social Insects (IUSSI),
Dr. Gustavo Makert dos Santo

Leipziger Initiative für Biotechnologie e. V. (LIB),
Prof. Dr. Frank Emmrich

Leipziger Stiftung für Innovation und Technologietransfer,
Prof. Dr. Frank Emmrich

Nationalen Forschungsplattform für Zoonosen,
Alexandra Rockstroh,
Dr. Gustavo Makert dos Santo,
PD Dr. Sebastian Ulbert

New York Academy of Sciences,
Prof. Dr. Hans-Ulrich Demuth

Protein Society (PS),
Prof. Dr. Hans-Ulrich Demuth

regenerate Europe e. V. (EUROPEAN NETWORK FOR REGENERATIVE MEDICINE),
Prof. Dr. Frank Emmrich

PUBLICATIONS

Regenerative Medicine Initiative Germany (RMIG), Prof. Dr. Frank Emmrich

Society for Neuroscience (SfN), Dr. Holger Cynis

Society for Neurosciences (SfN), Prof. Dr. Hans-Ulrich Demuth

Tierärztliche Vereinigung für Tierschutz, Vera Nykiel

Verband der Elektrotechnik Elektronk Informationstechnik e.V. (VDE), Thomas Fritzsche

Verein zur Förderung der Gesundheitswirtschaft in der Region Leipzig e. V. (VfG), Prof. Dr. Frank Emmrich

Vereinigung für Allgemeine und Angewandte Mikrobiologie (VAAM), Dr. Walter Stöcklein

Vereinigung von Freunden und Förderern der Universität Leipzig e. V., Prof. Dr. Frank Emmrich

Zentrale Tierschutzkommission der Landesdirektion Sachsen in Leipzig, Dr. Jörg Lehmann

Agocs E, Kozma P, Nador J, Hamori A, Janosov M, Kalas B, Kurunczi S, Fodor B, Ehrentreich-Förster E, Fried M, Horvath R, Petrik P. **Grating coupled optical waveguide interferometry combined with in situ spectroscopic ellipsometry to monitor surface processes in aqueous solutions.** Applied surface science 421 (2017), Pt. B, S. 289-294. dx.doi.org/10.1016/j.apsusc.2016.07.166

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Cynis H, Nykiel V. **Belastungseinschätzung von Tierversuchen durch Verwendung von Score Sheets.** Versuchstierkundliches Kolloquium der Medizinischen Fakultät der Martin-Luther-Universität Halle-Wittenberg, 14.12.2017, Halle (Saale), Germany

Cynis H, Nykiel V. **Gewichtseinschätzung in Experimenten.** 10. Fortbildungsveranstaltung der GV-SOLAS für Tierschutzbeauftragte und Behördenmitglieder, 31.5.-1.6.2017, Berlin, Germany

Demuth HU. **Age-dependent posttranslational protein modification – driving force in neurodegeneration?**

Modulating Ageing Antiageing from Molecular Biology to Clinical Perspectives, 1.-3.9.2017, Halle (Saale), Germany

Demuth HU. **Diabetes and Alzheimer's disorder: Common molecular matters?**

LIN (Leibnitz-Institut für Neurobiologie) Symposium: Neuroplasticity in Health and Disease. 8.-9.6.2017, Magdeburg, Germany

Demuth HU. **Do Posttranslational Modifications of AB drive AD-Pathology?**

Pharmaceutical Colloquium of Bonn University, 19.6.2017, Bonn, Germany

Demuth HU. **Posttranslational protein modifications driving toxic aggregate formation in neurodegenerative diseases.**

6th Central European Congress of Life Science, 11.-14.9.2017, Krakau, Poland

Demuth HU. **Status of dementia research and pathways to new therapies.**

Potsdam Days on Bioanalysis, 23.-24.11.2017, Potsdam, Germany

Diebold V, Müller D, Baltes N, Menger M. **Implementierung von aptamer-modifizierten Dickschicht-Elektroden zur elektrochemischen Detektion von Kokain.** ANAKON, 3.-6.4.2017, Tübingen, Germany

Dondapati SK, Wüstenhagen DA, Kubick S. **Cell-Free Synthesis of Membrane Proteins: Methods for Cotranslational Integration into Biomembranes.** EMBO/FEBS lecture, 14.-20.5.2017, Erice, Italy

Dondapati SK, Wüstenhagen DA, Kubick S. **Cell-free Synthesis and Reconstitution of Membrane Proteins into Planar Lipid Bilayers for Functional Analysis.** New and emerging technologies, 11.-13.9.2017, Potsdam, Germany

Dondapati S, Wüstenhagen D, Kubick S. **Incorporation of cell-free synthesized membrane proteins into microsomes and nanodiscs.** Proteomic Forum, 2.-5.4.2017, Potsdam, Germany

Eichentopf R, Carstensen S, Barendrecht S, Schulze J, Schilling S, Demuth HU, Cynis H. **Comprehensive Phenotyping of 5xFAD Mice.** The 13th International Conference on Alzheimer's & Parkinson's Diseases, 29.3.-2.4.2017, Wien Austria

Emmrich F. **Hightech-Therapieprodukte und globalisierte Verwertung.** Nationale Branchenkonferenz Gesundheitswirtschaft, 23.-24.5.2017, Warnemünde, Germany

Emmrich F. **Innovationsstau in der Biomedizin – Was nun?** GRM-Herbstforum, 24.11.2017, Berlin, Germany

Emmrich F. **Streamlining of Endogenous Regeneration for Embedding of Allogenic Transplants.** 11. World Congress of Regenerative Medicine & Stem Cell, 14.-16.11.2017, Singapore

Fabian C. **Therapeutic potential of stem cells.** Workshop Bilateral cooperation SIKT, University of Leipzig and Instituto de Quimica, University of Sao Paulo, 25.9.2017, Leipzig, Germany

Friedl T, Kryvenda A, Leya T, Jorde F. **EU FP7 project PUFACHain – bringing links of value chain together.** 10. Bundesalgenstammtisch, 11.-12.9.2017, Merseburg, Germany

Gajovic-Eichelmann N. **Peptide decorated electropolymer films for biosensors: Comparison of different strategies for oriented peptideimmobilization.** EBS/DBS 2017, 20.-23.3.2017, Potsdam, Germany

Gajovic-Eichelmann N, Ay B, Bier FF. **Smart Dry Reagents: Novel freeze-drying applications.** New and emerging technologies, 11.-13.9.2017, Potsdam, Germany

Gajovic-Eichelmann N. **Three-dimensional structuring of polymer films.** Potsdam Days on Bioanalysis, 23.-24.11.2017, Potsdam, Germany

Glaser M. **Altering Synthetic Semiflexible DNA Nanotube Networks by Tunable Cross-linking.** Soft Matter Physics Winterschool, 25.2.-3.3.2017, Spindelmühle, Czech Republic

Glaser M. **Altering Synthetic Semiflexible DNA Nanotube Networks by Tunable Cross-linking.** ERC Advanced kick off meeting, 22.-24.8.2017, Freyburg, Germany

Glaser M. **Rheology on cross-linked DNA nanotube networks.** DPG-Frühjahrstagung, 19.-24.3.2017, Dresden, Germany

Glaser M, Mollenkopf P, Möser C, Schuldt C, Schnauß J, Händler T, Käs J, Smith D. **Altering Synthetic Semiflexible DNA Nanotube Networks by Tunable Cross-linking.** 8th Annual Symposium - Physics of Cancer, 4.-6.10.2017, Leipzig, Germany

Glaser M, Mollenkopf P, Möser C, Schuldt C, Schnauß J, Händler T, Käs J, Smith DM. **Altering Synthetic Semiflexible DNA Nanotube Networks by Tunable Cross-linking.** Soft Matter Day, 23.6.2017, Leipzig, Germany

Glaser M. **Actin Filaments and Networks.** Cellular Machines II: Lecture, 5.12.2017, Dresden, Germany

Golde T, Glaser M, Händler T, Schnauß J, Herrmann H, Käs JA. **Composite networks of actin and intermediate filaments.** CellMech 2017, 21.-23.6.2017, Windermere, UK

Golde T, Glaser M, Händler T, Schuldt C, Schnauß J, Herrmann H, Käs JA. **Composite networks of actin and intermediate filaments.** DPG-Frühjahrstagung, 19.-24.3.2017, Dresden, Germany

Golde T, Huster C, Glaser M, Händler T, Käs JA, Schnauß J. **Glassy dynamics in composite biopolymer networks.** 8th Annual Symposium Physics of Cancer, 4.-6.10.2017, Leipzig, Germany

Görner C, Godino N, Prill S, Duschl C, Kirschbaum M. **Dynamisches Testverfahren zur in-vitro-Evaluation der Hämokompatibilität kardiovaskulärer Implantate unter kontrollierten, hydrodynamischen Bedingungen und in geringen Blutvolumina.** 36. Jahrestagung der Deutschen Gesellschaft für Klinische Mikrozirkulation und Hämorheologie, 9.-10.6.2017, Greifswald, Germany

Gröger V, Emmer A, Staeger MS, Kornhuber M, Hause B, Cynis H. **Expression and characterization of HERV-K and HERV-Fc1 envelope proteins in mammalian cells.** HERVs and Disease - Second International Workshop on Human Endogenous Retroviruses and Diseases, 13.-14.3.2017, Washington DC, USA

Gros O. **Knowledge extraction from free text medical records, i:DSem-EPP.** i:DSem German Medical Text Mining, 14.7.2017, HU Berlin, Germany

Grünberg M, Quandt D, Cynis H, Demuth HU, Forssmann WG, Seliger B, Mägert HJ. **Kallikrein-related peptidases are potent activators of the CC-chemokine CCL14.** Tumor Immunology meets Oncology (TIMO XIII), 4.-6.5.2017, Halle (Saale), Germany

Habaza M, Kirschbaum M, Guernth-Marschner C, Barnea I, Korenstein R, Duschl C, and Shaked NT. **Dielectrophoretic cell rotation for label-free phase optical cell tomography.** Bioelectronics Workshop Berlin, 30.11.2017, Berlin, Germany

Henning K, Makert GR, Ulbert S, Mertens K. **Project Q-GAPS - The meaning of ticks for the transmission of Coxiella burnetii.** Workshop on Arthropod-Borne Diseases, 16.-17.11.2017, Jena, Germany

Henning K, Makert GR, Ulbert S, Mertens K. **Haben Zecken eine Bedeutung für die Übertragung von Coxiella burnetii? – Vorstellung eines Forschungsprojektes.** Gemeinsame Arbeitstagung der NRL Chlamydiose, Q-Fieber, Paratuberkulose & Tuberkulose der Rinder, 18.-20.10.2017, Jena, Germany

Jorde F, Gutschmann B, Leya T. **Facing the challenges of pure microalgae production in pilot scale photobioreactors.** Algae Biorefineries for Europe, 17.-18.10.2017, Brussels, Belgium

Jorde F, Leya T, Pereira S, Badenes SM, Santos E, Costa L, Verdelho V, Friedl T, Kryvenda A. **Benefits of the algae crop rotation principle in algal mass production.** 11th International Phycological Congress, 14.-18.8.2017, Szczecin, Poland

Jorde F, Leya T, Thomas R, Pereira S, Badenes SM, Santos E, Costa L, Verdelho V, Friedl T, Kryvenda A. **Algae Crop Rotation (ACR).** 10. Bundesalgenstammtisch, 11.-12.9.2017, Merseburg, Germany

Jorde F, Wenzel D, Gutschmann B, Leya T. **Photobioreaktoren zur Kultivierung unter sterilen Bedingungen.** 10. Bundesalgenstammtisch, 11.-12.9.2017, Merseburg, Germany

Kalkhof S. **H/D exchange and Chemical Crosslinking Mass Spectrometry in combination with protein structure prediction – two powerful approaches paving the way to full-length structures of Glycoprotein hormone receptor complexes.** Colloquium on Molecular Biosciences, 9.5.2017, Bayreuth, Germany

Kalkhof S. **Mass spectrometry - a powerful approach for structural characterization of GPCR complexes.** Novartis Seminarreihe, 29.8.2017, Basel, Switzerland

- Kebbel K. **Technical challenges and requirements transferring an early ATMP from laboratory to authorized GMP manufacturing: A case study report.** The Product is the Process – Is it? Qualitätsaspekte bei der Herstellung von ATMP, 7.11.2017, Berlin, Germany
- Kleinschmidt M, Schönfeld R, Göttlich C, Bittner D, Metzner J, Leplow B, Demuth HU. **Combination of blood-based biomarkers and neuropsychological assessment enables reliable classification of tested subjects by controls, mild cognitive impairment and Alzheimer's disease.** Düsseldorf-Jülich Symposium on Neurodegenerative Diseases: Formation, aggregation and propagation of amyloids, 27.-29.11.2017, Düsseldorf, Germany
- Klevesath A, Czepluch D, Orgel D, Menger M. **Aptamers as specific recognition elements.** New and Emerging Technologies, 11-13.9.2017, Potsdam, Germany
- Knigge X, Bier FF, Wenger C, Hölzel R. **Immobilization and detection of single nanoobjects on nanoelectrodes.** EBS/DBS2017, 20.-23.3.2017, Potsdam, Germany
- Knigge X, Wenger C, Bier FF, Hölzel R. **AC electrokinetic immobilisation of nanoobjects as individual singles in regular arrays.** 19th IUPAB congress and 11th EBSA congress, 16.-20.7.2017, Edinburgh, UK
- Knoll T, Gajovic-Eichelmann N, Velten T. **High-throughput R2R production of disposable, low-cost electrodes for EIS, biosensors and electrochemical immunoassays.** EBS/DBS 2017, 20.-23.3.2017, Potsdam, Germany
- Köppen J, Wermann M, Guthardt M, Hähnel M, Menzel M, Klehm J, Demuth HU, Schilling S. **Accelerated Aggregation of alpha-synuclein by A β Peptides in vitro.** The 13th International Conference on Alzheimer's & Parkinson's Diseases, 29.3.-2.4.2017, Wien, Austria
- Kranz A. **Building your own light sheet fluorescence microscope.** 10th Photonic Workshop; 26.2.-2.3.2017, Kopaonik, Serbia
- Kreuz M, Blumert C, Otto D, Reiche K, Puppel S, Buschmann T, Füssel S, Christ S, Friedrich M, Bertram C, Toma M.I., Fröhner M, Specht M, Baretton G.B., Löffler M, Wirth M, Hackermüller J, Horn F. **Long noncoding RNA as prognostic biomarkers for prostate cancer.** EMBL Symposia The non-coding Genome, 13.-16.9.2017, Heidelberg, Germany
- Kryvenda A, Stehr M, Leya T, Jorde F, Olberg B, Friedl T. **The European PUFACHain project (FP7) - a value chain from algal biomass to lipid-based products.** 11th International Phycological Congress, 14.-18.8.2017, Szczecin, Poland
- Kubick S. **Cell-free Bioproduction: Engineering Proteins for Therapy, Diagnostics and Biotechnological Applications.** Seminar Series Compu-Gene TU Darmstadt, 1.3.2017, Darmstadt, Germany
- Kubick S. **Cell-free Production, Labeling and functional Analysis of Membrane Proteins.** Imaging CoE Summit, 20.- 22.11.2017, Melbourne, Australia
- Kubick S. **Cell-free synthesis of glycoproteins.** Tagung Glycobiotec 2017, 7.-9.2.2017, Berlin, Germany
- Kubick S. **New and Emerging Technologies.** New and emerging technologies, 11.-13.9.2017, Potsdam, Germany
- Kubick S. **Techniques for the Production and functional Analysis of Membrane Proteins.** Jahreskongress 2017 Biotechnologie 220+ Nächste Generation biotechnologischer Verfahren, 4.10.2017, Jülich, Germany
- Kuhlmeier D, Tröger V. **Rapid on-chip detection of chlamydia trachomatis for using loop-mediated isothermal amplification.** Fraunhofer Life Science Symposium 2017, 8.-9.11.2017, Leipzig, Germany
- Küpper J, Kern K, Ehrentreich-Förster E, Szardenings M. **Determining the immunome of patient sera at amino acid resolution.** Biotechnology symposium, 5.10.2017, Leipzig, Germany
- Küpper J, Kern K, Ehrentreich-Förster E, Szardenings M. **Determining the immunome of patient sera at amino acid resolution.** Fraunhofer Life Science Symposium, 8.-9.11.2017, Leipzig, Germany
- Lang B, Hilger N, Stahl L, Müller A, Müller C, Fricke S. **Entwicklung eines Testsystems zur prädiktiven Detektion der GvL-Reaktion während immunologischer und supportiver Therapien.** 2. Transferworkshop des Leistungszentrums Chemie- und Systemtechnik, 16.10.2017, Halle (Saale), Germany
- Laux EM. **Detection of dielectrophoretically accumulated bacteria at nanoelectrode arrays by surface enhanced Raman spectroscopy.** EBS/DBS2017, 20.-23.3.2017, Potsdam, Germany

- Laux EM, Docoslis A, Wenger C, Bier FF, Hölzel R. **Combination of dielectrophoresis and surface enhanced Raman spectroscopy for bacteria detection and characterization.** 19th IUPAB congress and 11th EBSA congress, 16.-20.7.2017, Edinburgh, UK
- Laux EM, Gibbons J, Ermilova E, Bier FF, Hölzel R. **Broadband dielectric spectroscopy of bovine serum albumin in the GHz range.** 19th IUPAB congress and 11th EBSA congress, 16.-20.7.2017, Edinburgh, UK
- Laux EM, Knigge X, Wenger C, Bier FF, Hölzel R. **AC electrokinetic manipulation of nanoparticles and molecules.** 19th IUPAB congress and 11th EBSA congress, 16.-20.7.2017, Edinburgh, UK
- Lenz KW, Bier FF, Gajovic-Eichelmann N. **Peptide decorated electropolymer films for biosensors: Comparison of different strategies for oriented peptide immobilization.** EBS/DBS2017, 20.-23.3.2017, Potsdam, Germany
- Leya T, Baqué M, Rabbow E, De Vera, JP. **Cryophilic algae survive in space.** 11th International Phycological Congress, 14.-18.8.2017, Szczecin, Poland
- Leya T, Jorde F, Thomas R, Pereira S, Badenes SM, Santos E, Costa L, Verdelh Vieira V, Friedl T, Kryvenda A. **The Algae Crop Rotation principle as a potential basis for algae mass production.** Algae Biorefineries for Europe, 17.-18.10.2017, Brüssel, Belgium
- Lindner N, Dandekar G, Werno C, Bohle K, Schmitz J, Seitz S, Küfer KH, Bailer S, Lange F, Grunwald T. **Preclinical testing of HSV-1 based oncolytic viruses for lung tumor therapy.** TCRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference, 6.-9.9.2017, Mainz, Germany
- Linnert M, Spahn C, Parthier C, Schlenzig D, Ramsbeck D, Stubbs MT, Schilling S. **Structure determination of Meprin β in complex with specific inhibitor MWT-S270.** DLS-CCP4 Data Collection and Structure Solution Workshop, 30.11.-7.12.2017, Oxford, UK
- Makert GR, Ulbert S. **An immunological strategy for the control of the poultry mite *Dermanyssus gallinae*: a potential vector of pathogenic agents.** Highly virulent agents and their vectors, 2.-4.5.2017, Komorný Hrádek, Czech Republic
- Makert GR, Ulbert S. **Development of a vaccine for the control of the red mite: Fipronil scandal confirmed that *Dermanyssus gallinae* still remains a challenge for the poultry industry.** Workshop on Arthropod-Borne Diseases, 16.-17.11.2017, Jena, Germany
- Makert GR, Ulbert S. **The development of a vaccine for the control of the ectoparasite *Dermanyssus gallinae*: Fipronil scandal confirmed the need of alternative methods.** Jahrestagung der Deutschen Gesellschaft für Medizinische Entomologie und Acarologie, 18.-20.9.2017, Leipzig, Germany
- Makert GR, Ulbert S. **Vaccine development for the control of the ectoparasite *Dermanyssus gallinae*: a potential vector of pathogenic agents.** 11th Central and Eastern European Proteomic Conference (CEEPC), 26.-29.9.2017, Kosice, Slovakia
- Menger M. **Aptamer-basierte online Prozesskontrolle in Fermentationsprozessen.** Cross-Innovation-Workshop Bio-PAT: Zellerkennung und Einwegsensorik in der Biotechnologie, 14.12.2017, Berlin, Germany
- Menger M. **Automatisierte DNA-Aptamer Generierung & Aptamer Charakterisierung.** Dechema-Aptamer-Infotag, 3.4.2017, Frankfurt, Germany
- Menger M. **Spezifische molekulare Erkennung mittels Aptameren.** ZIM-Netzwerk VetDx, 29.9.2017, Berlin, Germany
- Menger M. **Aptamers as specific recognition elements in biosensors.** EBS/DBS2017, 20.-23.3.2017, Potsdam, Germany
- Menger M. **Specific molecular recognition by aptamers.** Bionnale, 17.5.2017, Berlin, Germany
- Mollenkopf P, Strehle D, Glaser M, Schuldt C, Golde T, Schnauß J, Käs JA, Smith D. **Mechanical properties of anisotropic polymer structures investigated by optical tweezers.** 8th annual symposium on Physics of Cancer, October 4-6 2017, Leipzig, Germany
- Mollenkopf P. **Extensibility measurements on DNA Helix tubes.** 11th Soft Matter Physics Winterschool, February 25-March 3 2017, Vitkovice, Czech Republic
- Mollenkopf P. **Single Molecule Manipulation and Extensibility Measurements on DNA Helix Tubes.** DNA Mitteldeutschland, 18.5.2017, Jena, Germany

Möser C, Lorenz JS, Herbig M, Otto O, Guck J, Bier FF, Smith DM. **DNA nanostructures as multivalent carriers for peptides.** Soft Matter Day, June 23 2017, Leipzig, Germany

Möser C, Lorenz JS, Lauster D, Stöcklein W, Memczak H, Herrmann A, Bier FF, Smith DM. **DNA nanostructures as multivalent carriers for peptides.** Fraunhofer Life Science Symposium, 8-9.11.2017, Leipzig, Germany

Möser C, Lorenz JS, Lauster D, Stöcklein W, Memczak H, Herrmann A, Bier FF, Smith DM. **DNA nanostructures as multivalent carriers for peptides.** 4th International Symposium of the Collaborative Research Center 765 Multivalency in Chemistry and Biochemistry, 4-6.10.2017, Berlin, Germany

Möser C. **DNA nanostructures as multivalent carriers for peptides.** PhD Workshop on Bioanalysis, November 27.-28.2017, Luckenwalde, Germany

Möser C. **Targeting and activation of RTK with DNA-based synthetic antibodies.** DNA Mitteldeutschland, 18.5.2017, Jena, Germany

Mostafa A, Möser C, Rockstroh A, Schilling S, Smith D. **Development of Dengue virus VLPs as tools for probing DNA nanoparticle-mediated multivalent inhibitors.** Soft Matter Day, 23.6.2017, Leipzig, Germany

Mostafa A. **Development of Dengue virus VLPs as tools for probing DNA nanoparticle-mediated multivalent inhibitors.** DNA Mitteldeutschland, 18.5.2017, Jena, Germany

Nitzsche B, Ferrara F, Boltze J, Hainsworth A, Bridges L, Deuter-Konrad W, Dreyer A, Gräßer F, Großmann U, Lobsien D, Patt M, Härtig W, Sabri O, Barthel H. **Sheep models for cerebrovascular pathology.** New Animal Models to understand the brain-INRA, 15.5.2017, Tours, France

Nykiel V, Gröger V, Cynis H. **Gewichtsreduktion im Versuch und dessen Bedeutung für das Wohlbefinden von Versuchstieren.** 55. Wissenschaftliche Tagung der Gesellschaft für Versuchstierkunde GV-SOLAS und 17. Fortbildungsveranstaltung der IGTP, 11.-13.9.2017, Cologne, Germany

Obendorf J, Fabian C, Thome UH, Laube M. **Mesenchymal stem cell conditioned medium enhances functional and structural lung maturation.** 6th symposium of the young physiologists, 28.-29.9.2017, Jena, Germany

Otto D. **Independent Component Analysis as Signal Deconvolution.** 15. Herbstseminar der Bioinformatik, 2.-7.10.2017, Doubice, Czech Republic

Otto D, Füssel S, Wirth M, Horn F, Reiche K. **Factor Extraction from transcriptome-wide expression data as a method for robust prognosis of prostate carcinoma.** ISMB/ECCB 2017, 21.-25.-7.2017, Prag, Czech Republic

Otto D. **A Factor Extraction from RNA-Seq Data.** 33rd TBI Winterseminar in Bled, 11.-18.2.2017, Bled, Slovenia

Penk J, Rositzka L, Jehmlich U, Leibner R, Hoffmann M, Lehmann J. **Establishment of a small-scale manufacturing facility for the GMP production of therapeutic monoclonal antibodies.** Biotechnology Symposium, 5.10.2017, Leipzig, Germany

Pereira S, Parreira C, Mota R, Semião F, Badenes SM, Santos E, Costa L, Leya T, Friedl T, Verdelho Vieira V. **Overcoming the challenges in the very first closed photobioreactor pilot scale cultivations of cryophilic and dinoflagellate microalgae strains for PUFA production.** Algae Biorefineries for Europe, 17.-18.10.2017, Brüssel, Belgium

Peter H, Wienke J, Bier FF. **Highly-integrated Lab-on-a-chip System for Multiparameter Analysis.** EBS/DBS2017, 20.-23.3.2017, Potsdam, Germany

Peter H, Wienke J, Guest PC, Bistolos N, Bier FF. **Lab-on-a-chip proteomic assays for psychiatric disorders.** ESACT Meeting, 14.-17.5.2017, Lausanne, Switzerland

Peter L. **Lab-on-a-Chip with Incorporated Microarrays for the Detection of Antimicrobial Resistances.** Lab-on-Chip-SectBio Conferences, 10.11.5.2017, Munich, Germany

Pfisterer F, Behm LVJ, Duschl C, Kirschbaum M. **Controlling the temperature distribution on a biochip surface for conducting temperature-dependent bioprocesses on the microscale.** New and Emerging Technologies, 11.-13.9.2017, Potsdam, Germany

Przybylski S. **Biodistribution, pharmacological and immunological profiling.**

Bionection, 17.-18.10.2017, Jena, Germany

Quandt D, Grünberg M, Cynis H, Demuth HU, Forssmann WG, Mägert HJ, Seliger B. **A new function for Kallikrein as activator of chemokine CCL14.**

47. Jahrestagung der Deutschen Gesellschaft für Immunologie, 12.-15.9.2017, Erlangen, Germany

Rade M. **Long non-coding RNAs related to MAPK-inhibitor resistance in melanoma.**

15. Herbstseminar der Bioinformatik, 2.-7.10.2017, Doubice, Czech Republic

Rahfeld JU, Piechotta A, Gnoth K, Kleinschmidt M, Cynis H, Demuth HU, Schilling S.

Targeting Post-translationally modified A β : A Differential Approach of Passive Immunotherapy. 2017 Düsseldorf-Jülich Symposium on Neurodegenerative Diseases, 27.-29.11.2017, Düsseldorf, Germany

Ramirez Caballero L, Delaroque N, Szardenings M. **Mapping the antibody response to Hepatitis B and Influenza vaccinations direct from patient sera.** Fraunhofer Life Science Symposium, 8.-9.11.2017, Leipzig, Germany

Ramirez Caballero L, Szardenings M. **B-cell epitope profile determination before and after hepatitis B and influenza vaccinations direct from patient sera.**

Biotechnology symposium, 5.10.2017, Leipzig, Germany

Ramm F. **Synthesis and functional characterization of Apoptin and Dianthin in eukaryotic cell-free systems.**

PhD Workshop on Bioanalysis, 27.-28.11.2017, Luckenwalde, Germany

Ramsbeck D, Hamann A, Schlenzig D, Schilling S, Buchholz M. **First insight into structure-activity relationships of selective Meprin β inhibitors.** 254th ACS National Meeting & Exposition, 20.-24.8.2017, Washington DC, USA

Ramsbeck D, Hamann A, Schlenzig D, Schilling S, Buchholz M. **First insight into structure-activity relationships of selective Meprin β inhibitors.** 34th Winterschool on Proteases and Inhibitors 2017, 8.-12.3.2017, Tiers, Italy

Richter T. **Fluorescent Labeling and Functional Characterization of the Adenosine A2a Receptor in a Eukaryotic Cell-Free System.** PhD Workshop on Bioanalysis, 27.-28.11.2017, Luckenwalde, Germany

Richter T, Zemella A, Thoring L and Kubick S. **Cell-Free Synthesis of the Adenosine A2a Receptor: Fluorescent Labeling and Functional Characterization.** New and emerging technologies, 11.-13.9.2017, Potsdam, Germany

Rockstroh A, Ulbert S. **Differentiation of dengue and Zika virus antibodies using envelope proteins with mutations in the conserved fusion loop domain.** Fraunhofer Life Science Symposium, 8.-9.11.2017, Leipzig, Germany

Rockstroh A, Ulbert S. **Differentiation of flavivirus infections using a multi antigen ELISA based on recombinant envelope proteins with mutations in the conserved fusion loop domain.** First International Conference on Zika Virus, 22.-25.2.17, Washington DC, USA

Rockstroh A, Ulbert S. **Differentiation of flavivirus infections using a multi antigen ELISA based on recombinant envelope proteins with mutations in the conserved fusion loop domain.** 27th Annual Meeting of the Society for Virology, 22.-25.3.2017, Marburg, Germany

Sajfutdinow M, Uhlig K, Prager A, Schneider Ch, Abel B, Smith D. **Single Molecule Contact Printing.** Fraunhofer LifeScience Symposium, 8.-9.11.2017, Leipzig, Germany

Sajfutdinow M. **Elucidating DNA brick structures assembly by dynamic light scattering.** DNA Mitteldeutschland, 18.5.2017, Jena, Germany

Sandetskaya N. **Strategies and solutions for sample preparation in the diagnostics of infectious diseases.** Fraunhofer Life Science Symposium, 8.-9.11.2017, Leipzig, Germany

Sass S, Stöcklein WF, Klevesath A, Hurpin J, Menger M, Hille C. **Binding affinity data of DNA aptamers for therapeutic anthracyclines from microscale thermophoresis and surface plasmon resonance spectroscopy.** Potsdam Days on Bioanalysis, 23-24.11.2017, Potsdam, Germany

Schilling S, Demuth HU. **Antikörper gegen isoAsp-modifiziertes A β : Ein neuer Ansatz der Wirkstoffforschung zur Behandlung der Alzheimer-Krankheit.** Gesundheit im Alter, 8.9.2017, Hannover, Germany

Schilling S, Gnoth K, Rahfeld JU, Cynis H, Piechotta A, Demuth HU. **Modified A β peptides - emerging targets for immunotherapy in Alzheimer's disease.** New and Emerging Technologies, 11.-13.11.2017, Potsdam, Germany

- Schilling S, Schlenzig D, Spahn C, Cynis H, Linnert M, Ramsbeck D, Roßner S, Stubbs M, Buchholz M, Demuth HU. **A Dipeptidylpeptidase-Activity of Meprin β Potentially Contributes to Accumulation of N-truncated A β in Alzheimer's Disease.** 10th General Meeting of the International Proteolysis Society, 28.10.-2.11.2017, Banff, Canada
- Schilling S, Schlenzig D, Spahn C, Cynis H, Linnert M, Ramsbeck D, Rossner S, Stubbs MT, Buchholz M, Demuth HU. **A Dipeptidylpeptidase-Activity of Meprin β potentially Contributes to Accumulation of N-truncated A β in Alzheimer's Disease.** SfN - Neuroscience 2017, 11.-15.11.2017, Washington DC, USA
- Schimmelpfennig C. **Comparison of gene fusion detection tools to detect novel gene fusions using a custom annotation.** 33rd TBI Winterseminar in Bled, 11.-18.2.2017, Bled, Slovenia
- Schlenzig D, Cynis H, Hartlage-Rübsamen M, Ramsbeck D, Wermann M, Roßner S, Buchholz M, Schilling S, Demuth HU. **Processing of amyloid precursor Protein (APP) by Meprin β results in formation of pGLU-A β .** 13th International Conference on Alzheimer's & Parkinson's Diseases, 29.3.-2.4.2017, Wien, Austria
- Schmidt J, Vogel S, Förster Y, Rammelt S, von Bergen M, Hempel U, Kalkhof S. **Studying bone healing induced by glycosaminoglycan-coated implants in vitro and in situ using proteomics.** Advances in Biomedical Research, 3.-7.7.2017, Split, Croatia
- Schnauß J. **Emergent mechanics of DNA-crosslinked biopolymer hydrogels.** DNA Mitteldeutschland, 18.5.2017, Jena, Germany
- Schnauß J. **Mechanics and dynamics of semiflexible polymer structures.** Soft Matter Day 2017, 23.6.2017, Leipzig, Germany
- Schnauß J. **Mechanics and dynamics of the cytoskeleton.** ERC Advanced Kick-off meeting, 22.8.2017, Freyburg/U., Germany
- Schnauß J. **Non-genetic programming of biology by DNA-based cross-linkers.** 11th Käslab Winterschool 2017, 27.2.2017, Vítkovice, Czech Republic
- Schnauß J. **Probing mechanical properties of biological, semiflexible polymers.** Seminar of the Molecular Spectroscopy group - Institute of Analytical Chemistry, 29.3.2017 Leipzig, Germany
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Stech M, Nikolaeva O, Teichmann T, Thoring L, Wenzel D, Wüstenhagen DA, Stöcklein WFM, Kubick S. **Cell-free synthesis of antibodies using a coupled in vitro transcription-translation system based on CHO cell lysates.** PEGS Europe, 13.-17.11.2017, Lissabon, Portugal

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Stech M. **Cell-free antibody production.** Bionnale, 17.5.2017, Berlin, Germany

Stech M. **Cell-free systems for the production, engineering and modification of antibodies; Marlitt Stech.** New and emerging technologies, 11.-13.9.2017, Potsdam, Germany

Stech M. **Eukaryotic cell-free systems: A novel source for functional antibodies.** PEGS Europe, 13.-17.11.2017, Lissabon, Portugal

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Szardenings M. **Rapid and Extensive Epitope Fingerprinting of Monoclonal and Polyclonal Antibodies.** PepTalk, 9.-13.1.2017, San Diego, USA

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Thoring L, Stech M, Pietruschka G, Dondapati SK, Wüstenhagen DA, Kubick S. **Development of Eukaryotic Cell-free Systems based on Chinese Hamster Ovary Cells for the Production of Difficult-to-Express Proteins.** New and emerging technologies, 11.-13.9.2017, Potsdam, Germany

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Tradler T. **Combining different funding sources in one research institute.** Seminar Funding Strategies & Sources for International Research Cooperation; 13.-14.2.2017, Berlin, Germany

Tradler T. **Commercialization of applied research derived IP at Fraunhofer- Gesellschaft.** Technologietransfer-Workshop der Helmholtz-Gesellschaft, 24.5.2017, Dresden, Germany

Tradler T. **IP Management in der Fraunhofer-Gesellschaft.** Jahrestreffen der Technologietransferbeauftragten der medizinischen Fakultäten in Deutschland, 9.-10.10.2017, Mainz, Germany

Tradler T. **Strategy to diversify the sources of revenues for a research institute.** Seminar Funding Strategies & Sources for International Research Cooperation, 13.-14.2.2017, Berlin, Germany

Tradler T. **Vergleichende Analyse von US- und europäischen Zelltherapieunternehmen.** Kooperations-Workshop BCRT, 7.8.2017, Berlin, Germany

Tschirner T, Glaser M, Käs J, Smith D, Schnauß J. **Higher ordered assembly of chiral DNA nanotubes induced by depletion forces.** Soft Matter Physics Winterschool, 25.2.-3.3.2017, Spindelmühle, Czech Republic

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Wilcke A. **Genetics and early testing of dyslexia - Project LEGASCREEN: Mission accomplished?** International workshop: Dyslexia and Traumatic Experiences, 22.9.2017, Leipzig, Germany

Wilcke A. **Genetics of Dyslexia - The development of a multimodal test for early diagnostic.** EU-Arbeitsgruppen tagung Legasthenie, 27.1.2017, Leipzig, Germany

Wilcke A. **LEGASCREEN - A multimodal screening test for dyslexia and its acceptance.** Biotechnology Symposium 2017, 5.10.2017, Leipzig, Germany

Wittenbecher J, Händler T, Glaser M, Golde T, Smith D, Käs J, Schnauß J. **Microrheology on mechanically tunable DNA nanotube networks.** Soft Matter Physics Winterschool, 25.2.-3.3.2017, Spindelmühle, Czech Republic

Wüstenhagen D, Thoring L, Korpys A, Kubick S. **Eukaryotic Lysates for Cell-Free Synthesis of Proteins.** New and emerging technologies, 11.-13.9.2017, Potsdam, Germany

Wüstenhagen D. **Eukaryotische Zellfreie Proteinsynthese.** Cross-Innovation-Workshop, 14.12.2017, Berlin, Germany

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Zemella A, Thoring L, Kubick S. **Cell-free systems as novel tools for directed engineering of difficult-to-express proteins.** Proteomic Forum, 2.-5.4.2017, Potsdam, Germany

Zemella A, Thoring L, Wüstenhagen D, Kubick S. **Site-specific functionalization of difficult-to-express proteins by using cell-free systems.** PEGS, 1.-5.5.2017, Boston, USA

Zemella A, Thoring L, Wüstenhagen D, Kubick S. **The potential of cell-free protein synthesis for glycoengineering of active human erythropoietin.** New and emerging technologies, 11.-13.9.2017, Potsdam, Germany

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Schnauß J, Käs JA, Smith DM. **Contact-free mechanical manipulation of biological materials.** In: Bhushan, Bharat (Ed.): Springer Handbook of Nanotechnology. Berlin : Springer, 2017, S.617-641 http://dx.doi.org/10.1007/978-3-662-54357-3_20

GRADUATION (CLASS OF 2017)

Alexandrova, Vera. **Etablierung und Validierung des Herstellungsprozesses und der zugehörigen Qualitätskontrollen für ein Zelltherapeutikum zur Behandlung der chronischen Herzmuskelschwäche.** Rheinisch-Westfälische Technische Hochschule Aachen, Master

Bettinelli, Alexandra. **In vitro Selektion von DNA-Aptameren mittels eines neuartigen, auf Graphenoxid basierten Verfahrens.** Technische Universität Berlin, Bachelor

Caballero, Lisbeth Ramirez. **Development of the immune of a patient by comparative peptide phage display.** Martin-Luther-Universität Halle-Wittenberg, Master

Connor, Daniel. **Identifikation und Charakterisierung neuer immunogener Proteine und anschließende Generierung rekombinanter Antikörper mittels Phage Display.** Universität Potsdam, Promotion

Dahm, Katrin. **Naturally occurring substances in cancer therapy – The anti-cachectic properties of curcumin and other naturally occurring substances in an in vitro model.** Fachhochschule Südwestfalen, Bachelor

Dippong, Martin. **Direkte und indirekte Hapten-selektive Immunfluoreszenzmarkierung von Hybridomazellen zur Generierung monoklonaler Antikörper.** Universität Potsdam, Promotion

Döring, Marietta. **Analyse der molekularen Wirkungsweise langer nicht-codierender RNAs.** Universität Leipzig, Master

Dürschmid, Andreas. **Automatische Detektion und Einzellverfolgung für fluoreszenzmikroskopische Zeitserien.** Hochschule für Technik, Wirtschaft und Kultur Leipzig, Master

Ebert, Marcus. **Untersuchungen zur Inaktivierung von Polioviren mittels Elektronenstrahlen.** Universität Leipzig, Master

Ehrlich, Vivian. **Implementierung eines künstlichen neuronalen Netzes zur Klassifizierung von Zellen des Zervixkarzinoms.** Hochschule für Technik, Wirtschaft und Kultur Leipzig, Master

El Kassem, Ghanem. **Heterologous Expression and Characterization of the Astacin Proteases BMP1 and meprin α .** Martin-Luther-Universität Halle-Wittenberg, Master

Fischbach, Jens. **DNA- und Pyrophosphat-abhängige Detektionsmethoden in der isothermalen Amplifikation.** Universität Potsdam, Promotion

Fritzsche, Thomas. **Konstruktion, Aufbau und Inbetriebnahme einer temperierbaren Probenkammer für die Lightsheet-Mikroskopie.** Ernst-Abbe-Hochschule Jena, Master

Gärtig, Cornelia. **Entwicklung eines Point-of-Care-Systems zur Identifizierung und Quantifizierung Sepsis-relevanter Erreger.** Friedrich-Schiller-Universität Jena, Promotion

Gold, Caroline. **Proteomanalyse von isotoopenmarkierten Listeria monocytogenes.** Hochschule für angewandte Wissenschaften Coburg, Bachelor

Gümpel, Jessica. **Herstellung von Papilloma-Pseudoviren in Insektenzellkultur und Aufreinigung mit Größenausschlusschromatographie.** Berufsakademie Riesa, Bachelor

Heyner, Adrian. **Methoden der 3D-Punktmusterstatistik und deren Anwendung in der Histologie.** Hochschule für Technik, Wirtschaft und Kultur Leipzig, Master

Issmail, Leila. **Immunization with DNA vaccines encoding different variants of human respiratory syncytial virus glycoproteins.** Martin-Luther-Universität Halle-Wittenberg, Master

Kistenmacher, Ann-Kathrin. **Innovative electron beam irradiation for NK cell therapy of cancer.** Friedrich-Schiller-Universität Jena, Master

Konrath, Sandra. **Expression, Reinigung und Charakterisierung monoklonaler Antikörper gegen das Isoaspartat-7-Amyloid-beta-Peptid (A β isoD7).** Martin-Luther-Universität Halle-Wittenberg, Master

Köppen, Janett. **Expression und Charakterisierung des CrossSeedings von alpha-Synuclein und Huntingtin.** Martin-Luther-Universität Halle-Wittenberg, Master

Kreibich, Julia Maria. **Entwicklung und Charakterisierung eines homogenen Immunoassays für ein Lab-on-a-chip-System zum Nachweis des Parodontitis-relevanten Biomarkers Interleukin-1 β .** Technische Universität Braunschweig, Master

Lagoda, Florain. **Generierung von in-silico-Modellen zur Vorhersage der Bioverfügbarkeit potentieller Arzneistoffe.** Hochschule Mittweida, Bachelor

Lubitz, Timo. **Etablierung eines labelfreien Nachweises von in vitro Phosphorylierung durch die Protein Kinase A.** Charité - Universitätsmedizin Berlin, Master

Mükusch, Sandra. **Identifizierung post-translationaler Modifikationen mittels Peptid Mikroarrays.** Freie Universität Berlin, Promotion

Müller, Bent. **Identification and characterization of genetic risk variants for dyslexia with regard to predictive aspects.** Universität Leipzig, Promotion

Nykiel, Vera. **Einfluss eines Inhibitors der Glutaminylzyklase auf die in-Stent Restenose im atherosklerotischen Kaninchenmodell.** Universität Leipzig, Promotion

Nikolaeva, Olga. **Zellfreie Synthese funktioneller Antikörper in eukaryotischen Zelllysaten basierend auf kultivierten CHO-Zellen.** Technische Universität Berlin, Diplom

Pahlke, Claudia. **Towards next-generation sequencing-based identification of norovirus recognition elements and microfluidic array using phage display technology.** Technische Universität Dresden, Promotion

Pfisterer, Felix. **Untersuchungen zur Temperatursausbreitung auf einer mit Mikroelektroden beheizten Biochipoberfläche.** Technische Universität Berlin, Diplom

Philipp, Karolin. **Entwicklung eines Lyseverfahrens für die Anwendung in einem point-of-care-Test zum Nachweis von Trachoma.** Technische Universität Dresden, Master

Piechotta, Anke. **Charakterisierung von Antikörpern gegen das Pyroglutamat-3Amyloid-beta Peptid (A β pE3-Peptid) als Voraussetzung für eine potentielle Anwendung in der Alzheimer Immuntherapie.** Martin-Luther-Universität Halle-Wittenberg, Promotion

Pietruschka, Georg. **Cell-free synthesis and functional characterisation of the human Toll-like receptor 9.** Freie Universität Berlin, Master

Ponath, Falk. **The role of complement activation in A β immunotherapy - a comparison of pyroGlu-3-A β antibodies.** Martin-Luther-Universität Halle-Wittenberg, Master

Püllmann, Pascal. **Heterologe Produktion und Reinigung viraler Hüllproteine des humanen endogenen Retrovirus Fc1.** Martin-Luther-Universität Halle-Wittenberg, Master

Rade, Michael. **A Meta-Analysis of novel lncRNAs related to MAPK-Inhibitor resistance mechanisms in melanoma.** Universität Leipzig, Master

Ramirez-Caballero, Lisbeth. **Development of the Immune of a Patient by Comparative Phage Display.** Martin-Luther-Universität Halle-Wittenberg, Master

Ramm, Franziska. **Synthesis and functional characterization of Apoptin and Dianthin in eukaryotic cell-free systems.** Charité – Universitätsmedizin Berlin, Master

Richter, Georg. **Synthese und Charakterisierung neuartiger Meprin β Inhibitoren.** Martin-Luther-Universität Halle-Wittenberg, Master

Riedel, Diana. **Überlebensfördernde Wirkung nichtkodierender RNAs im Multiplen Myelom.** Universität Leipzig, Promotion

Schimmelpfennig, Carolin. **Screening of Prostate Cancer Tissue Samples for Gene Fusions in a Custom Assembly.** Universität Leipzig, Master

Schmidt, Alina. **Entwicklung peptid-basierter antimikrobieller Oberflächen auf Silikon-Hydrogel-Polymeren.** Universität Potsdam, Bachelor

Schumacher, Sarah. **Etablierung eines parallelen immunologischen Nachweises von Drogen in Serum.** Humboldt-Universität zu Berlin, Promotion

Shaffai, Amr. **Development of Dengue virus VLPs as tools for probing DNA nanoparticle-mediated multivalent inhibitors.** Martin-Luther-Universität Halle-Wittenberg, Master

Sheim, Zeinab. **Nachweis und Charakterisierung von Antibiotika-resistenten mittels Multiplex-PCR und DNA-Mikroarray.** Charité Universitätsmedizin Berlin, Promotion

Sobotta, Michael. **Innovative Bestrahlung von therapeutischen NK-Zelllinien für die Tumorthherapie.** Rheinisch-Westfälische Technische Hochschule Aachen, Master

Stahl, Maik. **Echtzeit-Messung des pH-Wertes in 3D-Zellkultursystemen mittels Sensorpartikel.** Hochschule Mittweida, Bachelor

Thoring, Lena. **Development of Eukaryotic Cell-free Systems based on Chinese Hamster Ovary Cells for the Production of »Difficult-to-Express« Proteins.** Technische Universität Berlin, Promotion

Warmt, Christian. **Entwicklung eines Microarrays zur Detektion spezifischer, zirkulärer RNA für die Diagnostik.** Universität Potsdam, Master

Wieland, Lisa. **Charakterisierung des Hüllproteins des humanen endogenen Retrovirus K113 insbesondere hinsichtlich Limitation der Expression in Säugerzellen.** Martin-Luther-Universität Halle-Wittenberg, Master

Wolf, Ruslana. **Etablierung eines immunologischen Nachweises im Serum.** Beuth Hochschule für Technik Berlin, Bachelor

Yakoub, Mina. **Investigation of the interaction of TRPCs and NCAM proteins and the functional consequences.** Martin-Luther-Universität Halle-Wittenberg, Master

Zielonka, Adalbert. **Prototyping of a low-cost microfluidic flow cell for the fast detection of Chlamydia trachomatis.** Fachhochschule Aachen, Master

PRIZES AND AWARDS

Fraunhofer IZI publication prizes awarded to Yarúa Jaimes on the topic "Mesenchymal stem cell-derived microvesicles modulate lipopolysaccharides-induced inflammatory responses to microglia cells", to Bent Müller on the topic "Association, characterisation and meta-analysis of SNPs linked to general reading ability in a German dyslexia case-control cohort", and to Nadja Hilger on the topic "Attenuation of graft-versus-host disease in NOD scid IL-2R $\gamma^{-/-}$ (NSG) mice by ex-vivo modulation of human CD4+ T-cells".

Fraunhofer IZI Science Day poster prizes awarded to Claudia Müller and Lukas Rositzka on the topic "In-vitro analysis of a new potential therapeutic biomarker for an antibody-based therapy against triple-negative breast cancer", to Claudia Spahn on the topic "Heterologous expression of human procollagen and the role of astacins for the formation of functional collagen fibers" and to Nadja Lindner for the topic "Effectivity of antiviral therapy against human Herpes simplex virus type 1 (HSV-1) in an infection mouse model".

Poster prize awarded by Coburg University of Applied Sciences to Simone Kess on the topic "Application of histochemical and immunofluorescent staining to assess chronic DSS-induced colitis in the murine model" and to Wilhelm Schieferdecker on the topic "Quality control of cell lines using an impedance-based real-time analysis".

2017 BuildMoNa award for "Outstanding scientific results" handed to Martin Glaser on the topic "Building with Molecules and Nano-objects".

6th SYMPOSIUM OF THE YOUNG PHYSIOLOGISTS poster prize awarded to Janine Obendorf on the topic "Mesenchymal stem cell conditioned medium enhances functional and structural lung maturation".

Chamber of Industry and Commerce distinction for the best thesis in Germany relating to the profession of animal care supervisor (research and clinical practice) awarded to Marion Fink.

Riesa Professional Academy for Biotechnology distinction for an outstanding bachelor thesis awarded to Jessica Gumpel on the topic "Manufacturing pseudoviruses in insect cell culture and purification with size-exclusion chromatography".

Advancement award handed out by Richard Wolf GmbH to Sandra Haas for her exceptional bachelor thesis on the topic "Epitope mapping with peptide phage display and in-silico evaluation".

Berlin State Prize for Alternative Methods to Animal Testing in Research and Training awarded by the Senate Department for Justice, Consumer Protection and Anti-discrimination, the German Association of Research-based Pharmaceutical Companies, Berlin State Office for Health and Social Affairs and Berlin Veterinary Medical Association, Professor Frank F. Bier, Dr Nenad Gajovic-Eichelmann.

Poster prize at the New and Emerging Technologies conference awarded to Theresa Richter on the topic "Cell-Free Synthesis of the Adenosine A2a Receptor: Fluorescent Labeling and Functional Characterization."

PATENTS

The patent portfolio of the Fraunhofer IZI currently holds 46 patent families which are available for use in cooperation projects as well as for direct commercialization and licensing.

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Fraunhofer IZI holds patent families in the following fields of technology:

- Technologies for generating pluripotent stem cells
- Procedures for diagnosing infecting agents
- Procedures for diagnosing cancerous diseases
- New treatment procedures for cancer and other diseases
- New procedure for preventing Graft-versus-Host-Disease (GvHD)
- Method for immobilizing cells on surfaces
- Procedure for diagnosing dyslexia
- Methods for ascertaining liver function and regeneration
- Methods for targeted isolation of nucleic acids
- Mineral compounds for the prevention / treatment of kidney and bowel diseases
- Methods of treating neurological and neuropsychological diseases
- Substrate, cultivation facility and cultivation procedures for biological cells
- Electrochemical detection methods for binding reactions
- Cell-free protein synthesis procedure
- Procedure for manufacturing zinc fingers and concatemers
- Coimmobilization of several chemical species
- Procedure for manufacturing transparent films from cellulose dispersions and their use as multifunctional ligand carriers
- Device for measuring luminescence
- Procedure for manufacturing a leukocyte preparation
- Development of antimicrobial peptides
- Diagnosis of chronic obstructive pulmonary disease

FURTHERANCE



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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.

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und Forschung



Advisory board

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

Members of the advisory board:

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

FRAUNHOFER- GESELLSCHAFT



THE FRAUNHOFER-GESELLSCHAFT IN PROFILE

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

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

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

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

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

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

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

Executive board

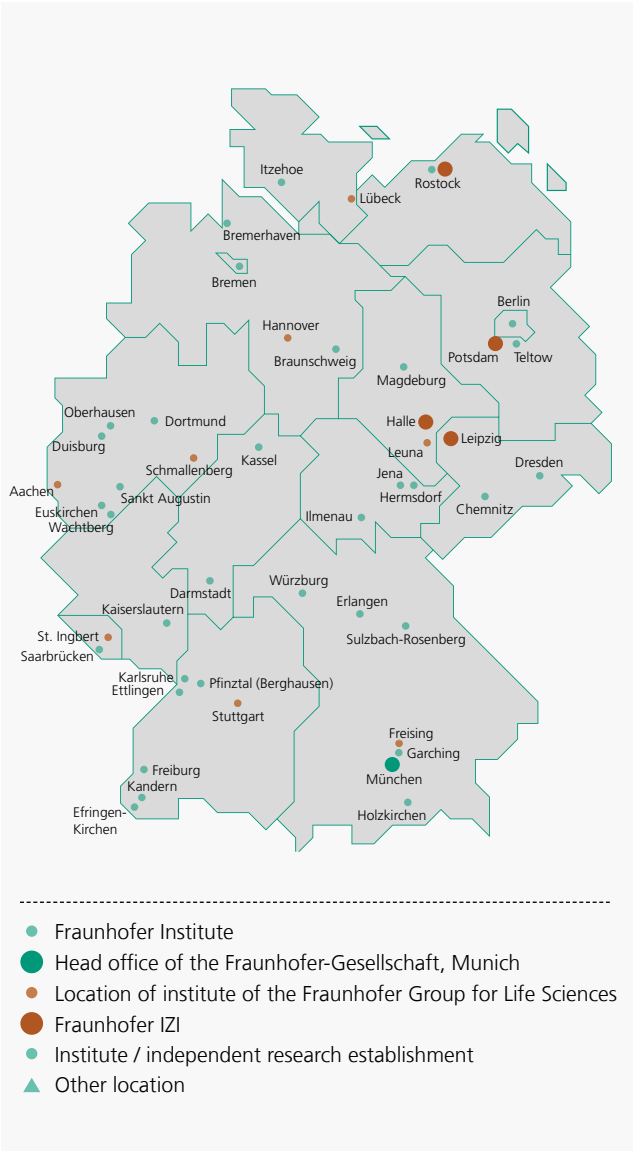
- Prof. Dr.-Ing. Reimund Neugebauer, President, Corporate Policy and Research Management
- Prof. Dr. Georg Rosenfeld, Technology Marketing and Business Models
- Prof. Dr. Alexander Kurz, Human Resources, Legal Affairs and IP Management
- Dipl.-Kfm. Andreas Meuer, Executive Vice President Controlling and Digital Business Processes

Head office

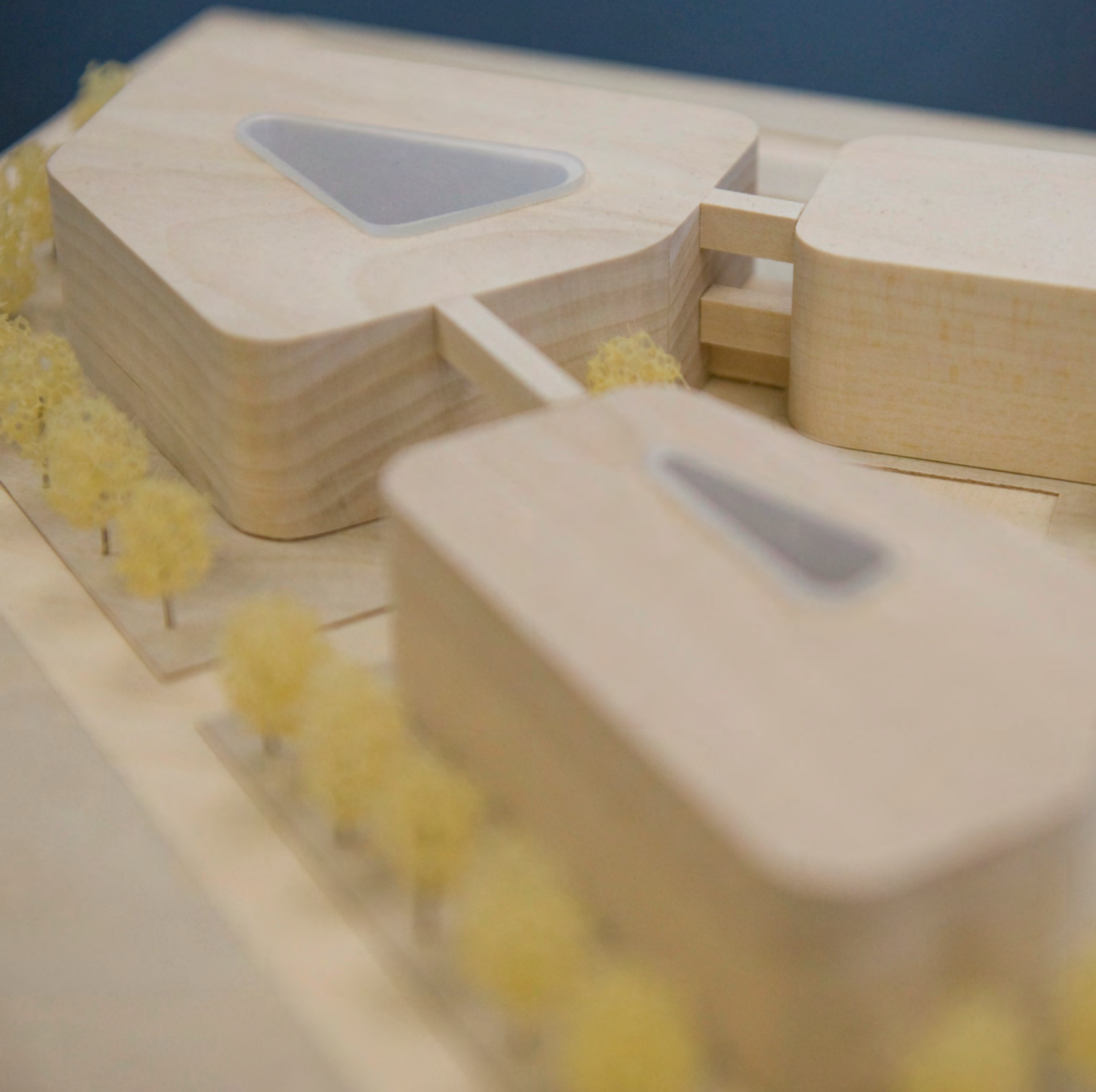
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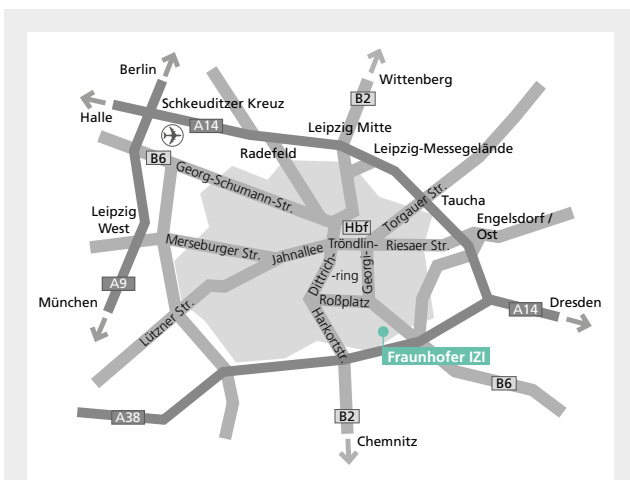
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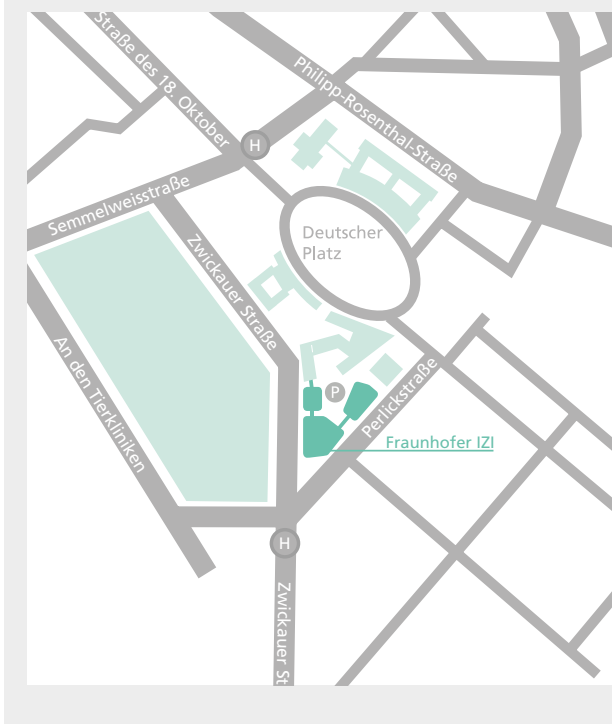
Fraunhofer Institute for Cell Therapy and Immunology
Perlickstraße 1
04103 Leipzig
Germany

By car

A9 – Exit Leipzig-West: Take the B181 in the direction of the city center ("Zentrum") and follow the B87 (Merseburger Straße, Lützner Str., Jahnallee). After passing the central station, turn right towards Augustusplatz (Leipzig Opera House). At Augustusplatz turn left and keep to the right, then follow Prager Straße. Turn right at Semmelweisstraße, follow the road and then turn left onto Zwickauer Straße. Follow this road until you turn left into Perlickstraße.

A14 – Exit Leipzig-Mitte: Take the B2 (via Maximilianallee) in the direction of the city center ("Zentrum") and follow the B2 (via Gerichtsweg). Turn left onto Prager Straße (B2) in the direction of "Alte Messe", then turn right onto "Alte Messe". Turn right at Semmelweisstraße, follow the road and then turn left onto Zwickauer Straße. Follow this road until you turn left into Perlickstraße.

A38 – Exit Leipzig-Süd: Take the B2 in the direction of the city center ("Zentrum") and turn off at exit "Richard-Lehmann-Straße". Follow Richard-Lehmann-Straße and turn off before the BMW car dealership onto Zwickauer Straße in



the direction of "Alte Messe", then turn right onto Perlickstraße.

The car park is accessible from Perlickstraße. You will find visitors' parking right in front of the façade of the institute.

By train and public transport

Take the train to Leipzig Hauptbahnhof central station, and then continue with tram line 16 towards Löbnig. Get off at the stop "An den Tierkliniken", directly opposite the institute. The closest S-Bahn train station is "Leipzig MDR" and all S-Bahn trains stop there (10–15 minute walk to the institute).

From the airport

With the overground Train ("S-Bahn") towards Leipzig Central Station, then follow the directions given under "Train and Public Transport".

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