

10 YEARS IZI



ANNUAL REPORT
2015

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PREFACE



DIRECTOR

PROF. DR. FRANK EMMRICH

What stands out the most when looking back over 2015 is the ten-year anniversary of our Fraunhofer Institute, which we celebrated on April 29. This also marked the opening of the second extension building, home to many new divisions. We now have 551 members of staff working across six sites, of which one is located in South Korea and another in Canada. Young scientists from more than ten nations are employed by the institute. The majority of these scientists count among the 362 members of staff based at the parent institute in Leipzig, which generates the lion's share of project turnover. Last year saw us put the orientation of our research work and our plans for the future under the microscope as part of an active, structured exchange of experiences and opinions. After an external audit and feedback, we now feel best prepared to face new challenges and compete on a national and international level in pursuit of our ultimate goal: To offer the best scientific and technical solutions in our core competencies.

Last spring, as part of the third construction phase, Fraunhofer IZI gained access to two additional 460 m² laboratory and office spaces within a main usable floor space of 3,050 m². This closes the construction gap between the institute and the Biocube on Perlickstraße, on the edge of the former technical exhibition grounds. The City of Leipzig again, very kindly, made the required plot available to us and the project was completed on time and within the allocated budget thanks to the excellent cooperation between established architects' office Heinle, Wischer und Partner and the Fraunhofer-Gesellschaft's central construction department. We now also have our own block-unit power station for generating energy, which helps manage the high electricity costs incurred as a result of the air-conditioning and ventilation required under the official regulations governing our various special laboratories.

With its newly developed biomarker platform and continued funding from the Fraunhofer Future Foundation, the major joint project RIBOLUTION has found a home on the first floor of the new building. Moreover, the additional capacities in our GMP (good manufacturing practice) Cell Engineering department were able to be established and qualified. We will repeat this process this year for the GMP-compliant antibody facilities, which will also be housed in the new building. In this regard, the foundations were laid for establishing the new Department of Therapy Validation at the start of 2016 under the leadership of Dr. Jörg Lehmann. The new building also accommodates an S3 laboratory area for developing vaccines at the institute, overseen by Dr. Sebastian Ulbert. Until now, this kind of work had to be carried out elsewhere in Europe.

At the end of the year, a young colleague from Leipzig University (Dr. Jana Burkhardt) won a five-year grant after competing to set up a junior research team as part of the Fraunhofer-Gesellschaft's Attract program. Her OpTcell Unit (optimization of T-cell modulation procedures) will also be housed in the new building.

In order to assess efficiency and, as the case may be, the need for change in terms of research orientation and projects, the Fraunhofer institutes have to undergo an external appraisal every five years. Fraunhofer IZI commenced with this strategy process, as planned, at the end of 2014 and completed it with resounding success in November 2015 with the scheduled two-day strategy audit conducted by external consultants, primarily from the respective industry. In accordance with the manual developed specifically for this purpose, the established processes were analyzed with regard to competencies, core competencies and business units over the course of structured discussions held in smaller and larger groups and at varying operational and management levels. The committee determined "that the institute is still in an excellent position". The off-site departments in Halle (Saale) and Rostock have also experienced positive development within this context.

The latest international development to arise from the institute's core area, i. e. cell engineering, brings with it a great deal of potential. Sensational successes in initial clinical trials involving new cell therapy procedures, for example in the case of CAR T-cell technology used in certain types of leukemia, have raised hopes of achieving long-term treatment successes in cases which were unable to be treated using conventional methods in the past.

In terms of optimizing and adapting procedures, Fraunhofer IZI is at the top of its game in Europe. It aims to help innovative German and international companies obtain manufacturing licenses and market approval. By doing this, we hope to also be able to present our own innovative concepts in the future, although we are fully aware that reaching the stage of implementation will require a great amount of time and patience. Interesting established intellectual property rights in the field of induced pluripotent stem cells and concerning new procedures in antibody and gene therapy should help us reach this goal. In all, we will place greater emphasis on developing innovative products and active agents in the years to come.

This can be achieved by a number of means. As part of an effective cooperation with Fraunhofer IKTS in Dresden, we set up the Bio-Nanotechnology Application Laboratory (BNAL) in Leipzig last year. Funded by the EU and the Free State of Saxony, the BNAL offers a range of highly sophisticated special devices to investigate the interaction of cells and tissues with mechanical materials. Researchers from both institutes are working in close collaboration here. Thanks to this strong cooperation, a junior research team (Bioceramics in the biological system – primary adhesion of proteins and signal transduction on ceramic implant materials) headed up by Dr. Juliane Pasold has already been set up in this area, cofinanced by Fraunhofer IKTS.

Just before the end of the year, we received the delightful news that our application for the funding of a laboratory building in Canada for the Fraunhofer Project Centre BEAM (Bioengineering and Advanced Manufacturing) on the McMaster University science campus in Hamilton has been approved. This application was completed together with McMaster University and submitted to the Canadian Government. Run by Dr. Thomas Tradler and Christopher Oelkrug, and supported by Canadian colleagues Professor Jonathan Bramson and Professor John Brennan, BEAM has successfully got to work in the laboratories and offices available on site and acquired several projects, thus fulfilling its ambitious scientific and economic plan. The construction project in Canada is expected to be completed by mid-2017.

The World Conference on Regenerative Medicine (WCRM) was once again held in Leipzig in fall 2015, welcoming guests from 50 countries and hosting a series of bilateral project meetings. Several prizes were awarded to outstanding young researchers in recognition of their work, which were presented on occasion of the conference.

Fraunhofer IZI will again organize a number of scientific events in 2016, opening up plenty of opportunities to share and exchange knowledge. For example, the 9th International Symposium on Neuroprotection and Neurorepair (ISN&N) will be held together with Fraunhofer EMB (Lübeck) from April 19–22 in the new conference venue Kongresshalle am Zoo Leipzig, and the Fraunhofer Life Science Symposium will be held together with the German Society for Laboratory Animal Science from April 14–15. At the end of April we are also taking part in the German Biotechnology Conference, which is being held for the first time in former East Germany, and therefore also for the first time in Leipzig (April 26–27).

An especially positive signal, which of course I am particularly pleased with in my role as Director, came in the outcome of the staff survey, which was conducted last fall across the entire Fraunhofer-Gesellschaft and enabled a comparison with a similar survey conducted in 2011. We can report that the level of satisfaction among our members of staff has increased to surpass even the level reported for the Fraunhofer-Gesellschaft as a whole, and that collaboration within the institute was noted as being highly valued. The quality of management as well as the emphasis on scientific excellence and successful projects with academic institutes stood out in particular.

Above and beyond these positive developments, all of the economic parameters that concern the institute's core areas have also experienced extremely encouraging development, which is why I have every confidence in the future of Fraunhofer IZI.

A handwritten signature in blue ink that reads "Frank Emmrich". The signature is written in a cursive, flowing style.

Prof. Dr. Frank Emmrich

2005–2015 MILESTONES

April 29, 2005

The institute was founded in the BIO CITY



September 22, 2006

The foundation stone was laid for the main building



2008

Opening of the main building in Leipzig

January 23, 2013

Opening of the first extension building



July 2010

Positive evaluation and transition into basic funding



March 14, 2011

The EXIM Project Group was set up in Rostock



July 2014

Affiliation of the Bioanalytics and Bioprocesses Branch in Potsdam-Golm



July 1, 2013

The Drug Design and Target Validation Project Group was set up in Halle (Saale)



March 28, 2013

The "Joint Laboratory of CNUHH in Collaboration with Fraunhofer IZI" (JLCI) was set up in Gwangju, South Korea



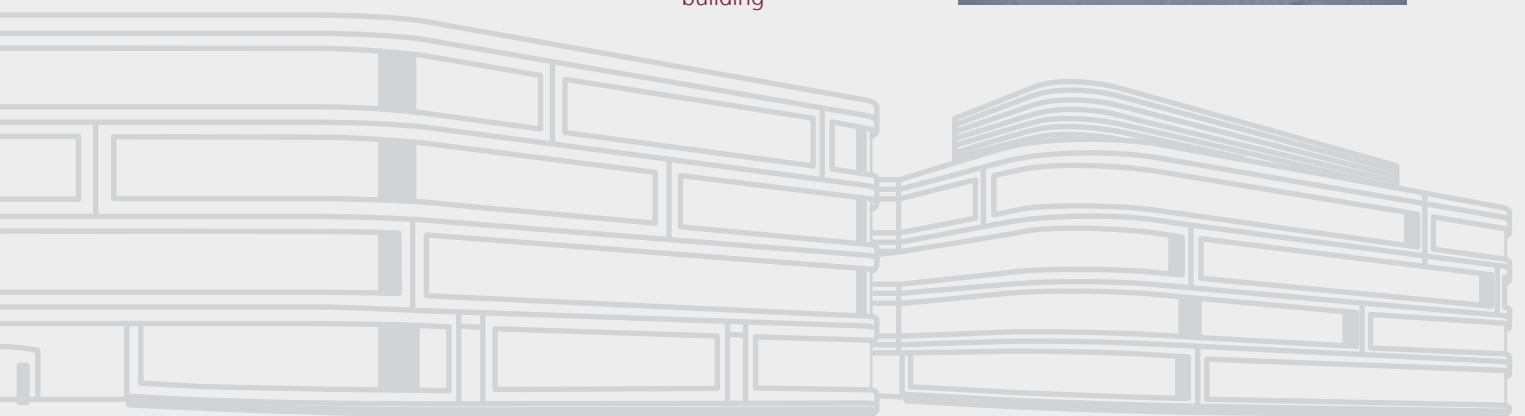
January 19, 2015

The "Fraunhofer Project Centre for Biomedical Engineering and Advanced Manufacturing" was set up in Hamilton, Canada



April 29, 2015

Anniversary and opening of the second extension building



2005 – 2015 IN PUBLIC



Summer of Science



Ceremonial opening of the main building



Graduate fair



Open day



Day of Mobility and Technology



Long Night of the Sciences



Movie talk



Children's lecture



New Year's reception



Long Night of the Sciences



Girls' Day



Pupils' congress

2005 – 2015 CONFERENCES



Fraunhofer Life Science Symposium 2006



World Conference on Regenerative Medicine 2013



Research Conference 2014



International Symposium on Albumin Dialysis 2013



International Symposium on Neuroprotection and Neurorepair 2012



International Symposium on Neuroprotection and Neurorepair 2014



World Conference on Regenerative Medicine 2011



Fraunhofer Life Science Symposium 2012



Science Day 2014



World Conference on Regenerative Medicine 2015

2005 – 2015 THE FRAUNHOFER IZI IN THE POLITICAL SPHERE



Saxon Minister President Georg Milbradt visits the institute in 2006



Visit from EU Commissioner Janez Potocnik in 2007



Bernat Soria, Spanish Minister for Health, is our guest at the World Conference on Regenerative Medicine in 2007



Thomas Jurk, Saxon State Minister for Economic Affairs and Labour, visiting in 2008



Professor Sabine von Schorlemmer, Saxon State Minister for Science and the Arts, attends the podium discussion of the Association of Research-Based Pharmaceutical Companies (vfa) in 2011



Minister President of Saxony Stanislaw Tillich when the foundation stone was laid for the first extension building in 2009



Minister President of Saxony-Anhalt Dr. Reiner Haseloff and Fraunhofer President Professor Reimund Neugebauer at the opening of the Drug Design and Target Validation Project Group in Halle (Saale) in 2013



Wolfgang Tiefensee, Federal Minister for Transport, Building and Urban Development (photo left) as well as Saxon State Minister for Science Dr. Eva-Maria Stange and Mayor of Leipzig Burkhardt Jung (photo right) at the opening of the main building in Leipzig in 2008



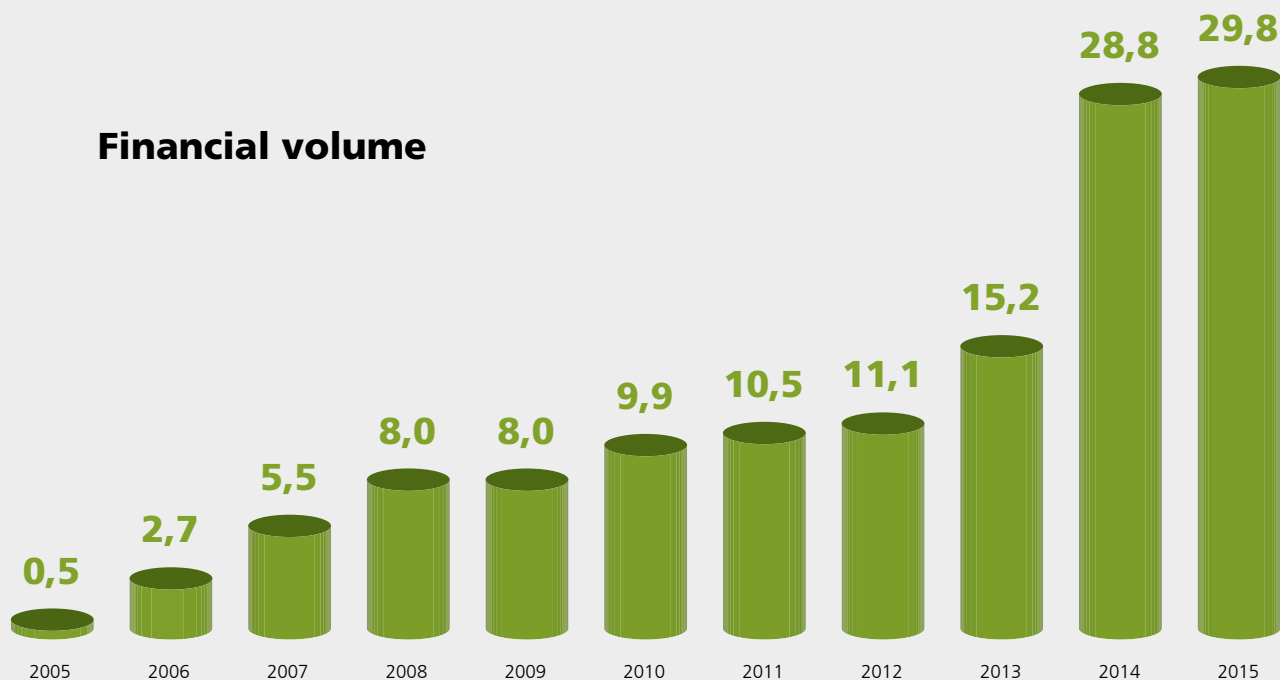
EU Commissioner Dr. Johannes Hahn and Sven Morlock, Saxon State Minister for Economic Affairs and Labour, visiting in 2010



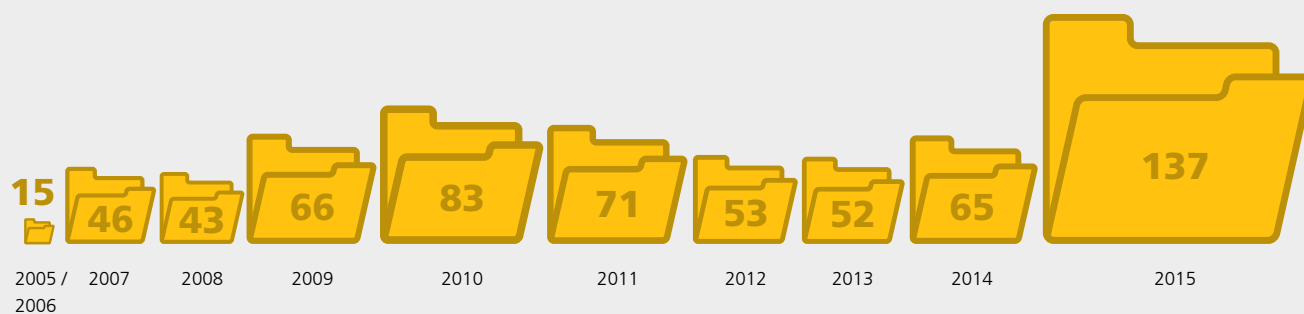
Dr. Reiner Haseloff (3rd from l.) and Stanislaw Tillich (4th from l.), Minister Presidents of Saxony-Anhalt and Saxony, together with the rectors of Halle-Wittenberg University and Leipzig University, Professor Udo Sträter (1st from l.) and Professor Beate Schücking (2nd from l.) as well as Prorector of the HTWK Leipzig Professor Markus Krabbes (3rd from r.) at a press conference in 2014

2005–2015 DEVELOPMENT

Financial volume



Number of projects



Graduate papers in total



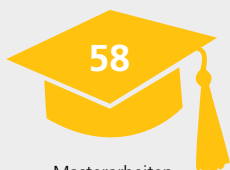
Diplomarbeiten



Bachelorarbeiten



Promotionen



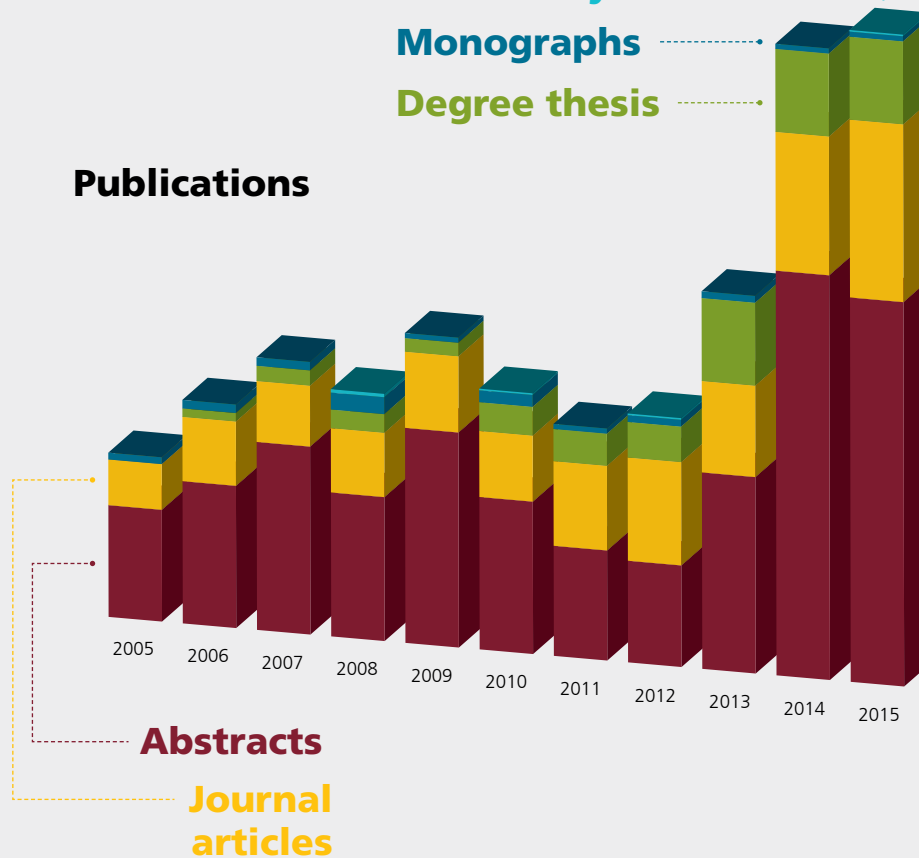
Masterarbeiten

Book essays

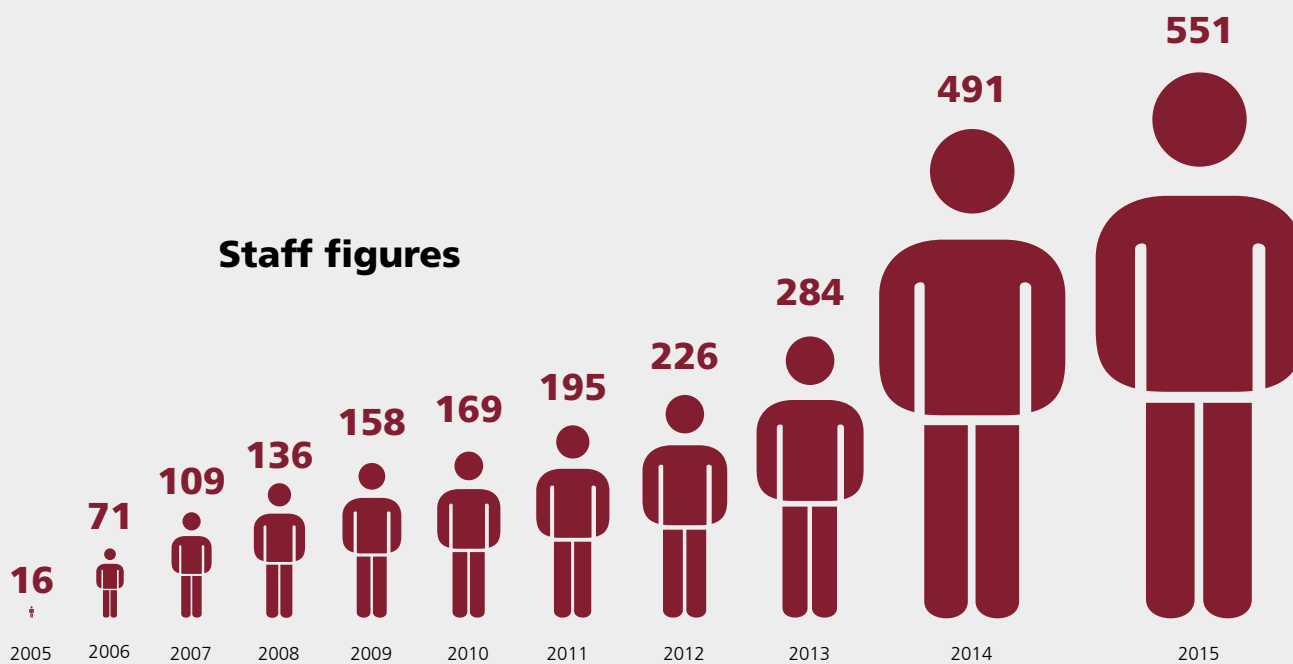
Monographs

Degree thesis

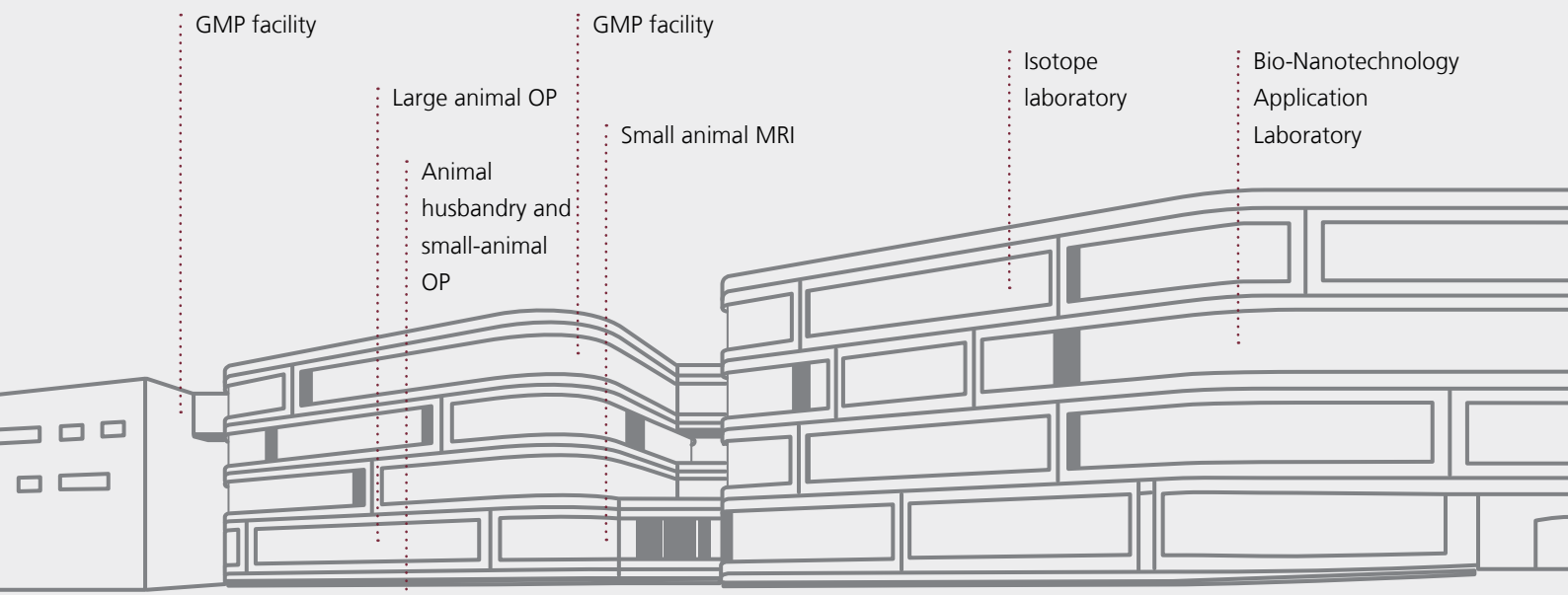
Publications



Staff figures



2005 – 2015 RESEARCH INFRASTRUCTURE AT THE LEIPZIG SITE



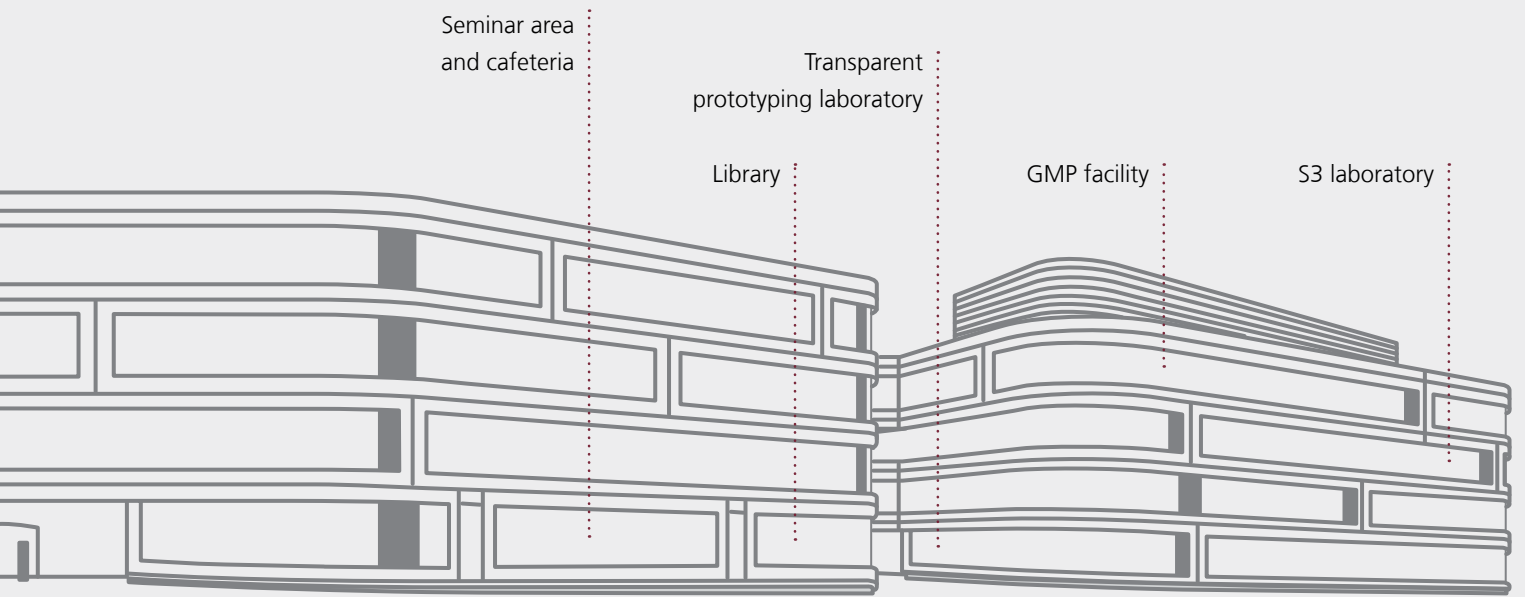
First extension building

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

Main building

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





Second extension building

Start-up operations: 2015 | Usable area: 3 050 m² |
Lab space: 1 171 m² | Offices: 881 m² |
Clean rooms: 408 m²



April 2007



October 2007



October 2007



August 2013



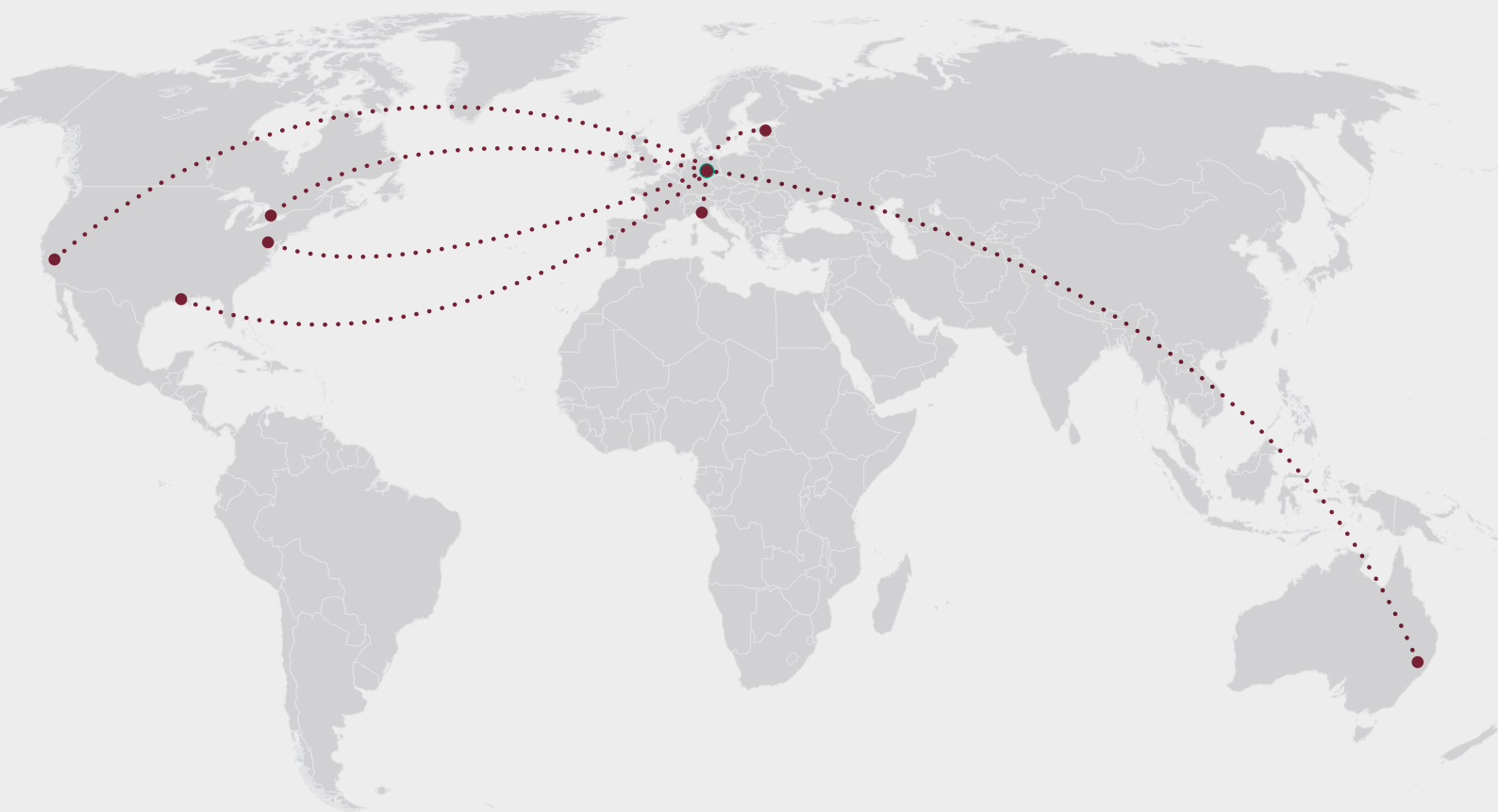
October 2013



January 2015

2005–2015 **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 fifteen companies. The site's appeal and its local cooperation with the Fraunhofer IZI were important factors in the partners' decision to settle there.



Nuvo Research GmbH (settled in 2009)*

- Origin: Canada, Nuvo Research Inc.
- Business model: Developing immunomodulatory drugs to treat inflammatory diseases such as rheumatoid arthritis and allergic rhinitis

Northwest Biotherapeutics GmbH (settled in 2011)*

- Origin: USA, Northwest Biotherapeutics, Inc.
- Business model: Developing an immunotherapeutic to treat glioblastomas

InnovaStem GmbH (settled in 2009)*

- Origin: Italy, I.M.S. Innovative Medical Solutions S.r.l.
- Business model: Establishing a stem cell bank to store adult stem cells from various neonatal tissues

Sonovum AG (founded in 2011)

- Origin: Germany, Fraunhofer IZI
- Business model: Developing diagnostic procedures on the basis of ultrasounds

Bioville GmbH (founded in 2010)*

- Origin: Germany, Fraunhofer IZI
- Business model: Developing and managing projects with a focus on the former trade fair grounds

MD-5 GmbH / Nervive (settled in 2012)*

- Origin: USA
- Business model: Medical device for stroke therapy

Magna Diagnostics GmbH (founded in 2010)*

- Origin: Germany, Fraunhofer IZI
- Business model: Developing an innovative diagnostics platform for the rapid diagnosis of infectious diseases based on a lab-on-a-chip system

Oncotriton GmbH (founded in 2012)*

- Origin: Germany, Fraunhofer IZI
- Business model: Nutritional supplement concepts for the prevention of cachexia and the development of tumor-preventative strategies

Prima BioMed GmbH (settled in 2010)*

- Origin: Australia, Prima BioMed Ltd.
- Business model: Developing an immunotherapeutic to treat ovarian cancer

SelfD Technologie GmbH (settled in 2012)*

- Origin: Estonia, Selfdiagnostics, OÜ
- Business model: In vitro diagnostics

Cognate Bioservices GmbH (settled in 2011)*

- Origin: USA, Cognate BioServices, Inc.
- Business model: Providing development services for cell therapy products

ApoCell (settled in 2013)*

- Origin: USA, ApoCell Inc.
- Business model: Development of a procedure to improve cancer diagnostics

CellProTec GmbH (settled in 2015)

- Origin: The Netherlands
- Business model: Development of cell-based immunotherapeutic agents for the treatment of cancer

Tutelacell GmbH (founded in 2014)

- Origin: Germany, Fraunhofer IZI
- Business model: Project development and project management

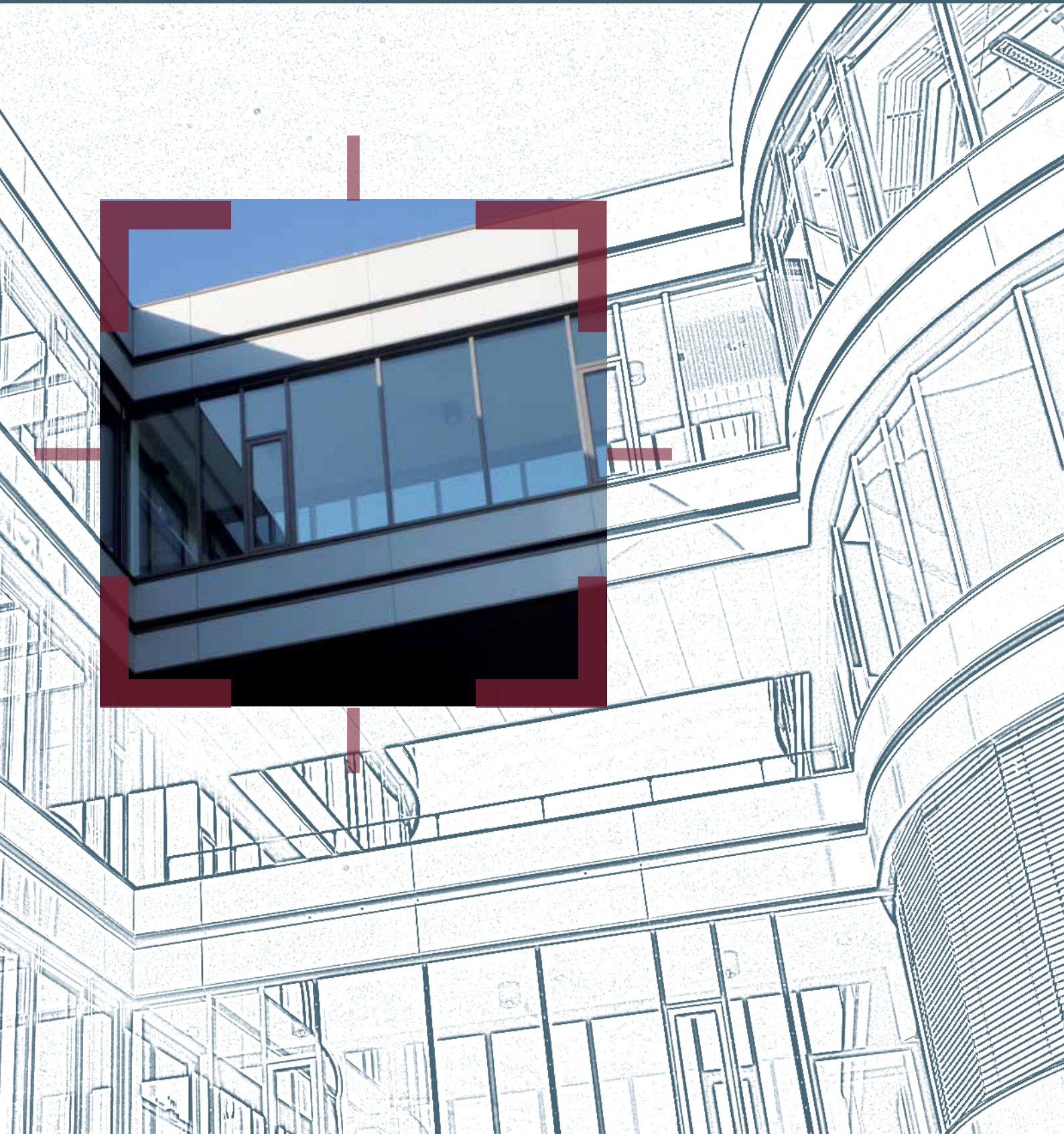
IPDx Immunoprofiling Diagnostics GmbH (settled in 2015)

- Origin: Estonia
- Business model: Development of innovative diagnostic solutions



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

STRUCTURES AND FIGURES 2015



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 and additionally the term describes the repairing of defects by means of treatment with cells. Stem cells can be transferred in order to induce the formation or repair of tissue.

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

The institute's tasks

The institute operates four sites. The five departments GMP Cell and Gene Therapy, Therapy Validation, Immunology, Cell Therapy and Diagnostics are based at the Leipzig head-quarters. The Potsdam-Golm branch is home to the four departments Biosystem Integration and Automation, Cellular Biotechnology, Cell-free and Cell-based Bioproduction as well as Bioanalytics and Biosensors. Two additional off-site departments are located in Halle (Saale) and Rostock. A total of 37 units thus represent a broad spectrum of expertise and qualifications.

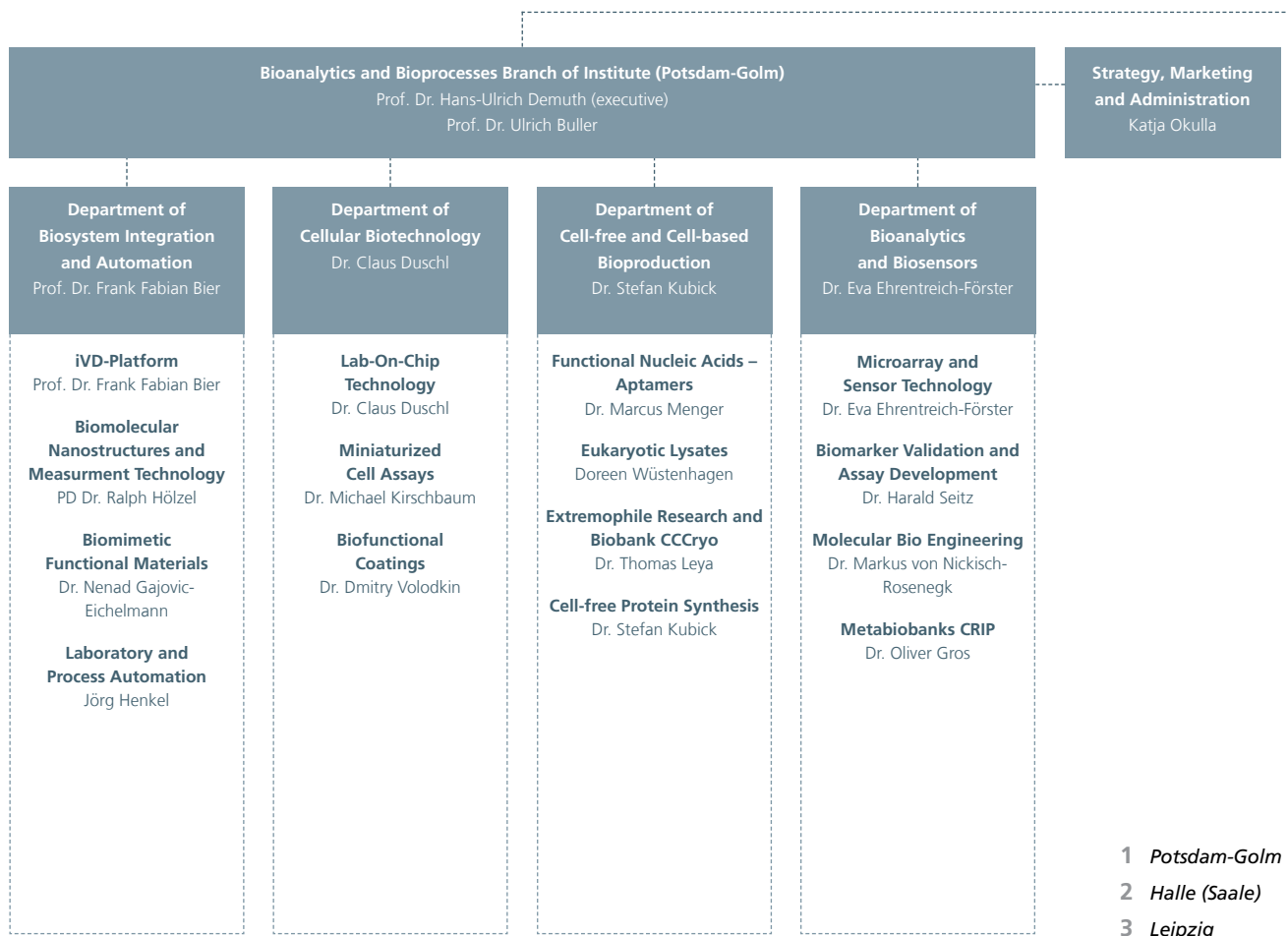
The institute's spectrum of services is aimed at specific problem solutions at the interfaces of medicine, biosciences and engineering. With this, the Fraunhofer IZI addresses not only the biomedical industry, including pharmaceutical and biotechnological companies and diagnostic laboratories, but also 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 clinical test samples according to GMP guidelines and contracted clinical trials. In addition, we support our partners in obtaining manufacturing and marketing authorizations.

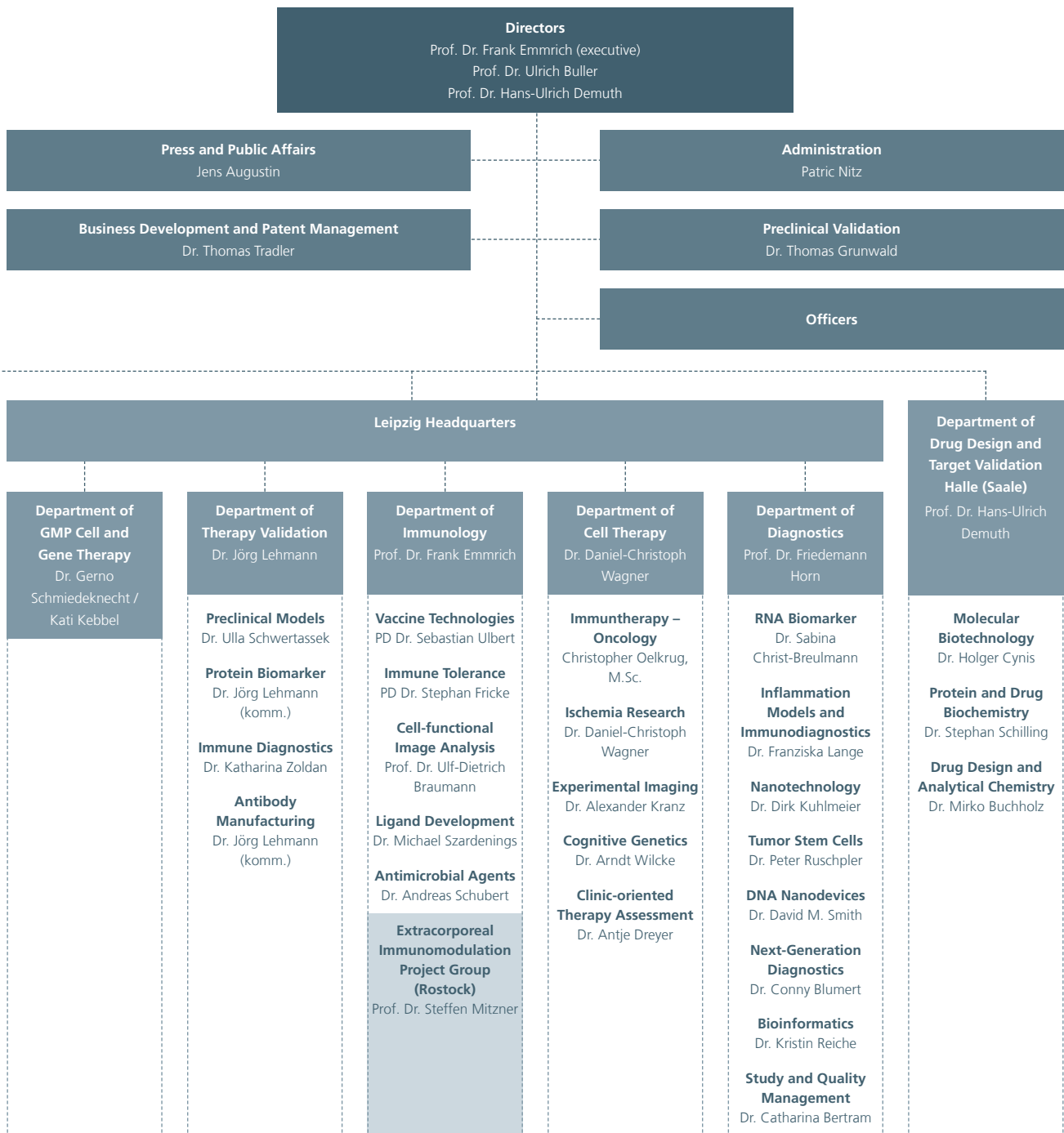


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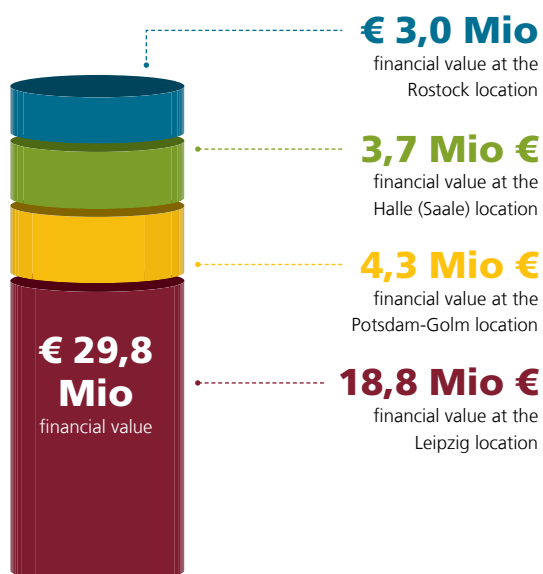
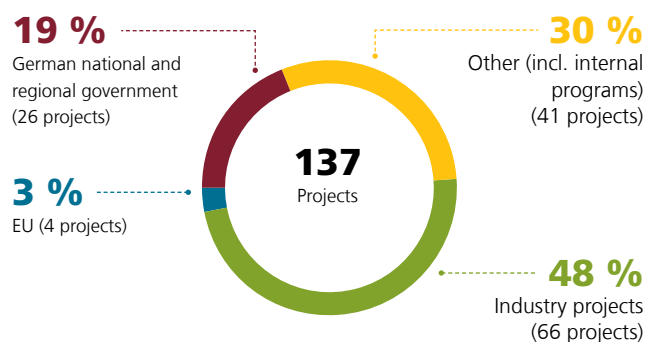
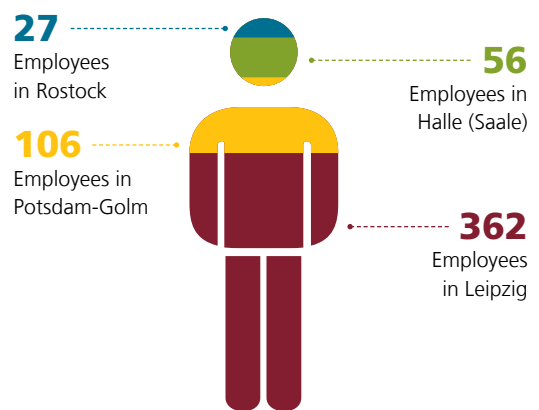
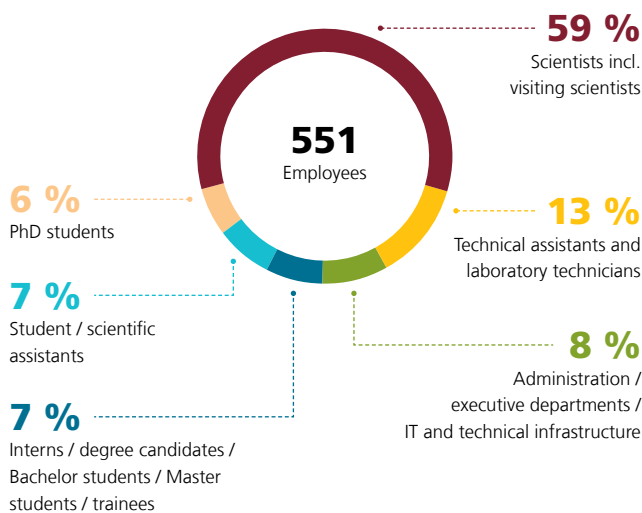
ORGANIZATION (JANUARY 2016)



- 1 Potsdam-Golm
- 2 Halle (Saale)
- 3 Leipzig



KEY INSTITUTE FIGURES 2015*



Project revenue 2015 in kEUR

	Leipzig	Halle	Potsdam	Rostock	Total
German national and regional government	2421	3180	1970	2609	10180
EU	0	150	260	0	410
Industry projects	7669	395	900	376	9340
Other (incl. internal programs)	6345	20	715	0	7080
Total	16435	3745	3845	2985	27010

* as at 2015 / 12 / 31

Financial value

We were able to increase our financial value to 29.8 million euros in the reporting year. Included in this amount are financial resources from internal programs and special allowances from strategic investments. The institute's overall financial value thus breaks down as follows: 18.8 million euros at the Leipzig headquarters, 3.7 million euros at the Halle site, 3.0 million euros at the Rostock site and 4.3 million euros through the Potsdam-Golm branch, which was affiliated in July 2014. Not included are expenses for construction work in the third construction phase at the Leipzig branch: This work is being funded by the European Union, the Free State of Saxony and the Fraunhofer-Gesellschaft.

Projects

With an overall sum of 27.01 million euros, project revenue increased compared with the previous year (25.54 million euros). The number of projects also increased to a total of 137 in the reporting period, up from 65 in 2014. The majority of these projects came from industry, accounting for 66 in total with overall revenue of 9.3 million euros. The industrial proportion thus amounts to 48 per cent.

Besides conducting traditional industry projects, Fraunhofer IZI provides significant assistance to industrial cooperations, for example through projects run under the Central Innovation Programme for SMEs and collaboration projects funded through the Sächsische Aufbaubank (Saxon Development Bank, SAB) using means provided by the EU. In many cases, these cooperations have given way to follow-up projects and settlements. As partner companies have to contribute co-financing of 40 to 70 per cent, these projects

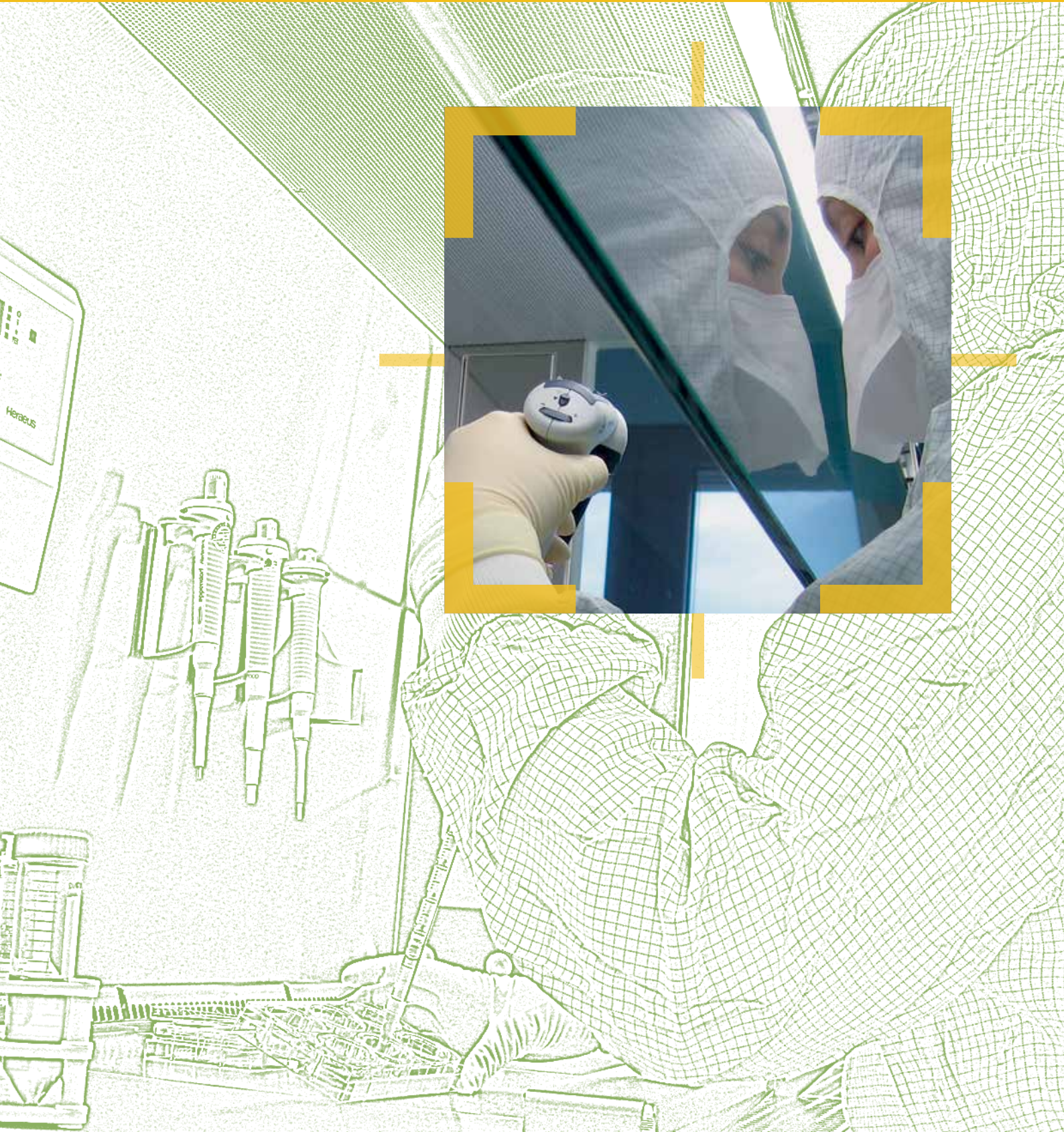
take up a special position among the projects funded by the government and Länder. Due to changes in the accounting procedures, we are now less focused on large EU collaboration projects. The overall value of SAB projects for Fraunhofer IZI amounted to approx. 1.95 million euros for the reporting period. These projects primarily support medium-sized industry in Saxony.

Members of staff

In 2015, the institute once again saw an increase in staff numbers. The overall number of employees rose from 491 to a total of 551. At the Leipzig headquarters, a total of 362 people were employed on the reference date (December 31, 2015), while 106 people were employed in Potsdam, 56 in Halle and 27 in Rostock. Research fellows make up the majority of employees.

This dynamic development forms the basis of the institute's scientific excellence, the continuous promotion of young scientists, and the sustainable consolidation of partnerships both in Germany and abroad. Interdisciplinary and intercultural teams help maintain high-quality results. With over 20 branches of study, our staff's qualifications are as diverse as their cultural backgrounds. Female employees make up over 60 per cent of staff at Fraunhofer IZI; the institute therefore ranks highly within the entire Fraunhofer-Gesellschaft in terms of employing women.

DEPARTMENT OF CELL ENGINEERING



DR. GERNO SCHMIEDEKNECHT

Highlights and challenges in the 2015 reporting year

Thanks to a newly established major project carried out together with an international pharmaceuticals company, the Cell Engineering / GMP Unit increased its capacities to 90 members of staff over a short space of time and significantly rearranged its structure. Quickly integrating so many new members of staff in the existing team and providing them with effective training on the regulations governing our complex quality assurance system and the complicated manufacturing and quality control procedures by far posed the greatest challenge of last year. Also the structural adjustment of the unit, which primarily entailed a stronger subdivision into highly specialized functional areas, required a great deal of effort and rethinking within the team. While these personnel challenges were being tackled, the spatial capacities related to quality control were doubled and the qualification of the new clean room facility in the second extension building was driven forward. The team did a brilliant job of incorporating this additional infrastructure into our quality assurance system while still carrying out their usual day-to-day tasks. I would like to take this opportunity to say a huge thank you for their marvelous dedication! In 2015, the Cell Engineering / GLP Unit successfully completed the preliminary market-oriented strategic research project LowAllergen. The generated data formed the basis of an application submitted to the Fraunhofer Future Foundation. Furthermore, the unit commenced with several industry projects, for example in the field of therapeutic agents to combat chronic inflammatory bowel diseases. The Cell Engineering / GLP unit's achievements are rounded off by the fact that a master's thesis written in the unit was honored as best in class with the Biotechnology Prize awarded by Anhalt-Köthen University of Applied Sciences, while a number of scientific publications also came out of the unit, e. g. on the safety testing of ATMPs.

Outlook over the department's key tasks and plans for 2016 and beyond

2016 will be marked by further staff growth, as well as forward-looking restructuring. Attributable to the sustained scientific and economic success of the two units Cell Engineering / GMP and Cell Engineering / GLP, the formation of two independent departments was analyzed and a conclusion reached by the strategy team and institute management team as part of the institute's strategy process completed in 2015. The outcome was that the Cell Engineering / GMP Unit will be transferred to the Department

of GMP Cell and Gene Therapy on January 1, 2016, under my and Ms Kebbel's management, while the Cell Engineering / GLP Unit will move to the Department of Therapy Validation under the leadership of Dr. Lehmann. Setting up these departments, intensifying existing projects, and commencing with upcoming projects are all associated with further strong staff growth in 2016. In addition to this, both departments will be able to take full advantage of the high-end infrastructure in the institute's second extension building in 2016, while the Department of GMP Cell and Gene Therapy will also have access to another clean room facility for the manufacture of cell and gene therapeutic agents and the Department of Therapy Validation will have access to a clean room facility for the manufacture of therapeutic, monoclonal antibodies for early-stage clinical trials.

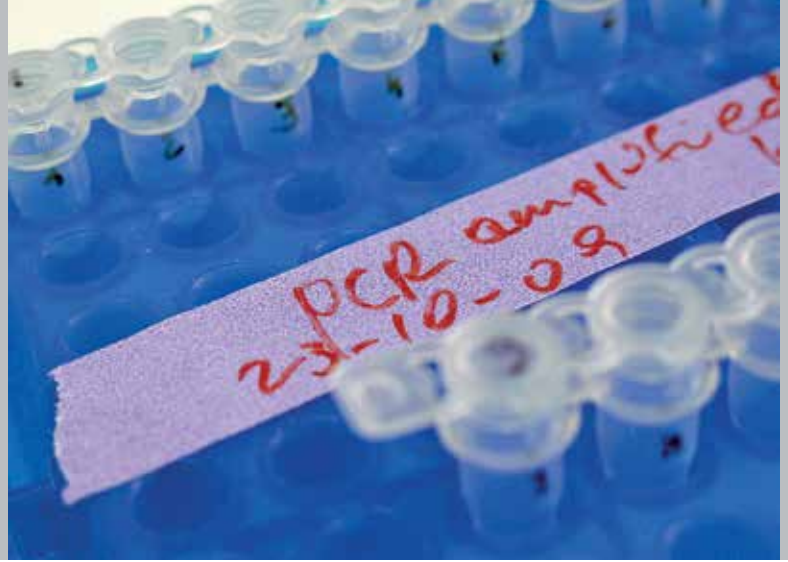
Competencies / technologies in the department

- GMP manufacture of investigational medicinal products in the field of ATMPs
- Set-up and validation of GMP-compliant manufacturing processes
- Set-up and validation of GMP-compliant quality controls
- Quality assurance according to Good Manufacturing Practice / Good Laboratory Practice
- Conduct of GLP trials – in vitro and in vivo immunotoxicology
- Conduct of GLP trials for ATMPs in small and large animal models
- Identification and validation of biomarkers – in vitro assay development
- Development of antibodies (e. g. using hybridoma technology, also of human monoclonal antibodies)

Contact

Dr. Gerno Schmiedeknecht
Head of department
Phone +49 341 35536-9705
gerno.schmiedeknecht@izi.fraunhofer.de





UNITS

Cell Engineering / GLP Unit

The unit focuses on three main topics: 1) Planning and conducting preclinical efficacy and safety studies for new drug candidates, in particular ATMPs, (in vitro and in vivo) under GLP and GLP-analogous conditions. This also includes the development, establishment and validation of new in vitro and in vivo models. 2) Identification and validation of new protein biomarkers for application in diagnostics and in the treatment of chronic inflammatory and tumor diseases as well as for veterinary medicine/animal breeding. 3) Developing and optimizing methods and techniques for the diagnostic detection of protein biomarkers and for the separation of cells. This includes the development, manufacturing and modification of monoclonal antibodies as well as participation in the development of analytical equipment and cell separation robots.

Contact

Dr. Jörg Lehmann
Phone +49 341 35536-1205
joerg.lehmann@izi.fraunhofer.de



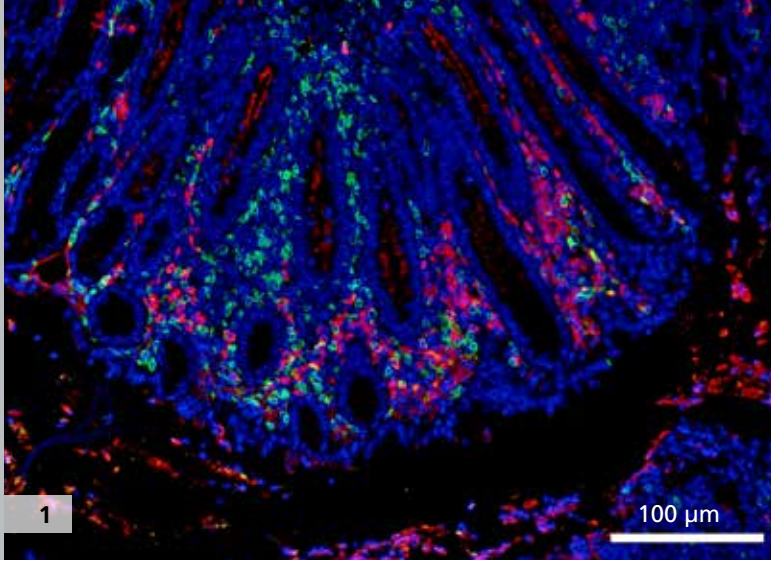
Cell Engineering / GMP Unit

The Cell Engineering/GMP Unit operates Fraunhofer IZI's three modern GMP clean room facilities consisting of ten separate clean room suites (altogether 21 clean room grade B manufacturing rooms) which are optimal for manufacturing Advanced Therapy Medicinal Products (ATMPs). The more than 90 highly qualified staff members specialize in the GMP-compliant manufacturing and quality control of investigational medicinal products. Transferring and establishing GMP-compliant processes and quality controls as well as creating Standard Operating Procedures (SOPs) are discussed in detail with the partner at the start of the project and then implemented in practice, with a strong emphasis on quality. Project leaders have many years of experience in designing GMP-processes in the cell therapy area.

Contact

Dipl.-Ing. Kati Kebbel
Phone +49 341 35536-9712
kati.kebbel@izi.fraunhofer.de





PROJECT EXAMPLES

Preclinical animal models for the development of new CIBD therapies

Chronic inflammatory bowel diseases (IBD) such as Crohn's disease and ulcerative colitis are multifactorial disorders of the gastrointestinal tract, the incidence and prevalence of which have been rising constantly for several decades, especially in industrial and newly industrialized countries. Although the diseases have a low mortality rate, patients suffer from episodes of severe pain and bloody diarrhea throughout their entire lives. The etiology of IBD is suspected to be a combination of genetic predisposition, environmental factors and a dysregulated immune response to the gut microbiota. Current therapies therefore mainly focus on inhibiting the chronic immune response in the gut using immunosuppressive drugs and biologics. As these therapies are often associated with strong side effects, pharmaceutical companies are pursuing the development of new IBD therapies based on a better understanding of the etiological factors.

In the Cell Engineering / GLP Unit, different animal models have been developed for testing new therapies and elucidating pathogenic mechanisms. The model of acute dextran sulfate sodium (DSS)-induced colitis is often used for such studies but cannot adequately represent the chronic immune reaction observed in patients. A model of chronic DSS colitis has thus been established that reflects typical symptoms such as weight loss and chronic, bloody diarrhea. Furthermore, the colon tissue of the animals shows a continuous immune reaction with resulting ulcerations. Besides this, bacteria-induced chronic colitis was established as an alternative animal model for IBD that mainly focuses on

the role of the microbiota in disease pathogenesis and/or as target for novel treatment strategies.

The model of chronic DSS colitis has already been successfully used in several industrial projects. In the future, both models are to be used for preclinical studies and for elucidating disease pathogenesis and developing new therapies. With regard to the latter, we will focus on analyzing the therapeutic potential of phytochemicals. The use of phytopharmaceuticals could result in the dose of a classic therapeutic being reduced, leading to fewer side effects. Moreover, such therapies could be used in phases of remission and thereby prevent the development of a resistance to classic therapeutics. The goal is to make the lifelong therapy depended on by IBD patients as effective and tolerable as possible and thus to improve the patients' quality of life.

Contact

Dr. Ulla Schwertassek
 Phone +49 341 35536-1206
ulla.schwertassek@izi.fraunhofer.de

1 *Detection of immunoglobulin A (red) and T-helper cells (CD4; green) in the distal colon of an animal with chronic DSS colitis*



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

Fraunhofer IZI is producing and optimizing an investigational medicinal product in Europe, the efficacy of which is currently being investigated as part of a phase III clinical trial. American biotechnology company Northwest Biotherapeutics Inc. has already successfully used the immunotherapeutic product DCVax®-L in clinical trials in the US. This advanced therapy medicinal product (ATMP) is based on autologous dendritic cells for the treatment of glioblastomas, a particularly aggressive type of brain tumor.

To be able to manufacture DCVax®-L for each individual patient, tumor tissue and a blood product have to be taken from the respective patient. Numerous clinics taking part in the study have undergone an elaborate qualification and auditing process in order to obtain the required authorization for the procurement of tissues in accordance with Section 20b (2) of the German Drug Act (AMG).

Besides monitoring quality standards at the clinics, manufacturing company Cognate BioServices Inc. also established the manufacturing process and related analytic methods in 2011/2012 at Fraunhofer IZI. Following successful validation, manufacturing authorization was granted specifically for DCVax®-L by the Landesdirektion Sachsen (Saxony Land authorities) and the Paul-Ehrlich-Institut (responsible federal pharmaceutical supervisory authority) in accordance with Section 13 AMG.

Furthermore, applications to conduct respective clinical trials were submitted to the responsible authorities in the United Kingdom and Germany and initially authorized in the UK. Consequently, in June 2013, production commenced for the treatment of patients there. Authorization of the trial in

Germany the following year then also gave the green light for the production of batches for German patients, which has been ongoing since August 2014.

Alongside the clinical trial, a special provision pursuant to Section 4b AMG was also granted by the Paul-Ehrlich-Institut (manufacture since October 2014). Treatment pursuant to Section 4b AMG is permitted using advanced therapy medicinal products provided such products are individually prepared for patients who are unable to be enrolled in clinical trials due to strict exclusion criteria.

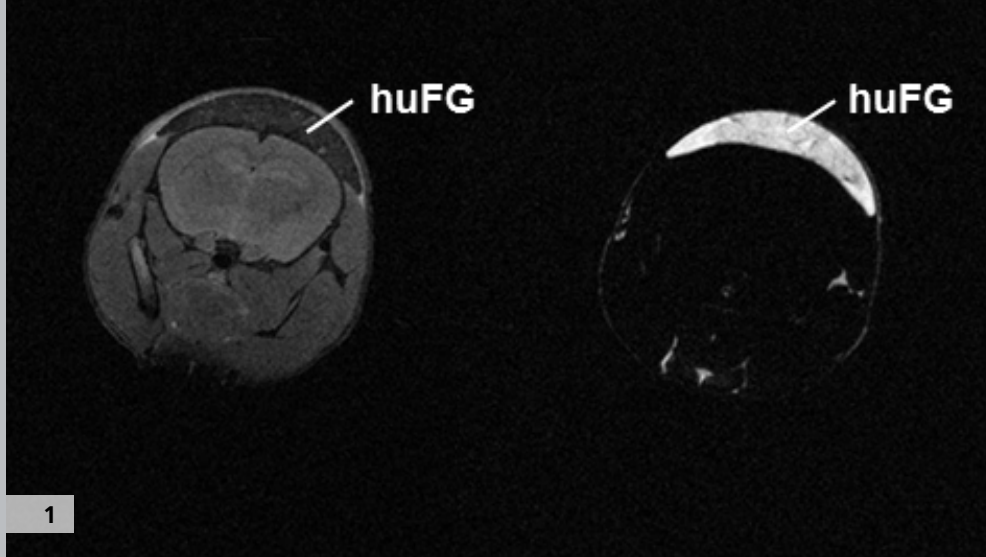
The capacity increases surrounding the new clean rooms and staff, which have been ongoing since 2013, and the regular updates to the submission documents continued to pose a major challenge to the entire group.

Elaborate manufacturing processes in the clean rooms, quality control and the dispatch of DCVax®-L to be administered to patients will also form the focus of our work in the coming year. During the course of this, involved clinics will be closely supervised and additional clinics will soon be qualified in Germany and the UK.

Contact

Caroline Sonnabend
Phone +49 341 35536-9744
caroline.sonnabend@izi.fraunhofer.de

1 *Microscopic assessment of cells in the DCVax®-L product in the clean room*



1

Development of a small animal model and in vivo studies to evaluate the vitality of human, cryopreserved adipose tissue grafts using modern imaging procedures

In reconstructive and aesthetic plastic surgery, autologous adipose tissue is used as an ideal filling material for tissue augmentation. The vitality of adipocytes plays a significant role in the successful engraftment of adipose tissue at the site of transplantation. The surgical practice is currently based on liposuction (removal of adipose tissue) immediately followed by engraftment to ensure the optimal integration of a vital graft. If several transplants are carried out, both the medical risk to the patient and the cost of treatment increase. The combination of a novel surgical method which prevents damage to the adipocytes, i. e. water-assisted liposuction (WAL), and the subsequent cryopreservation of the autologous adipose tissue for repeated transplantation at a later stage would be hugely beneficial to patients and could potentially decrease treatment costs.

Our project partner Vita 34 AG is looking to obtain manufacturing authorization for a cryotechnology procedure to prepare a vital adipose tissue product that is safe for human use. In order to evaluate the safety and efficacy of the adipose tissue product, comprehensive in vitro and in vivo studies are being conducted to determine the vitality and functionality of the WAL-derived human adipocytes as part of a project publicly funded by the German Federation of Industrial Research Associations (AiF) under the ZIM-KF program. In nude mice which are T-cell deficient and therefore capable of tolerating human xenografts – in this case human adipose tissue – follow-up studies will be conducted after subcutaneous transplantation using magnetic resonance imaging (MRI), which will look at the behavior of cryopreserved adipocytes treated with different cryoprotective agents. Six or twelve weeks later, the xenograft will be

examined macroscopically as well as histologically in terms of vascularization, vitality and signs of potential degradation or rejection processes.

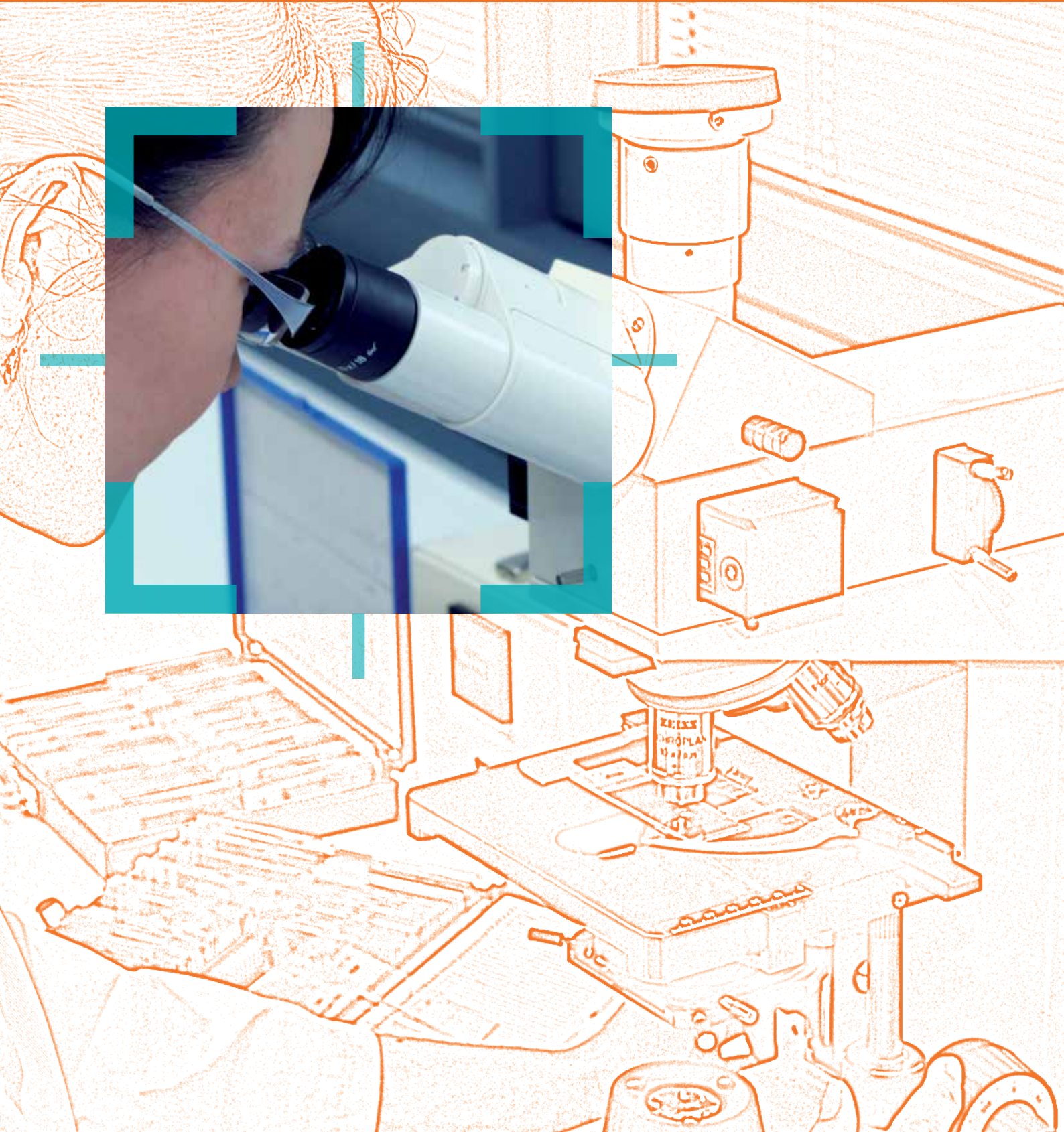
The results obtained so far are impressive: They show that optimally cryopreserved human adipocytes are suitable for the intended purpose. Moreover, MRI has shown itself to be the method of choice for this study.

Contact

Dr. Jörg Lehmann
 Phone +49 341 35536-1205
 joerg.lehmann@izi.fraunhofer.de

1 MRI image following adipose tissue injection. Depicted here are the anatomical (left) and the adipose tissue sequence images (right) as a skull cross section (huAT – human adipose tissue). The images were acquired by Dr. Alexander Kranz (Experimental Imaging Unit) using 7 Tesla small animal magnetic resonance imaging.

DEPARTMENT OF IMMUNOLOGY



PROF. DR. FRANK EMMRICH / DR. SEBASTIAN ULBERT

Highlights and challenges in the 2015 reporting year

The department deals with various aspects concerning immune defense systems, both in human and veterinary medicine. The immune response has to be dissected in order for improved serological tests to be developed, for instance, which can later be taken as a basis for creating market-ready products in cooperation with the diagnostics industry. On the other hand, efforts are being made to actively modulate the immune system with the aim of inducing protective immune responses against various pathogens using vaccines, for example. Inhibiting defense measures in the case of organ transplantation is, however, also an important topic addressed through the development of antibody-based therapies.

With the second extension building, the department now has access to several special laboratories and devices. For example, a safety level 3 laboratory for experiments involving infectious materials, a core facility for implementing the latest nano-biotechnology methods and a facility for the GMP-compliant production of antibodies were completed and prepared for operation. These expanded instrument-based and lab technology facilities have already provided the basis for several newly acquired projects in the department.

Another important development in the department is the study into the effectiveness of African medicinal plants. We managed to win a project in this regard that will span several years. The focal areas of this study lie in anti-infectives and in the identification and experimental evaluation of immunomodulatory and anti-inflammatory substances. Similar to traditional Chinese medicine, traditional African medicine commands a huge potential in terms of high-potency medicinal plants and herbal mixtures, which are to gradually also be made available to the European market. Based on initial findings, applications are being sought in the fields of tumor treatment / prevention, infectious diseases and inflammation inhibition. Besides developing classical pharmaceuticals, however, product developments in the area of so-called nutraceuticals / functional food, a market with a great deal of potential for the future, are also being tested.

The market-oriented, preliminary research project LowAllergen was successfully completed in close collaboration with associated Fraunhofer institutes. Building on this, the technological expertise gained through the project was

contributed to the preparatory stages of an extended project (FoodAllergen) with the aim of recognizing or guarding against intolerances in certain food staples. Besides Fraunhofer IZI, Fraunhofer IVV in Freising and Fraunhofer IME in Aachen are also involved in this work.

Outlook over the department's key tasks and plans for 2016 and beyond

Work on the FoodAllergen project will commence at the start of the new year after the Fraunhofer Future Foundation approved funding in the sum of 6.6 million euros, of which 4.5 million euros will be allocated to Fraunhofer IZI sites, following an ambitious competition. Further developments being worked on as part of major cooperation projects are to be brought closer to the application stage over the coming year. These include an innovative treatment method against ectoparasites in birds and a new technique to make pathogens inactive for vaccine development. Moreover, the technical prerequisites for clinically testing the treatment procedure for GvHD (graft-versus-host disease), which has been developed over the past few years at Fraunhofer IZI, are to be created this year.

Competencies / technologies in the department

- Vaccine development
- Tolerance induction
- Antibody development
- Immunological models
- Immunome mapping
- Rheologic models
- Antimicrobial peptides
- Cellular adsorbers

Contact

Prof. Dr. Frank Emmrich
Head of department
Phone +49 341 9725-500
frank.emmrich@izi.fraunhofer.de



PD Dr. Sebastian Ulbert
Deputy head of department
Phone +49 341 35536-2106
sebastian.ulbert@izi.fraunhofer.de



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, 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.

Contact

PD Dr. Sebastian Ulbert
Phone +49 341 35536-2106
sebastian.ulbert@izi.fraunhofer.de



Ligand Development Unit

The unit focuses on developments for detecting biomolecules. A new peptide phage display method (patent filed) is combined with modern devices and measurement methods. This allows peptide phage display for epitope mapping as well as the immunome of patient sera (e. g. allergy research) and the identification of peptide ligands for the characterization of

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.

Contact

Dr. Michael Szardenings
Phone +49 341 35536-2805
michael.szardenings@izi.fraunhofer.de



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.

Contact

Dr. Andreas Schubert
Phone +49 341 35536-5105
andreas.schubert@izi.fraunhofer.de





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.

Contact

PD Dr. Stephan Fricke
Phone +49 341 35536-2205
stephan.fricke@izi.fraunhofer.de



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.

Contact

Dr. Thomas Grunwald
Phone +49 341 35536-5423
thomas.grunwald@izi.fraunhofer.de



Extracorporeal Immunomodulation Project Group

The project group focuses on the development and evaluation of extracorporeal (outside the body), organ-supporting 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.

Contact

Prof. Dr. Steffen Mitzner
Phone +49 381 494-2600
steffen.mitzner@izi.fraunhofer.de



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.

Contact

Prof. Dr. Ulf-Dietrich Braumann
Phone +49 341 3076-3143
u-dietrich.braumann@izi.fraunhofer.de





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PROJECT EXAMPLES

Inactivation of pathogens for vaccine development

Many infectious diseases can be successfully tackled in human and veterinary medicine through the use of vaccines. The global market in this field is experiencing a time of strong growth. However, despite advances in vaccine development, there is still a huge demand for vaccine technologies that offer effective protection against infection and are long-lasting, while posing no risks to the individual being vaccinated.

This is notable in the manufacture of killed vaccines: For many decades, toxic chemicals such as formaldehyde have been used to inactivate viruses, enabling them to be used as vaccines. Formaldehyde-inactivated vaccines constitute the majority of all vaccines in veterinary medicine; in human medicine they are used, for instance, to combat influenza, polio and hepatitis A. The use of formaldehyde, however, leads to a chemical change in the antigens contained in the pathogens, which weakens the vaccine's efficacy. This has to be counterbalanced through repeated booster vaccinations, increased amounts of infectious source material and adjuvants. As a result, enormous costs are incurred and the social acceptance of many vaccines is diminished due to fear of side effects. Furthermore, vaccines could not be developed for a number of infections in the past due to the given limitations of the formaldehyde method.

A technique to circumvent these problems is clearly required in the vaccine industry. In a joint project with Fraunhofer Institutes IPA, IGB and FEP coordinated by Fraunhofer IZI, a new way of inactivating pathogens for the manufacture of effective vaccines without having to use chemicals is therefore to be developed. As part of this project, pathogens will

be inactivated by being irradiated with low-energy electrons. This destroys the viral RNA / DNA while almost completely preserving the protein antigens crucial to the success of the vaccination.

The project aims to identify the molecular foundations of inactivation and the conditions required to inactivate the most significant types of pathogen while at the same time preserving the antigens. A successful proof of concept for a vaccine manufactured in this way has already been produced in the animal model. Moreover, developing an automated irradiation technique and establishing standardized processes will supply the basis for developing and implementing an inactivation process on an industrial scale.

Contact

PD Dr. Sebastian Ulbert
Phone +49 341 35536-2106
sebastian.ulbert@izi.fraunhofer.de

1 *Vaccinations: Huge demand for vaccines inactivated without formaldehyde*



1



2

Detection of toxins produced by the body in the plasma of dialysis patients

The kidneys are central to removing toxins produced naturally in the body. In the case of reduced kidney function, many of these toxins, or uremic toxins, are by contrast only partially filtered from the blood, or not filtered at all. As a result, uremic toxins accumulate in the blood and can lead to a series of secondary diseases. In the case of complete kidney failure, poisoning with lethal consequences sets in after just a short amount of time. The only chance of survival for these patients lies in a kidney transplant or, as there is usually a lack of donor kidneys, dialysis. Dialysis is a blood purification treatment which takes place outside the patient's body (extracorporeally), however it has so far proven itself to be an inadequate substitute for kidney function.

Only a very small number of toxins produced by the body can be effectively removed by dialysis. Posing the most problems are the protein-bound uremic toxins, the majority of which often remain in the blood as carrier proteins such as albumin are unable to pass through the membrane. However, water-soluble molecules are also not completely purified. Different filters, made of extremely fine-pored, hollow fiber membranes, can be used for dialysis and are selected according to the medical need of the patient. As part of one project, a number of already known uremic toxins were detected in the plasma samples of dialysis-dependent patients using established chemical-analytical methods. During these investigations, however, two potentially new substances were also identified for which there were not yet any quantification standards in this laboratory. Of these, phenylacetylglutamine is a substance of particular medical interest as this molecule is suspected of playing a significant role in the emergence of cardiovascular complications in patients with kidney failure and contributes considerably to the mortality and morbidity of this patient group. This work,

carried out by chemist Ekaterina Peters, was submitted as a master's thesis to Aalen University in fall and received high praise.

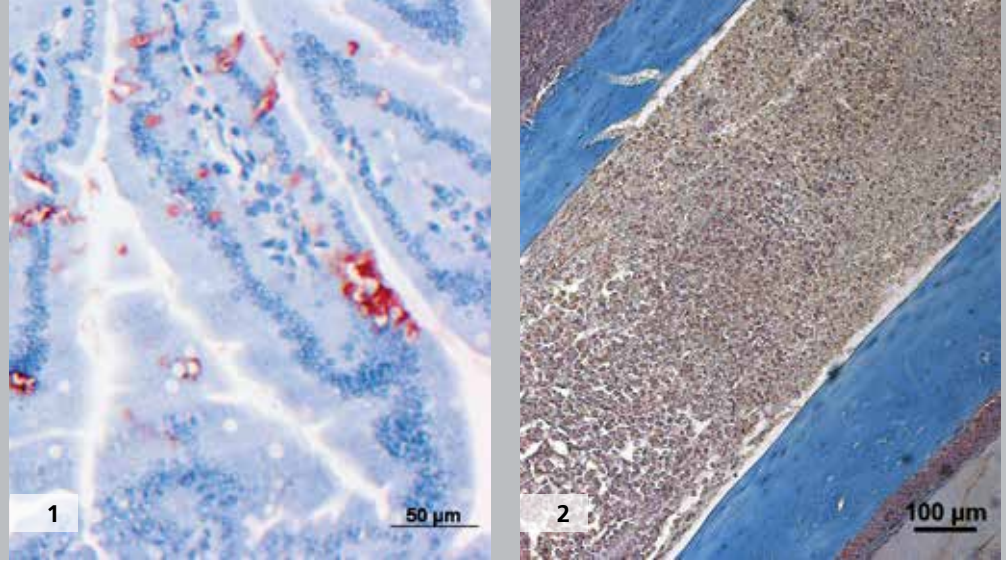
In order to improve the efficacy of the dialysis process in future, further investigations of this kind are vital in enabling the purification efficiency of dialyzers to not only be described in vitro, but primarily in the clinical context. In this regard, much greater consideration is to be given to clinical trials, chemical analysis and hollow fiber membrane manufacture as interlinked areas in order to achieve practice-oriented results.

Contact

Dr. Reinhold Wasserkort
 Telefon +49 381 494-2610
reinhold.wasserkort@izi.fraunhofer.de



1/2 *Chemical-analytical investigation of uremic toxins*



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

The main complication following an allogeneic hematopoietic stem cell transplant 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.

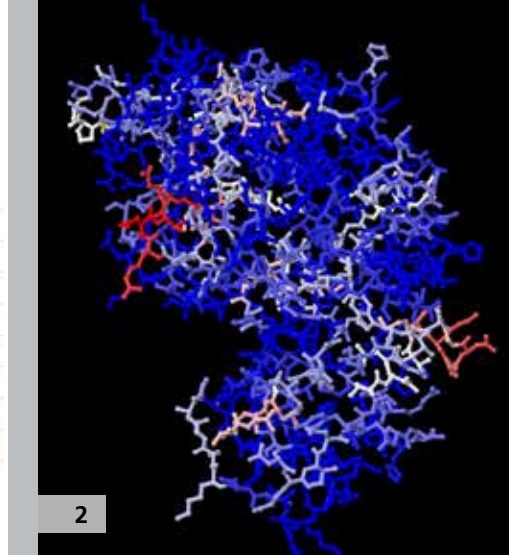
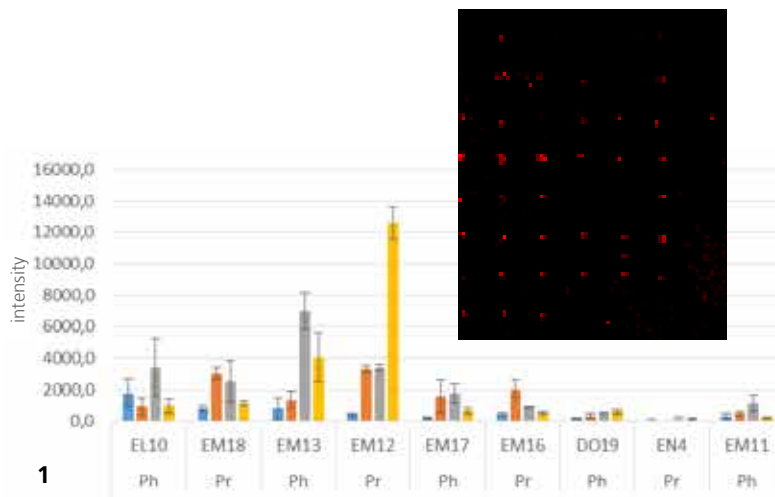
A new approach involves the use of a specific anti-human CD4 antibody. The antibody specifically reduces adverse immune reactions, thus minimizing the chances of aGvHD emerging following stem cell transplantation. The influence of this anti-human CD4 antibody with regard to the prevention of GvHD and under consideration of the graft-versus-leukemia (GvL) effect in a clinically relevant, humanized leukemia model is currently being investigated. Models are being used for this purpose 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 the hospital environment. Existing leukemia models are being further developed and the anti-human CD4 antibody and other drugs are being evaluated.

Through the use of 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).

Contact

PD Dr. Stephan Fricke
Phone +49 341 35536-2205
stephan.fricke@izi.fraunhofer.de

- 1 *Apoptosis examination of the intestine (TUNEL staining)*
- 2 *Tumor cell migration in murine bone marrow (KAO staining)*



Antibody epitopes in molecular resolution: Soy allergy

As little as a single drop of blood can help determine the spectrum of antibodies that differentiates a patient from a healthy person. Similarly, antibodies can also be identified in the case of infectious diseases, which are directed against the proteins of an infectious agent. The epitopes, mostly made up of short stretches of a few amino acids, recognized by the antibodies can be precisely characterized right down to the amino acids. This even allows individual differences to be revealed between different patients.

While infections usually give rise to larger quantities of antibodies, allergens are recognized by special IgE antibodies, which tend to be much rarer. Despite this, the "LowAllergen" project, which is currently in its final stages, has managed to identify peptide epitopes from the sera of many soy-sensitive patients that are recognized on soy proteins by antibodies.

Willingly or not, we come into contact with soy as a food ingredient every single day. As a result, the number of people suffering from soy allergies is on the rise. This is why the Fraunhofer-Gesellschaft is conducting the LowAllergen project, which looks to promote a way of reducing the allergenic potential of soy ingredients. In order to do this, Fraunhofer institutes in Leipzig (IZI), Freising (IVV), Aachen (IME) and Hannover (ITEM) worked together to find holistic solutions. Under the lead of Fraunhofer IVV, an entire chain of new processes was developed and established, starting from the use of the discovered epitopes in allergy diagnostics to the detection of allergens in food, up to the reduction of allergenic potential in the finished food ingredient, which is so far unique.

The epitopes identified at Fraunhofer IZI were synthesized as peptides and tested in arrays to see whether they could be identified by allergy-relevant IgE or normal IgG antibodies in the patient sera. This test, which requires only minimal

amounts of blood, allows an individual conclusion to be drawn on the allergenic proteins right through to the essential amino acids for each patient rather than coming to the general diagnosis "soy allergy". This opens up completely new opportunities, from monitoring the progression of an allergic disease to designing a form of therapy or sensitization, on a theoretical level at least.

This project is set to be successfully completed in the coming months. Follow-up projects will commence for other allergies and the obtained results will be put into practice in 2016.

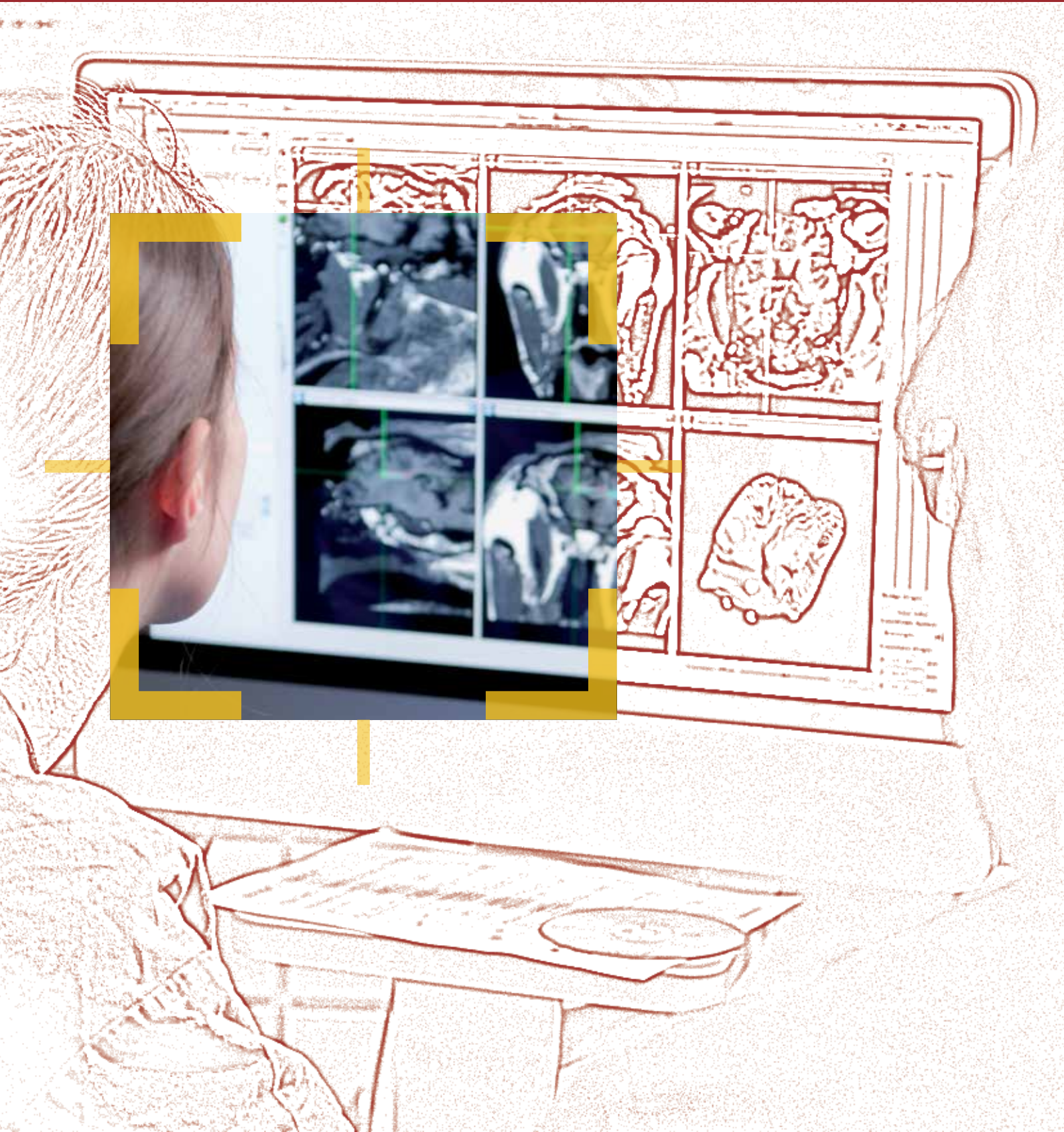
Contact

Dr. Michael Szardenings
 Phone +49 341 35536-2805
 michael.szardenings@izi.fraunhofer.de

1 Peptide (epitope) array for the quantitative evaluation of antibody binding; bar chart shows signals for four different patient sera.

2 Partial depiction of a soy antigen, red – preferential, white / gray – isolated and blue – unidentified protein areas.

DEPARTMENT OF CELL THERAPY



DR. DANIEL-CHRISTOPH WAGNER

Highlights and challenges in the 2015 reporting year

Over the past year, we have further developed our methods in respect of flow cytometric analyses of solid tissues and immunological cell culture models. With regard to oncology and ischemia research in particular, we have gained a much greater understanding of immunological processes in recent years which has thrown up numerous interesting new target families. As a result, clients are increasingly inquiring after new immunological end points in preclinical trials. Developing such end point and adapting them to the respective issues is complicated and takes time, however it also gives us an important unique selling point.

Together with the specialist group Image Analysis of Cell Function (Department of Immunology), we have experienced several extremely interesting technical highlights over the past year. Under the leadership of Professor Braumann and in cooperation with the Experimental Imaging Unit, members of staff from the specialist group designed a light sheet microscope and built it screw by screw. I cannot wait to receive the first measurements with our tissue samples and look forward to being able to discuss and comment on our neuroimmunological issues in an application-related manner with engineers, computer scientists and physicists. The greatest challenge we faced last year had to be the departure of long-standing Head of Department of Cell Therapy Professor Boltze, who accepted a chair in Lübeck. Despite the distance, we will continue to work closely on scientific matters.

Outlook over the department's key tasks and plans for 2016 and beyond

In the future, we will work even more intensely on fundamental scientific issues in preliminary research projects. Only by doing this can we develop our own patents and products and expand our sophisticated range of methods. Our research staff also have the opportunity to make a name for themselves on an academic level by publishing their work in competitive specialist journals, which we see as a hugely important factor in staff retention.

Competencies / technologies in the department

- Stroke models
- Models of chronic brain ischemia and neurodegenerative diseases
- Experimental imaging (including MRI, BLI, and confocal microscopy)
- Experimental neurosurgical techniques including stereotaxic surgery
- Preclinical study design and quality assurance
- Processing fundamental neuroimmunological issues
- Histology and immunohistochemistry
- Multiparametric flow cytometry of organ lysates
- T-cell infiltration patterns in vitro / in vivo
- Evaluation of tumor immunological parameters

Contact

Dr. Daniel-Christoph Wagner
Head of department
Phone +49 341 35536-5416
daniel-christoph.wagner@izi.fraunhofer.de



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.

Contact

Dr. Alexander Kranz
Phone +49 341 35536-5403
alexander.kranz@izi.fraunhofer.de



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.

Contact

Dr. Daniel-Christoph Wagner
Phone +49 341 35536-5416
daniel-christoph.wagner@izi.fraunhofer.de



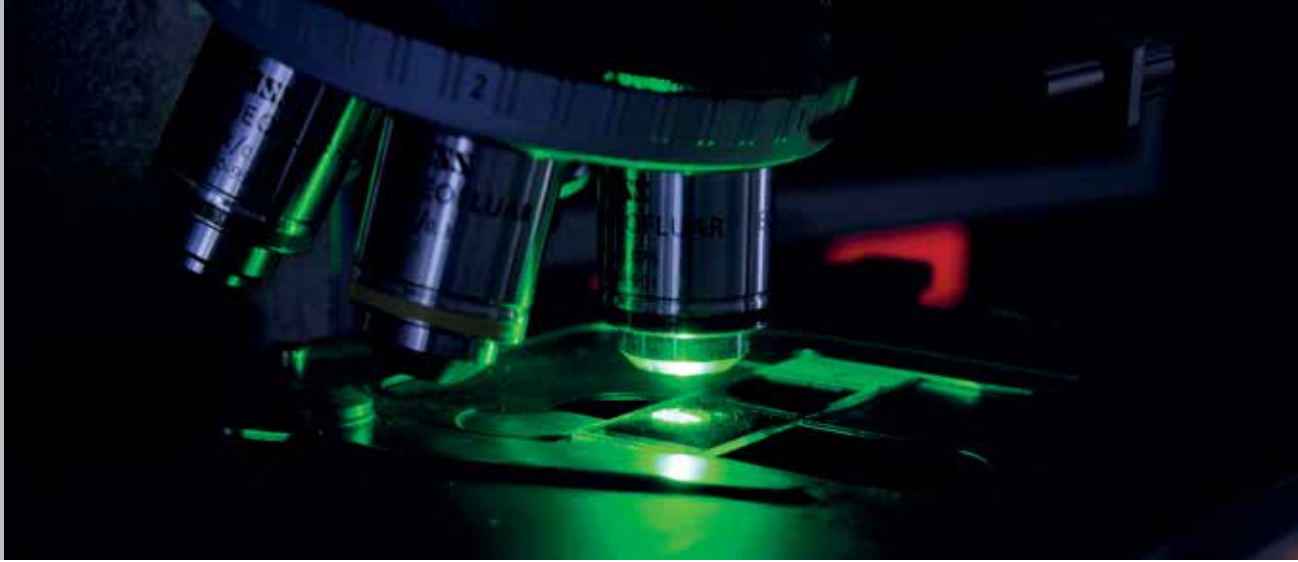
Immunotherapy – Oncology Unit

The unit encompasses two major areas of interest. New strategies for treating cancerous diseases are developed and tested with the aid of innovative tumor models. The unit also focuses on optimizing therapeutic cancer vaccines, e. g. through different administration strategies, in view of the fact that tumor immunology and re-engineering of the immune system show promising results compared with current types of treatment.

Contact

Christopher Oelkrug, M.Sc.
Phone +49 341 35536-3121
christopher.oelkrug@izi.fraunhofer.de





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.

Contact

Dr. Arndt Wilcke
Phone +49 341 35536-5422
arndt.wilcke@izi.fraunhofer.de



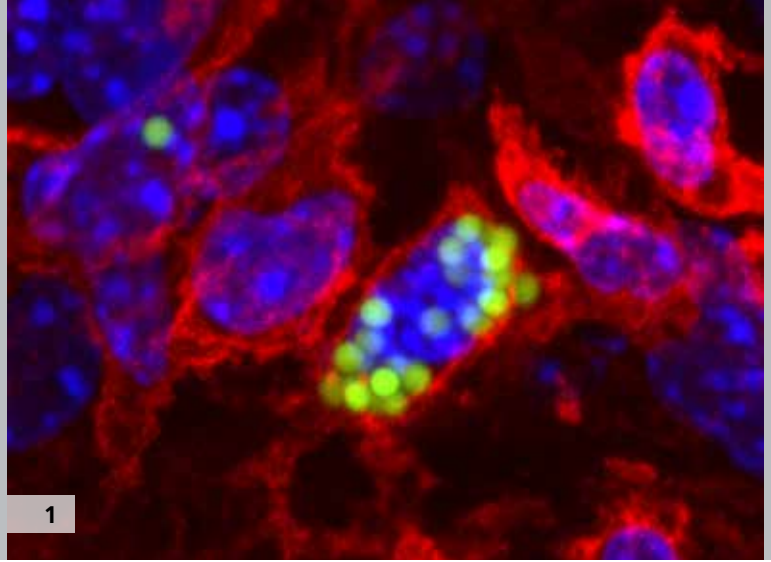
Clinic-oriented Therapy Assessment Unit

The unit tests and develops innovative diagnosis and therapy procedures for stroke. As the possibility of being able to transfer findings from small-animal models to human patients is sometimes only very limited, a globally unique, large-animal model was established for the translational approach. Using this model means that tests can be carried out under conditions which come close to patient treatment in a clinical setting. Both the gyrencephalic brain structure and the size of the brain in the human situation are much more similar in the sheep model than they are in the small animal.

Contact

Dr. Antje Dreyer
Phone +49 341 35536-3105
antje.dreyer@izi.fraunhofer.de





PROJECT EXAMPLES

Immunotolerance following a stroke

The dying off of nerve cells associated with a stroke leads to the activation of the immune system and to a huge influx of immune cells in the damaged brain. Certain immune cells, e. g. granulocytes, can damage healthy brain tissue in the early phase of a stroke and thus have a negative effect on disease progression. Other immune cell populations such as macrophages convey the resorption of dead cells and initiate tissue repair. It is extremely important during this phase that the immune system does not perceive the brain tissue to be foreign matter, consequently fighting against it; this process is referred to as immunotolerance and is, among other things, conveyed by dendritic cells. Depending on the concomitant immunological signals, these cells are able to trigger immune tolerance or an immune response from the adaptive immune system. Mismanagement of this system following a stroke, e. g. due to the simultaneous presence of pneumonia, may lead to an immune reaction which works against the person's own brain tissue. Possible consequences include, among other things, insufficient rehabilitation capacities and cognitive disorders through to dementia.

The aim is to better understand the process of immunotolerance development following a stroke and to potentially develop new therapeutic approaches that can be applied here. In order to do this, the infiltration, eating behavior and migration movement of macrophages and dendritic cells are analyzed after an experimental stroke has been triggered. It is presumed that dendritic cells exit the brain via a range of pathways and encounter the effector cells of the adaptive immune system in the cervical lymph nodes, which is where they determine their functional status. This idea is being put to the test by introducing different kinds of therapy which

stimulate the immune system and increase tolerance and by monitoring whether they have an impact on the functional status of the migrated dendritic cells and on the activity of the adaptive immune system.

A possible clinical application could involve the treatment of patients suffering from an inflammatory reaction following a stroke. A type of therapy which generates immunotolerance could limit the emergence of an autoimmune reaction to the brain caused by stroke and thus improve the healing process in the time that follows. However, numerous experiments are yet to be conducted before any type of clinical application is possible.

Contact

Dr. Daniel-Christoph Wagner
Phone +49 341 35536-5416
daniel-christoph.wagner@izi.fraunhofer.de

1 *Phagocytic cells in ischemic brain tissue*



LEGASCREEN – development of a multi-modal early screening test for diagnosing dyslexia

Dyslexia is a severe disorder in acquiring reading and writing skills, affecting about five percent 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 the current methods, dyslexia cannot be reliably diagnosed until the end of the 2nd grade. By this time, a large part of speech-development has, however, already taken place, and a lot of precious time for providing support and therapy is inevitably lost.

Our project, a joint venture between the Fraunhofer-Gesellschaft and the Max Planck Society, is based on our previous research into the genetics of dyslexia. The earlier a disposition towards dyslexia can be recognized in a child, the more likely it is that this disorder can be counteracted by providing a targeted form of language support, and the greater the chance of reducing later problems. To do this, different research approaches are combined: Genetics together with specific brain activity measurements (EEG).

The heritability of dyslexia is estimated at 50–70%. Genetic material (DNA) practically stays the same during a person's life span. Consequently, respective genetic risk variants can already be used for diagnostic purposes at an early stage, irrelevant of whether or not the child is yet able to read and write. Previously identified genetic variants that contribute towards the emergence of dyslexia will be taken as a starting point for the project and then optimized.

The other key part of our test is based on electroencephalography (EEG) – a procedure which allows brain activity to be measured without demanding the attention of the child. Research has shown that children who go on to develop dyslexia already demonstrate distinctive features in brain activity at an early age in response to specific language stimuli.

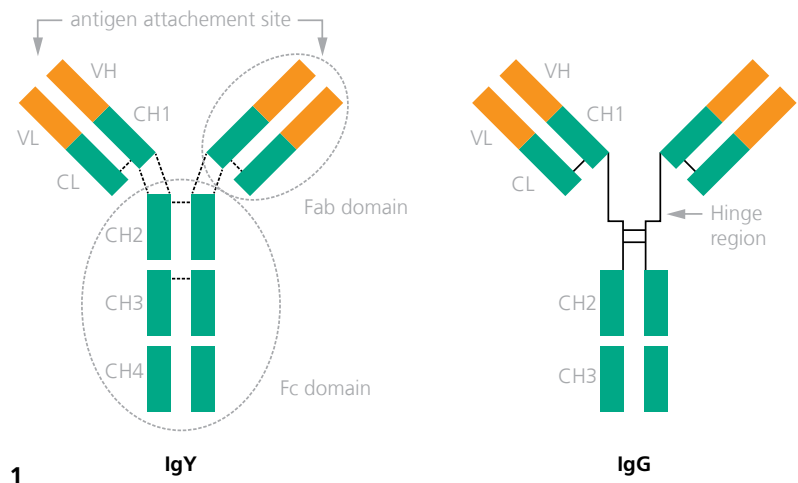
Magnetic resonance imaging (MRI), which is also involved in our study, is used as a link between genetics and EEG. It allows us to better understand structural features in the brain, however it will not form part of the test procedure which is to be developed.

To summarize, the aim of this project is to develop an early screening test for dyslexia which recognizes the respective disposition towards dyslexia long before this can be seen using conventional testing methods. This type of early warning test will be able to considerably improve access to therapy at an early stage in the future.

Contact

Dr. Arndt Wilcke
 Phone +49 341 35536-5422
arndt.wilcke@izi.fraunhofer.de

- 1 *Our aim: Taking pleasure in successful learning*
- 2 *EEG examination*
- 3 *MRI examination*



Development of an innovative treatment concept to eliminate multiresistant human pathogenic germs using specific antibodies from the yolk of immunized chickens

The excessive consumption of antibiotics in animal husbandry and the overly frequent prescription of antibiotics by doctors have massively accelerated the emergence of multiresistant bacteria and fungi. This project deals specifically with combating candida yeast fungi and intestinal bacteria which degrade, and thus neutralize, antibiotics from the penicillin group (so-called beta-lactam antibiotics). Reserve antibiotics or antimycotics are often the only substances capable of combating these pathogens.

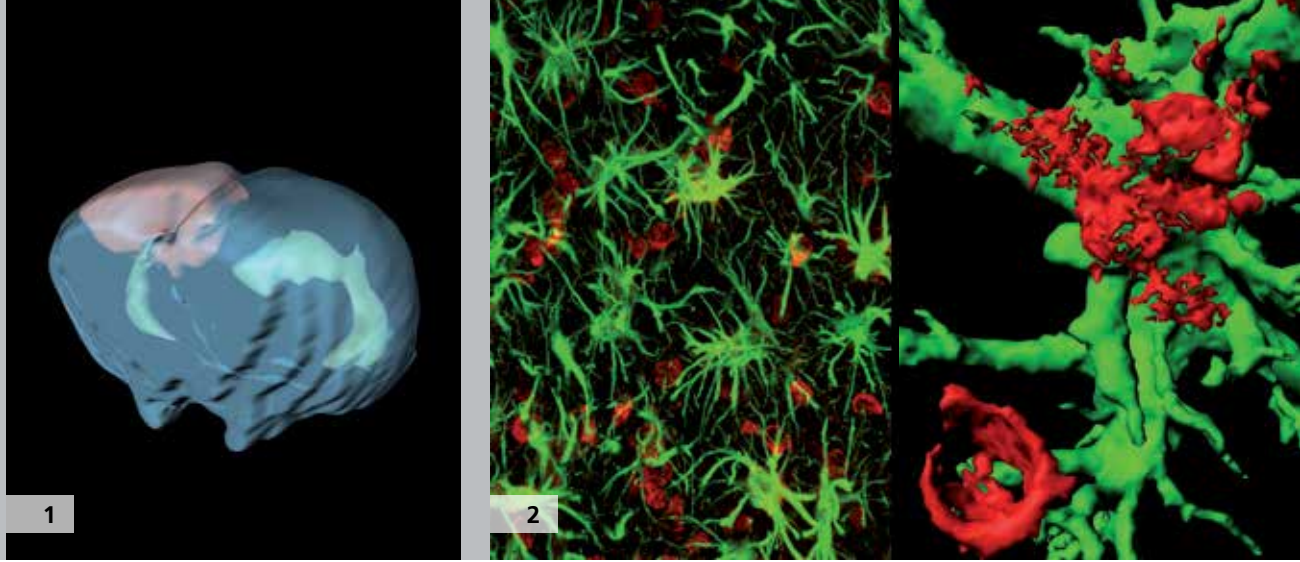
So-called IgY antibodies are present in poultry, e. g. chickens. They are the functional equivalent to human IgG antibodies, the difference being, however, that they are able to specifically bind themselves to selected surface antigens of bacteria and are therefore suitable as therapeutic antibodies. At present, it is assumed that it will not be possible to build up resistance using these antibodies, even if they are used over a longer period of time.

As part of this project, highly specific IgY antibodies will be developed which are effective against multiresistant intestinal bacteria and candida fungi. First of all, suitable immunogenic surface molecules will be identified in these two pathogen groups and used to inoculate chickens, thus stimulating the formation of antibodies. The antibodies will then be isolated from the yolk, purified, characterized and investigated as to their suitability to combat multiresistant pathogens.

By the end of the project we will have gained IgY antibodies that are effective against multiresistant pathogens and that can be used as pharmaceuticals or in functional food.

Contact

Julia Zajac, M.Sc.
Phone +49 341 35536-3122
julia.zajac@izi.fraunhofer.de



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 high frequency magnetic resonance imaging. 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 (hypertrophy) 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).

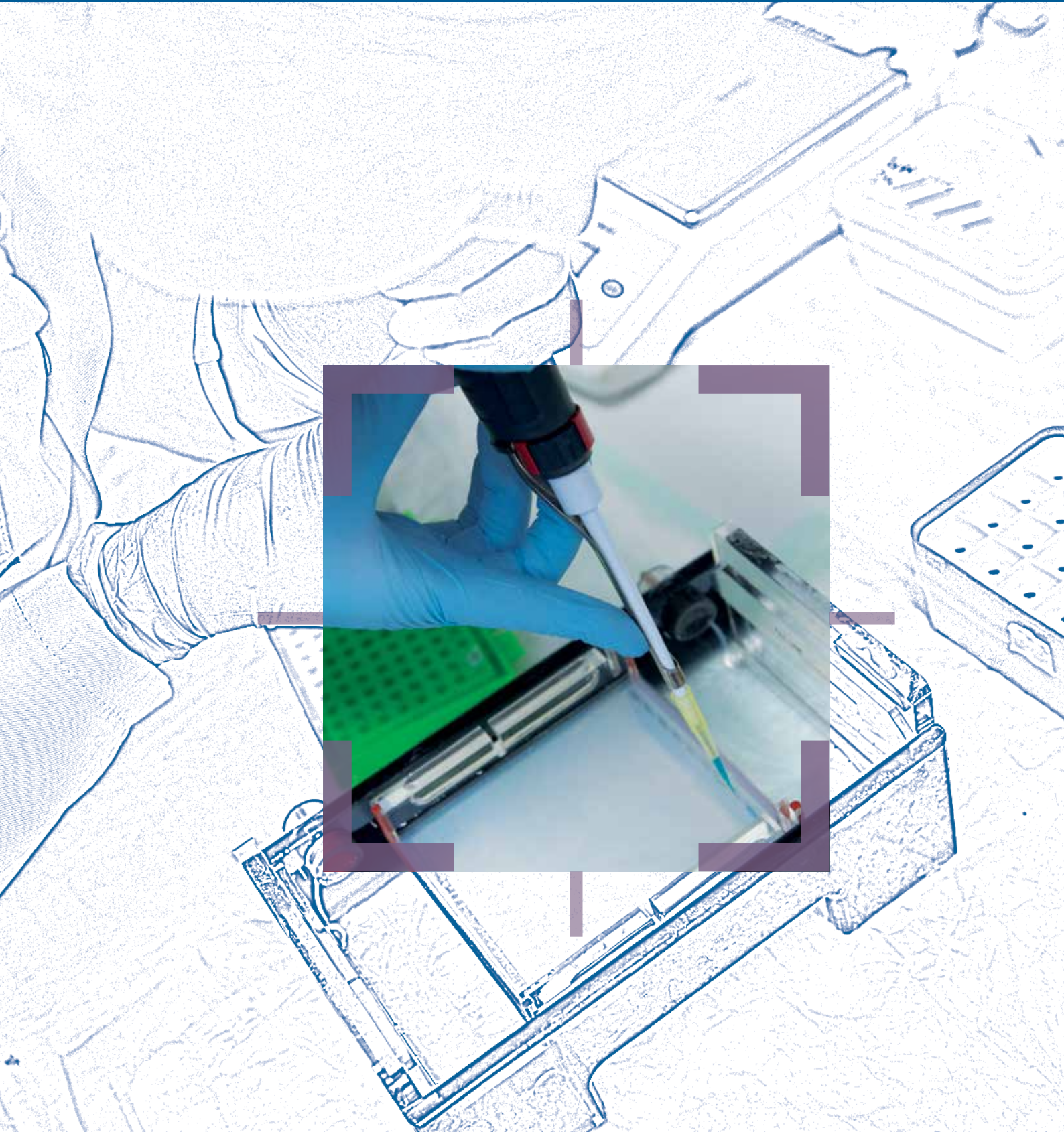
Both processes facilitate the evaluation of pathological changes following brain damage and are therefore suitable for verifying the effectiveness of new therapeutic procedures. The methods used to segment, evaluate, and assure quality are hugely similar here in spite of the different processes. Combining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

Contact

Dr. Alexander Kranz
 Phone +49 341 35536-5403
alexander.kranz@izi.fraunhofer.de

1 Visualization of a stroke in a 3D model of a rat's brain
2 3D model of astrocytes based on immunohistochemical staining

DEPARTMENT OF DIAGNOSTICS



PROF. DR. FRIEDEMANN HORN

Highlights and challenges in the 2015 reporting year

Increasing the proportion of industry contracts was one of the department's key goals. Progress was able to be made here in 2015. Identifying and validating new diagnostic and prognostic biomarkers forms an important focus in the Department of Diagnostics. A huge amount of attention is paid here to the R&D consortium RIBOLUTION, which is funded by the Fraunhofer Future Foundation. In 2015, the foundation granted additional funding which will take the consortium through to mid-2018. The knowledge previously developed by all partners was combined into one "RIBOLUTION Biomarker Center" at Fraunhofer IZI in 2015, which officially opens in spring 2016. The platform offers an especially efficient biomarker development process, paying special attention to RNA molecules. This results in exciting proposals for services in the field of genome-wide transcriptome, genome and epigenome investigations, also involving next-generation sequencing and microarrays.

Additional focal areas in the department in 2015 included innovative preclinical in vitro and in vivo models, mouse models with humanized immune systems, xenogeneic transplantation models and models for tumor stem cell research, all of which facilitate excellent approaches to investigating molecular causes of disease, as well as to testing innovative therapy strategies in cooperation with the pharmaceuticals industry and research institutions. The technical development of intelligent, new diagnostic test procedures, especially (but not limited to) point-of-care diagnostics and the further advancement of DNA origami technology formed further strengths in the department in the reporting year.

Outlook over the department's key tasks and plans for 2016 and beyond

The further expansion of attractive offers and competitiveness in the department thanks to innovations in the field of diagnostics will be assigned greater value in 2016 and the years that follow. The RIBOLUTION Biomarker Center will not only officially open in 2016, it will also be certified in accordance with the DIN EN ISO 13485 standard. This form of quality management will create the prerequisites for

developing and approving diagnostic tests in accordance with the German Medical Devices Act. Furthermore, a spin-off will be created in 2016 which will be responsible for launching the findings of the RIBOLUTION project onto the market.

Competencies / technologies in the department

- Biomarker identification and validation
- Transcriptome analyses (including next-generation sequencing, microarray studies)
- Genome and epigenome analyses (including next-generation sequencing)
- High-throughput quantitative RT-PCR analyses
- Bioinformatics (in particular the analysis of transcriptome and genome sequencing data)
- Molecular diagnostics
- Molecular diagnostic test systems
- Nanotechnology
- Lab-on-a-Chip diagnostics
- Tumor stem cells (isolation, characterization, testing)
- Animal models for tumor and chronic inflammatory diseases
- DNA origamis (DNA-based nanostructures)
- Analysis of noncoding RNAs as therapeutic targets
- In vitro functional studies
- Data management systems

Contact

Prof. Dr. Friedemann Horn
Head of department
Phone +49 341 35536-3305
friedemann.horn@izi.fraunhofer.de



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.

Contact

Dr. Franziska Lange
Phone +49 341 35536-1401
franziska.lange@izi.fraunhofer.de



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 (next-generation 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.

Contact

Dr. Sabina Christ-Breulmann
Phone +49 341 35536-3363
sabina.christ-breulmann@izi.fraunhofer.de



Next-Generation Diagnostics Unit

This unit develops and establishes analysis strategies for discovering novel biomarkers to diagnose and anticipate diseases. Special attention is paid here to the identification and functional characterization of non-coding RNAs (ncRNAs) as novel therapeutic targets. State-of-the-art approaches to analyzing nucleic acids based on next-generation sequencing and microarrays are optimized for applications concerning large clinical cohorts and for the detection of mutations as well as DNA, RNA and protein interactions.

Contact

Dr. Conny Blumert
Phone +49 341 35536-3301
conny.blumert@izi.fraunhofer.de



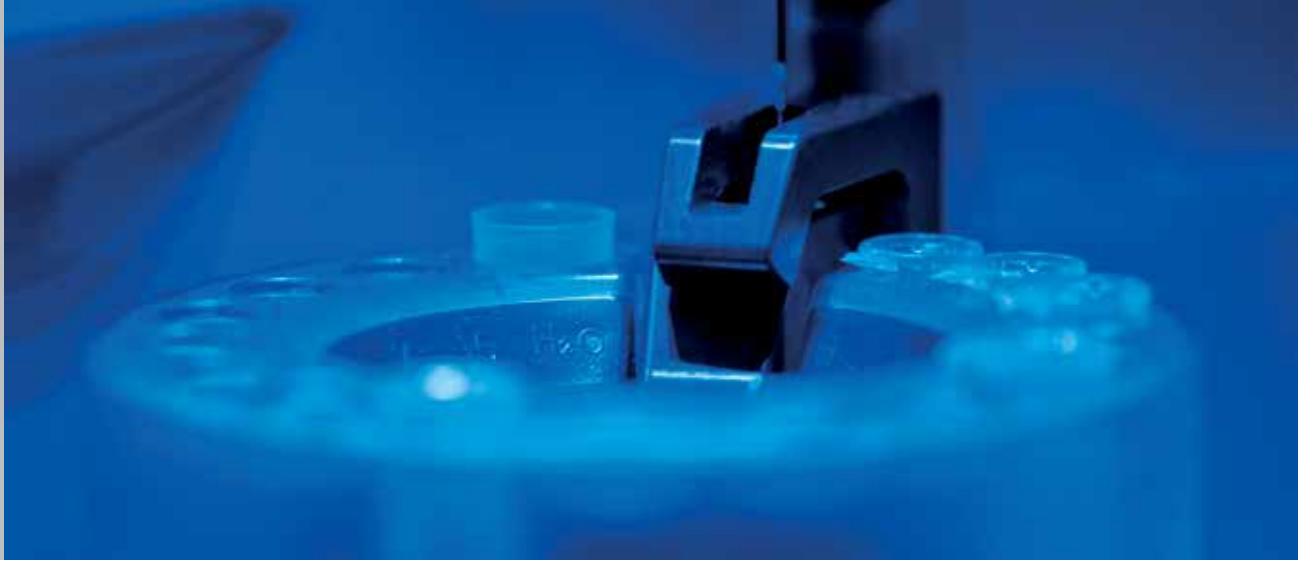
Tumor Stem Cells Unit

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.

Contact

Dr. Peter Ruschpler
Phone +49 341 35536-3605
peter.ruschpler@izi.fraunhofer.de





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. The unit has been funded by the Fraunhofer-Gesellschaft's Attract program since 2013.

Contact

Dr. David M. Smith
Phone +49 341 35536-9311
david.smith@izi.fraunhofer.de



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 unit has access to hot embossing methods.

Contact

Dr. Dirk Kuhlmeier
Phone +49 341 35536-9312
dirk.kuhlmeier@izi.fraunhofer.de



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 fine-regulatory tasks in gene regulation and are therefore suitable as markers for individual disease patterns and progression. The unit develops strategies for efficiently processing and (statistically) 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.

Contact

Dr. Kristin Reiche
Phone +49 341 35536-5223
kristin.reiche@izi.fraunhofer.de



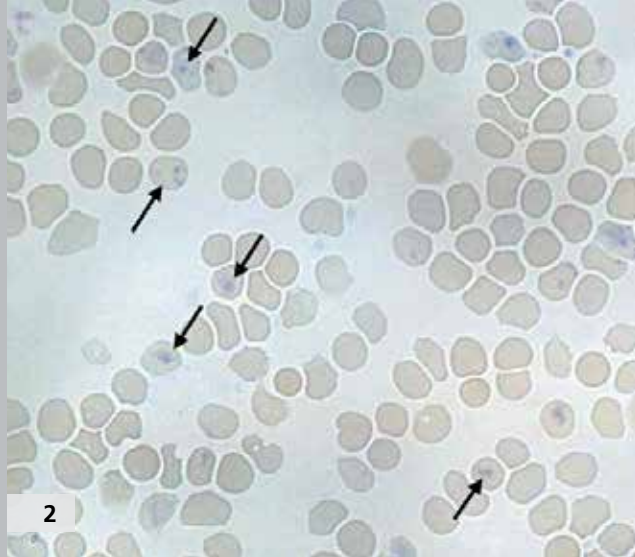
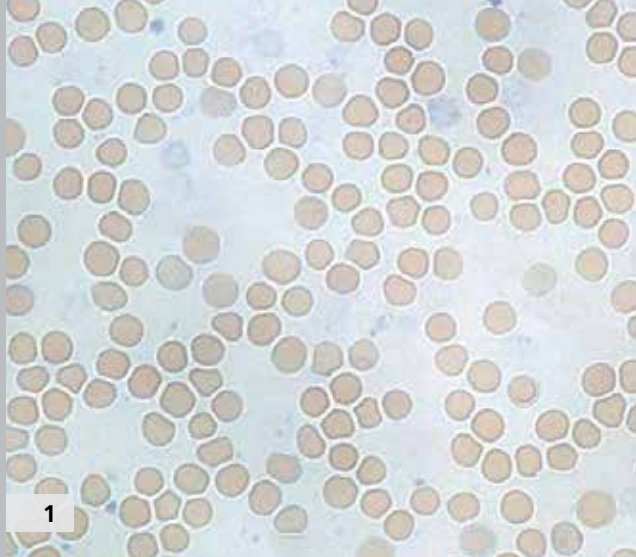
Study and Quality Management Unit

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).

Contact

Dr. Catharina Bertram
Phone +49 341 35536-5221
catharina.bertram@izi.fraunhofer.de





PROJECT EXAMPLES

Study into the effects of an immune modulator on the hematopoietic system of Dark Agouti rats

Past studies revealed that the immune modulator investigated here and its derivatives have an influence on the hematopoietic system. Therefore, the aim was to identify and analyze these effects in detail. The blinded study was carried out in Dark Agouti rats in accordance with strict internal quality criteria that were elaborated with the sponsor.

The treatment had an effect on various blood parameters. For instance, the white blood cell count, red blood cell count, hemoglobin, and hematocrit were all influenced. These effects were only observed during the treatment period and shortly afterwards.

The automated, microscopic blood smear analysis carried out together with the Experimental Imaging Unit and the flow cytometric examination of the blood revealed a marked increase in erythrocyte precursor cells during the treatment period. Both methods were independently applied and showed the same effects over time.

Furthermore, flow cytometric and histological investigations of the bone marrow, spleen and liver were conducted, none of which showed any peculiarities as a result of treatment.

During the course of the study, a viable and inexpensive assay was established to measure methemoglobin content in full blood lysates. For this parameter, too, no changes were noticeable throughout the duration of the study. The same applied to bilirubin, LDH and GSH levels in the blood plasma as shown by ELISA (enzyme-linked immunosorbent assay). By contrast, the substances were seen to have strong effects on

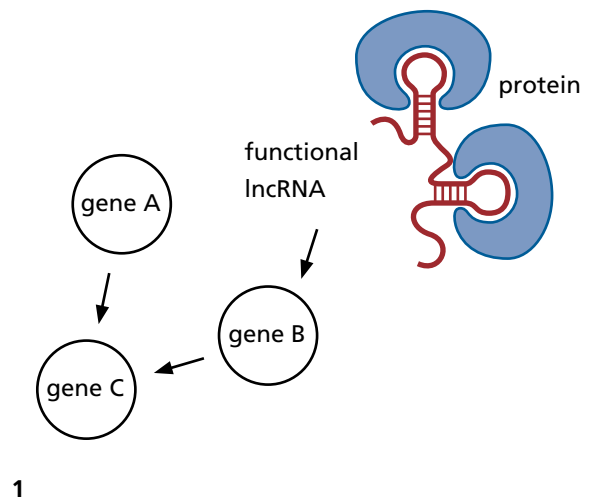
the amount of EPO in the blood plasma during the treatment period. At the end of the study, this dropped back to a normal level.

Mild effects of the immune modulating agents on the hematopoietic system were detected, however they only lasted a short period of time. Due to the wide variety of analysis techniques applied and the limited volume of blood samples, methods were used here which do not belong to the standard repertoire of a routine laboratory. This high degree of flexibility in selecting the parameters to be analyzed was a key consideration when being awarded the contract.

Contact

Dr. Franziska Lange
Phone +49 341 35536-1401
franziska.lange@izi.fraunhofer.de

- 1 Blood smears of periphery blood from rats – supravital staining (brilliant cresyl blue): Blood smear without reticulocytes, only erythrocytes are visible.
- 2 Blood smear with numerous reticulocytes (arrows), recognizable from the blue-colored intracellular RNA residues.



A computational model for prostate cancer prognosis

Prostate cancer (PCa) is the most common, and second-most lethal, type of cancer in men (DeSantis et al. CA Cancer J Clin 2014). However, it is difficult to assign patients to high and low risk groups, or at least this can only be done with uncertainty, using the currently available biomarkers and classification models. This gives rise to a non-negligible number of patients undergoing unnecessary operations, some of which with serious side effects. There is thus a high clinical need for an improved understanding of the systemic changes in the gene expression pattern in PCa in order to reliably differentiate between aggressive and non-aggressive tumors.

In its analyses, Fraunhofer IZI records so-called long non-coding RNAs (lncRNAs), which have a regulatory function that was undervalued for years. lncRNAs play an important role in the integrity of cellular structures, the modulation of the chromatin structure (Guttman et al. Nature 2009), and the regulation of the mitotic cell cycle, thus suggesting a substantial role in cancerogenesis and progression (Hackermüller & Reiche et al. Genome Biology 2014, Reiche et al. PLoS ONE 2014). Individual lncRNAs have already been associated with metastatic and aggressive prostate cancer (Prensner et al. Nature Genetics 2013), however a robust systems biology model for modified gene regulation in PCa, including lncRNAs, is currently not yet available. Traditional systems biology and systems medicine approaches follow a protein-centric view of gene regulation, which largely underestimates the complexity of gene regulation mechanisms.

Fraunhofer IZI has set itself the goal of developing a systems biological model for PCa survival and recurrence. A robust statistical model for prostate cancer prognosis will be developed by integrating lncRNA gene expression patterns and protein-coding genes from a representative group of patient samples.

This computationally intensive task is tackled, for example, by employing an in-house high-performance computing cluster.

A systems biology model that considers lncRNAs alongside protein-coding genes facilitates a more profound analysis of the different changes in the gene regulatory network than using traditional models. It will enable more individual patient prognoses with regard to survival in the short term and novel prostate cancer therapies in the long term.

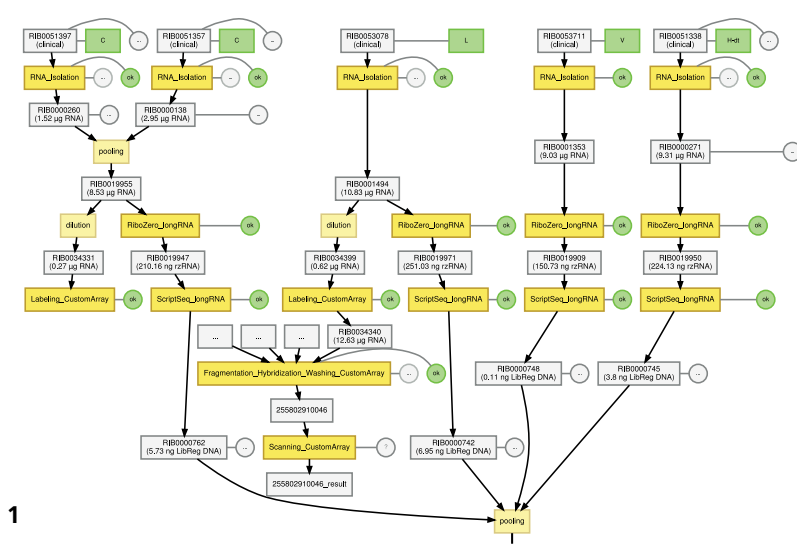
Contact

Dr. Kristin Reiche
Phone +49 341 35536-5223
kristin.reiche@izi.fraunhofer.de

Supported by the Fraunhofer-Zukunftsstiftung (Fraunhofer Future Foundation) – RIBOLUTION



1 *ncRNA-protein complex regulates the activity of various genes*



1

Quality management at the RIBOLUTION Biomarker Center

The implementation of a QM system pursuant to DIN EN ISO 13485 serves the continual adherence to and further development of the high quality standards at the RIBOLUTION Biomarker Center. Besides implementing general quality requirements, the unit is particularly tasked with the implementation of documented procedures for the design and development of IVDs (in vitro diagnostics). This includes, for example, compiling and specifying market and product requirements as well as a risk management process according to DIN EN ISO 14971. Securing continuous traceability of the implementation process shall be ensured, among other things, by using so-called development plans and protocols. Controlled records will be used to document and evaluated the development of new processes and the optimization of methods.

The planning of screening and validation studies and the selection of suitable sample material always takes place in close consultation with clinical Key Opinion Leaders (KOLs). During test development, the indication-specific network of KOLs shall serve, for example, to directly assess the IVD's usability or to make early contact with future recipients of IVD.

Besides using paper-based documentation, the comprehensive data will be stored in a data management system (DMS). This documentation system was developed in particular to meet the requirements of the RIBOLUTION Biomarker Center; it collects clinical data and enables each laboratory process to be recorded in detail. At every stage, records are made showing which person processed or analyzed a sample at what time, what the findings were and where the sample was ultimately stored. The links between samples can also be recorded using the DMS (see figure 1).

This ensures complete traceability of all samples and stages of analysis at any point in time. The data can be visualized as graphs in the DMS or exported in various file formats. The DMS is characterized by its unmatched flexibility, which allows it to be precisely adapted to specific (customer) requirements. Detailed operating instructions and a user-friendly graphical user interface ensure ease of use.

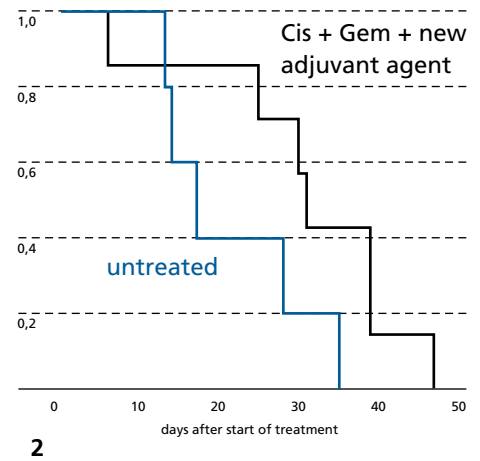
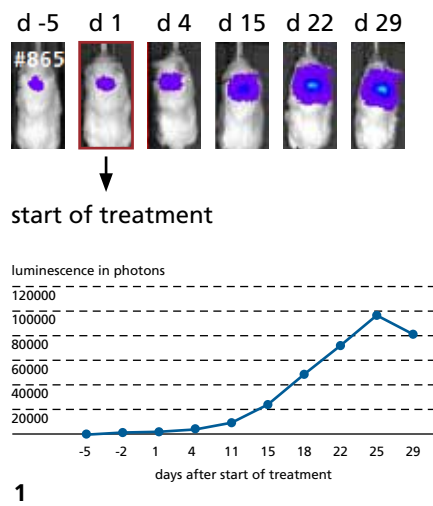
Contact

Dr. Catharina Bertram
 Phone +49 341 35536-5221
catharina.bertram@izi.fraunhofer.de

Supported by the Fraunhofer-Zukunftsstiftung (Fraunhofer Future Foundation) – RIBOLUTION



1 Example of a graph depicting the links between the samples and the traceability of each and every reprocessing stage with the respective information on sample quality.



Analysis of a new adjuvant agent candidate with respect to its tumoricidal efficacy compared with two different types of cancer in vivo (NSG tumor mouse model)

The aim of this investigation is to verify a significant coaction of a new adjuvant agent candidate with a common chemotherapeutic agent (cisplatin and/or gemcitabine) against different forms of cancer (including pancreatic cancer).

A tumor model using NSG mice will be used for the investigations and initialized through the application of an appropriate pancreatic cell line and other cancer cell lines. The cancer cells contain a luciferase transporter gene insertion which enables the noninvasive monitoring of tumor growth in real time. The primary endpoint of the investigation is represented by real-time monitoring of tumor growth facilitated by the tumor cell application. Furthermore, drug-based tumor remission is anticipated through the adjuvant therapeutic application of the new agent.

The proposed cancer types and their corresponding cell lines are stably transduced using a lentiviral vector system, including a luciferase reporter gene. Hereinafter, the most compound-sensitive cell lines will be applied for the two cancer types. To this end, a pilot study was first conducted which was able to determine the toxicity of the used compounds and thus find an optimal dosage combination. The main study will then take place (efficacy study; twice for each tumor type) using the optimal dosages of all compounds used. The therapeutic intervention (cis / gem / new adjuvant compound) will be performed after the administration of tumor cells and the

detection of tumor initiation using bioluminescence imaging (BLI), between seven and 14 days after tumor cell application. The intervention time point with respect to an engrafted tumor is defined by the threshold value of the tumor size, greater than 500 photons detected by bioluminescence (BLI) imaging. The fact that the luminescence intensity is directly proportional to the tumor size means that tumor volume can be calculated. Within the pilot and the main study, BLI monitoring begins with tumor cell application and runs over 56 days through to treatment observation.

Contact

Dr. Peter Ruschpler
 Phone +49 341 35536-3605
 peter.ruschpler@izi.fraunhofer.de

- 1 Documentation of tumor growth using bioluminescence imaging
- 2 Comparative depiction of disease progression without (blue) and with (black) treatment



World-wide innovation: Molecular biology mini laboratory for home use

The general public holds the topic of pathogens in high regard. Alongside multiresistant germs and food contaminants, sexually transmitted infections (STIs) also receive a great deal of attention and require better therapeutic and diagnostic strategies the world over. Every year, over 100 million people around the world become infected with the *Chlamydia trachomatis* bacteria alone. *Chlamydia* species are thus responsible for a fifth of all cases of illness caused by sexually transmitted pathogens.

A particular problem linked to STIs in the western industrialized nations is the reluctance of those affected to consult a doctor and receive treatment as soon as they suspect an infection. Third world countries have a considerably poorer health care system, a fact which increases the risk of carrying an infection.

This project aims to create a diagnostic platform which integrates highly specific and sensitive nucleic acid amplification on a chip and allows the user to discretely test for the infection in the comfort of their home. Together with the Leipzig-based company SelfD Technologie and with the support of the Sächsische Aufbaubank (Saxon Development Bank, SAB), a global novelty is therefore being developed which addresses the home care market.

This is based on a molecular biology laboratory with the dimensions of a credit card, which absorbs the sample and releases the nucleic acids from the cells of the pathogen. The nucleic acid, which may exist in extremely low concentrations, will be specifically reproduced a million times in a miniaturized reaction chamber before being detected. Detection takes place using a visible strip which displays the outcome of the test after approx. 30 minutes: Similar to a

pregnancy test, a control band will be visible which shows whether the test has, in principle, been successfully executed. A specific detection field appears in color if the sexually transmitted pathogen is present in the user's urine. In this case, the only option available is to consult a doctor, who will have to treat the infection using an antibiotic therapy in order to avoid late sequela such as infertility or even blindness.

The HomeCare diagnostic system is a simple, molecular biological test platform which can easily be adjusted to address different issues in the field of medical, environmental or nutritional analytics. It serves as an innovative basis for further applications.

Contact

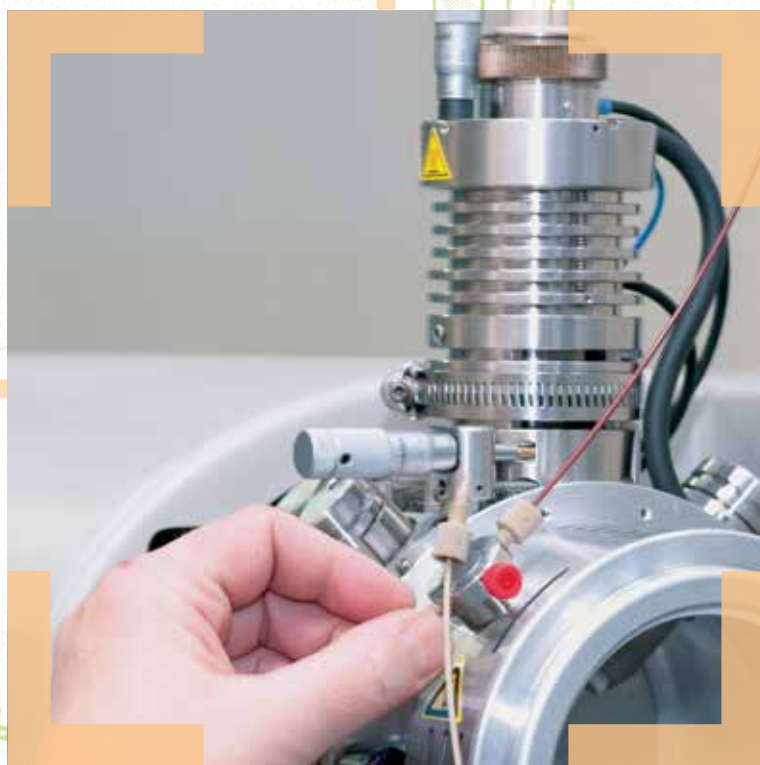
Dr. Dirk Kuhlmeier
Phone +49 341 35536-9312
dirk.kuhlmeier@izi.fraunhofer.de

Europa fördert Sachsen.



1 *Molecular biological mini laboratory*

DEPARTMENT OF DRUG DESIGN AND TARGET VALIDATION



PROF. DR. HANS-ULRICH DEMUTH

Highlights and challenges in the 2015 reporting year

After establishing and successively attaining the working capacity of the units in 2014, 2015 was marked by the consolidation of project work in the units. Initial industry cooperations in the fields of active ingredient synthesis, protein crystallization and active ingredient testing were successfully conducted and will require further interactions with respective industry partners in 2016. The acquisition of an EU-JPND joint project was a particular highlight; the project is being coordinated by the off-site department in Halle (Saale). With regard to the institute's own research projects, vital progress was made especially in the development of small molecules for alternative beta-secretases with regard to activity and selectivity.

Moreover, the network is constantly being expanded to include universities as well as non-university and private research facilities. The number of industry projects in 2015 (more than 40) reflects this activity. Around two years after being formed, we are able to look back on solid initial development and clear growth compared with the previous year, with an industrial rho of over ten per cent.

Outlook over the department's key tasks and plans for 2016 and beyond

In the course of 2015, we carved out three key areas from the projects handled across all of the departments:

- GLP certification of the laboratory for clinical and biophysical analytics for certain preclinical investigations on small molecules as a new site under the umbrella of the GLP testing facility at Fraunhofer IZI in Leipzig
- Advancement of our own research projects that have already commenced, including the selection of a preclinical candidate as proof of principle in the animal model, as the case may be:

- selective antibodies against neo-epitopes that have emerged through posttranslational modifications (Alzheimer's disease);
 - bacterial-strain-selective inhibitors of glutamyl cyclase with the aim of developing topical, oral active ingredients;
 - new mouse models to reflect human neurodegeneration of the Alzheimer's model by combining human genes, which are inert by themselves and only lead to a loss of neurons when combined.
- Continual increase in industry revenue, concentrating acquisition on higher-volume projects

Competencies / technologies in the department

- Design, synthesis and preclinical validation of active agents
- Synthesis of small molecules and protein agents
- Testing in cell-biological and animal experimentation systems
- Innovative protein expression and purification procedures
- Characterization of drug-protein interactions to optimize efficacy
- In-silico drug design and screening
- Medicinal and peptide chemistry to generate new drugs
- Identification of biomarkers
- Assay development
- Model development (in vivo and in vitro)
- Pharmacology

Contact

Prof. Dr. Hans-Ulrich Demuth
Head of department
Phone +49 345 131428-00
hans-ulrich.demuth@izi.fraunhofer.de



UNITS

Molecular Biotechnology Unit

The Molecular Biotechnology Unit develops and establishes cellular and molecular biology analysis and model systems. This involves cell-based assays, gene expression analysis, immunological and protein chemistry methods, sophisticated cell culture and animal models. The unit conducts a series of cell-based tests for characterizing substances with regard to effectiveness, toxicology and transport. Its service portfolio also includes establishing new animal models for investigating enzyme functions in vivo.

Contact

Dr. Holger Cynis
Phone +49 345 131428-35
holger.cynis@izi.fraunhofer.de



Protein and Drug Biochemistry Unit

The Protein and Drug Biochemistry Unit has in-depth experience in the purification of target proteins as well as their enzymatic characterization. Besides classic protein chromatography procedures, protein chemistry methods are also used, such as the spectroscopic analysis of structure and enzyme-kinetic mode of action. The unit specializes in the humanization of antibodies for the manufacture of protein drugs and their semi-preparative extraction. The subsequent structure-activity-analysis as well as structure-based molecular optimization round off the unit's portfolio.

Contact

Dr. Stephan Schilling
Phone +49 345 131428-15
stephan.schilling@izi.fraunhofer.de





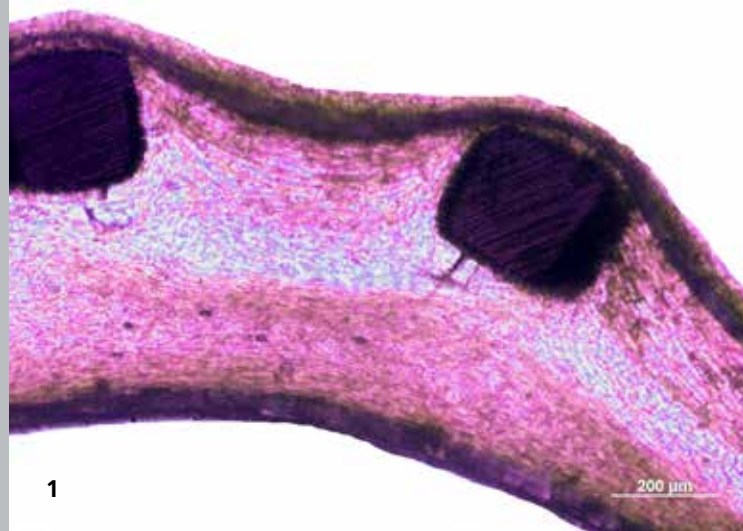
Drug Design and Analytical Chemistry Unit

The service portfolio offered by the unit comprises the entire spectrum of medicinal chemistry and analytics required to identify potential, new drug candidates from within the field of “small molecules” and develop them into clinical candidates. New target molecules can be generated in silico with the aid of computational procedures, besides being evaluated, synthesized and tested in terms of their effectiveness on the target protein. Moreover, the unit also offers analytical support as part of drug development in both preclinical and clinical trials.

Contact

Dr. Mirko Buchholz
Phone +49 345 131428-25
mirko.buchholz@izi.fraunhofer.de





PROJECT EXAMPLES

Rabbit model of in-stent restenosis for drug design

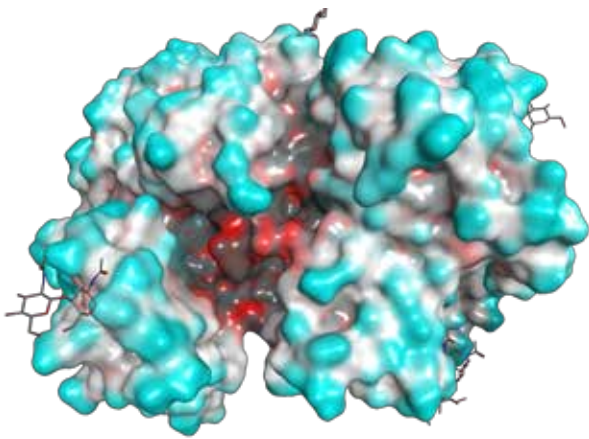
Atherosclerosis is the most common cause of arterial vascular occlusion, which can, among other things, lead to an acute undersupply of oxygen to the myocardium (myocardial infarction). Percutaneous transluminal angioplasty (PTA) with and without stent application is performed as a standard treatment to re-open an occluded vessel. However, neointima develops in up to 30 per cent of clinical cases due to the hyperproliferation of smooth muscle cells combined with the invasion of monocytes, which leads to the vessel reoccluding. The process is referred to as in-stent restenosis (ISR) if it occurs following stent application.

The Molecular Biotechnology Unit has access to an established in vivo model system for ISR. Stent application in the atherosclerotic rabbit model is an effective tool for investigating novel drug candidates, biomaterials and medicinal products.

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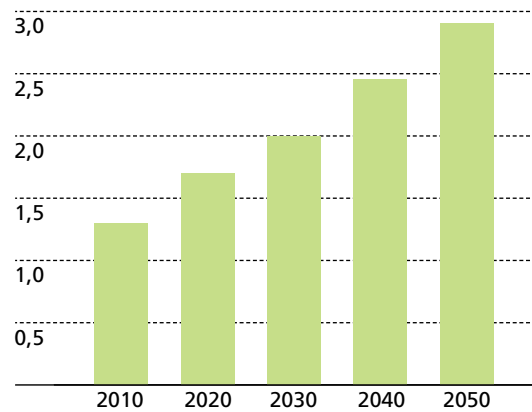
Dr. Holger Cynis
Phone +49 345 131428-35
holger.cynis@izi.fraunhofer.de

1 Stent struts and neointima formation 4 weeks post-surgery (HE staining, digitally modified)



1

number of ill persons (million)



2

Development of small molecules as innovative medicines to combat Alzheimer's disease

In today's ageing society, dementia, especially Alzheimer's disease, plays an ever more significant role in health care policy: It is estimated that every third person over the age of 85 suffers from dementia. This constantly increasing number of patients, however, does not have access to adequate treatment options. To date, it has not been possible to delay disease progress.

The disease is triggered by the accumulation of different proteins in the brain which damage the tissue and lead to the nerve cells dying off. It is evident that one of these protein molecules, the amyloid beta peptide ($A\beta$), initiates this cascade of changes. In recent years it has been successfully demonstrated that various other proteins (enzymes) are responsible for the formation of $A\beta$. It also became apparent that particularly toxic forms of $A\beta$ exhibit changes at their N-terminal end. These types of $A\beta$ and, in particular, their formation, form the object of the project presented here.

The aim is to develop pharmaceutical substances that inhibit the so-called alternative beta-secretase meprin and thus prevent the toxic protein molecules from being produced. The project will be conducted across all units as it contains many partial aspects that can only be effected using special technologies. For example, the Protein and Drug Biochemistry Unit successfully redeveloped a test system that can detect enzyme activity quickly and precisely, allowing potential new drugs to be characterized for the first time. Drug design, synthesis and analytics are being handled by the Drug Design and Analytical Chemistry Unit. In the reporting year, targeted design allowed molecules to be synthesized which specifically

inhibit the alternative beta-secretase with an extremely high level of activity. These innovative molecules now have to demonstrate whether they are ready for the next stages of development.

The aim of the project is to characterize molecules to such an extent that a "proof of principle", i. e. efficacy in the animal disease model, can be shown. Subsequent development will then take place in close collaboration with pharmaceutical companies. Alzheimer's disease is, however, just one target area: The drugs may also bear significance on the treatment of nephropathy.

Contact

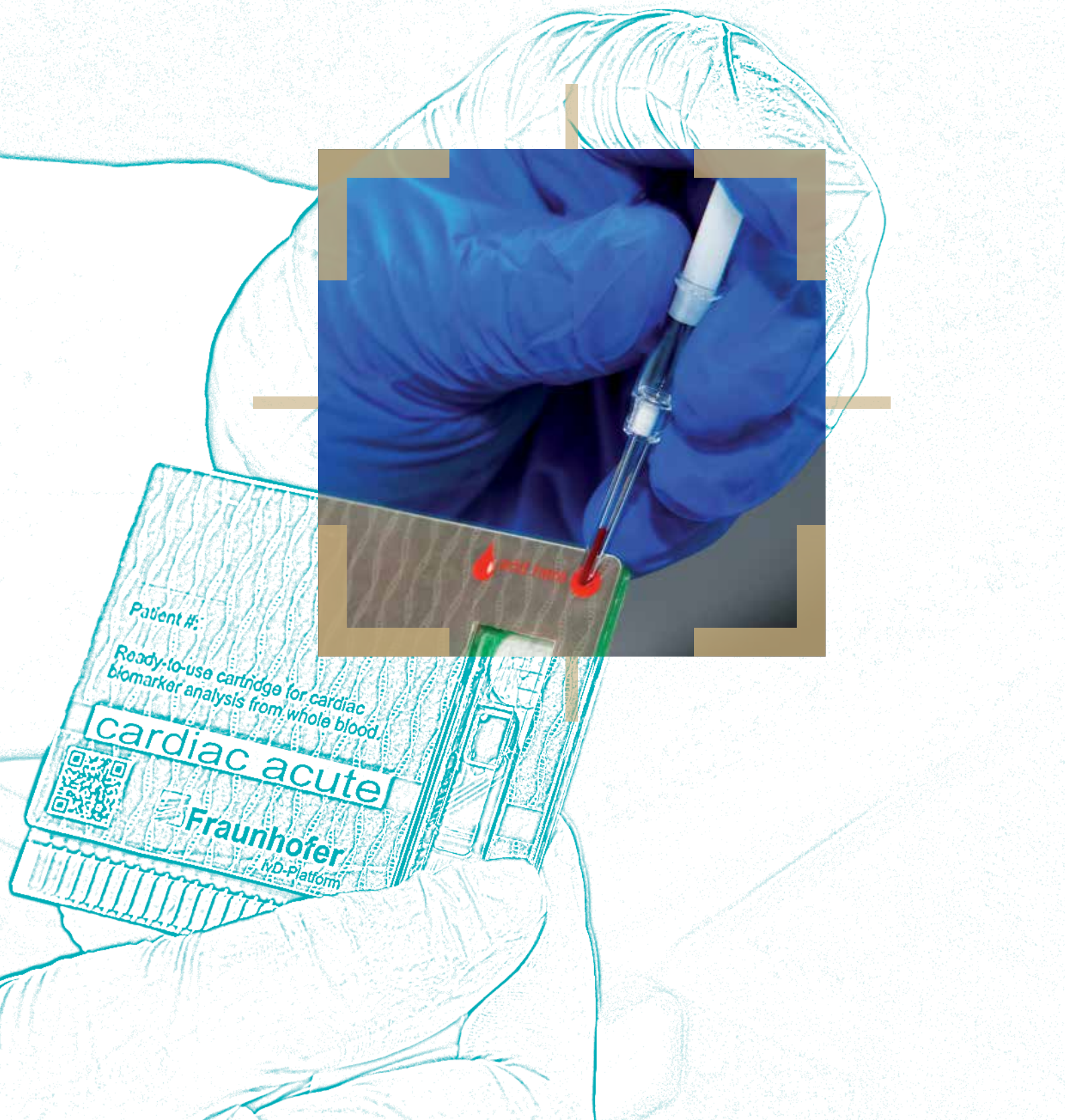
Dr. Stephan Schilling
Phone +49 345 131428-15
stephan.schilling@izi.fraunhofer.de

Dr. Mirko Buchholz
Phone +49 345 131428-25
mirko.buchholz@izi.fraunhofer.de

1 View of the catalytic center of the alternative beta-secretase meprin beta

2 Predicted development of Alzheimer's disease in Germany up to the year 2050 (source: German Alzheimer Association)

DEPARTMENT OF BIOSYSTEM INTEGRATION AND AUTOMATION



PROF. DR. FRANK BIER

Highlights and challenges in the 2015 reporting year

The Department of Biosystem Integration and Automation processes a broad spectrum of automation solutions for typical biological, biochemical or biotechnological laboratory procedures and processes. This is done both at micro and macro level. On the microscale, we employ Lab-on-a-Chip technology, for which both microfluidic solutions and biosensors are developed and existing platforms are used for adapting assays.

Macroscopic automation solutions imitate manual laboratory processes and thus improve procedures due to their increased precision. Using these methods, the first steps towards the complete automation of laboratory processes are being taken together with our customers and, with this, the transition from laboratory to production prepared.

2015 also saw a stronger orientation towards new production technologies, while the investment-related measures initiated in 2014 were concluded. The laboratories and technical center now offer customers the opportunity to put production process steps to the test and to manufacture pilot batches. The department's portfolio is rounded off by various rapid-prototyping methods and additive manufacturing techniques. This means that customers can count on the support of our automation know-how when developing their production technology following the proof-of-principle phase. Particularly noteworthy is our coating process line, which has helped laboratory processes relating to physical, chemical and biochemical surface conditioning to be conducted in a fully automated way for the first time and in any preferred order. It can be used to qualify highly complex coating protocols for production, such as those required for diagnostics or implants which are currently conceivable only as laboratory processes.

Outlook over the department's key tasks and plans for 2016 and beyond

The new facilities were implemented in 2015; now it is time to process the many pending projects. In order to do this, staff numbers will first have to be increased. Besides a number of larger industry contracts, however, smaller companies gradually working towards production technologies together with us via automation also form a significant proportion of our core target group. Moreover, the further development of dry reagents will provide decisive stimuli for on-site analytics as the on-site analytics and diagnostics concept can only be realized on site if the quality of the reagents and materials is guaranteed, even under conditions that are not ideal. In this regard, we are also increasingly looking to the market beyond Europe.

Competencies / technologies in the department

- Assay development for biomarkers
- Point-of-care technologies
- Production-relevant development, production technology for ivD products
- Automation of biomedical and biotechnological laboratory processes
- Microscopy techniques (fluorescence, AFM, REM, XPS, high resolution)
- THz spectroscopy
- Molecular dielectrophoresis
- Automated peptide synthesis
- Dry reagents
- Immunoassays
- Microarray technologies, genome and transcriptome analyses focused on detecting infection
- Device development and production for POC applications, from conceptual design to rapid prototyping and test series

Contact

Prof. Dr. Frank Bier
Head of department
Phone +49 331 58187-200
frank.bier@izi-bb.fraunhofer.de



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.

Contact

Prof. Dr. Frank Bier
Phone +49 331 58187-200
frank.bier@izi-bb.fraunhofer.de



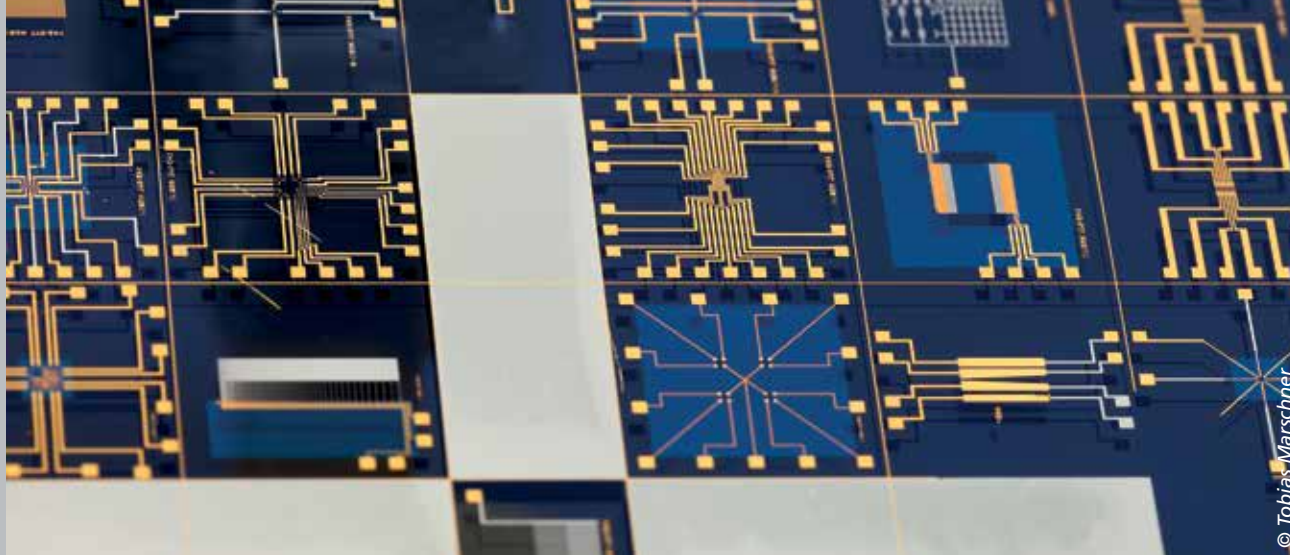
Biomolecular Nanostructures and Measurement Technology Unit

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.

Contact

PD Dr. Ralph Hölzel
Phone +49 331 58187-205
ralph.hoelzel@izi-bb.fraunhofer.de





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.

Contact

Dr. Nenad Gajovic-Eichelmann
Phone +49 331 58187-204
nenad.gajovic@izi-bb.fraunhofer.de



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.

Contact

Jörg Henkel
Phone +49 331 58187-209
joerg.henkel@izi-bb.fraunhofer.de

PROJECT EXAMPLES

XB microscope: Multilevel study of cell culture

In order to increase the efficiency of cell cultures and make better use of available incubator space, multi-bottom culture bottles for adherently growing cells have been offered for several years. These bottles are now available with up to 10 bottoms: The outer shape resembles that of a conventional bottle, or is built up higher with the same base dimensions.

The use of such culture bottles, however, is restricted by the fact that it is not possible to observe cell growth on all of the culture bottoms. Cell culture microscopes are set up to study the cells on the lower levels; adjusting the observation focus to a higher level is not provided for. The image quality is impaired by the fact that both the lighting and the optical distance to the lens in the higher bottoms passes through several plastic and also liquid layers. In addition, a mechanism is required which correctly focuses the particularly large object distance for the given situation. Phase contrast is often used in cell culture to improve image quality, which also results in additional focusing work in terms of illumination optics.

The microscope developed by the ivD Platform Unit resolves these issues, enabling cell growth to be observed in all bottle bottoms. Depending on the type of bottle and number of and distances between the bottoms used in the bottle, several bottoms can be observed also using the phase-contrast technique. The microscope works digitally, making sure that all images are immediately available for quality assurance and archiving purposes. Moreover, it can be fully controlled remotely, which makes it particularly well suited to working in sterile environments. To this end, a design was specifically developed that takes into account the flows in the laminar flow box and which can be easily sterilized without compromising the optics.

Contact

Prof. Dr. Frank Bier
Phone +49 331 58187-200
frank.bier@izi-bb.fraunhofer.de

Electrochemical characterization with simultaneous video microscopy of sensor electrodes

Cost-effective electrochemical rapid tests, e. g. for the detection of biomarkers or pathogenic bacteria, require inexpensive yet high-quality sensing electrodes. The challenge here is to produce thousands of sensing electrodes with identical characteristics. Besides the size and chemical composition of the surface, the design and arrangement of individual electrodes is paramount for the performance of planar electrode systems.

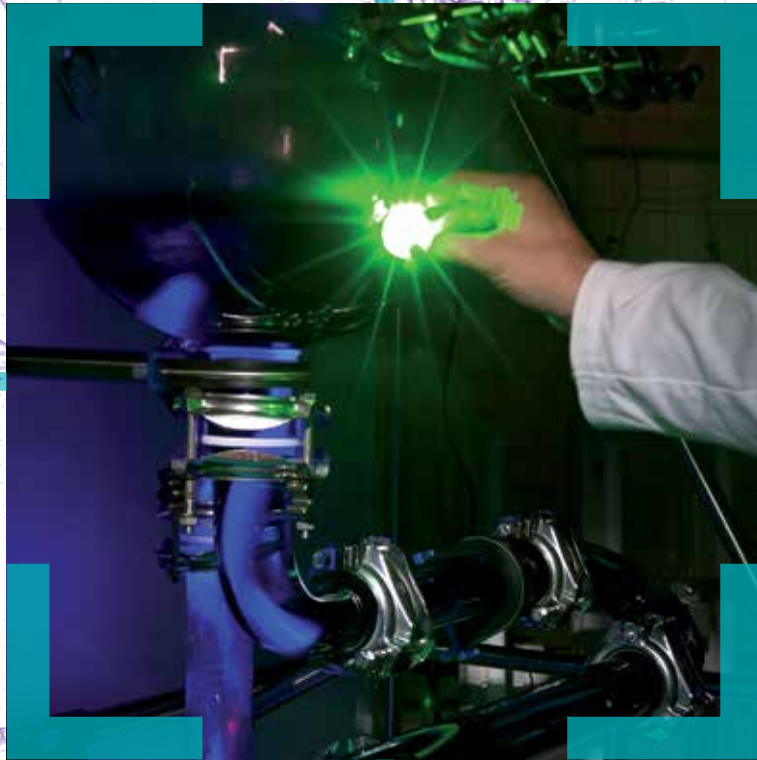
In this project, miniaturized, planar electrode systems made of platinum, gold and graphene were characterized using both cyclic voltammetry and high-speed video microscopy at the same time (with up to 230,000 images per second). The analysis of the video revealed previously hidden properties, e. g. the development of "hot spots" (sites of preferred water electrolysis), electrically actuated fluid flows, differences between electrode materials and between two and three-electrode systems. The straightforward testing workflow allows for the routine analysis and optimization of many electrode designs.

Contact

Dr. Nenad Gajovic-Eichelmann
Telefon +49 331 58187-204
nenad.gajovic@izi-bb.fraunhofer.de

1 *Passivation of a platinum triple-electrode chip (video microscopy): From left to right – activated platinum (black), two intermediate states (anisotropic passivation), all electrodes fully passivated (white)*

DEPARTMENT OF CELLULAR BIOTECHNOLOGY



DR. CLAUD DUSCHL

Highlights and challenges in the 2015 reporting year

The novel microreactor systems developed in the department had to be established and additional ways in which they could be flexibly adjusted to the various requirements of sophisticated cell cultivation procedures had to be created. Beyond this, we hope to be able to offer a series of toxicity tests in the medium term based on these systems. Likewise, the development of a test rig and of assays for the evaluation of hemo-biocompatibility has advanced to such an extent that we will hopefully be able to offer diagnostically conclusive tests as of 2016.

At the end of 2015, we were able to conclude the EU project HeMiBio with utmost success. The project was part of the Seurat-1 initiative (Safety Evaluation Ultimately Replacing Animal Testing) launched and financed by the EU together with the European Cosmetic Association (Colipa). In collaboration with our project partners, especially with our colleagues from the Hebrew University of Jerusalem, we managed to establish a microbioreactor that can be used to assess the toxicity of chemical substances, cosmetic ingredients and medications on hepatic cells in real time over a period of 28 days. At the closing event of the Seurat-1 program, which was held in Brussels in December 2015, this result was viewed by the cosmetics industry as one of the highlights of the entire program.

Outlook over the department's key tasks and plans for 2016 and beyond

The departments within Fraunhofer IZI-BB will be restructured at the start of 2016. This will result in the department's technology-oriented units merging together with the Department of Bioanalytics and Biosensors. Appropriate measures will be taken with the goal of intensifying the interaction of staff from both departments in such a way that

additional synergies in the fields of surface coatings, microfluidics and sensor technology emerge and are used both for acquiring and processing projects. Moreover, efforts are being made to bring these fields closer together and thus increase the level of integration of the solutions on offer.

Competencies / technologies in the department

- Development of Lab-on-a-Chip systems
- Analysis and manipulation of single cells
- Integration of sensors in microsystems
- Rapid prototyping of microfluidic devices
- Dielectrophoresis
- Optical high-end microscopy
- Bioactive cell cultivation substrates and polymer coatings
- Cultivation of mammalian cells
- Snow algae and microalgae: Taxonomy, cultivation and characterization
- Mass production of algae
- Development of photo bioreactors
- Cryobiology

Contact

Dr. Claus Duschl
Head of department
Phone +49 331 58187-300
claus.duschl@izi-bb.fraunhofer.de



UNITS

Lab-on-a-Chip Technology Unit

The unit develops customer-specific processes and prototypes based on Lab-on-a-Chip systems for the analysis and manipulation of complex biological samples. In this context, we focus on the noninvasive handling and characterization of sensitive cell samples right down to the single-cell level, employing microfluidic chips. The integration of sensor units in microfluidic devices to monitor crucial parameters of complex samples including cell lysates and cell clusters represents another important activity within the unit.

Contact

Dr. Claus Duschl
Phone +49 331 58187-300
claus.duschl@izi-bb.fraunhofer.de



Miniaturized Cell Assays Unit

The unit aims to develop powerful techniques for the highly controlled processing of cells and their cultivation under defined experimental conditions. In order to do this, the unit develops microfluidic systems and microstructured substrates that are coated with smart biopolymers and allow the natural microenvironment of cells to be mimicked as far as possible in vitro. The miniaturized assay formats enable us to process even the smallest sample quantities in a parallelized and automated fashion.

Contact

Dr. Michael Kirschbaum
Phone +49 331 58187-303
michael.kirschbaum@izi-bb.fraunhofer.de





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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 in which they withstand 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.

Contact

Dr. Thomas Leya
Phone +49 331 58187-304
thomas.leya@izi-bb.fraunhofer.de



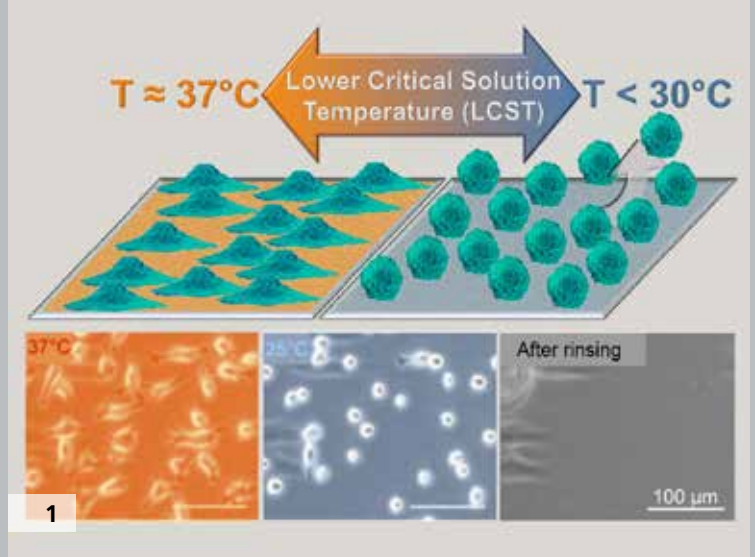
Biofunctional Coatings Unit

The unit develops novel substrates for cell culture and tissue engineering. The behavior of biological cells is controlled using multilayer films made of biopolymers, which are also externally activated. Planar films and also microcapsules with encapsulated biomolecules are employed. Microcapsules are assembled as templates on porous CaCO₃. The porous CaCO₃ particles, which allow encapsulation in mild conditions, are also employed for bio-applications such as drug delivery and separation as well as polymer scaffold fabrication.

Contact

Dr. Dmitry Volodkin
Phone +49 331 58187-327
dmitry.volodkin@izi-bb.fraunhofer.de





PROJECT EXAMPLES

Thermoresponsive substrates as functional elements of cell assay formats for applications in biomedicine and biotechnology – ThermoCell

Clusters of live cells under defined lab conditions are indispensable as scientific and medical test systems. They are of enormous importance in basic research for the development of new therapies and for the assessment of the toxicity and biocompatibility of drugs, chemicals and cosmetics. In order to ensure valid in vitro test systems and guarantee cell vitality, the cell material has to be processed in a noninvasive, efficient, robust and reproducible manner. In this context, control over cell adhesion on cell cultivation substrates is crucial. Cells are conventionally detached from their substrate through an enzymatic digest of their membrane proteins. This process damages cells, influences cell behavior, and thus impairs the test results. An alternative has already been used in the form of thermoresponsive polymer coatings, which allow cells to be detached from surfaces gently and at controlled temperatures. These polymer surfaces are cell adhesive at the cell cultivation temperature of 37 °C. If, however, the substrate is cooled to below the transition temperature (typically around 32 °C), the coating becomes cell repellent.

The project mainly intended to simplify the coating process and thus flexibly adapt the surface architecture to specific cell types and applications. One of the most promising results obtained concerns the establishment of simple production methods to generate locally defined polymer patterns on cultivation surfaces using spotting techniques and microprinting procedures. This approach enabled the local detachment of cells from a cell layer through slight cooling and mild rinsing. After restoring the temperature back to 37

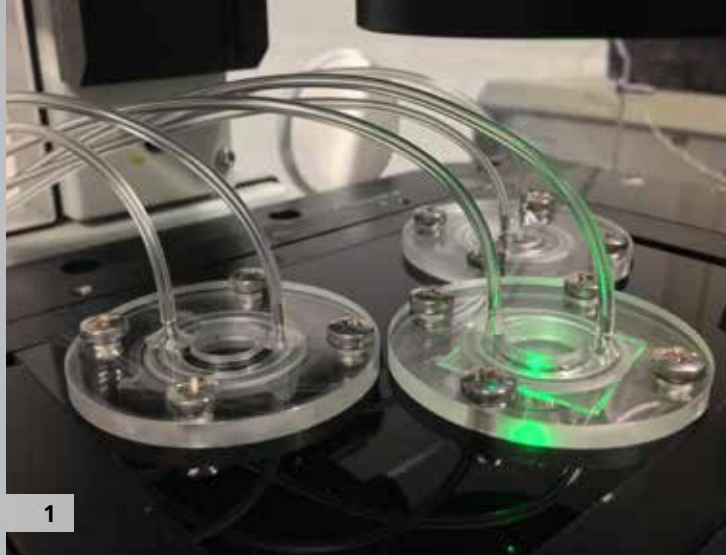
°C, the remaining cells once again migrate to the empty areas. Cell tests such as wound healing or migration assays become greatly simplified through such reversible, local detachment and are thus more user friendly. Structured polymer coatings are also useful for the simple production of cocultures of different cell types, as often used in stem cell research.

Based on the partial detachment of cells from their substrate, an automated cell culture is to be developed and established on a miniature scale in future in order to propagate sensitive and rare cell material noninvasively and efficiently.

Contact

Dr. Katja Uhlig
Phone +49 331 58187-310
katja.uhlig@izi-bb.fraunhofer.de

1 Scheme showing the non-invasive detachment of adherent cells by means of thermoresponsive polymer coatings



Microbioreactor for liver cells to assess the long-term toxicity of drugs and chemicals

Animal tests are still extensively used to assess drugs and evaluate the toxicity of chemicals that humans come into contact with. However, this practice is increasingly coming under pressure: On the one hand for ethical reasons; on the other due to the fact that animal models often give rise to predictions as to efficacy in humans that are insufficiently reliable. Legislation authorities have long since been aware of this situation. For example, in its 2013 cosmetics regulation, the EU banned the sale of any cosmetic products within the EU which contain ingredients that have been tested on animals. At the same time, there is an enormous demand for alternative testing methods that accurately assess the toxicity of agents, with a key emphasis on long-term effects.

As part of a major European program (Seurat-1 – Safety Evaluation Ultimately Replacing Animal Testing, 50 million euros), Fraunhofer IZI-BB has come together with a number of international partners to develop a liver microbioreactor to assess the liver toxicity of cosmetic ingredients. The novelty of this development is based on the following features:

- maintenance of the metabolic activity of spheroids from HepG2 liver cells in a microreactor over the course of 28 days;
- establishment of an oxygen gradient over the same period of time which depicts the *in vivo* microenvironment while continuously being supplied with the medium;
- continuous, noninvasive, optical determination of the oxygen concentration in real time over 28 days with a spatial resolution of less than 100 μm with simultaneous assessment of the glucose and lactate metabolism.

These properties allow information to be generated on the substance-related, toxic mechanisms of action which cannot be obtained using conventional endpoint methods. This was able to be demonstrated using a number of substances. For the analgesic acetaminophen (paracetamol), for example, two independent modes of action were able to be demonstrated for the first time, one of reversible nature, the other irreversible and dose-independent. The significance of this new approach can be demonstrated by comparing TD50 (toxic dose) values for a number of drugs.

Ongoing projects concentrate primarily on developing more meaningful cell models on the basis of primary cells and cocultures. By doing this, it is hoped that the function of the liver can be depicted in a more realistic manner.

Contact

Dr. Sebastian Prill
 Phone +49 331 58187-328
sebastian.prill@izi-bb.fraunhofer.de

The HeMiBio consortium is jointly funded by the European Commission and Cosmetics Europe as part of the SEURAT-1 cluster.

1 Three microbioreactors operating in parallel. The oxygen-sensitive microparticles are optically read by a reactor.

DEPARTMENT OF CELL-FREE BIOPRODUCTION



DR. STEFAN KUBICK

Highlights and challenges in the 2015 reporting year

Compared with conventional, cell-based systems, cell-free systems allow the rapid purification and functional characterization of cytosolic and membranous target proteins. In this context, several new, vesicle-based, eukaryotic, cell-free systems were developed which facilitate the synthesis of highly complex, multimeric membrane proteins followed by their functional characterization using a high-throughput technique. The systems, which are based on cell lysates of cultured CHO cells, enable an industrial use of cell-free bioproduction systems in scalable measures for the synthesis of pharmacologically relevant proteins. In this respect, research activities are predominantly focused on attaining a high overall yield of functional protein in new reactor geometries, besides achieving a significant reduction in costs through the substitution of expensive substrates in the reaction solutions.

Outlook over the department's key tasks and plans for 2016 and beyond

Cell-free systems developed from eukaryotic cell lysates facilitate the synthesis of proteins with posttranslational modifications. An efficient production of disulfide-bonded and lipid-modified proteins is therefore also focused on, as well as the defined cell-free glycoprotein synthesis. Due to their versatile properties, eukaryotic translation systems can be increasingly used in the near future to synthesize functional antibody fragments displaying a broad spectrum of specificities. The cotranslational labeling of proteins also represents an additional research focus with regard to cell-free protein synthesis which opens up additional areas of applications through the development of novel, chemoselective and bioorthogonal protein labeling systems. By using innovative labeling methods, antibody fragments can be coupled with low-molecular substances of vital significance for therapeutic purposes, even during their cell-free synthesis. This is highly important when considering the development of cytotoxic, therapeutic protein conjugates. A transdisciplinary approach to research is expected to contribute towards the development of bioproduction systems, which will overcome the limitations posed by conventional biotechnological production systems in the long term and facilitate applications which are not feasible today. Further research and development work is also on the agenda, particularly in terms of characterizing the foundations of bio-integrated and cell-free production

systems, the design and manufacture of synthetic or hybrid bioprocess components and modules, the generation of bioorthogonal systems and the technical realization of novel bioproduction systems.

Competencies / technologies in the department

- Development of translationally active eukaryotic cell lysates
- Large-scale protein expression and purification
- Representation of posttranslationally modified proteins in cell-free systems (glycoproteins, phosphorylated and lipid-modified proteins)
- Synthesis of constitutively active and cytotoxic proteins
- Cell-free synthesis of antibodies and membrane proteins
- Assay development for in vitro synthesized and functionally active membrane proteins
- Determination of solubility and optimization of expression patterns for complex proteins
- Incorporation and detection of radioisotopes in protein structures
- Amino-acid-specific and site-specific incorporation of non-canonical amino acids in cell-free synthesized proteins
- Protein detection via fluorescence microscopy and high-resolution mass spectrometry
- PCR-based generation of DNA templates suitable for cell-free protein synthesis
- RNA synthesis (transcription, analysis and purification of RNA)
- Multi-parallel cell-free protein synthesis
- "On-chip" synthesis and immobilization of proteins
- Protein-protein interaction assays

Contact

Dr. Stefan Kubick
Head of department
Phone +49 331 58187-306
stefan.kubick@izi-bb.fraunhofer.de



UNITS

Cell-free Protein Synthesis Unit

The unit focuses on the synthesis of recombinant proteins in cell-free systems. In this context, special emphasis is placed on the cell-free synthesis of antibodies and antibody fragments, followed by their characterization, modification and functional analysis. By using cell-free protein synthesis, a given target protein is produced using the translational machinery without the living cell. Thus, protein synthesis is disconnected from cell fate. Eukaryotic lysates offer the particular advantage of being able to produce posttranslationally modified proteins.

Contact

Dr. Stefan Kubick
Phone +49 331 58187-306
stefan.kubick@izi-bb.fraunhofer.de



In Vitro Protein Labeling Unit

Functional characterization of membrane proteins and the development of novel protein labeling technologies form the focus of the In Vitro Protein Labeling Unit. The incorporation of modified and non-canonical amino acids into the growing nascent peptide chain is facilitated by chemically or enzymatically preacylated tRNAs. Defined protein conjugates with biotinylated or fluorescent-labeled groups are prepared using prokaryotic and eukaryotic cell-free systems. Site-specific protein labeling serves as a gentle and easy way of characterizing and detecting the functionality of the synthesized proteins.

Contact

Dr. Stefan Kubick
Phone +49 331 58187-306
stefan.kubick@izi-bb.fraunhofer.de





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.

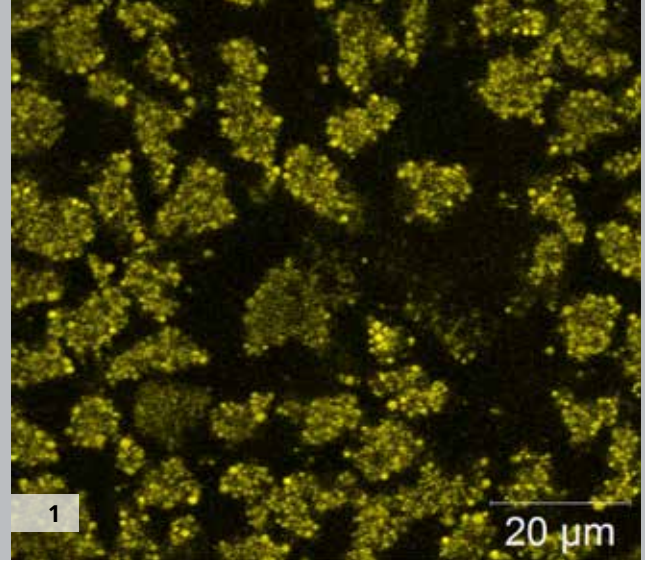
Contact

Doreen Wüstenhagen

Phone +49 331 58187-322

doreen.wuestenhagen@izi-bb.fraunhofer.de





PROJECT EXAMPLES

Cell-free systems for the preparation of modified antibody fragments

Antibodies are key reagents in molecular biology, diagnostics and therapeutics. By using cell-free protein synthesis, these proteins can be prepared in a highly parallel and thus time-saving manner for production and screening purposes. Moreover, targeted modifications of antibodies are of growing interest for diagnostic and therapeutic applications. However, the site-specific labelling of target molecules represents one of the main challenges to produce homogenous products with identical properties.

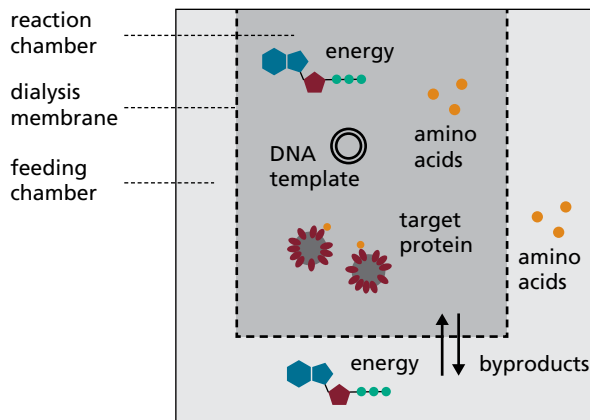
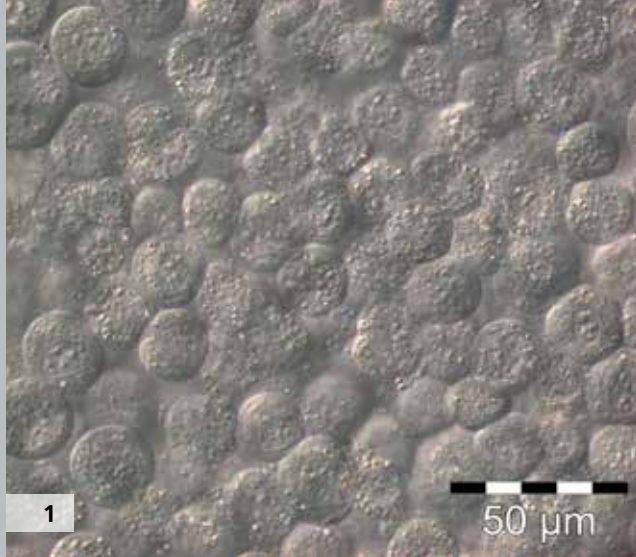
This project therefore aimed to explore the potential of eukaryotic cell-free systems from synthesis to the site-specific modification of recombinant antibody fragments. Selected antibody fragments were labelled at defined positions with non-canonical amino acids in order to extend their characteristics and thus create new fields of applications for the manufactured proteins. In this context, the successful incorporation of non-canonical amino acids in cell-free synthesized antibody fragments has been shown (by using an orthogonal tRNA / synthetase pair). In a subsequent reaction step, the incorporation of these reactive amino acids enables site-specific conjugation with small and larger molecules, which also support a radioactive group. In order to demonstrate the general feasibility of this approach, labeled antibody fragments were first conjugated with a fluorescent dye. Then, fluorescent protein bands could be detected, demonstrating the successful incorporation of the non-canonical amino acids and thus the subsequent chemoselective coupling with the fluorescent dye.

The possibility to manufacture and label antibody formats in eukaryotic lysates in a cell-free manner offers new ways of coupling these molecules with cytotoxic proteins or peptides, which cannot be expressed in cultivated cells due to their toxicity, besides coupling fluorescent dyes or biotin. These possibilities are hugely significant, especially for developing therapeutic antibodies. Establishing this kind of pipeline, which allows for highly parallel and also scalable synthesis, through to labeling and coupling with other molecules, will make a decisive and future-oriented contribution to the development.

Contact

Dr. Marlitt Stech
 Phone +49 331 58187-305
marlitt.stech@izi-bb.fraunhofer.de

1 Confocal microscopic image of ER microsomes containing fluorescent antibody fusion proteins



2

New cell-free protein synthesis system based on CHO cell lysates

At present, the production of therapeutic proteins is based predominantly on biotechnological procedures. Industrial productions here include the cultivation of different cell lines which manufacture the desired target protein. Pharmacologically relevant proteins often have to be compatible for use in the human body. The use of mammalian cell lines is therefore preferred in order to attain human-compatible modifications, such as specific glycosylations. One of the most frequently used production lines involves CHO cells, an immortalized cell line which was originally isolated from the ovaries of the Chinese hamster (CHO – Chinese Hamster Ovary). More than 80 per cent of all industrial therapeutic protein productions are currently produced in a cell-based manner in CHO fermentation processes. The evaluation of defined CHO production cell lines for specific proteins is, however, time-consuming.

Cell-free systems based on CHO cell lysates offer an efficient alternative here to the fast generation of proteins. Cell-free protein synthesis, based on CHO cell lysates, addresses a variety of application areas. Endogenous microsomes in the lysates, which are obtained from the endoplasmatic reticulum during cell disruption, represent a natural environment for the integration of membrane proteins. Furthermore, the endogenous microsomes contain specific enzymes for carrying out posttranslational modifications which are essential to the folding and function of many proteins. The diversity of the system is clear from the fact that various translation initiation processes can be performed. Different DNA constructs such as circular plasmids or linear PCR products can be directly used for rapid protein synthesis. The system thus presents a technology platform which allows various templates to be screened for subsequent industrial production processes. Establishing different cell-free process

modes, which can be classified as batch or dialysis, allows the cell-free CHO system to be specifically adapted to a respective application. The batch mode is used for fast and cost-effective protein syntheses and evaluations. If an application is focused on the high yield of the target protein, cell-free synthesis can be conducted in dialysis mode. This enables, for example, the production of toxic proteins and of membrane proteins that are difficult to express for pharmacological studies, as well as the clarification of protein structures. Eukaryotic cell-free systems therefore make a significant contribution to the development of innovative drugs.

Contact

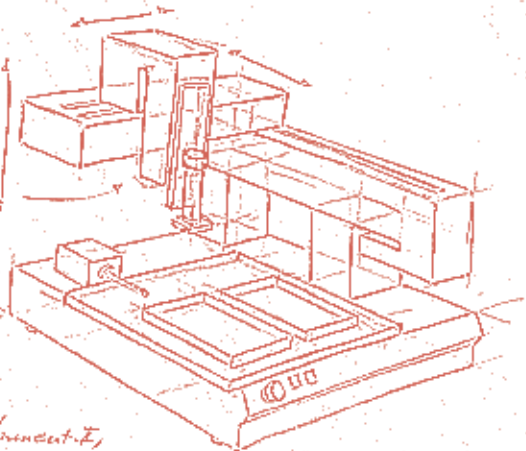
Doreen Wüstenhagen
 Phone +49 331 58187-322
doreen.wuestenhagen@izi-bb.fraunhofer.de

- 1 CHO cells from a high cell-density fermentation for the production of eukaryotic lysates
- 2 Schematic depiction of a dialysis system for cell-free protein synthesis

DEPARTMENT OF BIOANALYTICS AND BIOSENSORS

Phloga Instrument II

Phloga



Instrument II



DR. EVA EHRENTREICH-FÖRSTER

Highlights and challenges in the 2015 reporting year

For the most part, the department's range of services comprises complete problem solutions for analytical matters: From biological, biochemical or purely chemical sampling through to minimally required preparation, the selection of suitable methods from a large instrumental pool, besides analyzing, evaluating and handling data in line with constant quality controls in a short period of time.

In the 2015 reporting year, we also successfully focused our work on several niche business areas. For example, a project funded by the Federal Ministry of Food and Agriculture was commenced, which aimed to reduce multiresistant, pathogenic bacteria in dairy production. This includes, among other things, the use of antimicrobial peptides to fight bacterial infecting agents in biofilms. Moreover, a rapid test is to be developed to detect pathogens in milk. The department is also focusing its attention on the area of nutritional research together with the German Institute of Human Nutrition (DIfE) in the NutriAct competence cluster.

The successful out-licensing and negotiations with other interested parties in the field of antimicrobial peptides also shows that we are on the right track with our patent strategy. On the back of the PILOT project conducted by the State of Brandenburg, new technologies were able to be established in the department, which can be used immediately for new research and development projects.

Thanks to our competencies in process engineering, we were able to generate various industry contracts in the reporting year in the areas of sensor technology and process analytics. Over the past few years, as a result of our trade fair presence, we were able to spot a growing interest in the use of test strips as analytical tools within the biotechnological and medical engineering industry. We successfully and comprehensively managed to expand this field in 2015 and create additional interfaces with industry. In addition, we were able to commence with a project funded by the diagnostics competence network which aims to develop a lateral flow test for the detection of immunosuppressive agents.

Building on many years of preliminary work on metabiobanks such as P2B2 and CRIP (www.crip.fraunhofer.de), the BRICC workbench concept was developed, underpinned with an international workshop in April 2015 and published as a white paper (www.bricc.fraunhofer.de). Forming the basis of the

BRICC workbench, the Fraunhofer Metabiobank was restructured in the reporting year and will be available online from 2016 at www.metabiobank.fraunhofer.de and www.metabiobank.de.

Outlook over the department's key tasks and plans for 2016 and beyond

The business units seen to be especially promising in the reporting year and the related competencies and technologies will be further expanded and revised in 2016. This includes the services we offer as a reference laboratory, which have already been taken up by customers, e. g. for spotter equipment. Among other things, a planning session will be held in this regard as part of a joint workshop together with industry representatives in April 2016. Besides sharing information and experiences, the workshop also aims to pinpoint common goals and synergies. This will, once again, give us the opportunity to demonstrate from the very beginning the proximity between our application-oriented research and the user.

Competencies / technologies in the department

- Producing specific, functionalized surfaces
- Characterizing surfaces
- Dispensing (bio)molecules on functionalized surfaces
- Carrying out thermodynamic and kinetic analyses of interactions
- Developing specific assays and sensors
- Generating prokaryotic cDNA banks
- Selecting specific epitopes of bacterial pathogens
- Developing rapid tests for germs (swab test, "lateral flow" strategies)
- Finding user-friendly solutions for setting up metabiobanks
- Integrating existing biobanks into available metabiobank portals
- Customizing AMPs
- Developing bioinspired receptors

Contact

Dr. Eva Ehrentreich-Förster
Head of department
Phone +49 331 58187-203
eva.ehrentreich-foerster@izi.fraunhofer.de



UNITS

Microarray and Sensor 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 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.

Contact

Dr. Eva Ehrentreich-Förster
Phone +49 331 58187-203
eva.ehrentreich-foerster@izi.fraunhofer.de



Biomarker Validation and Assay Development Unit

The unit develops specific assays to validate biomarkers and adapt assays. In order to selectively immobilize biomolecules on a variety of surfaces such as microtiter plates, slides or membranes, the unit has a variety of spotting and dispensing techniques and can select the best one for each specific problem. All kinds of interactions can also be characterized on the basis of kinetic and thermodynamic measurements. Applications include system biology projects, the kinetic analysis of antibodies and the development of point-of-care applications e. g. for drugs and serum screening.

Contact

Dr. Harald Seitz
Phone +49 331 58187-208
harald.seitz@izi-bb.fraunhofer.de





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.

Contact

Dr. Markus von Nickisch-Roseneck
Phone +49 331 58187-207
markus.nickisch@izi-bb.fraunhofer.de



Metabiobanks CRIP Unit

The unit develops ICT infrastructure for 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 metabiobanks, 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.

Contact

Dr. Christina Schröder
Phone +49 331 58187-227
christina.schröder@izi-bb.fraunhofer.de



Dr. Oliver Gros
Phone +49 331 58187-227
oliver.gros@izi-bb.fraunhofer.de

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.

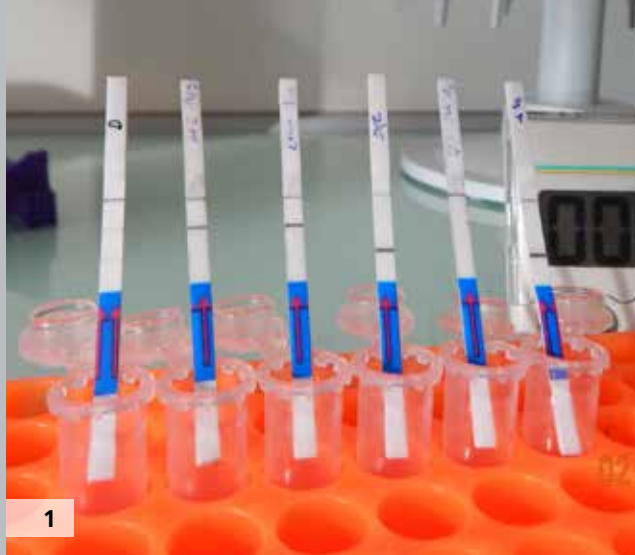
Primarily, aptamers are short, single-stranded DNA and RNA molecules with the particular feature of binding high-affine and high-specific targets such as antibodies. The very broad capabilities of aptamers as binding molecules are used in analytical, diagnostic and therapeutic applications.

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.

Contact

Dr. Marcus Menger
Phone +49 331 58187-316
marcus.menger@izi-bb.fraunhofer.de





PROJECT EXAMPLES

Apparatus-free “lateral flow detection” of pathogens

The on-site diagnosis of pathogens still poses a major challenge to diagnostics. In practice, however, these types of rapid tests are difficult to implement in the case of complicated analyses. In order to be applied economically, the manual and device-related outlay for such tests has to be kept very low. At the same time, sensitivity and specificity are to be just as analytical as in the established laboratory processes.

The developed test systems are used in the field of rapid diagnostics, also referred to as point-of-care testing (POCT), and combine sensitive and specific DNA amplification with the established technologies from “lateral flow” test strips. The first thing to happen is the isothermal amplification of a precisely defined section of the DNA strand. The method is analogous to PCR but with the added advantage that it can be conducted completely free of instruments. Through the use of modified primers in the reaction, the pathogens can be analyzed on the test strips, rendering any further steps unnecessary. A sudden change in color on the test strip indicates the existence of pathogenic germs or parasites. All that is required to evaluate the test is the naked eye; no special apparatus is required, meaning that the evaluation can also be carried out by laypeople. The methodology is comparable, for example, to that of pregnancy or drug test strips. Test strips used for such evaluation can be produced in house at a low cost and, moreover, can be used as open platforms in other test systems without the need for modification.

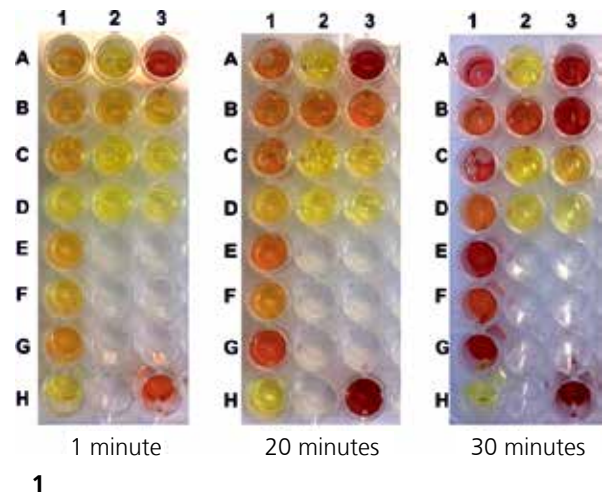
The high sensitivity of the assays was able to be demonstrated in trials, also with clinical isolates and under real-life conditions. Closely related species were able to be successfully and precisely differentiated. The findings demonstrate a diagnostic efficiency comparable to that of established laboratory tests, with significantly less outlay and a shorter processing time of less than 20 minutes. In addition, so-called multiplexing – the simultaneous amplification of several sequences in one reaction – is also possible. This differentiates between pathogens and apathogenic germs, and/or facilitates the more precise characterization of pathogens (e. g. resistances to antibiotics, toxin producers, subtyping) in just one test.

Depending on what is required, this mobile, analytical tool can be modularly adjusted to a specific, diagnostic issue for the simple, device-free detection of nucleic acids. Additional areas of application include environmental, food and agricultural analytics as well as in further investigations in which a quicker, on-site test would offer clear advantages.

Contact

Dr. Markus von Nickisch-Roseneck
Phone +49 331 58187-207
markus.nickisch@izi-bb.fraunhofer.de

1 *Lateral-flow test strips allow a robust and straightforward rapid diagnosis*



On-site detection of antibiotic resistances (extended spectrum beta-lactamase (ESBL) test)

Since the industrial production of antibiotics began, antibiotic resistances have constantly increased compared with natural background pollution, also in the environment.

In particular, the widespread use of antibiotics in agricultural animal husbandry, especially with regard to poultry and calf fattening, has come under criticism due to the associated risk of resistant pathogens emerging. In human medicine, too, the effectiveness of antibiotic use is being questioned and increasingly criticized. Being able to quickly assess exposure to resistant germs is therefore vital in many fields linked to our daily lives. The current state of technology used to identify these pathogens demands complex, sophisticated procedures. On-site tests that can be carried out quickly and without a great amount of technology can help improve consumer safety. The rapid test developed here for the biochemical detection of resistant germs is based on the principle of substrate cleavage, whereby a shift in the adsorption maximum occurs with the connected dye. The test result is determined by a visually distinctive change in color from yellow to red.

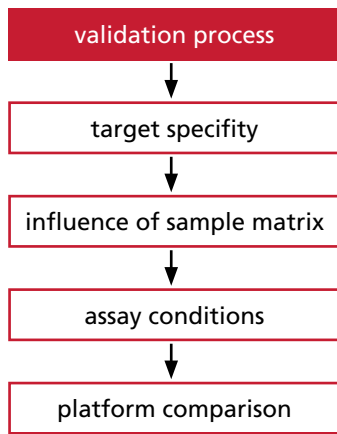
Resistance monitoring for the realistic use in diagnostic, environmental, water and food monitoring

- Sudden change in color from yellow to red seen with the naked eye
- Rapid test within 30 minutes
- Methods not reliant on a laboratory
- Handheld format
- Assessment of germ load with a Yes / No response
- Substrate as kit or strip test
- No germ specification
- Individual resistance mechanisms possible by adding special inhibitors to the substrate

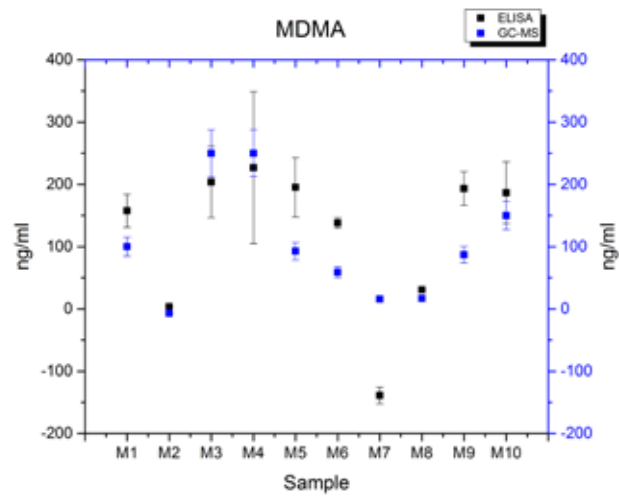
Contact

Dr. Eva Ehrentreich-Förster
 Phone +49 331 58187-203
 eva.ehrentreich-foerster@izi.fraunhofer.de

- 1 *Depiction of an antibody validation scheme. The steps are carried out one after the other. This process is independent of whether a primary drug-specific or secondary detection antibody has been examined.*
- 2 *Aim of the project: To detect up to nine different drugs in parallel.*



1



2

Immunoassay for quantitative detection of drug abuse in serum

The aim of this project was to enable the simultaneous detection of nine different illegal drugs based on immunological processes. Current standard procedures include ELISA (enzyme-linked immunosorbent assay) and gas chromatography coupled with mass-spectrometry (GC-MS). Both methods are characterized by specific features. ELISA depicts an easy protocol with relatively inexpensive equipment, but often suffers from unspecific binding due to the application of antibodies and generally only supplies qualitative data. GC-MS is well-known for its specificity and sensitivity, however it requires expensive measuring devices and elaborate sample preparation.

An assay is to be developed which combines the benefits of both standard procedures, i. e. it should be easy and inexpensive while demonstrating specific and sensitive quantification. To this end, specific drug detection was established based on ELISA which even remains stable when various drugs, metabolites or antibodies are present. In order to establish the simultaneous detection of various drugs, the approach was transferred to a microarray format, which entailed strict quality controls. Antibody validation was carried out using Western Blot and ELISA. A competitive ELISA was established for quantification purposes. Appropriate controls were included to determine the background and unspecific binding besides a control experiment. Furthermore, miniaturization onto a microarray was carried out with the aid of a non-contact microdispensing system.

At present, specific antibodies have been found for three drugs and the respective quantification was carried out. Validated antibodies are characterized by the absence of unspecific binding to serum and other components forming

part of the experiment. Synthesized serum samples or samples made available by the LKA Berlin were able to be analyzed with satisfactory coincidence with given values. Detection limits and reproducibility meet the requirements of the GTFCh (German Society for Toxicological and Forensic Chemistry).

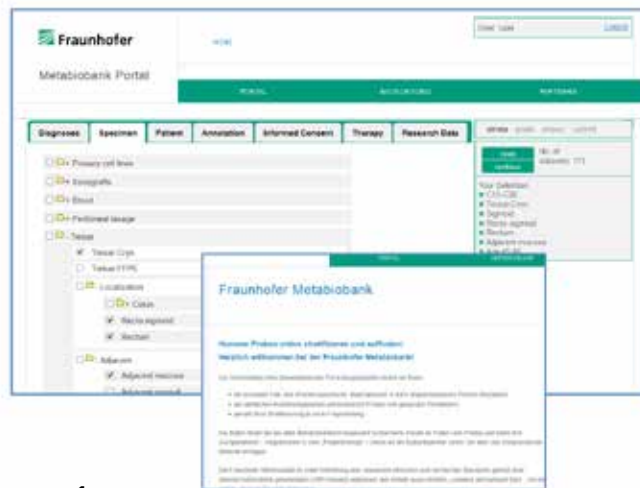
The presented approach enables a sensitive and reliable detection method for drug abuse in serum. Additional validation studies will be conducted in future for the remaining drugs and the miniaturized approach using microarrays will be advanced.

Contact

Dr. Harald Seitz
 Phone +49 331 58187-208
 harald.seitz@izi-bb.fraunhofer.de

1 *Depiction of an antibody validation scheme. The steps are carried out one after the other. This process is independent of whether a primary drug-specific or secondary detection antibody has been examined.*

2 *Comparison of ELISA (black) and GC-MS (blue) measurements. Concentration is plotted for each sample. A calibration line is used to calculate concentrations for ELISA. The GC-MS data were supplied by the Berlin State Office of Criminal Investigations (LKA).*



Fraunhofer Metabiobank

Biomarker-based medical research projects as well as research in the field of personalized medicine in general are always contingent on the availability of human specimens obtained using standardized methods. Alongside various biomaterials such as blood or tissue from patients, samples are also required from healthy donors. On the one hand, such specimens have to be thoroughly characterized or annotated using a large data set; on the other hand, they must be plentiful enough that the research findings can be statistically analyzed. Timely accrual of such highly annotated and statistically relevant sample sets often needs to be secured not from one hospital or biobank alone, but through cooperations between different biobanks.

The Fraunhofer Metabiobank enables researchers to simultaneously search a number of biobanks and countries and locate highly annotated human samples from all of the involved hospitals and biobanks on a case-by-case and sample-by-sample basis. Once the user has selected a disease in the web-based search interface for which they require samples and respective data, a set of appropriate search parameters will be actively suggested. After selecting the applicable parameters for a certain project, the number of available samples (a “statistical group”) will then be shown. If this group is large enough, the user can forward a request online to the biobanks in possession of the appropriate material and a project can be agreed between the parties.

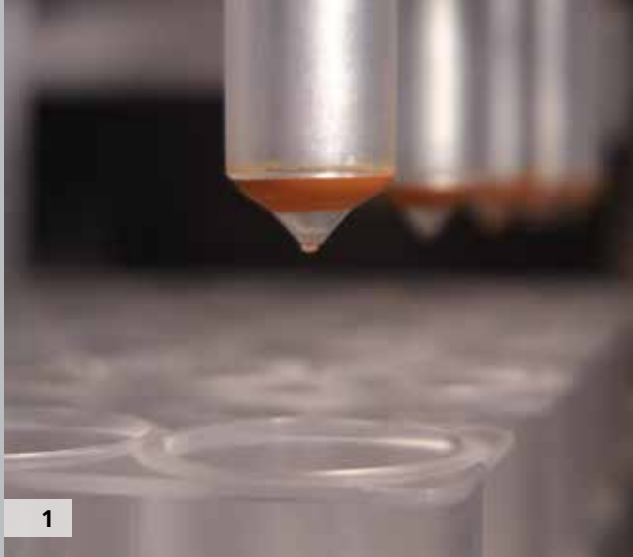
This sample-specific online search (“stratification”) gives the Fraunhofer Metabiobank a unique selling point, allowing it to stand out from the masses of national and international biobank registers and portals. The Metabiobank is based on an anonymous dataset that has breadth, depth and can be extended flexibly at any time, as well as on a widely spread database architecture developed using the CRIP toolbox (the

software portfolio of the Metabiobanks CRIP Unit). It complies with the CRIP Privacy Regime, which provides an internationally secure, ethical, legal and contractual basis for handling patient data in line with the data protection law. As of 2016, the Fraunhofer Metabiobank will be available online at www.metabiobank.de and www.metabiobank.fraunhofer.de.

Contact

Dr. Oliver Gros
 Phone +49 331 58187-515
oliver.gros@izi-bb.fraunhofer.de

1 The Fraunhofer Metabiobank allows human sample data to be sought across different biobanks and countries



APTACHIP – Aptamer array chip for real-time quantification of monoclonal antibodies in bioreactors

The manufacture of medicines and active agents in bioreactors with the aid of cell cultures is becoming more and more common. The efficacy, and thus success, of these processes is dependent on the chemical composition of the culture media and physical parameters, for example temperature, pH value or oxygen concentration. Physical parameters can already be observed well on bioreactors using online methods; nutrients or proteins, however, can only be efficiently detected in culture media at present using offline methods, e. g. HPLC (High Pressure Liquid Chromatography), capillary electrophoresis and labeling-based processes (fluorescence, chemiluminescence) or immunoassays (ELISA).

A monitoring procedure using online in situ sensors operated inside the bioreactor would facilitate the dynamic control of the culture medium and thus signify a huge improvement in the efficiency of cell production and quality control. In addition, a label-free procedure would entail lower costs and prevent cytotoxic materials (such as fluorescent dyes) from being introduced to the cell culture.

The APTACHIP project aims to develop an aptamer-based biosensor (aptasensor) which would allow the real-time measurement of biochemical species in the growth medium of a bioreactor. Aptamers – single-strand nucleic acids – function here as highly specific binding molecules for biochemical species and are employed in a label-free, ring resonator based detection procedure. In order to demonstrate functionality (proof of principle), the aptasensor is first adjusted to detect monoclonal antibodies.

This type of biosensor can be used for the quantitative detection of different chemical species in future and can, first and foremost, be used to optimize the nutrient supply of a bioreactor. Besides appealing to the bioreactor market, the aptasensor concept should also be adjusted for use in the areas of water control, food safety and industrial process control through additional research and development work upon conclusion of the project.

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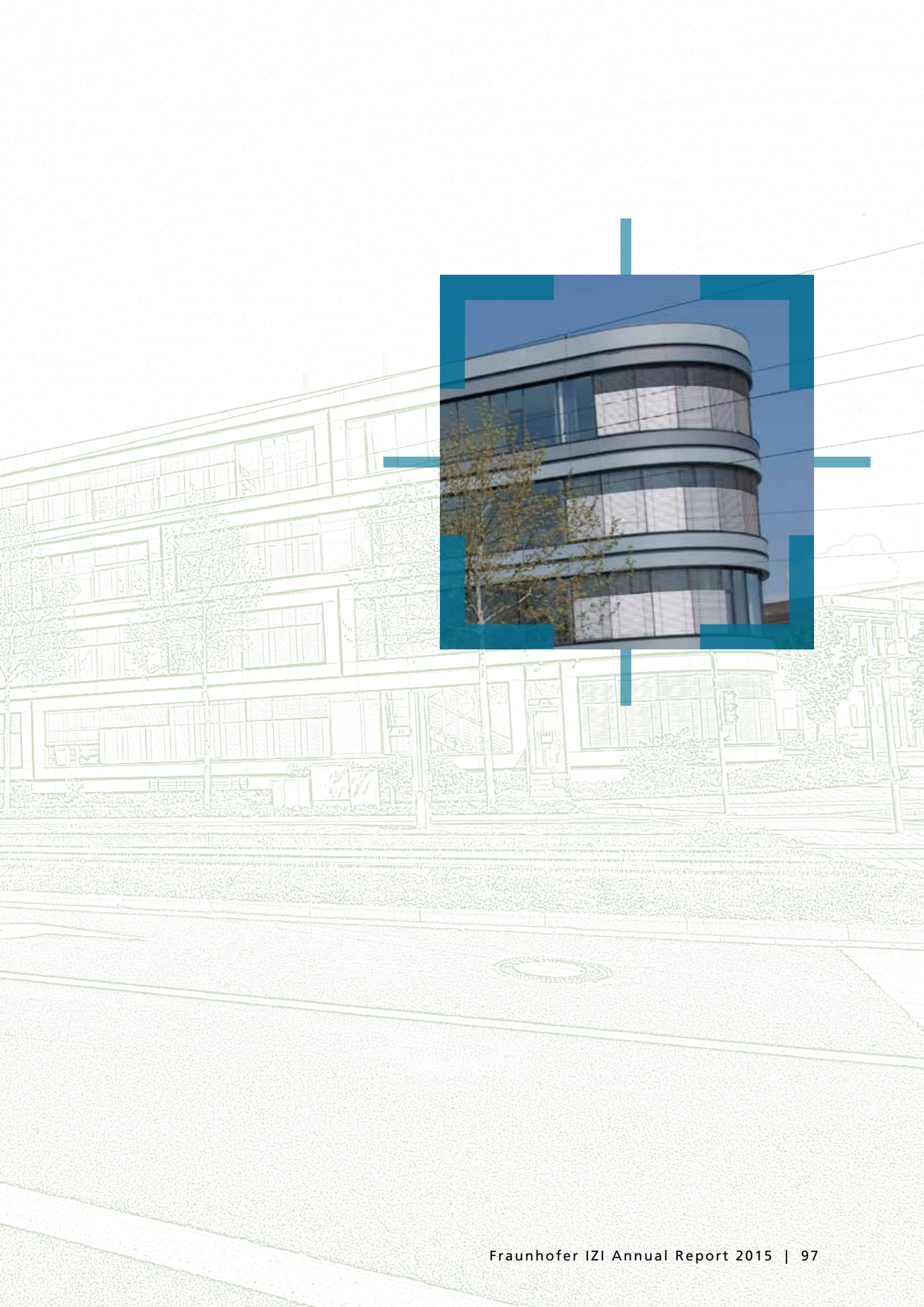
Dr. Marcus Menger
Phone +49 331 58187-316
marcus.menger@izi-bb.fraunhofer.de



1 Transfer of magnetic particles in the magnetic robot during aptamer generation

CENTRAL FACILITIES AND SERVICES







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.

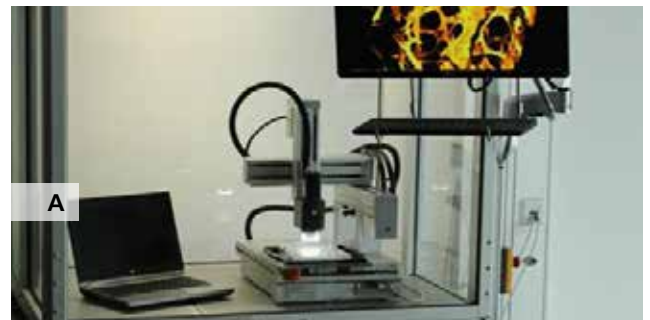
State-of-the-art equipment allows biological and medical issues to be handled in an interdisciplinary manner. BNAL provides research and development services from fundamental biomedical research by process development up to the development and validation of innovative technologies and system solutions.

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 within 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 analysis of cells and beads in suspension, e. g. for 3D characterization of complex biological structures and precise measurements of cell surface properties.



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

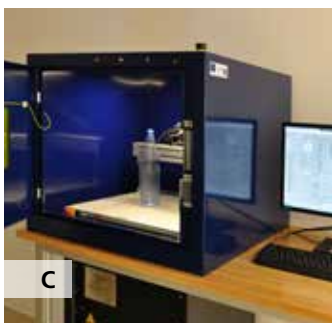
Micro-dosing unit (E): Automated dosing of tiny quantities of liquid (e. g. biological or organic solutions, or solutions containing nanoparticles) on a broad range of different surfaces for the production of microarrays.

Surface sterilization and modification

Electron beam dosimeter (C): Dose measurement of high-energy radiation (e. g. gamma or electron radiation) on bent 3D free-form surfaces.

System for electron irradiation of surfaces (D): Sterilization of packaging / surfaces, inactivation of microorganisms for vaccine production or targeted adjustment of material properties by means of electron irradiation.

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



Contacts

Dr. Michael Szardenings
 Coordinator of the Bio-Nanotechnology Application
 Laboratory (Fraunhofer IZI)
 Telefon +49 341 35536-2805
 michael.szardenings@izi.fraunhofer.de

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.

Dr. Jörg Opitz
 Coordinator of the Bio-Nanotechnology Application
 Laboratory (Fraunhofer IKTS)
 Telefon +49 351 88815-516
 joerg.opitz@ikts.fraunhofer.de

CENTER FOR EXPERIMENTAL MEDICINE (TEZ)

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

Moreover, the institute has access to one of the most 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

- Small animal endoscope
- Blood cell meter
- Surgical microscope
- Stereotactic manipulation
- Temperature control during operations

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

Contact

Dr. Thomas Grunwald
 Head of the Centre for Experimental Medicine
 Phone +49 341 35536-5423
 thomas.grunwald@izi.fraunhofer.de

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



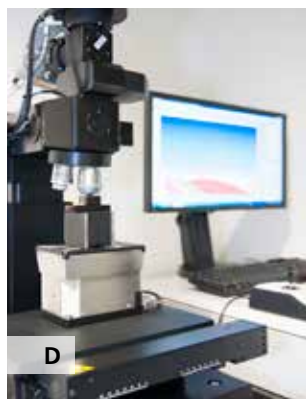
Agilent microarray scanner (C)

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



C



D

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.



E

Contacts

Prof. Dr. Friedemann Horn
 Head of RIBOLUTION Biomarker Center
 Phone +49 341 35536-3305
friedemann.horn@izi.fraunhofer.de

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

Dr. Christoph Sachsenmaier
 RIBOLUTION Business Development
 Phone +49 159 04158254
christoph.sachsenmaier@ribolution.org



F

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) (B)

- 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)

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

Fluorescence and bioluminescence imaging for small animals

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

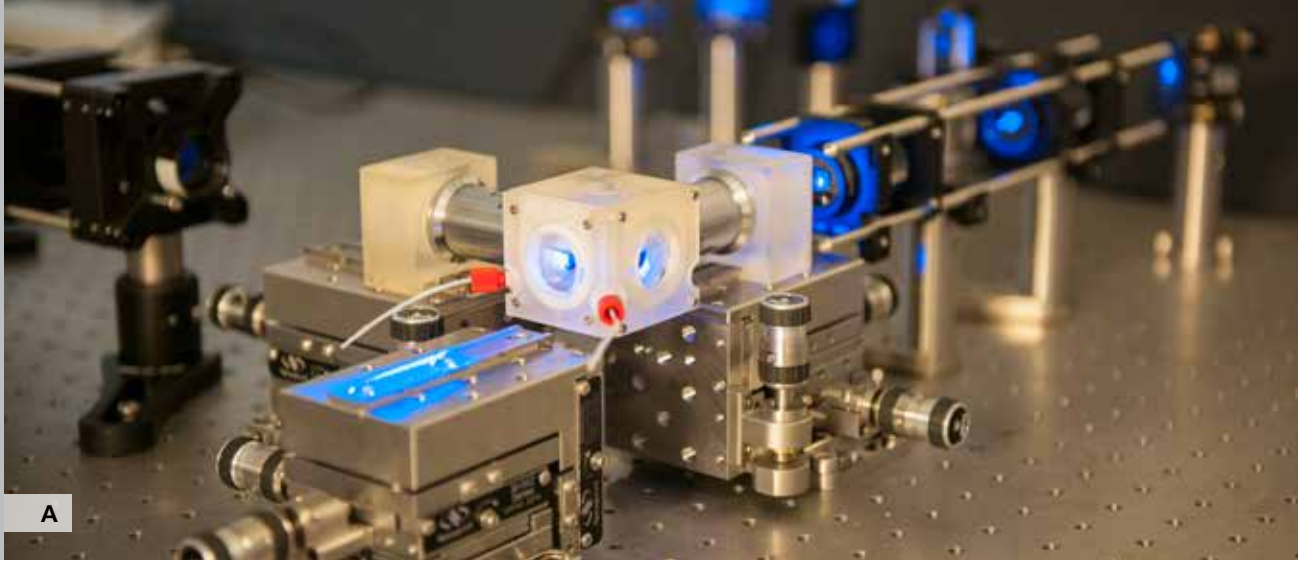
Bedside imaging for small animals

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

In vitro / ex vivo imaging

Confocal laser scanning microscope with live cell imaging

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



A



Light sheet microscopy (A)

- 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

- 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

Individual image evaluation and analysis

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

Contacts

Dr. Alexander Kranz (Image acquisition)
Phone +49 341 35536-5403
alexander.kranz@izi.fraunhofer.de

Prof. Dr. Ulf-Dietrich Braumann (Image analysis)
Phone +49 341 3076-1299
ulf-dietrich.braumann@izi.fraunhofer.de



QUALITY MANAGEMENT

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

GLP – “Good Laboratory Practice”

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

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

Contact

Dr. Jörg Lehmann | Head of Department of Therapy Validation | Phone +49 341 35536-1205 | joerg.lehmann@izi.fraunhofer.de

GMP – “Good Manufacturing Practice”

The Fraunhofer IZI maintains three GMP-compliant clean room facilities. Through the flexible design, the facilities are especially attractive for new biotechnology companies that seek to bring newly developed medicinal products into clinical application via clinical trials. The facilities are divided into different independent suites. Each has its own grade C clean rooms (preparation), own air locks from grade C to B (personnel and materials transport) and two grade B rooms (aseptic manufacturing). The clean room grade A is provided via laminar airflow cabinets that are installed in the B-rooms. The available clean room suites are specialized in conducting processes for manufacturing human autologous and/or allogeneic cell-based therapeutics (advanced therapy medicinal products). In addition to the clean rooms and the technical infrastructure, the Fraunhofer IZI offers assistance for the set-up and validation of GMP-compliant manufacturing processes as well as for obtaining a manufacturing authorization according to § 13 of the German Drug Act (AMG).

Contact

Kati Kebbel | Head of Department of GMP Cell and Gene Therapy | Phone +49 341 35536-9712 | kati.kebbel@izi.fraunhofer.de



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Why are GMP and GLP important?

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

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

GCP – "Good Clinical Practice"

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

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

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

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

Contact

Prof. Dr. Frank Emmrich | Director |
Phone +49 341 9725-500 |
frank.emmrich@izi.fraunhofer.de

STRATEGY PROCESS



INTRODUCTION / CONCLUSION

Fraunhofer IZI is set to face various challenges in the future, some of which as a result of stronger international competition and the extremely dynamic development of relevant technologies and markets. In order to remain successful here, it is necessary to carry out a detailed analysis of the markets and customers relevant to Fraunhofer IZI and the institute's position in this respect, as well as to initiate adaptation processes from a technological and structural point of view. This self-evaluation was carried out as part of the so-called Fraunhofer strategy process, which was successfully conducted at the institute over the past two years.

Process operation

The strategy process conducted by the Business Development department involved all management levels and was, for the most part, oriented towards the specifications set by Fraunhofer's central administration. The process was kicked off with a detailed inventory control of the technologies and products either available at the institute or currently being developed. The data collected here were then detailed further and analyzed in close collaboration with all of the units at the institute. Based on the outcome of these analyses, several workshops were then organized with managers from Fraunhofer IZI. Besides identifying and analyzing relevant business units and core competencies at the institute, these events were also concerned in particular with discussing and determining strategies for their future advancement. We set ourselves a number of highly ambitious goals here which will form an important basis for the further successful development of Fraunhofer IZI in the years to come. Presenting and defending these outcomes and goals as part of a multi-day audit at Fraunhofer IZI in November 2015 was a significant highlight of the strategy process. To this end, an expert panel was appointed by the Fraunhofer central administration made up of eight individuals, including senior representatives of renowned pharmaceutical and biotechnology companies and of several research facilities.

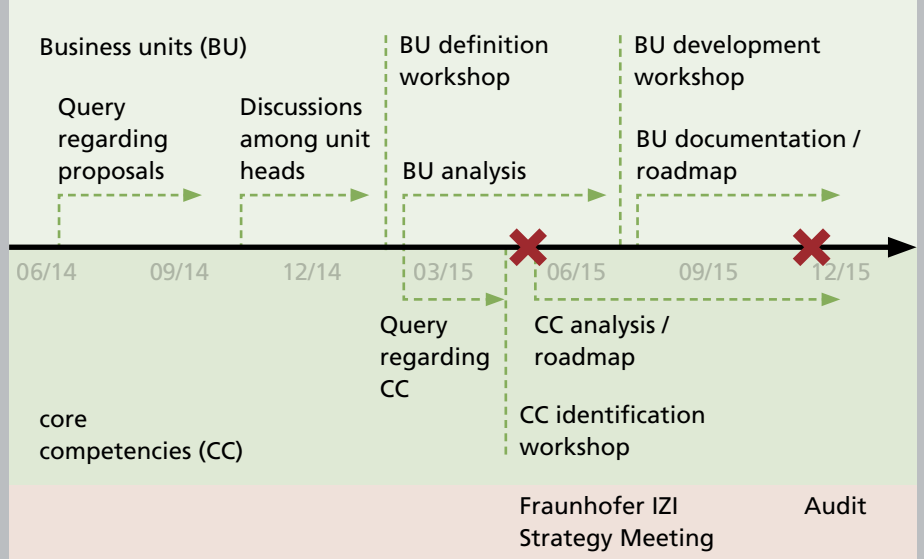
Outcome

Formulating strategic goals for the continued, successful development of the institute and defining respective, specific measures were identified as particularly important objectives of the strategy process. These measures should, in particular, contribute to strengthening the institute's unique features and fulfil the development potential identified in the strategy process.

The institute sees particular future potential in the intensified development of proprietary cell therapy concepts based on new scientific knowledge from immuno-oncology as well as in the automation of procedures to manufacture and monitor the quality of cell-based therapeutic agents. A further strategic objective lies in the achievement of synergy effects and innovation potential with regard to the diverse and extremely successful technological developments in the area of diagnostics at the various sites of the institute. In addition, Fraunhofer IZI will offer more services in the field of preclinical and clinical therapy validation and, in this vein, also further intensify its cooperation with local and regional partners.

The evaluation of the overall process and of the institute's strategic positioning was carried out in the form of an audit conducted by external consultants. All of the reports drawn up by the auditors attest to the highly professional conduct of the strategy process and related audit, as well as to the optimally selected strategic orientation and related objectives at Fraunhofer IZI. The analyses and objectives summarized in the strategy report and discussed during the strategy audit were appraised as being extremely logical and free of contradictions. The auditors were of the opinion that they should be implemented.

Furthermore, several auditors made additional suggestions regarding particular market opportunities and specific technological development potential. These recommendations will be discussed and analyzed at various levels within the institute. Their subsequent, prompt implementation will contribute significantly to the continued successful development of the institute.



BUSINESS UNITS

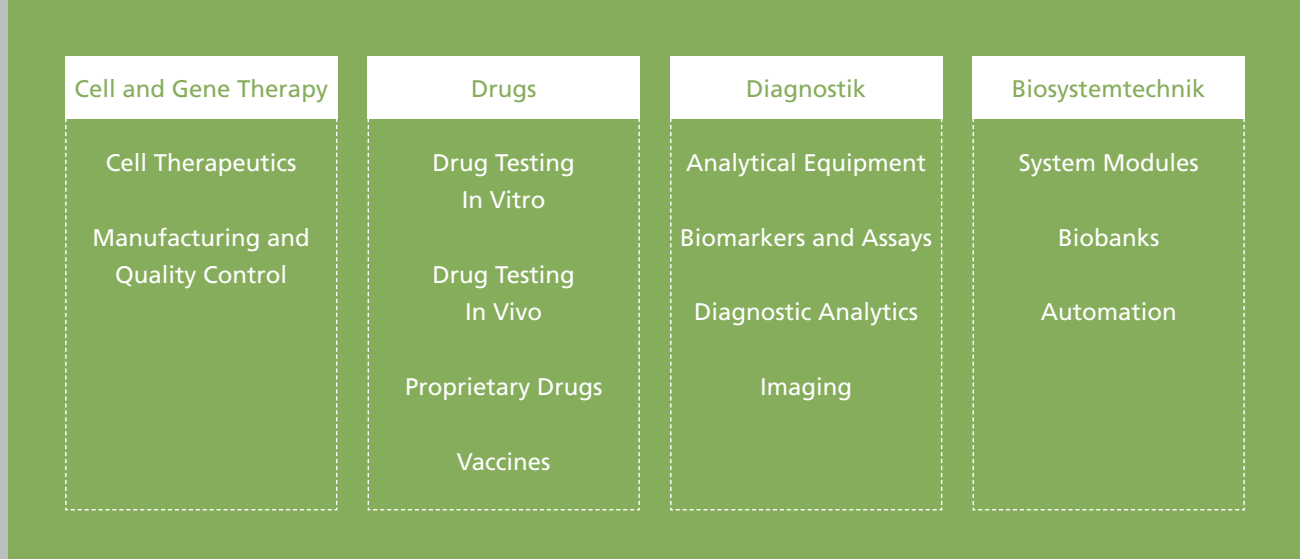
From a market perspective, a business unit is defined as a compilation of services rendered for specific groups of customers within a defined technological area which gives rise to customer value. Business units therefore form a basis for strategic planning within the context of market development and were identified by pooling and analyzing connected services and corresponding development activities as outlined below. Resulting from this, four business units were identified and described as part of the strategy process, which were further subdivided into additional business fields.

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.



Diagnosics 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. As part of the strategy process, six core competencies were identified at Fraunhofer IZI, which can be divided into indication-specific and technical core competencies depending on their nature. This approach aims both to take stock of the core competencies currently available at Fraunhofer IZI and to set the course for the development of new technologies and products.

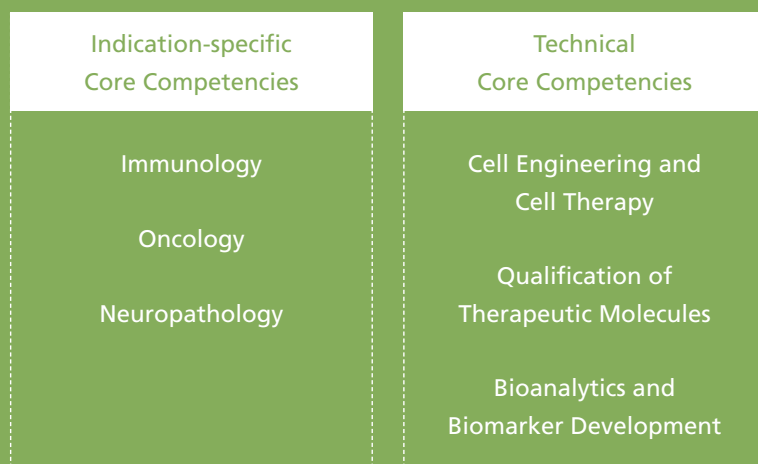
Indication-specific core competencies

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

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

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

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



Technical core competencies

The core competence **Cell Engineering and Cell Therapy** is one of the institute's most important core competencies and has been ever since Fraunhofer IZI was established, as clearly expressed in the institute's name. Over the past few years, comprehensive expertise and an extensive special infrastructure have been established for the commissioned testing and manufacture 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.

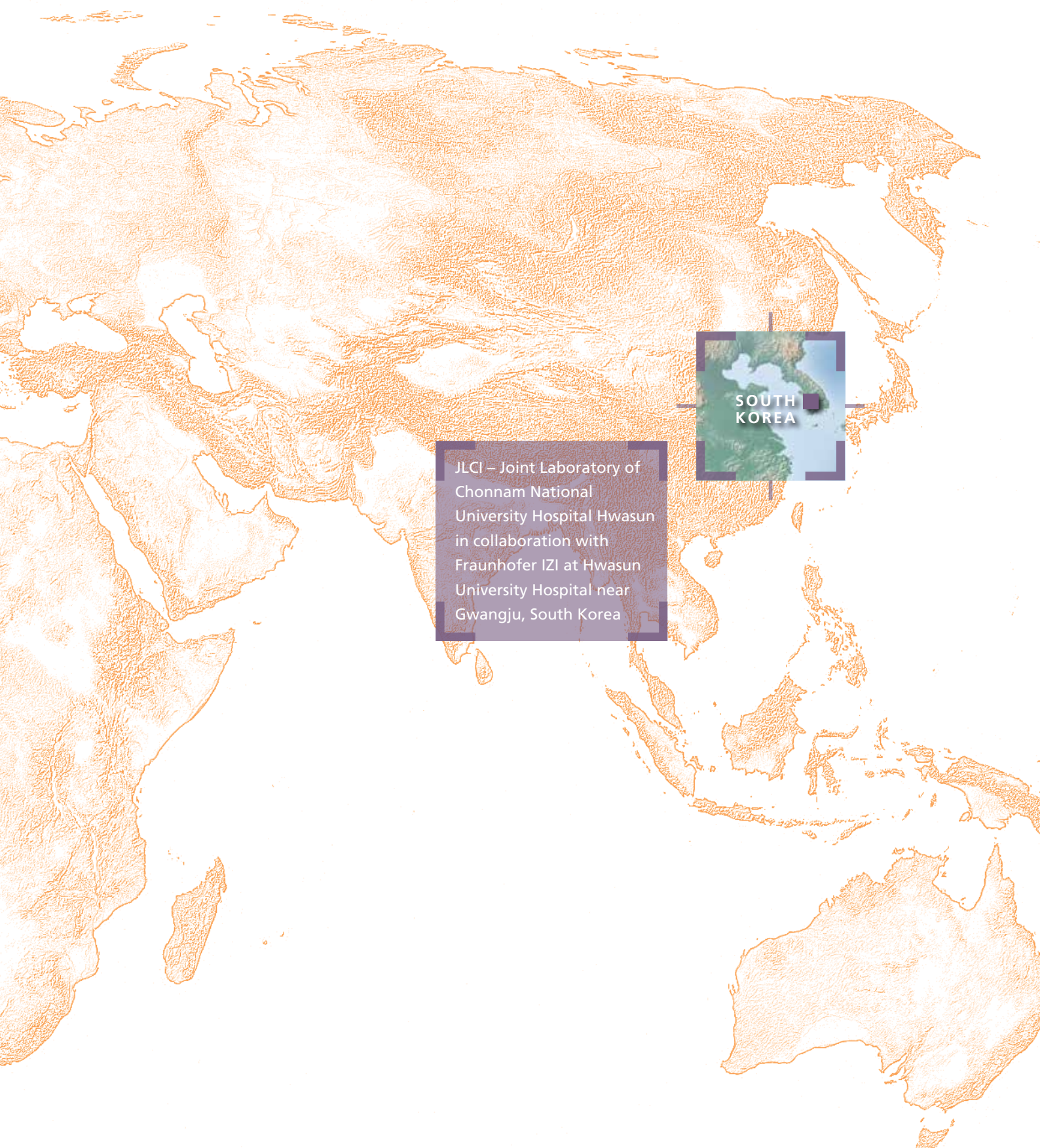
LOCATIONS



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



Fraunhofer Institute for Cell Therapy and Immunology, Headquarter in Leipzig (Saxony), Locations in Rostock (Mecklenburg-Western Pomerania), Halle (Saale) (Saxony-Anhalt) and Potsdam-Golm (Brandenburg)



JLCI – Joint Laboratory of Chonnam National University Hospital Hwasun in collaboration with Fraunhofer IZI at Hwasun University Hospital near Gwangju, South Korea





LEIPZIG HEADQUARTERS

Usable area: 8 749 m²

Employees: 362

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

Address: Perlickstraße 1, 04103 Leipzig, Germany

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 900 m².

Management



Prof. Dr. Frank Emmrich

Director

Phone +49 341 9725-500

frank.emmrich@izi.fraunhofer.de



Patric Nitz

Administration

Phone +49 341 35536-9205

patric.nitz@izi.fraunhofer.de





BIOANALYTICS AND BIOPROCESSING BRANCH OF INSTITUTE IN POTSDAM-GOLM

Usable area: 4 096 m²

Employees: 106

Focal areas: Biotechnology, bioproduction, bioanalytics, automation

Address: Am Mühlentberg 13, 14476 Potsdam-Golm, Germany

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



Prof. Dr. Hans-Ulrich Demuth

Director (executive)

Phone +49 345 131428-00

hans-ulrich.demuth@izi.fraunhofer.de



Prof. Dr. Ulrich Buller

Director

Phone +49 331 58187-100

ulrich.buller@izi-bb.fraunhofer.de



Katja Okulla

Administration

Phone +49 331 58187-108

katja.okulla@izi-bb.fraunhofer.de



DEPARTMENT OF DRUG DESIGN AND TARGET VALIDATION IN HALLE (SAALE)

Usable area: 1 300 m²

Employees: 56

Focal areas: Biochemistry, pharmacology, drug development, analytics

Address: Weinbergweg 22, 06120 Halle (Saale), Germany

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



Prof. Dr. Hans-Ulrich Demuth

Phone +49 345 131428-00

hans-ulrich.demuth@izi.fraunhofer.de



EXTRACORPOREAL IMMUNOMODULATION PROJECT GROUP IN ROSTOCK

Usable area: 700 m²

Employees: 27

Focal areas: Organ-supporting technologies, clinical trials

Address: Schillingallee 68, 18057 Rostock, Germany

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



Prof. Dr. Steffen Mitzner

Phone +49 381 494-2600

steffen.mitzner@izi.fraunhofer.de



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

The founding team at Fraunhofer IZI started looking for suitable Canadian cooperation partners back in 2011. On the back of these efforts, initial joint research projects were set up with McMaster University in Hamilton (Ontario, Canada). With approximately 29,000 students, the university is one of the leading universities in Canada, with exceptional strengths in the fields of health sciences, engineering and natural sciences.

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

In the first few months after being established, the project center already managed to attract significant funding on both the German and Canadian sides, as well as a series of industry cooperation projects including FedDev funding in the sum of approx. 12 million Canadian dollars for the construction of a joint research building in McMaster Innovation Park. The building is due to be finished at the start of 2017. Laid out over a usable space of approx. 2,000 m², it will provide joint German-Canadian research units and research subsidiaries of industrial companies with an outstanding, state-of-the-art research infrastructure.

Contact



Dr. Thomas Tradler

Managing Director
Phone +49 341 35536-9305
thomas.tradler@izi.fraunhofer.de



Christopher Oelkrug, M.Sc.

Director
Phone +49 341 35536-3121
christopher.oelkrug@izi.fraunhofer.de



JLCI – JOINT LABORATORY OF CHONNAM NATIONAL UNIVERSITY HOSPITAL Hwasun IN COLLABORATION WITH FRAUNHOFER IZI IN GWANGJU, 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 cooperation work with external partners from science and industry in Asia. Among other things, the Ligand Development Unit at Fraunhofer IZI, headed up by Dr. Michael Szardenings, uses the fresh tumor tissue accumulating from the frequently performed operations to select tissue-specific peptides. Thereby a method was established which has already led to the first tumor-specific and in vivo validated peptide binders.

For the most part, the laboratory is managed in accordance with the standards and regulations set by the Fraunhofer-Gesellschaft, thus guaranteeing a common basis when dealing with patients 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. In the meantime, several delegations from Fraunhofer IZI have travelled to Korea for conferences and scientists have stayed there for up to two months. Similarly, 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.

Contact



Dr. Michael Szardenings

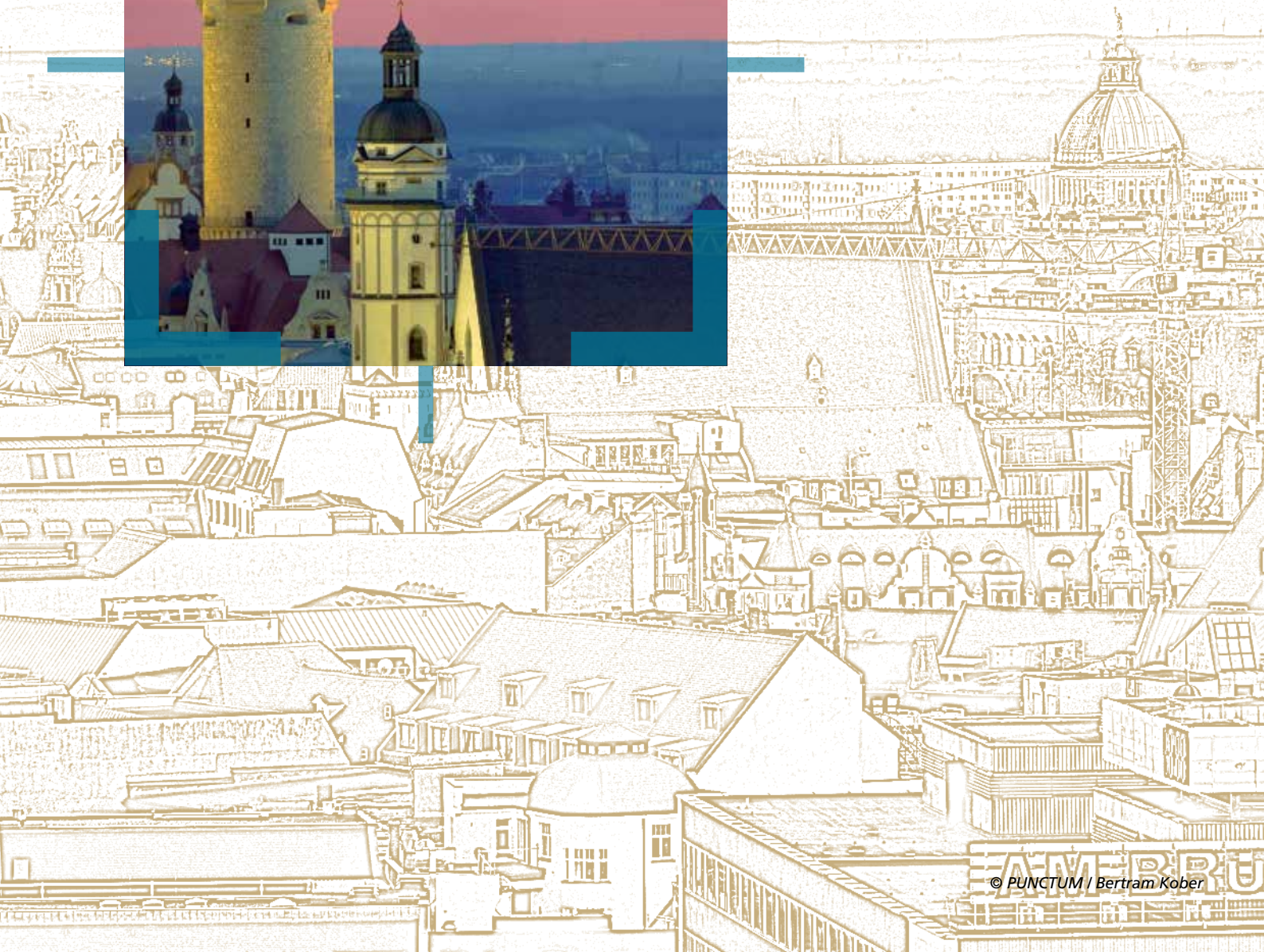
Phone +49 341 35536-2805
michael.szardenings@izi.fraunhofer.de



Il-Kwon Lee, Ph.D. ABD

Chonnam National University Hwasun Hospital, Genome Research Center for Hematopoietic Diseases
Phone +82 61 379 7640
ellerdin@chonnam.ac.kr

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.

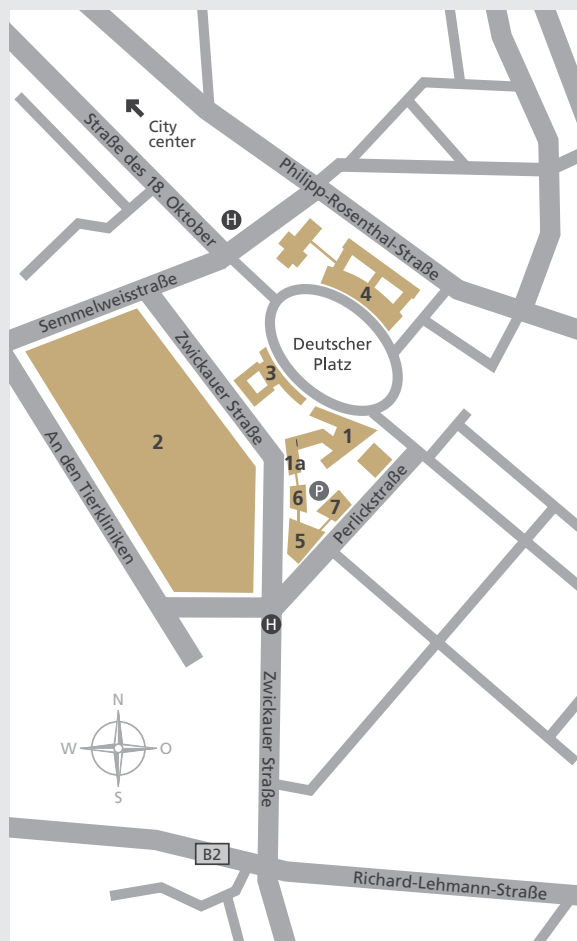
Thus, for example, students of business administration from the HHL have already been successfully involved in practical scientific projects with their development of business plans or marketing concepts. A particularly intensive cooperation connects the Fraunhofer IZI and the Institute for Clinical 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 Interdisciplinary Center for Bioinformatics (IZBI), the Center for Clinical Trials Leipzig GmbH (ZKS), the Institute for Clinical Immunology, the Center for Biotechnology and Biomedicine (BBZ), and the Max Planck Institute for Human Cognitive and Brain Sciences. Moreover, there are numerous interfaces with different special research areas that are located in Leipzig.



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).

Interdisciplinary Centre for Clinical Research (IZKF)
Liebigstraße 21 | 04103 Leipzig | www.izkf-leipzig.de

Center for Biotechnology and Biomedicine (BBZ)
Leipzig University | Center for Biotechnology and Biomedicine | Deutscher Platz 5 | 04103 Leipzig
www.bbz.uni-leipzig.de

University Hospital Leipzig AÖR
Liebigstraße 18 | 04103 Leipzig | www.uniklinik-leipzig.de

Heart Center Leipzig GmbH – University Hospital
Strümpellstraße 39 | 04289 Leipzig
www.herzzentrum-leipzig.de

Coordination Center for Clinical Trials Leipzig (ZKS)
Universität Leipzig | Härtelstraße 16–18 | 04107 Leipzig
www.kks.uni-leipzig.de

Interdisciplinary Center for Bioinformatics (IZBI)
Leipzig University | Härtelstraße 16–18 | 04107 Leipzig
www.izbi.uni-leipzig.de

Max Planck Institutes (MPI)
Max Planck Institute for Human Cognitive and Brain Sciences | Post office box 500355 | 04303 Leipzig | www.cbs.mpg.de

Max Planck Institute for Mathematics in the Sciences
Inselstraße 22 | 04103 Leipzig | www.mis.mpg.de

Max Planck Institute for Evolutionary Anthropology
Deutscher Platz 6 | 04103 Leipzig | www.eva.mpg.de

**Helmholtz Center for Environmental Research GmbH –
UFZ**

Permoserstr. 15 | 04318 Leipzig | www.ufz.de

Leibniz Institute for Surface Modification e.V.

Permoserstrasse 15 | 04303 Leipzig | www.iom-leipzig.de

**Association for the Advancement of the Health
Economics of the Region Leipzig (VGF) e.V.**

Deutscher Platz 5a | 04103 Leipzig | www.med-in-leipzig.de

Leipzig University

Ritterstraße 26 | 04109 Leipzig | www.uni-leipzig.de

Faculty of Medicine

Liebigstraße 27 | 04103 Leipzig | www.medizin.uni-leipzig.de

Faculty of Biosciences, Pharmacy and Psychology

Brüderstraße 32 | 04103 Leipzig

www.uni-leipzig.de/~biowiss

Faculty of Veterinary Medicine

An den Tierkliniken 19 | 04103 Leipzig

www.vmf.uni-leipzig.de

Leipzig University of Applied Sciences (HTWK)

Karl-Liebknecht-Str. 132 | 04277 Leipzig

www.htwk-leipzig.de

Graduate School of Management (HHL)

Jahnallee 59 | 04109 Leipzig | www.hhl.de

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 2014.

January 21, 2015: New Year's reception

Not long after the turn of the year, on January 21, 2015, the two Leipzig-based Fraunhofer Institutes IZI and MOEZ took the opportunity to reflect, take stock and look at what lies ahead. The third joint New Year's reception once again provided the many attending guests with a forum for sharing experiences face to face, discussing plans, making new contacts and maintaining old ones. The event was kicked off with a podium discussion on the current state of affairs with regard to the National High Performance Center Leipzig / Halle. This saw a continuation of the discussion started in summer 2014 and also outlined current developments. Professor Frank Emmrich (Fraunhofer IZI), Professor Andrea Robitzki (Leipzig University), Professor Thorsten Posselt (Fraunhofer MOEZ) and Professor Ralf Wehrspohn (Fraunhofer IWM) provided an overview of the project plans and expectations and also took questions from their attentive audience from politics, industry and science. The guests then spent the rest of the evening engaging in animated conversations and enjoying the relaxed atmosphere.

April 29, 2015: Ten-year anniversary of Fraunhofer IZI and inauguration of the third construction phase

Fraunhofer IZI had more than one reason to celebrate on April 29, 2015. A decade after being set up, it is fair to say that the institute has developed splendidly in the meantime. This is partly clear from the development of project, budget and staff numbers. Moreover, the research infrastructure has grown together with the institute, reflected in the fact that this date also marked the inauguration of the institute's third and (for the time being) final, new research building. After laying the foundation stone for the institute's first research building in September 2006, construction at the Alte Messe site in Leipzig is now complete.

300 guests with backgrounds in science, economics and politics came to take part in the festivities and take a look around the new building for the first time. The event was opened with welcome speeches from Uwe Gaul (State Secretary, Saxony's State Ministry for Science and the Arts), Wolfgang Tiefensee, who witnessed the foundation phase of Fraunhofer IZI first hand during his term as Mayor of Leipzig, Uwe Albrecht (Mayor and Councilor for Economic Affairs and Labor for the City of Leipzig), Professor Alexander Kurz (Fraunhofer-Gesellschaft Executive Board) and Professor Beate Schücking (Rector of Leipzig University).

In his laudation, Director Professor Frank Emmrich, a key player in founding the institute, first of all expressed his gratitude to everyone who had helped fund and support the project. "Special thanks also go to the City of Leipzig, which provided us with the premises in which we now research and work. The Leipzig Foundation for Innovation and Technology Transfer gave us additional support, particularly during the start-up phase, which was a difficult time for each institute."

July 10, 2015: 600 years of University Hospital Leipzig

University Hospital Leipzig celebrated its 600th anniversary in 2015. On July 10, 2015, the clinics and research institutes belonging to the faculty and university hospital came together with friends and partners and presented themselves to the general public with a medical adventure course.

On Augustusplatz, in the heart of the city, interactive activities, oversized organs, booths providing information on a broad range of illnesses and scientific research projects, and exciting short presentations gave diverse insights into research, theory and various patient topics.

As a long-standing cooperation partner, Fraunhofer IZI was also present, familiarizing interested visitors with the principles of cell biology and cell therapeutic drugs.



1



2

September 29–30, 2015: Workshop on arthropod-borne diseases

A workshop on arthropod-borne diseases was held at Fraunhofer IZI on September 29 and 30, 2015. The event was organized by the Vaccine Technologies Unit at Fraunhofer IZI together with the National Reference Laboratory for Q Fever from the Friedrich-Loeffler-Institut in Jena.

Besides an exchange of knowledge on diagnosing and combating diseases transferred by arthropods (e. g. insects and arachnids), there was a focus on diseases carried by ticks.

International guest speakers and representatives from companies, laboratories and research facilities discussed a number of issues with the almost 30 participants, including studies into rickettsias, borrelias and anaplasmas as well as work carried out by the Tick Cell Biobank run by the Pirbright Institute (UK). Furthermore, strategies to fight the red mite, body louse, ticks and bedbugs were presented. A third subject area was devoted to the principles of fighting arthropods under EU law.

October 2, 2015: Inauguration of the Bio-Nanotechnology Application Laboratory

On October 2, 2015, the Fraunhofer Institute for Cell Therapy and Immunology IZI in Leipzig and the Fraunhofer Institute for Ceramic Technologies and Systems IKTS in Dresden presented their new equipment pool for the interdisciplinary processing of material and bioscientific topics. Together with

the jointly operated Bio-Nanotechnology Application Laboratory, interdisciplinary topics are able to be processed from biomedical foundational research through to process development, right over to the validation of innovative technologies. The combination of biological and medical know-how at Fraunhofer IZI with competencies in the development of new ceramic materials and innovative measuring systems contributed by Fraunhofer IKTS forms the basis upon which international projects are realized.

The newly created infrastructure was inaugurated as part of the bionection partnering conference. Following brief welcome speeches by State Secretary Uwe Gaul (Saxony's State Ministry for Science and the Arts) as well as the two Directors Professor Alexander Michaelis (Fraunhofer IKTS) and Professor Frank Emmrich (Fraunhofer IZI), curious visitors were given an initial insight into the newly set-up equipment pool during guided tours.

The Bio-Nanotechnology Application Laboratory was established with the support of Saxony's State Ministry for Science and the Arts (SMWK) with investment funds totaling 3 million euros, using means made available by the European Regional Development Fund (ERDF).

1 *Opening of the second extension building of the Fraunhofer IZI*

2 *Dr. Makert dos Santos and Dr. Henning open the "Workshop on Arthropod-Borne Diseases"*



October 21–23, 2015: World Conference on Regenerative Medicine

The World Conference on Regenerative Medicine was held in Leipzig from October 21–23, 2015. The event has been organized by Fraunhofer IZI every two years since 2007 and has grown to become one of the largest events in Europe in the field of regenerative medicine. The conference offers a platform for the interdisciplinary scientific exchange of knowledge and ideas, especially in the fields of stem cell research, cell and gene therapy, biomaterials and tissue engineering. This year the event was once again attended by a number of renowned researchers such as Oliver Brüstle (University of Bonn), Irving Weissman (Stanford University), Katharina Le Blanc (Karolinska Institutet) and many others, who spoke about current developments in their research areas. The approx. 800 participants from 50 different nations were also able to discuss exciting new technologies and their application in regenerative medicine. For example, Boris Chichkov from the Laser Zentrum Hannover presented various laser-based bioprinting technologies – from the 3D printing of transplantable bioscaffolds to printing living cells to form tissue grafts. In all, over 400 scientific contributions (talks and posters) were presented and discussed at the three-day conference.

LOOKING TO 2016

January 21, 2016

New Year reception

April 14–15, 2016

Fraunhofer Life Science Symposium

www.fs-leipzig.com

April 19–22, 2016

9th International Symposium on Neuroprotection and Neurorepair

www.neurorepair-2016.de

April 26–27, 2016

German Biotechnology Days 2016

www.biotechnologietage.de

April 28, 2016

Girls' Day 2016

www.girls-day.de

June 26, 2016

Long Night of Sciences

www.wissenschaftsnacht-leipzig.de

- 1 *Opening of the Bio-Nanotechnology Application Laboratory*
- 2 *World Conference on Regenerative Medicine at the Congress Center Leipzig*

SCIENTIFIC PRESENCE



CONVENTIONS AND CONFERENCES

10th European Biophysics Congress, July 18–22, 2015, Dresden, Germany

10th Spring Meeting of the Working Group Transplant Immunology, May 8–9, 2015, Würzburg, Germany

10th Workshop Molecular Interactions, May 6–8, 2015, Berlin, Germany

11th GESENT Congress, December 11, 2015, Bonn, Germany

11th National Conference for Health Economy, July 15–16, 2015, Rostock, Germany

11th Annual European Antibody Congress, November 9–11, 2015, Basel, Switzerland

11th German Conference on Chemoinformatics, November 8–10, 2015, Fulda, Germany

11th Spring School on Immunology, March 8–13, 2015, Kloster Ettal, Germany

12th Annual Biochemistry Retreat, January 21–24, 2015, Wesendorf, Germany

12th Annual Conference on Foundations of Nanoscience, April 13–16, 2015, Snowbird, USA

12th Dresden Sensor Symposium, December 7–9, 2015, Dresden, Germany

12th International Conference on Alzheimer's and Parkinson's Diseases, AD/PD™, March 18–22, 2015, Nice, France

12th International Symposium on the Neurobiology and Neuroendocrinology of Aging, July 27 – August 1, 2014, Bregenz, Austria

12th Student Symposium in Innovative Medical Technology and Biotechnology 2015, April 28, 2015, Hamburg, Germany

13th biosaxony vor Ort, September 14, 2015, Radebeul, Germany

13th Herbstseminar-Meeting held by the Bioinformatics Group, September 28 – October 3, 2015, Doubice, Czech Republic

15th Annual Meeting of the European Light Microscopy Initiative, May 19–22, 2015, Sitges, Spain

15th EuCheMS International Conference on Chemistry and the Environment, September 20–24, 2015, Leipzig, Germany

15th World Congress on Health and Biomedical Informatics, August 19–23, 2015, Sao Paulo, Brasil

17th International Congress of Mucosal Immunology, July 14–18, 2015, Berlin, Germany

19th European Congress on Alternatives to Animal Testing, September 20–23, 2015, Linz, Austria

1st Düsseldorf-Jülich Symposium on Neurodegenerative Diseases, October 29–30, 2015, Düsseldorf, Germany

2015 BIO International Convention, June 15–18, 2015, Philadelphia, USA

2015 International Nonthermal Processing Workshop "Sustainable innovation based on science and applied research of nonthermal technologies", November 12–13, 2015, Athens, Greece

2015 PDA Europe Conference: Advanced Therapy Medicinal Products, June 2–3, 2015, Amsterdam, The Netherlands

22nd Essen Information Meeting for Animal Welfare Officers, Animal Experiment Officers and Officials dealing with Animal Experiments, March 4, 2015, Essen, Germany

250th American Chemical Society National Meeting & Exposition, August 16–20, 2015, Boston, USA

25th Annual Meeting of the Society for Virology, March 18–21, 2015, Bochum, Germany

25th European Congress of Clinical Microbiology and Infectious Diseases, April 25–28, 2015, Copenhagen, Denmark

29th Annual Symposium of the Protein Society, July 22–25, 2015, Barcelona, Spain

29th EFFoST International Conference, November 10–12, 2015, Athens, Greece

2nd LightSheet Fluorescence Microscopy International Conference, July 5–8, 2015, Genoa, Italy

32nd Winter School Tiers, February 25–28, 2015, Tiers, Italy

3rd European Seminars in Virology, June 19–21, 2015, Bertinorio, Italy

3rd International Annual Conference of the GSCN, September 9–11, 2015, Frankfurt (Main), Germany

4th National Biobank Symposium, December 9–10, 2015, Berlin, Germany

45th Annual Meeting of the Society for Neuroscience, October 17–21, 2015, Chicago, USA

4th International Academy Symposium on Neurosciences, May 4–5, 2015, Halle (Saale), Germany

4th International Conference on Tissue Science and Regenerative Medicine, July 27–29, 2015, Rome, Italy

53rd Annual Meeting of the German Society for Nuclear Medicine, April 22–25, 2015, Hannover, Germany

53rd Scientific Meeting of the Society for Laboratory Animal Science GV-SOLAS and 16th Advanced Training Course of the GV-IGTP, September 14–16, 2015, Hannover, Germany

57th ASH Annual Meeting & Exposition, December 4–8, 2015, Orlando, USA

5th Annual Advanced Therapies Summit, March 12, 2015, Paris, France

5th Halle Conference on on Recombinant Proteins, February 19–20, 2015, Halle (Saale), Germany

5th International School on Biological Crystallization, May 24–29, 2015, Granada, Spain

5th Munich Biomarker Conference, December 1–2, 2015, Munich, Germany

6th Geriatrics Conference of the Medical Faculty of the Martin-Luther University Halle-Wittenberg, November 6, 2015, Halle (Saale), Germany

60th Annual Meeting of the German Association for Medical Informatics, Biometry and Epidemiology, September 6–9, 2015, Krefeld, Germany

6th Annual Meeting Industrial Cell Technology, September 10–11, 2015, Lübeck, Germany

6th Annual Symposium Physics of Cancer, September 7–9, 2015, Leipzig, Germany

6th European Phycological Congress, August 23–28, 2015, London, Great Britain

7th Alpbach Workshop on Affinity Proteomics,

March 9–11, 2015, Alpbach, Austria

7th Annual Meeting of the German Society for Nephrology,

September 12–15, 2015, Berlin, Germany

7th Annual PEGS Europe Protein & Antibody Engineering Summit,

November 2–6, 2015, Lisbon, Portugal

7th Autumn School – Current Concepts of Immunology,

October 4–9, 2015, Merseburg, Germany

7th Cooperation Forum Drug Development,

December 10, 2015, Würzburg, Germany

7th International Symposium on Recent Advances in Food Analysis,

November 3–6, 2015, Prague, Czech Republic

7th TMF Annual Congress,

March 25–26, 2015, Hannover, Germany

7th Urological Research Symposium of the German Society of Urology,

November 19–21, 2015, Dresden

79th DPG Annual Conference and DPG Spring Meeting,

March 15–20, 2015, Berlin, Germany

81st Annual Congress of the German Society for Experimental and Clinical Pharmacology and Toxicology,

March 10–12, 2015, Kiel, Germany

8th Annual Proteins & Antibodies Congress 2015,

April 20–21, 2015, London, Great Britain

9th German BioSensor Symposium,

March 11–13, 2015, Munich, Germany

9th International Congress on Vascular Dementia,

October 16–18, 2015, Ljubljana, Slovenia

ADeKo General Meeting (Alumni Network Germany-Korea),

March 11, 2015, Seoul, South Korea

American Physical Society March Meeting 2015,

March 2–6, 2015, San Antonio, USA

Animal Protection Conference,

March 6–8, 2015, Bad Boll, Germany

Annual Conference of the German, Austrian and Swiss Societies for Hematology and Medical Oncology,

October 9–13, 2015, Basel, Switzerland

Annual Conference of the Graduate School BuildMoNa,

March 23–24, 2015, Leipzig, Germany

Annual Conference of the DGAF,

March 26–28, 2015, Rauschholzhausen, Germany

Annual Conference of the Research Organizations on the Biotechnology 2020+ Strategy Process,

September 22–23, 2015, Berlin, Germany

Annual Meeting on Frontiers in Medicinal Chemistry,

March 16–18, 2015, Marburg, Germany

Annually TRIGGER conference,

May 15–17, 2015, Krakow, Poland

Aptamers 2015,

March 31 – April 1, 2015, Oxford, Great Britain

ATMP 2015 – Issue and Challenges from Bench to Bedside,

November 4–6, 2015, Tutzing Castle, Germany

BioBilanz 2015,

December 3, 2015, Potsdam, Germany

BioData World Congress,

October 21–22, 2015, Hinxton, Great Britain

BIO-Europe,

November 2–4, 2015, Munich

Biofluid Biopsies & High-Value Diagnostics 2015,

November 16–17, 2015, Boston, USA

Bioinstruments and Microfluidics User Seminar – GeSiM

1995–2015, September 29–30, 2015, Dresden, Germany

BioJapan 2015,

October 14–16, 2015, Yokohama, Japan

bionection – Partnering Conference for Technology Transfer in Life Sciences,

October 1–2, 2015, Leipzig, Germany

Bionnale 2015,

May 27, 2015, Berlin, Germany

BIOTECHNICA,

October 6–8, 2015, Hannover, Germany

Bruker Preclinical Imaging Users` Meeting,

October 13–14, 2015, Ettlingen, Germany

BZMB Colloquium,

June 16, 2015, Bayreuth, Germany

Central German Meeting on Bioinformatics 2015,

August 26–27, 2015, Halle (Saale), Germany

Day of Biotechnology,

July 16, 2015, Berlin, Germany

Day of Science at HTWK Leipzig,

June 10, 2015, Leipzig, Germany

Day of Science Potsdam,

May 9, 2015, Potsdam, Germany

Drug Discovery & Therapy World Congress 2015, July 22–25, 2015, Boston, USA

Drug Discovery USA 2015, February 9–11, 2015, Baltimore, USA

e:Med Meeting 2015 on Systems Medicine, October 26–28, 2015, Heidelberg, Germany

EAU 2015, March 20–24, 2015, Madrid, Spain

EMBO / EMBL Symposium: Mechanisms of Neurodegeneration, June 14–17, 2015, Heidelberg, Germany

EMBO / EMBL Symposium: Seeing is Believing – Imaging the Processes of Life, October 6–10, 2015, Heidelberg, Germany

EMBO / EMBL Symposium: The non-coding Genome, October 18–21, 2015, Heidelberg, Germany

EMBO Conference Protein Synthesis and Translational Control, September 9–13, 2015, Heidelberg, Germany

Emerging Methods and Technologies for Medical Research Conference, September 1–2, 2015, Stockholm, Sweden

Engineering Life 2015 – Synthetic Biology meets Bioinspired Materials, September 29 – October 1, 2015, Dresden, Germany

Entomology Congress 2015, March 2–5, 2015, Frankfurt (Main), Germany

ERA-EDTA Congress, May 28–31, 2015, London, Great Britain

ESBB 2015 Annual Conference, September 29 – October 2, 2015, London, Great Britain

Europe Global Export Forum, May 20–22, 2015, Toronto, Canada

European Symposium of Porcine Health Management, April 22–24, 2015, Nantes, France

First International Scientific Conference on Human Endogenous Retroviruses (HERV) and Diseases, May 26–27, 2015, Lyon, France

Focus on Microscopy, March 29 – April 1, 2015, Göttingen, Germany

Forum Companion Diagnostic Network, September 16, 2015, Berlin, Germany

Forum Life Science 2015, March 11–12, 2015, Munich, Germany

Fraunhofer-Okinawa Institute of Science and Technology (OIST) Workshop, April 8–10, 2015, Okinawa, Japan

futureSAX Innovation Summit 2015, July 2, 2015, Dresden, Germany

German Biotechnology Conference 2015, April 22–23, 2015, Cologne, Germany

GDCh Colloquium: Synthesis of Membrane Proteins in Eukaryotic Cell-free Systems, May 18, 2015, Greifswald, Germany

GRM Workshop “Regenerative Medicine after the Hype: What Now?”, November 6, 2015, Berlin, Germany

HeMiBio Fourth Annual Consortium Meeting, January 14–15, 2015, Chur, Switzerland

HeMiBio International Symposium, December 2–3, 2015, Leuven, Belgium

IFT15 – IFT Annual Meeting & Food Expo, July 11–14, 2015, Chicago, USA

IGV 20th International Scientific Conference “Healthy Grain for a Healthy Diet”, April 22–23, 2015, Berlin, Germany

Information and Network Event held by the German NanoBioMedizin Platform, November 23, 2015, Frankfurt (Main), Germany

Innovation Days 2015, December 8–9, 2015, Berlin

International Conference on Brain Disorders and Therapeutics, August 24–26, 2015, London, Great Britain

International Symposium on Flaviviruses, October 8–10, 2015, Vienna, Austria

International Symposium on Smart Biomaterials, March 19–20, 2015, Gwangju, South Korea

International Workshop Dyslexia and Coping Behaviour, December 8–9, 2015, Leipzig, Germany

ISSCR 2015 Annual Meeting, June 24–27, 2015, Stockholm, Sweden

i-WING 2015 – from Material to Innovation, April 27–29, 2015, Dresden, Germany

Korean-German Joint Symposium, October 20, 2015, Leipzig, Germany

LAB-SUPPLY – Trade Fair for Laboratory Technology, July 1, 2015, Berlin, Germany

Leaders in Biobanking Congress, June 14–16, 2015, Toronto, Canada

Long Night of the Sciences, July 3, 2015, Halle (Saale), Germany

Macromolecular Colloquium, February 25–27, 2015, Freiburg, Germany

MEDICA – World Forum for Medicine, November 16–19, 2015, Düsseldorf, Germany

Meeting of the Parasitology and Parasitic Diseases Group, German Veterinary Medical Society, June 29 – July 1, 2015, Stralsund, Germany

Meeting Point of In Vitro Diagnostics “Autoimmune Diagnostics”, November 30, 2015, Berlin, Germany

micro photonics Preview Event 2015 – “Biophotonics”, November 26–27, 2015, Berlin, Germany

Molecular Diagnostics Europe, April 13–15, 2015, Lisbon, Portugal

Molecular Plasmonics 2015 International Symposium, May 7–9, 2015, Jena, Germany

Musicians: Born or Made, April 10–11, 2015, Montreal, Canada

New Models to Understand the Brain, April 16, 2015, Tours, France

New Technologies, New Vaccines 2015, March 22–25, 2015, Wilmington, USA

Non-canonical amino acids in proteins: Structural investigations and biocatalysis, February 10, 2015, Frankfurt (Main), Germany

OASIS Workshop on Food and Water Safety, April 21, 2015, Berlin

Parliamentary Evening – University of Rostock’s Department of Medicine, June 6, 2015, Schwerin, Germany

PepTalk: The Protein Science Week, January 19–23, 2015, San Diego, USA

Point-of-Care Diagnostics & Global Health World Congress, September 28–30, 2015, San Diego, USA

Potsdam Days of Bioanalysis, November 4–5, 2015, Potsdam, Germany

“Reading in the forest” – International Workshop on Reading and Dyslexia, October 26–28, 2015, Annweiler, Germany

Science Day Fraunhofer IZI, July 3, 2015, Leipzig

Scientific Colloquium – University Hospital Carl Gustav Carus Dresden, May 4, 2015, Dresden, Germany

Scientific Colloquium – Halle University Hospital, October 29, 2015, Halle (Saale), Germany

SEURAT-1 Symposium, December 4, 2015, Brussels, Belgium

Spring Meeting of the East German Study Group Hematology / Oncology, May 8–9, 2015, Wörlitz, Germany

Stammtisch Life Sciences, March 11, 2015, Leipzig, Germany

Statistical Methods for Omics Data Integration and Analysis, September 14–16, 2015, Valencia, Spain

Summer School Soft Matter Physics, June 28, 2015, Zingst, Germany

Symposium at Okinawa Institute of Science and Technology (OIST), April 8–10, 2015, Okinawa, Japan

Symposium The immune-brain axis: From molecules to behavior, March 12–13, 2015, Diepenbeek, Belgium

Taconic Symposium: Advanced Preclinical Models, October 12, 2015, Berlin

The GRDC Symposium 2015, October 20, 2015, Leipzig

TMF Workshop Sharing Experiences and Lessons Learned while Operating National Biobank Registers, February 18–19, 2015, Berlin, Germany

VII Chemistry of Nucleic Acid Conference, September 17–18, 2015, Berlin, Germany

Winter School Soft Matter Physics, February 14, 2015, Marburger Haus, Austria

Workshop on “Computational Models in Biology and Medicine”, September 10–11, 2015, Leipzig, Germany

Workshop on Arthropod-Borne Diseases – diseases transmitted by ticks, mites, fleas, and lice, June 29–30, 2015, Leipzig, Germany

World Conference on Regenerative Medicine, October 21–23, 2015, Leipzig, Germany

XIX Symposium of the Society of Toxicological and Forensic Chemistry, April 16–18, 2015, Mosbach, Germany

xMAP Connect, November 25–26, 2015, Amsterdam, The Netherlands

RESEARCH PARTNERS

Aachen University of Applied Sciences, Jülich, Germany

AIT Austrian Institute of Technology, Vienna, Austria

Albert Ludwigs University of Freiburg, Freiburg, Germany

Alfred Wegener Institute, Helmholtz Centre for Polar and Marine Research, Heligoland, Germany

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Berlin State Office of Criminal Investigations, Berlin, Germany

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Biomedical Primate Research Centre, Rijkswijk, The Netherlands

Brandenburg University of Applied Sciences, Brandenburg, Germany

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Brigham & Women's Hospital, Harvard Medical School, Boston, USA

Caritas Hospital St. Josef, University of Regensburg, Regensburg, Germany

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Chonnam National University Hwasun Hospital, Hwasun, South Korea

CIDEIM Centro Internacional de Entrenamiento e Investigaciones Medicas, Cali, Columbia

Coburg University of Applied Sciences and Arts, Coburg, Germany

Competence Center for scalable data services and solutions ScaDS, Dresden / Leipzig, Germany

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Essen University Hospital (public-law institution), Essen, Germany

Federal Institute for Materials Research and Testing, Berlin, Germany

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Flensburg University of Applied Sciences, Flensburg, Germany

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Fraunhofer Institute for Applied Information Technology FIT, Sankt Augustin, Germany

Fraunhofer Institute for Applied Polymer Research IAP, Potsdam, Germany

Fraunhofer Institute for Biomedical Engineering IBMT, St. Ingbert, Germany

Fraunhofer Institute for Ceramic Technologies and Systems IKTS, Dresden, Germany

Fraunhofer Institute for Electronic Nano Systems ENAS, Chemnitz, Germany

Fraunhofer Institute for Interfacial Engineering and Biotechnology IGB, Stuttgart, Germany

Fraunhofer Institute for Manufacturing Engineering and Automation IPA, Stuttgart, Germany

Fraunhofer Institute for Manufacturing Technology and Advanced Materials IFAM, Bremen, Germany

Fraunhofer Institute for Molecular Biology and Applied Ecology IME, Aachen, Germany

Fraunhofer Institute for Organic Electronics, Electron Beam and Plasma Technology FEP, Dresden, Germany

Fraunhofer Institute for Process Engineering and Packaging IVV, Freising, Germany

Fraunhofer Institute for Reliability and Microintegration IZM, Berlin, Germany

Fraunhofer Institute for Toxicology and Experimental Medicine ITEM, Hannover, Germany

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German Center for Neurodegenerative Diseases (DZNE), Berlin, Germany

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German Prostate Cancer Consortium (DPKK), Düsseldorf, Germany

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HELIOS Klinikum Berlin Buch, Berlin, Germany

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Helmholtz Centre for Infection Research, Braunschweig, Germany

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Helmholtz Zentrum München, German Research Center for Environmental Health, Munich, Germany

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Humboldt-Universität zu Berlin, Berlin, Germany

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Innovations for High Performance Microelectronics, Leibniz Institute for Innovative Microelectronics, Frankfurt (Oder), Germany

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Mahidol University, Nakhon Pathom, Thailand

Manipal University, Manipal, India

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Max Planck Institute of Molecular Cell Biology and Genetics, Dresden, Germany

Max Planck Institute of Psychiatry, Munich, Germany

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National Institute for Standards and Technology (NIST), Gaithersburg, USA

Newcastle University, Newcastle upon Tyne, Great Britain

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Ospedale San Raffaele, Mailand, Italy

Otto von Guericke University Magdeburg, Magdeburg, Germany

Paul Flechsig Institute for Brain Research, Leipzig, Germany

Pilot Pflanzöltechnologie Magdeburg e.V., Magdeburg, Germany

Public Service Centre for Rural Development in the Region Mosel, Bernkastel, Germany

Research Center Borstel, Leibniz-Center for Medicine and Biosciences, Borstel, Germany

Robert Koch Institute, Berlin, Germany

Rostock University Medical Center, public-law institution, Rostock, Germany

Ruhr University Bochum, Bochum, Germany

RWTH Aachen University, Aachen, Germany

Saarland University, Homburg, Germany

Saarland University Medical Center, Homburg, Germany

Saxon State Ministry of the Environment, Agriculture and Geology, Köllitsch, Germany

Skåne University Hospital, Malmö, Sweden

St. Elisabeth-Krankenhaus Leipzig, academic teaching hospital forming part of Leipzig University, Leipzig, Germany

Stanford University, Stanford, USA

Technical University of Applied Sciences Wildau, Wildau, Germany

Technical University of Berlin, Berlin, Germany

Tel Aviv University, Tel Aviv, Israel

The Hebrew University of Jerusalem, Jerusalem, Israel

The University of Adelaide, Adelaide, Australia

The University of Nottingham, Nottingham, Great Britain

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Universidad Autónoma de Aguascalientes, Aguascalientes, Mexico

Universidad Nacional Autónoma de México, Ciudad de México / Querétaro, Mexico

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Universität Hamburg, Hamburg, Germany

Universitätsklinikum Erlangen, Erlangen, Germany

Universiteit Gent, Gent, Belgium

Universiteit Leiden, Leiden, The Netherlands

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Universitetet i Oslo, Oslo, Norway

University Hospital Carl Gustav Carus Dresden, Dresden, Germany

University Hospital Halle (Saale), Halle (Saale), Germany

University Hospital Leipzig, public-law institution, Leipzig, Germany

University Hospital Regensburg, public-law institution, Regensburg, Germany

University Medical Center Hamburg-Eppendorf (UKE), Hamburg, Germany

University Medical Center of the Johannes Gutenberg University Mainz, Mainz, Germany

University Medical Center Schleswig-Holstein, Kiel, Germany

University of Applied Sciences Bremerhaven, Bremerhaven, Germany

University of Applied Sciences Potsdam, Potsdam, Germany

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INDUSTRY PARTNERS

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ibidi GmbH, Martinsried, Germany

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microfluidic ChipShop GmbH, Jena, Germany

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Germany

OntoChem IT Solutions GmbH, Halle (Saale), Germany

opTricon – Entwicklungsgesellschaft für Optische Technologien mbH, Berlin,
Germany

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Germany

PharmGenomics GmbH,
Mainz, Germany

Pilot Pflanzenöltechnologie Magdeburg e. V. (PPM),
Magdeburg, Germany

pluriSelect Life Science UG (haftungsbb.) & Co.KG, Leipzig,
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PolyQuant GmbH, Bad
Abbach, Germany

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Germany

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Berlin, Germany

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Germany

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Spain

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Rathenow, Germany

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Aviv, Israel

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büttel, Germany

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Germany

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Germany

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Germany

Sabel-Schülerzentrum,
Dresden / Freital, Germany

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Germany

SCIENION AG, Berlin /
Dortmund, Germany

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Germany

Seramun Diagnostica GmbH,
Heidesee, Germany

Siemens AG, München /
Erlangen, Germany

Sonovum AG, Leipzig,
Germany

Surflay Nanotec GmbH, Berlin,
Germany

TWINCORE, Zentrum für Experimentelle und Klinische Infektionsforschung GmbH,
Hannover, Germany

Vita 34 AG, Leipzig, Germany

Vita 34 AG, Geschäftsbereich BioPlanta, Leipzig, Germany

Wrig Nanosystems Pvt. Ltd.,
Neu Delhi, India

ZELLMECHANIK DRESDEN GmbH, Dresden, Germany

ADVANCED VOCATIONAL TRAINING

44th Seminar on Experimental Animals and Animal Experiments, Society of Laboratory Animal Science,
Berlin, Germany

8th GV-Solas Advanced Training Course for Animal Welfare Officers and Authority Representatives, Society of Laboratory Animal Science,
Berlin, Germany

A3 – Equipment Qualification and Monitoring in the Analysis Laboratory, Concept Heidelberg GmbH, Heidelberg,
Germany

Acquisition Seminar, Fraunhofer IZI, Leipzig, Germany

Advanced Course in Laboratory Animal Science 1 + 4, Leipzig University, Leipzig,
Germany

Advanced First Aid Training, German Red Cross, Halle (Saale),
Germany

Advanced Imaging Course, Bruker, Ettlingen, Germany

Advanced Preclinical Models for Immunology, Oncology and Infectious Disease Symposium, Taconic Biosciences, Inc., Berlin, Germany

Advanced Training for Medical Psychotherapists, Justus Liebig University, Gießen,
Germany

Agilent GC & GC/MS Seminar, Agilent Technologies Life Sciences & Chemical Analysis GmbH & Co. KG, Berlin, Germany

Allergy Management in Practice, Central College of the German Confectionery Industry ZDS, Solingen, Germany

Allergy Management in Practice, Die Akademie Fresenius GmbH, Mainz, Germany

ÄKTA Pure/Avant and Unicorn 6.0 Training, GE Healthcare GmbH, Munich, Germany

ÄKTA Training, GE Healthcare GmbH, Munich, Germany

Animal Protection Conference, Protestant Academy Bad Boll, Bad Boll, Germany

Applying for Research Funding, Leipzig University, Leipzig, Germany

Assessment of Working Conditions, Verwaltungs-Berufsgenossenschaft (VBG), Storkau, Germany

Autumn School – Current Concepts of Immunology, German Society for Immunology, Merseburg, Germany

Aviation Security pursuant to 11.2.2 in Conjunction with 11.2.5 of Regulation (EU) No 185/2010, koal | training | coaching, Norderstedt, Germany

Basic Course in Cell Culture, PromoCell GmbH, Heidelberg, Germany

Basic Training in Analytical Method Validation, Concept Heidelberg GmbH, Heidelberg, Germany

bbb Certification Workshop, Biotechnologieverbund Berlin-Brandenburg e.V., Berlin, Germany

BD FACS Workshop, Becton Dickinson, Leipzig, Germany

BD Influx Training, BD Biosciences, Erembodegem, Belgium

Biacore User Meeting, GE Healthcare GmbH, Berlin, Germany

Biomolecular Interaction Analytics using MicroScale Thermophoresis, NanoTemper Technologies GmbH, Potsdam, Germany

Briefing on the Operation of the BD FACSVerser Flow Cytometer, Becton Dickinson, Heidelberg, Germany

C3 Biosaxony Workshop, State Minister for Science and the Arts (SMWK) in Saxony, Dresden, Germany

cGMP in Biotechnology, Concept Heidelberg GmbH, Heidelberg, Germany

Chromatography & Western Blot, GE Healthcare GmbH, Halle (Saale), Germany

Cloning Technologies, Dr. Battke SCIENTIA GmbH - Life Science Services, Taufkirchen, Germany

Compact Laboratory Course on Apoptosis Assay, Promo-Cell GmbH, Heidelberg, Germany

Compact Seminar on Medical Software, Johner Institut GmbH, Konstanz, Germany

Contract Design for Research and Development Projects, Fraunhofer-Gesellschaft, Munich, Germany

Course on Acquiring Technical Knowledge in Radiation Protection according to the German X-Ray Ordinance, Leibniz Universität Hannover, Hannover, Germany

Crash Course in Business Administration for Engineers, Technicians and Scientists, Haufe Akademie GmbH & Co. KG, Cologne, Germany

D5 – The Product Quality Review, Concept Heidelberg GmbH, Mannheim, Germany

Developing and Expanding Project Management Expertise, biosaxony e.V., Dresden, Germany

DGAKI Allergy Academy, German Society for Allergology and Clinical Immunology, Hannover, Germany

EVG Hot Embosser Basic Training Course, EV Group Europe & Asia/Pacific GmbH, Sankt Florian, Austria

FACS Verse Flow Cytometry Training, Becton Dickinson, Heidelberg, Germany

Factory Course MALDI Imaging and Statistical Data Training, Bruker Daltonik GmbH, Bremen, Germany

FELASA B Course, Fraunhofer IZI, Leipzig, Germany

Flow Cytometry Workshop, Universität Regensburg, Regensburg, Germany

Fraunhofer-Gesellschaft Summer School: Marketing, Industrial Acquisition, Fraunhofer Marketing Network, Berlin, Germany

Fraunhofer Workshop on Library and Information Systems 2015, Fraunhofer-Gesellschaft, Fulda, Germany

GDP 1 – GMP/GDP Requirements on Storage and Transport, Concept Heidelberg GmbH, Mannheim, Germany

Genes & Society, Coursera, online

GLP and QM Basic Course, PromoCell GmbH, Heidelberg, Germany

GLP Training, Fraunhofer IZI, Leipzig, Germany

GMP and GLP Intensive Seminar, Dr. Bichelmeier Beratung und Seminare, Munich, Germany

Good Scientific Practice, Leipzig University, Leipzig, Germany

How to Conduct Professional Interviews with Job Applicants, Haufe Akademie GmbH & Co. KG, Berlin, Germany

HR Practice 2015, Fraunhofer-Gesellschaft, Berlin, Germany

Hygiene, Personnel and Clean Room – Module 2: Aseptic Areas, PTS Training Service, Unna, Germany

Industry Acquisition “Strategies – Instruments – Conducting Negotiations”, Fraunhofer Marketing Network, Berlin, Germany

Information Meeting for Animal Welfare Officers, University of Duisburg-Essen, Essen, Germany

Introduction to Medical Chemistry, German Chemical Society, Frankfurt / Main, Germany

Kaluza Software Analysis, Leipzig University, Leipzig, Germany

Laboratory Animal Science Working Group, German Veterinary Association for Animal Welfare (TVT), Fulda, Germany

Leading with Experience – Management Module, Fraunhofer-Gesellschaft, Hamburg, Germany

Lean Qualification, Concept Heidelberg GmbH, Heidelberg, Germany

Luminex Seminar, Fraunhofer IZI, Potsdam-Golm, Germany

M9 – Microbiological Data – Trending, Analysis, Statistics, Concept Heidelberg GmbH, Karlsruhe, Germany

MALDI – Application Training, Bruker Daltonik GmbH, Leipzig, Germany

MALDI – Basic Operator Training Course, Bruker Daltonik GmbH, Leipzig, Germany

MALDI – Essential Operator Training, Bruker Daltonik GmbH, Leipzig, Germany

Managing Manufacturing, Concept Heidelberg GmbH, Hamburg, Germany

Micro-Batches – Manufacture, Quality Control and Handling, Concept Heidelberg GmbH, Wiesbaden, Germany

MicroCal Course – Advanced Isothermal Titration Calorimetry, Malvern Instruments GmbH, Halle (Saale), Germany

New Technology Funding in Saxony, Sächsische Aufbaubank - Förderbank, online

OBE Introductory Training, Fraunhofer-Gesellschaft, Munich, Germany

Patent Workshop, Fraunhofer-Gesellschaft, Leipzig, Germany

Pest Control in Pharmaceutical and Medical Technology Companies, BB LIFE, Berlin, Germany

Presentation Seminar (Speech – Presentation – Impact Awareness), SMILE – Self Management Initiative LEipzig, Leipzig, Germany

Principles and Applications of Time-Resolved Fluorescence, PicoQuant GmbH, Berlin, Germany

Principles of Animal Experiment Projects, Fraunhofer IZI, Leipzig, Germany

Principles of Gas Chromatography, CS-Chromatographie Service GmbH, Berlin, Germany

Principles of Microbial Fermentation, PromoCell GmbH, Heidelberg, Germany

Project Management in Science, SMILE – Self Management Initiative LEipzig, Leipzig, Germany

Quality Aspects in the Manufacture of ATMP, BB LIFE, Berlin, Germany

Quality Management in Cell Culture, PromoCell GmbH, Heidelberg, Germany

QV 27 – Update Annex 15 Revision, Concept Heidelberg GmbH, Mannheim, Germany

Requirements of the Modern-Day Training System, Concept Heidelberg GmbH, Heidelberg, Germany

Revisiting Refinement in Care and Use of Laboratory Rodents, Fondazione Guido Bernardini (FGB), Varese, Italy

Safe Working Environment in Scientific Laboratories, Verwaltungs-Berufsgenossenschaft (VBG), Untermerzbach, Germany

Safety in Genetic Engineering – Biological Safety, Leipzig University, Leipzig, Germany

TEACHING ACTIVITIES

Sartorius Single-Use Process Systems, Sartorius Stedim Biotech GmbH, Göttingen, Germany

Scientific Writing Workshop, Leipzig University, Leipzig, Germany

sciFLEXARRAYER S3 Basic Training Course, Scienion AG, Leipzig, Germany

Seminar Series – Biomedical Lectures Leipzig (2014 / 2015 / 2016), Leipzig University, Leipzig, Germany

Service Seminar Autoclaves, Systec GmbH, Osnabrück, Germany

Specialized Training Course in Radiation Protection (Unsealed Radioactive Substances; 4.1), Helmholtz Centre for Environmental Research – UFZ, Leipzig, Germany

Springer Library Summit, Springer-Verlag GmbH, Leipzig, Germany

Statistics Seminar, Fraunhofer IZI / Leipzig University, Leipzig, Germany

Structural Damage and Construction Errors, Institut für Kommunalberatung Roland Halang GmbH (IfKb), Leipzig, Germany

Taconic Symposium: Advanced Preclinical Models, Taconic Biosciences, Inc., Berlin, Germany

The Climatically Optimized Workplace: How to Measure, Evaluate and Improve Room Temperature and Air Quality, Verwaltungs-Berufsgenossenschaft (VBG), Untermerzbach, Germany

The Federal Law on Travel Expenses, Practitioners' Workshop, Fraunhofer-Gesellschaft, Leipzig, Germany

The Future of Outpatient Care, Sächsische Krebsgesellschaft e.V., Zwickau, Germany

The Regulation on In Vitro Diagnostics – New Regulatory Requirements, mdc medical device certification GmbH, Stuttgart, Germany

The Union Customs Code 2016, TANGENS Wirtschaftsakademie GmbH, Leipzig, Germany

Translational Cytomics, Leipzig University, Leipzig, Germany

Transplant Academy, DAG-KBT e. V., Essen, Germany

Transplant Academy: Complications following Allogeneic Stem Cell Transplantation, DAG-KBT e. V., Hamburg, Germany

Transporting Dangerous Goods, Mayo Medical Laboratories, Leipzig, Germany

Update Course on the Radiation Protection Act, B·A·D Gesundheitsvorsorge und Sicherheitstechnik GmbH, Munich, Germany

User Training in Laboratory Automation (Tecan EVO 100), Tecan Group Ltd., Leipzig, Germany

UV/Vis User Seminar, Basic Course + Advanced Course, Analytik Jena AG, Jena, Germany

Vienna Summer School Drug Design, University of Vienna, Vienna, Austria

Workshop on Aptamers as Diagnostic Markers and Therapeutic Inhibitors in Infectious Diseases, Leipzig University, Leipzig, Germany

Young Leaders in Science 2014/2015 (4th + 5th Modules), Ernst Schering Foundation, Langwedel, Germany

Anhalt University of Applied Sciences

Protein Biotechnology (lecture), Prof. Hans-Ulrich Demuth

Beuth University of Applied Sciences Berlin

Cell-Free Protein Synthesis (lecture), Dr. Stefan Kubick

Proteomics / Biosensors (lecture), Dr. Eva Ehrentreich-Förster

EBC Hochschule

Genetic Principles of Dyslexia and Development of an Early-Screening Test (talk), Dr. Arndt Wilcke

Fraunhofer IZI

FELASA B Course (course), Dr. Thomas Grunwald

FELASA B Course – Presentation and Practical Demonstration "Biolmaging" (seminar), Dr. Alexander Kranz

Principles of Animal Experimentation Projects (talk + course), Dr. Franziska Lange, Dr. Anna Leichsenring

Project Acquisition (talk), Pierre Tangermann, Daniela Bosler, Dr. Thomas Tradler, Annette Schäfer, Dr. Sebastian Ulbert

Free University of Berlin

Cell-Free Synthesis of Membrane Proteins (practical training + seminar), Dr. Stefan Kubick

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

Optical Microscopy of the Submicroscopic (practical training + seminar), Dr. Ralph Hölzel

Leipzig University

Active Ingredient Analytics – Drug Monitoring I (seminar), Dr. Mirko Buchholz

Active Ingredient Analytics – Drug Monitoring II (practical training), Dr. Daniel Ramsbeck

Autoimmunity (seminar), Dr. Stephan Fricke / Claudia Müller / Nadja Hilger

Clinical Research and Translational Medicine “Preclinical Models” (lecture), Dr. Jörg Lehmann / Dr. Franziska Lange

Core Lecture on Immunology (lecture), Prof. Frank Emmrich

Extended Practical Training for Medical Practitioners, Immunology (practical training), Nadja Hilger

Environmental Medicine for Adults 1 (seminar), Nadja Lindner / Veronika Storbeck

Environmental Medicine for Adults 2 (seminar), Tina Bischoff / Anne Kühlmann

Foundations of Immunology (as part of the lecture on pharmaceutical biology; lecture), Dr. Jörg Lehmann

Foundations of Statistical Learning (lecture), Dr. Kristin Reiche

Genetics of Dyslexia (lecture), Dr. Arndt Wilcke

History of Natural Sciences: Spotlight on Pharmacy (lecture), Dr. Mirko Buchholz

Immune Status (seminar), Dr. Stephan Fricke / Claudia Müller / Nadja Hilger

Immunological Methods (as part of the lecture on pharmaceutical biology; lecture), Dr. Jörg Lehmann

Infectiology and Immunology (lecture), Prof. Frank Emmrich

Infectiology and Immunology (problem-oriented learning), Dr. Andreas Schubert / Dr. Daniel-Christoph Wagner

Medical Biotechnology / Regenerative Medicine (lecture), Prof. Frank Emmrich

Medical Chemistry for Biochemists and Chemists (practical training), Dr. Mirko Buchholz

Medical Microbiology (lecture), Dr. Thomas Grunwald

Model Organisms in Research – Arthritis Models (lecture), Dr. Franziska Lange

Molecular Medicine (lecture), Dr. Thomas Grunwald

Molecular Medicine / Practical Training for Students (practical training), Dr. Thomas Grunwald / Wierich Lea

Molecular Medicine / Virology (lecture), Dr. Sebastian Ulbert

Molecular Oncology and Immunology for Biochemists (practical training), Prof. Friedemann Horn / Dr. Conny Blumert / Dr. Stefanie Binder

New Technologies in Vaccine Development (lecture), Dr. Sebastian Ulbert

Practical Lab Training in Molecular Medicine / Virology (practical training), Dr. Sebastian Ulbert / Jasmin Fertey

Practical Training in Immunology, 6th Semester Human Medicine, Immunology Part 3 + Part 4 (practical training), Dr. Conny Blumert / Dr. Stefanie Binder

Prevention and Health Promotion (lecture), Prof. Frank Emmrich

Response Mechanisms in Organic Chemistry (seminar), Dr. Daniel Ramsbeck

Terminology for Pharmacists (seminar), Dr. Daniel Ramsbeck

Tissue Typing (seminar), Dr. Stephan Fricke / Claudia Müller / Nadja Hilger

Tissue Typing / Transplantation Immunology for Medicine Students (Module QSB 4) (seminar), Dr. Peter Ruschpler

Vector-Transferred Viral Infections (lecture), Dr. Sebastian Ulbert

Leipzig University of Applied Sciences

Biometric Planning and Analysis of Biomedical Experiments (lecture), Prof. Ulf-Dietrich Braumann

Digital Image Processing (lecture), Prof. Ulf-Dietrich Braumann

Microscopic Imaging (lecture), Prof. Ulf-Dietrich Braumann / Dr. Daniel-Christoph Wagner / Dr. Alexander Kranz

Microscopic Image Processing (lecture), Prof. Ulf-Dietrich Braumann

Martin Luther University of Halle-Wittenberg

Biochemistry and Molecular Biology I and II for Human Medicine Students (seminar), Dr. Holger Cynis

Biochemistry / Molecular Biology for Medicine and Dentistry Students (practical training), Dr. Holger Cynis

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

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

Project Module Plant Biochemistry for Bachelor Students (practical training), Dr. Holger Cynis

Miltenyi Biotec GmbH

Biotech Business Workshop (Naturimmun EU program) (talk), Dr. Thomas Tradler

Ruhr University Bochum

Immunotherapy and Prophylaxis of Infectious Diseases (lecture), Dr. Thomas Grunwald

Virology for Natural Scientists (lecture), Dr. Thomas Grunwald

Technical University of Berlin

Cell-Free Synthesis of Membrane Proteins (practical training + seminar), Dr. Stefan Kubick

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

TMF – Technologie- und Methodenplattform für die vernetzte medizinische Forschung e.V.

Discussion Forum on the Harmonization of S3 Facilities of Safety Standards for S3 Laboratories: "Experiences in the Authorization of Genetic Engineering Facilities (S3*/S3)" (seminar), Dr. Thomas Grunwald

University of Potsdam

Analytical Biochemistry (practical training), Dr. Cornelia Hettrich

Analytical Biochemistry II (practical training), Dr. Eva Ehrentreich-Förster

Cell-Free Protein Synthesis (seminar + lecture + practical training), Dr. Stefan Kubick

Interaction Analyses with SPR and Thermophoresis, Dr. Walter Stöcklein

Introduction to Quality Management in Diagnostic Agents Development (lecture), Dr. Nenad Gajovic-Eichelmann

Lecture Series on Applied Limnology: Snow Algae as an Interesting Bioresource for Foundational Research and an Industrial Bioproduction of Algae Metabolites (lecture), Dr. Thomas Leya

University of Rostock

Biomedical Engineering (lecture), Prof. Steffen Mitzner

Emergency Medicine: Cardiac Arrhythmias in Emergency Medicine (lecture), Dr. Martin Sauer

Emergency Medicine: Organ Replacement and Organ Support Systems (lecture), Dr. Martin Sauer

Internal Medicine I (lecture), Prof. Steffen Mitzner

Medical Technology / Imaging Procedures (lecture), Prof. Steffen Mitzner

EVALUATOR ACTIVITIES

9th International Conference on Biomedical Electronics and Devices, PD Dr. Ralph Hölzel

ACS Macro Letters (Journal), Dr. Sebastian Ulbert

Advances in Biochemical Engineering / Biotechnology (Book review series), Dr. Harald Seitz

Alzheimer's Association, Prof. Dr. Hans-Ulrich Demuth

Alzheimer's Society, Dr. Daniel-Christoph Wagner

American Journal of Physiology, Prof. Dr. Hans-Ulrich Demuth

Analytical Chemistry (Journal), Dr. Eva Ehrentreich-Förster

Biochimica et Biophysica Acta (Journal), Prof. Dr. Hans-Ulrich Demuth

Biosensors and Bioelectronics (Journal), Dr. Eva Ehrentreich-Förster, Prof. Dr. Frank Bier

Biotechnology and Applied Biochemistry (Journal), Dr. Stephan Schilling

Chemical Biology & Drug Design (Journal), Dr. Mirko Buchholz

Chemical Sciences, Electrophoresis (Journal), Eva-Maria Laux

- Cellular and Molecular Life Sciences (Journal)**, Prof. Dr. Frank Emmrich
- Drug Design Reviews (Journal)**, Prof. Dr. Hans-Ulrich Demuth (Editorial Advisory Board Member)
- Engineering in Life Sciences (Journal)**, Dr. Stefan Kubick
- European Journal of Biochemistry**, Prof. Dr. Hans-Ulrich Demuth
- Expert Committee of the AWIPEV German-French Arctic Research Base in Ny-Alesund, Spitzbergen**, Dr. Thomas Leya
- Fachzeitschrift "The Open Veterinary Science Journal"**, Dr. Jörg Lehmann (Gutachter, Editorial Board)
- Fachzeitschrift "Veterinary Immunology and Immunopathology"**, Dr. Jörg Lehmann (Gutachter)
- Fachzeitschrift "Perspectives in Phycology"**, Dr. Thomas Leya
- Faculty of 1000**, Dr. Sebastian Ulbert
- FEBS-Letters**, Prof. Dr. Hans-Ulrich Demuth
- Future Virology (Journal)**, Dr. Sebastian Ulbert
- Gene (Journal)**, Dr. Sebastian Ulbert
- German BioSensor Symposium 2015, Munich**, Prof. Dr. Frank Bier
- German Research Foundation**, Dr. Eva Ehrentreich-Förster, Prof. Dr. Hans-Ulrich Demuth
- High-Tech Gründerfonds of the Federal Ministry of Education and Research**, Prof. Dr. Hans-Ulrich Demuth
- IQ Innovation Award Berlin-Brandenburg**, Prof. Dr. Frank Bier
- IQ Innovation Award Central Germany**, Prof. Dr. Hans-Ulrich Demuth
- Journal Biological Chemistry**, Prof. Dr. Hans-Ulrich Demuth
- Journal of Alzheimer's Disease**, Prof. Dr. Hans-Ulrich Demuth (Handling Editor), Dr. Stephan Schilling
- Journal of Biological Chemistry**, Dr. Kristin Reiche
- Journal of Biotechnology**, Dr. Stephan Schilling, Dr. Stefan Kubick
- Journal of Biotechnology and Applied Biochemistry**, Prof. Dr. Hans-Ulrich Demuth
- Journal of Medical Imaging**, Prof. Dr. Ulf-Dietrich Braumann
- Journal of Medical Microbiology**, Prof. Dr. Frank Bier
- Journal of Medical Virology**, Dr. Sebastian Ulbert
- Journal of Nanomedicine & Nanotechnology**, Dr. Eva Ehrentreich-Förster
- Journal of Neurochemistry**, Prof. Dr. Hans-Ulrich Demuth
- Journal of Neuroscience Research**, Dr. Alexander Kranz
- Journal of the American Chemical Society**, Prof. Dr. Hans-Ulrich Demuth
- Lab on a Chip (Journal)**, Dr. Stefan Kubick
- Metabolic Brain Disease (Journal)**, Dr. Daniel-Christoph Wagner
- Neural Regeneration Research (Journal)**, Dr. Stephan Schilling
- PLOS ONE (Journal)**, Dr. Sebastian Ulbert, Dr. Daniel-Christoph Wagner, Dr. Alexander Kranz, Dr. Thomas Grunwald
- Potsdam Days on Bioanalysis**, Prof. Dr. Frank Bier
- Psychiatric Genetics (Journal)**, Dr. Holger Kirsten
- Reviewer Panel for Doctorate Students as Part of the International Graduate School in Molecular Medicine Ulm**, Dr. Thomas Grunwald
- RNA (Journal)**, Dr. Kristin Reiche
- Scientific Reports (Journal)**, Dr. Arndt Wilcke
- SPIE Medical Imaging Conference: Digital Pathology**, Prof. Dr. Ulf-Dietrich Braumann
- Strategy Circle of the Federal Ministry of Education and Research "New Biotechnological Procedures – Biotechnologie2020plus"**, Prof. Dr. Frank Bier
- Stroke (Journal)**, Dr. Alexander Kranz
- Translational Stroke Research (Journal)**, Dr. Daniel-Christoph Wagner
- Vaccine (Journal)**, Dr. Thomas Grunwald, Dr. Sebastian Ulbert
- Virus research (Journal)**, Dr. Sebastian Ulbert
- Weston Garfield Family Funds, Canada**, Prof. Dr. Hans-Ulrich Demuth
- World Conference on Regenerative Medicine 2015**, PD Dr. Stephan Fricke, Dr. Franziska Lange

ASSOCIATION MEMBERSHIPS

Academy for Advanced Veterinary Training, Dr. Antje Dreyer

Alumni der Leipziger Medizinischen Fakultät e. V.
- ALM, PD Dr. Stephan Fricke

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

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

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

American Physical Society (APS), Dr. David Smith

American Society of Biochemistry and Molecular Biology (ASBMB), Dr. Claus Kerkhoff

American Society of Human Genetics (ASHG), Dr. Holger Kirsten

Association for Cancer Immunotherapy (CIMT), Christopher Oelkrug, Julia Zajac

Association for General and Applied Microbiology (VAAM), Dr. Walter Stöcklein

Australasian Neuroscience Society Inc., Dr. Antje Dreyer

Berlin-Brandenburg School for Regenerative Therapies (BSRT), Prof. Dr. Frank Bier

Biohybride Technologien e.V., Prof. Dr. Frank Bier

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

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

Brandenburg Economic Development Board (ZAB), Prof. Dr. Frank Bier

Brandenburg State Association of Non-University Research (LAUF e.V.), Prof. Dr. Frank Bier

Center for Molecular Diagnostics and Bioanalysis (ZMDB), Prof. Dr. Frank Bier

Central Animal Welfare Committee of the Landesdirektion Sachsen in Leipzig, Dr. Jörg Lehmann

DECHEMA Society for Chemical Engineering and Biotechnology, Dr. Stefan Kubick, Dr. Mirko Buchholz, Prof. Dr. Frank Bier, Prof. Dr. Frank Emmrich

DiagnostikNet Berlin-Brandenburg e.V., Dr. Marcus Menger, Prof. Dr. Frank Bier

Doctors for Madagascar, Prof. Dr. Frank Emmrich

European Macrophage and Dendritic Cell Society (EMDS), Dr. Claus Kerkhoff

European, Middle-Asian and African Society for Biopreservation and Bio-banking (ESBB), Dr. Christina Schröder, Oliver Gros

European Molecular Biology Laboratory (EMBL), Alumni relations program, Dr. Sebastian Ulbert

European Renal Association / European Dialysis and Transplantation Association (ERA-EDTA), Prof. Dr. Steffen Mitzner

European Society for Artificial Organs (ESAO), Prof. Dr. Steffen Mitzner

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

European WNV Research Platform, Dr. Sebastian Ulbert

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

Forschungsgesellschaft für Messtechnik, Sensorik und Medizintechnik e.V. Dresden, Prof. Dr. Frank Bier

Foundation for Innovative New Diagnostics (FIND), Prof. Dr. Frank Bier

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

German-Canadian Association (DKG), Dr. Thomas Tradler

German Chemical Society (GDCh), Dr. Eva Ehrentreich-Förster, Dr. Marcus Menger, Dr. Michael Szardenings, Dr. Nicole Berthold, Dr. Walter Stöcklein, Prof. Dr. Frank Bier, Prof. Dr. Hans-Ulrich Demuth

German Ethics Council, Prof. Dr. Frank Emmrich

German Institute for Standardization (DIN), Dr. Christina Schröder

German Interdisciplinary Association for Intensive Care and Emergency Medicine (DIVI), Prof. Dr. Steffen Mitzner

German Neuroscience Society (GNS), Dr. Anna Leichsenring

German Nucleic Acid Chemistry Society (DNG), Dr. Marcus Menger

German Pharmaceutical Society (DPhG), Dr. Daniel Ramsbeck, Dr. Julia Stäker, Dr. Mirko Buchholz, Carsten Schuldt, Dr. Jörg Schnauß, Martin Glaser, PD Dr. Ralph Hölzel, Prof. Dr. Frank Bier, Tina Händler

German Physical Society (DPG), Dr. Claus Duschl

German QP Association, Dr. Gerno Schmiedeknecht, Kati Kebbel

German Research Platform for Zoonoses, Alexandra Rockstroh, Dr. Gustavo Makert dos Santo, Dr. Sebastian Ulbert

German Sepsis Society (GSS), PD Dr. Martin Sauer, Prof. Dr. Steffen Mitzner

German Society for Allergy and Clinical Immunology (DGAKI), Dr. Elke Ueberham

German Society for Clinical Chemistry and Laboratory Medicine (DGKL), Prof. Dr. Frank Emmrich

German Society for Epidemiology (DGEpi), Dr. Holger Kirsten

German Society for Good Research Practice (DGGF), Stefanie Jahr

German Society for Immunology (DGfi), Aleksandra Seydel, Christopher Oelkrug, Dr. Andreas Grahnert, Dr. Christiane Földner, Dr. Franziska Lange, Dr. Jörg Lehmann, Dr. Ulla Schwertassek, Janine Kohlschmidt, Katharina Zoldan, Lea Wierich, PD Dr. Stephan Fricke, Prof. Dr. Frank Emmrich, Sina Riemschneider

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

German Society of Food Chemistry (LChG), Dr. Nicole Berthold

German Society of Medical Physics (DGMP), Prof. Dr. Ulf-Dietrich Braumann

German Society of Nephrology (DGfN), Prof. Dr. Steffen Mitzner

German Society for Parasitology (DGP), Dr. Markus von Nickisch-Rosenegk

German Society for Proteome Research (DGPF), Dr. Stefan Kubick

German Society for Regenerative Medicine (GRM), PD Dr. Stephan Fricke, Prof. Dr. Frank Emmrich

German Society for Stem Cell Research, Prof. Dr. Frank Emmrich

German Society for the History of Pharmacy (DGGP), Dr. Mirko Buchholz

German Society for Virology (GfV), Dr. Sebastian Ulbert, Dr. Thomas Grunwald

German Society of Anaesthesiology and Intensive Care Medicine (DGAI), PD Dr. Martin Sauer

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

German Veterinary Medical Society (DVG), Anne Kühlmann

German Zoological Society (DZG), Dr. Gustavo Makert dos Santo

glyconet Berlin-Brandenburg e.V., Dr. Stefan Kubick

Institute for Regenerative Medicine and Stem Cell Therapy, Prof. Dr. Frank Emmrich

International Dyslexia Association, Dr. Arndt Wilcke

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

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

International Society for Nanoscale Science, Computation and Engineering (ISNSCE), Dr. David Smith

International Society of Psychiatric Genetics (ISPG), Bent Müller

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

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

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

Leipzig Foundation for Innovation and Technology Transfer, Prof. Dr. Frank Emmrich

MEDICA German Society for Interdisciplinary Medicine, Prof. Dr. Frank Emmrich

Molecular Biology Cluster Network Potsdam (MoBiCluP), Prof. Dr. Frank Bier

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

Rotary Club Leipzig, Prof. Dr. Frank Emmrich

Section Phycology within the German Botanical Society, Berlin, Dr. Thomas Leya

PUBLICATIONS

Society for Biochemistry and Molecular Biology (GBM),

Dr. Christina Schröder,
Dr. Claus Kerkhoff, Dr. Harald Seitz, Dr. Holger Cynis,
Dr. Marcus Menger, Dr. Markus von Nickisch-Rosenegk,
Dr. Michael Szardenings,
Dr. Stefan Kubick, Dr. Stephan Schilling, Dr. Walter Stöcklein,
Prof. Dr. Frank Bier, Prof. Dr. Frank Emmrich, Prof. Dr. Friedemann Horn, Prof. Dr. Hans-Ulrich Demuth, Sandra Mükusch

Society for Biological Systematics (GfBS), Dr. Markus von Nickisch-Rosenegk

Society for Neuroscience (SfN), Dr. Alexander Kranz,
Dr. Björn Nitzsche, Dr. Holger Cynis, Prof. Dr. Hans-Ulrich Demuth, Vilia Zeisig

Society for Virology (GfV),
Dr. Thomas Grunwald

Society of Laboratory Animal Science (GV-SOLAS),
Dr. Jörg Lehmann, Dr. Thomas Grunwald

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

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

Verein zur Förderung der Gesundheitswirtschaft in der Region Leipzig e.V. (VfG),

Prof. Dr. Frank Emmrich

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

Working Group for Experimental Stem Cell Transplantation, PD Dr. Stephan Fricke

Barzon L, Pacenti M, Ulbert S, Palù G. **Latest developments and challenges in the diagnosis of human West Nile virus infection.** Expert review of anti-infective therapy. 13 (2015), 3, S. 327-42. DOI: <http://dx.doi.org/10.1586/14787210.2015.1007044>.

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Bosserdt M, Erdőssy J, Lautner G, Witt J, Köhler K, Gajovic-Eichelmann N, Yarman A, Wittstock G, Scheller FW, Gyurcsányi RE. **Microelectrospotting as a new method for electrosynthesis of surface-imprinted polymer microarrays for protein recognition.** Biosensors and bioelectronics. 73 (2015), S.123-9. DOI: <http://dx.doi.org/10.1016/j.bios.2015.05.049>.

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- Couturier J-P, Sütterlin M, Laschewsky A, Hettrich C, Wischerhoff E. **Responsive inverse opal hydrogels for the sensing of macromolecules.** *Angewandte Chemie-International Edition*. 54 (2015), 22, S. 6641-6644. DOI: <http://dx.doi.org/10.1002/anie.201500674>.
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Gaertig C, Niemann K, Berthold J, Giel L, Leitschuh N, Boehm C, Roussak L, Vetter K, Kuhlmeier D. **Development of a point-of-care-device for fast detection of periodontal pathogens.** *BMC oral health.* 15 (2015), 165. DOI: <http://dx.doi.org/10.1186/s12903-015-0155-y>.

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Georgi V, Georgi L, Blechert M, Bergmeister M, Zwanzig M, Wüstenhagen DA, Bier FF, Jung E, Kubick S. **On-chip automation of cell-free protein synthesis: new opportunities due to a novel reaction mode.** *Lab on a Chip.* 16 (2015), 2, S. 269-281. DOI: <http://dx.doi.org/10.1039/c5lc00700c>.

Giri P, Ebert S, Braumann UD, Kremer M, Giri S, Machens HG, Bader A. **Skin regeneration in deep second-degree scald injuries either by infusion pumping or topical application of recombinant human erythropoietin gel.** *Drug design, development and therapy.* 9 (2015), S. 2565-2579. DOI: <http://dx.doi.org/10.2147/DDDT.S79425>.

Godino N, Jorde F, Lawlor D, Jaeger MS, Duschl C. **Purification of microalgae from bacterial contamination using a disposable inertia-based microfluidic device.** *Journal of Micromechanics and Micro-engineering.* 25 (2015), 8, 084002. DOI: <http://dx.doi.org/10.1088/0960-1317/25/8/084002>.

Grunwald T, Ulbert S. **Improvement of DNA vaccination by adjuvants and sophisticated delivery devices: vaccine-platforms for the battle against infectious diseases.** *Clinical and experimental vaccine research.* 4 (2015), 1, S. 1-10. DOI: <http://dx.doi.org/10.7774/cevr.2015.4.1.1>.

Hahn M B, Solomun T, Wellhausen R, Herrmann S, Seitz H, Meyer S, Kunte H-J, Zeman J, Uhlig F, Smiatek J, Sturm H. **The influence of the compatible solute ectoine on the local water structure: implications for the binding of the protein G5P to DNA.** *The Journal of Physical Chemistry, B.* 119 (2015) 49, S. 15212–15220. DOI: <http://dx.doi.org/10.1021/acs.jpcc.5b09506>.

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Heathman TR, Stolzing A, Fabian C, Rafiq QA, Coopman K, Nienow AW, Kara B, Hewitt CJ. **Serum-free process development: improving the yield and consistency of human mesenchymal stromal cell production.** *Cytotherapy.* 17 (2015), 11, S. 1524-35. DOI: <http://dx.doi.org/10.1016/j.jcyt.2015.08.002>.

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Demuth HU. **Nach so vielen Fehschlägen: Gibt es neue therapeutische Ansätze zur Behandlung der Alzheimer-schen Demenz?** 6. Geriatrie-tag, Medizinische Fakultät der Universität Halle-Wittenberg, 6.11.2015, Halle (S.).

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Ermilova E, Bier FF, Hölzel R. **Broadband dielectric investigation of aqueous DNA solutions in the higher GHz range.** 10th European Biophysics Congress, 18.-22.7.2015, Dresden. European Biophysics Journal. 44 (2015), 1 Supplement, S. 154.

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Fabian C. **Cell based therapies for neurodegenerative diseases.** 3rd bilateral Workshop - Leipzig University and University of São Paulo, 3.3.2015, Leipzig.

Fabian C. **Cell therapeutics for neurological disorders.** Symposium: The immune-brain axis: from molecules to behavior, 12.-13.3.2015, Hasselt University, Campus Diepenbeek, Belgium.

Fabian C. **Cell-based therapy in age and disease.** Korean-German Joint Symposium, 20.10.2015, Leipzig.

Fabian C. **iPS reprogramming using mRNA: Pitfalls and possibilities.** World Conference on Regenerative Medicine, 21.-23.10.2015, Leipzig.

Fabian C. **Real time PCR for gene expression: step by step.** 5th Progress Meeting of BIOART Project FP7-PEOPLE-2012-ITN-316690, Universität Leipzig, 9.-13.2.2015, Leipzig.

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Fricke S. **Prevention of Graft-versus-Host-Disease (GvHD) with preserved anti-tumor effect (GvL) following hematopoietic stem cell transplantation.** Wissenschaftliches Kolloquium – Universitätsklinikum Dresden, 4.5.2015, Dresden.

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Glaser M, Händler T, Schuldt C, Golde T, Käs JA, Schnauß J, Smith DM. **Reptation of single filaments within entangled networks of tunable biopolymers.** Summerschool Physik der weichen Materie, 28.6.2015, Zingst.

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- Glaser M, Tschirner T, Moebius-Winkler M, Schuldt C, Händler T, Golde T, Smith DM, Schnauß J, Käs J. **Higher ordered assembly of rigid biopolymers induced by depletion forces.** Annual conference of the graduate school BuildMoNa, 24.3.2015, Leipzig.
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- Greim T, Braumann UD, Muders M, Löffler M. **Malignitätsgrading des Prostatakarzinoms mittels morphometrischer Deskriptoren.** GMDs 2015: 60. Jahrestagung der Deutschen Gesellschaft für Medizinische Informatik, Biometrie und Epidemiologie, 6.-9.9.2015, Krefeld.
- Grochowska KM, Bär J, Sahu G, Schilling S, Demuth HU, Kreuz MR. **Abeta3(pE)-42 induces synaptic dysfunction by different mechanisms than Abeta1-42.** EMBO | EMBL SYMPOSIUM: Mechanisms of neurodegeneration, 14.-17.6.2015, Heidelberg.
- Gros O, Schröder C. **CRIP.CodEx: Knowledge extraction from medical free text records.** 4. Nationales Biobanken-Symposium der TMF, 9.-10.12.2015, Berlin.
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- Halbich C. **Untersuchung und Beeinflussung der GVHD und des GVL-Effektes in einem murinen Transplantationsmodell.** DGHO, 9.-13.10.2015, Basel, Switzerland.
- Händler T, Schuldt C, Glaser M, Schnauß J, Käs JA, Smith D. **Microrheological characterization of DNA nanotube networks.** 79. Jahrestagung der DPG und DPG-Frühjahrstagung, 15.-20.3.2015, Berlin.
- Händler T, Smith D, Käs J. **Measuring the mesh size of DNA helix tube networks.** Department Seminar Physik der weichen Materie, 29.5.2015, Leipzig.
- Hartlage-Ruebsamen M, Meissner J, Waniek A, Morawski M, Schilling S, Jaeger C, Demuth HU, Rossner S. **Region and cell specific expression of Isoglutaminyl Cyclase and its substrate CCL2 in mouse and human brain.** 12th International conference on Alzheimer's and Parkinson's diseases, AD/PD™, 18.-22.3.2015, Nice, France.
- Hassert R., Bielefeldt P, Grunwald T, Vahlenkamp T, Hoffmann R. **Antigenic fingerprinting of murine Norovirus infections on Amino acid level.** 53. Wissenschaftliche Tagung der Gesellschaft für Versuchstierkunde GV-SOLAS, 14.-16.9.15, Hannover.
- Hettrich C, Rapsch K, Bier FF. **Entwicklung eines Schnelltest auf Extended Spectrum β -Laktamasen (ESBL).** 9. Deutsches Biosensor Symposium (DBS), 11.-13.3.2015, München.
- Hettrich C. **Rapid on-site detection of extended-spectrum- β -Lactamase-producing bacteria.** OASIS Workshop "Food and Water Safety". Forum Adlershof, 21.4.2015, Berlin.
- Hilger N, Müller C, Fricke S. **Prevention of adverse immunological complications while retaining anti-tumor effect following stem cell transplantation using anti-human CD4 antibodies.** Bionection 2015, 1.-2.10.2015, Leipzig.
- Hoffmann M, Seydel A, Schwertassek U, Lehmann J. **Efficacy of phytotherapeutics in a refined chronic DSS-induced colitis model.** International Congress of Mucosal immunology (ICMI), 14.-18.7.2015, Berlin.
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Jager C, Stephan A, Schilling S, Buchholz M. **Predicting potential protein-protein binding sites as pattern generator for further biological experiments.** ACS Fall Meeting, 18.-20.8.2015, Boston, USA.

Jäger C, Wiczorek V, Demuth HU, Buchholz M. **The use of force field and quantum chemistry based methods to overcome the lack of structural information in PDB structures with very low resolution.** 11th German Conference on Chemoinformatics, 8.-10.11.2015, Fulda.

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Kirsten H. **Genome-wide eQTL analysis.** Workshop on "Computational Models in Biology and Medicine", 10.-11.9.2015, Leipzig.

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Kubick S. **Eukaryotic cell-free protein synthesis: In vitro translation of membrane proteins and glycoproteins.** Vortrag an der Universität Bayreuth im Rahmen des BZMB-Kolloquiums, 16.6.2015, Bayreuth.

Kubick S. **Eukaryotic cell-free protein synthesis: In vitro translation of membrane proteins and glycoproteins.** Vortrag an der Rheinisch-Westfälisch Technischen Hochschule Aachen, Lehrstuhl für Biotechnologie (Prof. Schwaneberg). 10.7.2015, Aachen.

Kubick S. **Eukaryotic in vitro Translation Systems: Cell-free synthesis of posttranslationally modified membrane proteins.** Vortrag am Max Planck Institut für Biochemie in Martinsried (Prof. Schwille), 7.12.2015, München.

Kubick S. **Synthesis of membrane proteins in Eukaryotic cell-free systems.** Vortrag an der Ernst Moritz Arndt Universität Greifswald anlässlich des Kolloquiums der GDCh auf Einladung des Instituts für Biochemie (Prof. Bornscheuer) gemeinsam mit dem Ortsverband der Gesellschaft Deutscher Chemiker, 18.5.2015, Greifswald.

Kubick S. **Zellfreie Protein-synthese am Institutsteil Bioanalytik und Bioprozesse in Potsdam-Golm.** Vortrag beim Bundesverband der Pharmazeutischen Industrie e.V. (BPI), 18.11.2015, Berlin.

Kubick S. **Cell-free bioproduction for the synthesis of proteins with applications in the biotechnological industry.** Bayern Innovativ – Forum Life Science 2015, 12.3.2015, München.

Kubick S. **Eukaryotic in vitro translation systems: cell-free production of posttranslationally modified membrane proteins.** Kongress new technologies, new vaccines 2015, 24.3.2015, Wilmington, USA.

Kubick S. **Protein modification in eukaryotic cell-free systems through incorporation of non-canonical amino acids.** Non-canonical amino acids in proteins: structural investigations and biocatalysis, der DECHEMA, 10.2.2015, Frankfurt.

Kubick S. **Zellfreie Protein-synthese: Neue Systeme für die Darstellung von Membranproteinen, Antikörperfragmenten und zytotoxischen Proteinen.** Deutsche Biotechnologietage 2015, 22.4.2015, Köln.

Kubick S. **Cell-free synthesis of posttranslationally modified membrane proteins.** Seminars am Institut für Biologie der Humboldt Universität Berlin, Arbeitsgruppe Experimentelle Biophysik, Prof. Hegemann. 20.1.2015, Berlin.

Lahrman KH, Ehrentreich-Förster E. **Two novel rapid tests for indirect detection of boar taint from blood or from swabs of blood and of saliva.** 7th European symposium of Porcine health management, 22.-24.4.2015, Nantes, France.

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Lehmann J, Schulz RM. **Preclinical good laboratory practice-compliant safety study to evaluate biodistribution and tumorigenicity of a cartilage therapeutic.** ATMP 2015 – Issue and challenges from bench to bedside, 4-6.11.2015, Tutzing.

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Lidzba N, Ueberham E, Scholz U, Lehmann J. **Tracing allergens in one-shot approach - A multiplex Luminex assay for simultaneous detection of allergenic soy proteins.** Recent advances in food analysis (RAFA), 3.-6.11.2015, Prague, Czech Republic.

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Lidzba N. **Multiplex with Luminex.** The GRDC Symposium 2015, 20.10.2015, Leipzig.

Lorenz J, Möser C, Schuldt C, Neundorf I, Bier FF, Smith DM. **Functionalization of DNA nanostructures with biomolecules.** World Conference on Regenerative Medicine, 21.-23.10.2015, Leipzig.

Lorenz J, Möser C, Neundorf I, Smith DM. **Modulation of cellular uptake using peptide-functionalized DNA nanostructures.** 10th Molecular Interactions Workshop, 6.-8.5.2015, Konrad-Zuse Institut, Berlin.

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Lorenz J, Schuldt C, Moebius-Winkler M, Tschirner T, Schnauß J, Glaser M, Käs J, Smith D. **Polymer Physics 2.0: Exploiting programmable nanomaterials to control phase and material properties of soft matter.** Advanced materials and nanotechnology, 8.-12.2.2015, Nelson, New Zealand.

Lorenz J. **Conjugation of biomolecules from the standpoint of a biochemist.** Winterschool Physik der weichen Materie, 12.-19.2.2015, Marburger Haus, Austria.

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Makert G, Ulbert S. **An immunological control strategy for Dermanyssus gallinae.** Entomology Congress 2015, 2.-5.3.2015, Frankfurt.

Makert G, Ulbert S. **An immunological strategy for the control of the ectoparasite Dermanyssus gallinae.** Tagung der Deutsche Veterinärmedizinische Gesellschaft (DVG- Fachgruppe Parasitologie), 29.6.-1.7.2015, Stralsund.

Makert G, Ulbert S. **An immunological strategy for the control of the ectoparasite Dermanyssus gallinae.** Workshop on Arthropod-Borne Diseases – diseases transmitted by ticks, mites, fleas, and lice, 29.-30.6.2015, Leipzig.

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Mascher C, Wüstenhagen DA, Stech M, Sachse R, Zemella A, Kubick S. **Cell-free synthesis of "difficult to express" toxic proteins based on eukaryotic lysates.** 81. DGPT, 10.-12.3.2015, Kiel.

Meinlschmidt P, Schweiggert-Weisz U, Ueberham E, Lehmann J, Reineke K, Schlüter O, Eisner P. **Mitigation of soybean allergy by pulsed ultraviolet light, nonthermal atmospheric plasma, and gamma-irradiation.** INPW, 12.-13.11.2015, Athens, Greece.

Meinlschmidt P, Ueberham E, Lehmann J, Schweiggert-Weisz U, Eisner P. **Fermentation - A powerful method to overcome soybean allergenicity.** EFFoST, 10.-12.11.2015, Athens, Greece.

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Menger M. **Rapid aptamer generation for highly specific binding.** Innovation Day 2015, 8.-9.12.2015, Berlin.

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Möser C, Lorenz J, Guck J, Otto O, Lauster D, Bier FF, Smith D. **DNA nanostructures as platform for multivalent ligands.** 6th Annual Symposium Physics of Cancer, 7.-9.9.2015, Leipzig.

Möser C. **Activation of EphA2 receptor by multivalent presentation of SWL-12.** DNA Nanotechnology Mitteldeutschland Workshop, 24.9.2015, Dresden.

Möser C. **Engineering functionalized DNA nanostructures for biomedical applications.** Winterschool Physik der weichen Materie, 12.-19.2.2015, Marburger Haus, Austria.

Mükusch S, Seitz H. **Detection of post-translational modifications.** xMAP connect sharing multiplexing solutions 2015, 25.-26.11.2015, Amsterdam, The Netherlands.

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Towards a genetic screening test for Dyslexia: Genetic modulators of dyslexia-related MMR. "Reading in the forest" - International Workshop on reading and Dyslexia, 26.-28.10.2015, Annweiler.

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Real-time monitoring of metabolic function in liver-on-chip microdevices. HeMiBio International Symposium, 2.-3.12.2015, Leuven, Belgium.

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Sajfutdinov M, Schneider C, Smith D.

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Sauer M, Altrichter J, Doß S, Doß F, Wild T, Richter R, Ehler J, Mencke T, Nöldge-Schomburg G, Mitzner S. **Bioartificial extracorporeal therapy of severe sepsis: hemodynamic changes in patients and influence on liver cells.** World Conference on Regenerative Medicine, 21.-23.10.2015, Leipzig.

Sauer M. **Cell-based hepatotoxicity-testing of drugs.** Bionection 2015, 1.-2.10.2015, Leipzig.

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Schmiedeknecht G. **Challenges of manufacturing of ATMP's for clinical trials.** PDA Europe conference advanced therapy medicinal products, 2.-3.6.2015, Amsterdam, The Netherlands.

Schmiedeknecht G. **Challenges of manufacturing of ATMP's for clinical trials.** World Conference on Regenerative Medicine, 21.-23.10.2015, Leipzig.

Schnauß J. **Artificial DNA based cross-linkers drastically alter actin networks.** DNA Nanotechnology Mitteldeutschland Workshop, 27.11.2015, Leipzig.

Schröder C. **Normsetzung im internationalen Kontext: WG 2 (Biobanks and Bioresources) des ISO TC 276.** TMF-Jahreskongress 2015, 25.-26.3.2015, Hannover.

Schröder C. **Promoting quality biobanks and biobank quality: The metabiobank p-BioSPRE.** Leaders in Biobanking Congress, 14.-16.7.2015, Toronto, Canada.

Schroeder, C. **From meta-biobanks to translational research platforms: integrating Big Data through CRIP tools.** ESBB Annual Conference, 29.9.-2.10.2015, London, UK.

Schuldt C, Händler T, Glaser M, Lorenz J, Käs J, Schnauß J, Smith DM. **Tailoring micro-environments via mechanical programming of synthetic biopolymer networks.** World Conference on Regenerative Medicine, 21.-23.10.2015, Leipzig.

Schuldt C, Händler T, Glaser M, Lorenz J, Schnauß J, Käs JA, Smith DM. **Scaling with persistence length: Expanding the accessible phase space of semi-flexible polymer networks via DNA tubes.** 6th Annual Symposium Physics of Cancer, 7.-9.9.2015, Leipzig.

Schuldt C, Lorenz J, Glaser M, Händler T, Moebius-Winkler M, Tschirner T, Schnauß J, Käs J, Smith D. **Non-genetic programming of biological systems through nanoscale components.** Engineering life 2015 - synthetic biology meets bioinspired materials, 29.9.-1.10.2015, Dresden.

Schuldt C, Lorenz J, Glaser M, Händler T, Moebius-Winkler M, Tschirner T, Schnauß J, Käs J, Smith D. **Expanded experimental parameter space of semiflexible polymer assemblies through programmable nanomaterials.** 12th Annual conference on foundations of nanoscience, 13-16.4.2015, Snowbird, USA.

Schuldt C, Lorenz J, Glaser M, Händler T, Moebius-Winkler M, Tschirner T, Schnauß J, Käs J, Smith D. **Programming macroscale mechanics of biomaterials through nanoscale components.** Emerging Methods and Technologies for Medical Research Conference, 1.-2.9.2015, Stockholm, Sweden.

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Schumacher S, Seitz H.
Multiplex approach for an immunological detection of drug abuse: a validation study. GTFCh-Symposium, 16.-18.4.2015, Mosbach.

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Schüttler A, Reiche K, Altenburger R, Busch W.
Transcriptome studies in ecotoxicology need time and dose resolved data. Statistical methods for Omics data integration and analysis, 14.-16.9.2015, Valencia, Spain.

Schüttler A, Reiche K, Altenburger R, Busch W.
Transcriptome studies in ecotoxicology need time and dose resolved data. 15th EuCheMS international conference on chemistry and the environment, 20.-24.9.2015, Leipzig.

Seydel A, Hoffmann M, Schwertassek U, Lehmann J.
Immunological aspects of chronic gut inflammation induced by infection with Salmonella enterica. World Conference on Regenerative Medicine, 21.-23.10.2015, Leipzig.

Seydel A, Hoffmann M, Thiele M, Schwertassek U, Lehmann J.
Induction of chronic gut inflammation by infection with Salmonella enterica. International Congress of Mucosal Immunology (ICMI), 14.-18.7.2015, Berlin.

Smith D.
Bottom-up engineering of nanoscale devices to program biological systems. Invited Lecture McMaster University, 12.11.2015, Hamilton, Canada.

Smith D.
Fine-tuning biological systems on the macroscale through synthetic nanoscale building blocks. Invited Lecture University of Western Ontario, 11.11.2015, London, Canada.

Smith D.
Sculpting with DNA molecules. Nerd Nite, 10.12.2015, Leipzig.

Smith D, Schuldt C, Lorenz J, Tschirner T, Moebius-Winkler M, Kaes J, Glaser M, Haendler T, Schnauß J.
Expanded experimental parameter space of semiflexible polymer assemblies through programmable nanomaterials. American Physical Society March Meeting 2015, 2.-6.3.2015, San Antonio, USA.

Smith D.
How to beat biology: fine-tuning mechanical and structural properties of biomaterials through programmable nanomaterials. Invited Lecture Hochschule Furtwangen, 19.5.2015, Villingen-Schwenningen.

Smith D.
How to beat biology: fine-tuning mechanical and structural properties on the macroscale through programmable nanomaterials. Invited Lecture, Cambridge University Department of Chemistry, 5.6.2015, Cambridge, UK.

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How to beat biology: fine-tuning mechanical and structural properties on the macroscale through programmable nanomaterials. Invited Lecture, Raboud University, 6.8.2015, Nijmegen, The Netherlands.

Smith D.
Non-genetic programming of biological systems through nanoscale components. Invited Lecture Chonnam National University Hospital Hwasun, 15.9.2015, Gwangju, South Korea.

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Non-genetic programming of biological systems through nanoscale components. Invited Lecture Gwangju Institute of Science and Technology, 16.9.2015, Gwangju, South Korea.

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Programming biological systems through synthetic nanoscale components. 6th Annual symposium physics of cancer, 7.-9.9.2015, Leipzig.

Stech M, Hust M, Schenk JA, Sonnabend A, Stöcklein WFM, Thoring L, Wüstenhagen DA, Dübel S, Kubick S.
Cell-Free synthesis meets antibody production: Eukaryotic cell-free systems as novel source of antibody fragments. PEGS Europe Konferenz, 7.-9.11.2015, Lisbon, Portugal.

Stech M, Kubick S.
Eukaryotic cell-free systems for the synthesis of antibody fragments. 7. Workshop on affinity promeomics, 9.-12.3.2015, Alpbach, Austria.

Stech M, Quast RB, Sachse R, Wüstenhagen DA, Kubick S. **Eukaryotic cell-free systems for cell-free bioproduction.** 7. Workshop on affinity promeomics, 9.-12.3.2015, Alpbach, Austria.

Stech M. **Developing novel cell-free systems to improve risk assessment in food analysis and clinical diagnostics.** Innovation Days, 9.12.2015, Berlin.

Stech M. **Eukaryotic lysates for cell-free bioproduction.** PEGS Europe Konferenz, 2.-5.11.2015, Lisbon, Portugal.

Stech M. **Zellfrei macht's möglich: Proteinsynthese just-in-time.** Potsdamer Tag der Wissenschaften, 9.5.2015, Potsdam.

Stöcklein WFM, Memczak H, Lauster D, Herrmann A, Ehrentreich-Förster E. **SPR characterization of virus- and antibody-binding peptides.** Biacore™ User Meeting, 1.-2.10.2015, Berlin.

Stöcklein WFM, Memczak H, Lauster D, Herrmann A, Ehrentreich-Förster E. **Thermophoretic multivalent detection of proteins by GFP-coupled peptides.** 9. Deutsches Biosensor Symposium (DBS), 11.-13.3.2015, München.

Szardenings M. **A quarter century phage display.** ADeKo Generalversammlung, Goethe Institut, 11.3.2015, Seoul, South Korea.

Szardenings M. **Application of click chemistry for Biacore analysis.** Biacore user meeting, 1.-2.10.2015, Berlin.

Szardenings M. **Click chemistry applications for peptides.** Korean-German Joint Symposium, 20.10.2015, Leipzig.

Szardenings M. **Next generation sequencing meets last generation peptide phage display.** Chonbuk National University Medical School, 27.11.2015, Jeonju, South Korea.

Szardenings M. **Ultimate peptide phage display in epitope studies.** Gwangju Institute for Science and Technology (GIST), 20.11.2015, Gwangju, South Korea.

Taudte N, Liebe L, Ramsbeck D, Buchholz M, Kleinschmidt M, Rahfeld JU, Schilling S, Demuth HU. **Bacterial Glutaminyl Cyclases as novel target for drug development.** 5th Halle Conference on recombinant proteins, 19.-20.2.2015, Halle (S.).

Thoring L, Borowiak M, Wenzel D, Wüstenhagen DA, Kubick S. **Addressing "Difficult to Express Proteins": An innovative cell-free system based on CHO cell lysates.** Tag der Biotechnologie, TU Berlin 16.7.2015, Berlin.

Thoring L, Borowiak M, Sonnabend A, Wüstenhagen DA, Kubick S. **A novel cell-free protein synthesis system based on CHO cell extracts: Expression of membrane proteins and "difficult to express" proteins.** PepTalk: The Protein Science Week, 19.-23.1.2015, San Diego, USA.

Thoring L, Borowiak M, Wenzel D, Wüstenhagen D, Kubick S. **Addressing the production of membrane proteins and "Difficult to Express" proteins: an innovative cell-free system based on CHO cell lysates.** Molecular Interactions, 6.-8.5.2015, Berlin.

Thoring L, Sonnabend A, Schulze A, Wüstenhagen DA, Kubick S. **Innovative cell-free systems based on CHO cell lysates: future perspectives for the production of toxic and "Difficult to Express" proteins.** Protein synthesis and translational control, 9.-13.9.2015, Heidelberg.

Thoring L, Wüstenhagen DA, Stech M, Kubick S. **Designing cell-free systems for the production of membrane proteins.** Design of biosystems – Jahrestagung der Forschungsorganisationen zum Strategieprozess Biotechnologie 2020+, 22.-23.9.2015, Berlin.

Thoring L, Zemella A, Stech M, Wüstenhagen D, Dondapati S, Kubick S. **Cell-free bioproduction for the synthesis of proteins with applications in the biotechnological industry.** Bayern Innovativ – Forum Life Science 2015, 11.-12.3.2015, München.

Thoring L. **Future perspectives for the synthesis of "Difficult-to-Express" proteins: development of novel cell-free systems based on CHO cell lysates.** PhD Symposium, 26.-27.11.2015, Luckenwalde.

Tröger V, Scherber A, Tulp I, Lehes M, Howitz S, Bohatzsch T, Pardy T, Kuhlmeier D. **Development of a nucleic acid-based home care device for the fast detection of sexually-transmitted diseases.** Point-of-Care Diagnostics & Global Health World Congress, 28.-30.9.2015, San Diego, USA.

Tschirner T, Glaser M, Moebius-Winkler M, Schuldt C, Händler T, Golde T, Käs J, Smith D, Schnauß J. **Higher ordered assembly of DNA nanotubes induced by depletion forces.** Summer-school Physik der weichen Materie, 28.6.2015, Zingst.

Uhlig K, Wellhausen R, Zeiser M, Wegener T, Hellweg T, Seitz H, Ehrentreich-Foerster E, Duschl C. **Establishing cell patterns for cell assays.** World Conference on Regenerative Medicine, 21.-23.10.2015, Leipzig.

Ulbert S. **Latest developments and challenges in the diagnosis of human flavivirus infection.** European Seminars in Virology, 19.-21.6. 2015, Bertinorio, Italy.

Ulbert S. **Specific and sensitive detection of antibodies against different emerging flaviviruses using mutant envelope proteins.** International Symposium on Flaviviruses, 8.-10.10.2015, Wien, Austria.

Vorreiter F, Hösler N, Schreiber S, Reiche K, Hackermüller J. **Cis regulatory long non-coding RNAs in human naive and activated T helper cells.** EMBO/EMBL Symposium: The non-coding genome, 18.-21.10.2015, Heidelberg.

Waniek A, Hartlage-Rübsamen M, Höfling C, Kehlen A, Schilling S, Demuth HU, Roßner S. **Identification of Thyrotropin-releasing hormone as hippocampal Glutaminy Cyclase substrate in neurons and reactive astrocytes.** 12th International conference on Alzheimer's and Parkinson's diseases, AD/PD™, 18.-22.3.2015, Nice, France.

Wiedemann K, Hackermüller J, Reiche K. **Semi-automatic interpretation of local secondary structure motifs in lncRNAs.** EMBO/EMBL Symposium: The non-coding genome, 18.-21.10.2015, Heidelberg.

Wiedemann K, Reiche K, Hackermüller J. **Semi-automatic interpretation of local secondary structure motifs in lncRNAs.** Central German meeting on bioinformatics 2015, 26.-27.8.2015, Halle (S.).

Wierich L, Grunwald T. **A novel platform for the delivery of DNA-vaccines.** Spring School Immunology, 8.-13.3.2015, Kloster Ettal.

Wilcke A, Müller B, Schaad G, Kirsten H, Boltze J. **Towards a genetic screening test for Dyslexia: high acceptance of an early Dyslexia screening test involving genetic analyses in Germany.** World Conference on Regenerative Medicine, 21.-23.10.2015, Leipzig.

Wilcke A, Müller B, the LEGASCREEN consortium, Boltze J, Kirsten H. **LEGASCREEN – a multimodal test for early diagnostic of dyslexia.** Bionection 2015, 1.-2.10.2015, Leipzig.

Wilcke A, Müller B, the LEGASCREEN consortium, Kirsten H, Friederici AD. **LEGASCREEN – A multimodal test for early diagnostic of Dyslexia and its acceptance.** "Reading in the forest" - International Workshop on reading and Dyslexia, 26.-28.10.2015, Annweiler.

Wilcke A. **Dyslexia, language and music - linked by genes and brain?** Musicans-Born or Made, International Symposium, 10.-11.04.2015, Montreal, Canada.

Wilcke A. **Genetics of Dyslexia - an early screening test and its acceptance.** Dyslexia and coping behaviour - International Workshop, 8.-9.10.2015, Leipzig.

Willbold D, Brenner O, Dunkelmann T, Gremer L, van Groen T, Kadish I, Demuth HU, Langen KJ, Willuweit A, Nagel-Steger L. **Therapy development for Alzheimer's disease based on Abeta oligomer elimination.** 12th International conference on Alzheimer's and Parkinson's diseases, AD/PD™, 18.-22.3.2015, Nice, France.

Zajac J, Schubert A, Oelkrug C. **Targeting H. pylori infections for the prevention of gastric cancer by IgYs.** World Conference on Regenerative Medicine, 21.-23.10.2015, Leipzig.

Zeisig V, Jochimsen TH, Werner P, Barthel H, Dreyer A, Boltze J, Sattler B, Sabri O. **Simultane PET/MRT-Bildgebung zur automatisierten Berechnung einer bildbasierten Inputfunktion.** 53. Jahrestagung der Deutschen Gesellschaft für Nuklearmedizin, 22.-25.4.2015, Hannover.

Zemella A, Bottke A, Sonnabend A, Sachse R, Wüstenhagen DA, Kubick S. **Fluorescent labeling of membrane proteins for the analysis of ligand-receptor interactions in an eukaryotic cell-free translation system.** Molecular Interactions, 6.-8.5.2015, Berlin.

OTHER PUBLICATIONS

Zemella A, Bottke A, Sonnabend A, Wüstenhagen DA, Kubick S. **Membrane protein engineering using non-canonical amino acids in eukaryotic cell-free systems.** Protein synthesis and translational control, 9.-13.9.2015, Heidelberg.

Zemella A, Bottke A, Thoring L, Wüstenhagen DA, Kubick S. **Analysis of fluorescent labeled membrane proteins using a eukaryotic cell-free orthogonal system.** Konferenz "Seeing Is Believing", 6.-10.10.2015, Heidelberg.

Zemella A, Sonnabend A, Quast R, Sachse R, Wüstenhagen DA, Kubick S. **Orthogonal systems designed for membrane protein engineering.** Design of biosystems – Jahrestagung der Forschungsorganisationen zum Strategieprozess Biotechnologie 2020+, 22.-23.9.2015, Berlin.

Zemella A. **Membrane protein engineering in Eukaryotic cell-free systems: functional characterization of G protein-coupled receptors.** PhD Symposium, 26.-27.11.2015, Luckenwalde.

Zemella A. **Reconstitution of tyrosine kinase signaling in cell-free systems: Synthetic membrane protein dimerization and lipid modification.** Doktoranden-Workshop des SPP 1623, 11.-13.5.2015, Herrsching.

Bier FF. **Lab in a hanky - what comes next after Lab-on-Chip.** selsctBio Conferences Proceedings Point of Care Doagnostics, Berlin, 2015.

Flemmig J, Leichsenring A, Lange F. **Myeloperoxidase – ein neuer Marker zur Erforschung von Entzündungen?** BioSpektrum. 21 (2015), 7, S. 725-727. DOI: <http://dx.doi.org/10.1007/s12268-015-0640-5>.

Herrmann S, Seitz H. **Personalisierte Medizin und Diagnostika: Der Stand der Dinge.** GIT Labor-Fachzeitschrift. 59 (2015), 8, S. 18–23.

Kubick S. **Zellfreie Bioproduktion: Neue Möglichkeiten für die ressourcenschonende Herstellung hochwertiger Biomoleküle.** Park'n'Science : Newsletter für den Wissenschaftspark Potsdam-Golm. 13 (2015), S. 4.

Menger M. **Aptamere auf dem Vormarsch in der Bioanalytik.** PS Park'n'Science : Newsletter für den Wissenschaftspark Potsdam-Golm, 14 (2015), S. 3.

Sonnabend A, Nikolaeva O, Kubick S. **Templatoptimierung in der zellfreien Proteinsynthese.** GIT Labor-Fachzeitschrift. 59 (2015), 11, S. 35–38.

Wagner D, de Vera J-P, Joshi J, Leya T, Schulze-Makuch D. **Astrobiologie - dem Leben im Universum auf der Spur.** System Erde. 5 (2015), 1, S. 40-47. DOI: <http://dx.doi.org/10.2312/GFZ.syser-de.05.01.7>.

BOOK ARTICLES

Findeiß S, Wachsmuth M, Mörl M, Stadler PF. **Design of transcription regulating riboswitches.** Riboswitches as targets and tools / ed. by Donald H. Burke-Aguero. Amsterdam : Elsevier, 2015. XIX, 423, [24] S. : Ill. (Methods in enzymology ; 550). ISBN 978-0-12-801123-2 S. 1-22. DOI: <http://dx.doi.org/10.1016/bs.mie.2014.10.029>.

Henkel S, Wellhausen R, Woitalla D, Marcus K, May C. **Epitope mapping using peptide microarray in autoantibody profiling.** Microarray technology: methods and applications / ed. by Paul C.H. Li... New York, NY : Humana Press, 2015. XIV, 294 S. : Ill. (Methods in Molecular Biology ; 1368). ISBN 978-1-4939-3135-4. S. 209-224. DOI: http://dx.doi.org/10.1007/978-1-4939-3136-1_15.

Kirschbaum M, Jaeger MS, Duschl C. **Measurement of surface-mediated Ca²⁺ transients on the single-cell level in a microfluidic lab-on-a-chip environment.** G protein-coupled receptor screening assays : methods and protocols / ed. by Duarte Miguel F. Prazeres ... New York, NY [u.a.] : Humana Press, 2015. XII, 296 S. : Ill., graph. Darst. (Methods in Molecular Biology ; 12729). ISBN 978-1-4939-2335-9. S. 247-256. DOI: http://dx.doi.org/10.1007/978-1-4939-2336-6_17.

BOOK

Biomarkervalidierung und Assayentwicklung. Biomarker validation: technological, clinical and commercial aspects / ed. by Harald Seitz Weinheim : Wiley-VCH, 2015. XVI, 248 S. : graph. Darst. ISBN 978-3-527-33719-4.

GRADUATION (CLASS OF 2015)

Anders, Toni. **Development of a Drop Detection Software Module for the Optimization of a Dispensing Platform.** Brandenburg University of Applied Sciences, bachelor's degree

Arnold, Stefanie. **Epitope Mapping of PBP2a and Identification of MRSA-Specific Immunodominant Peptide Sequences.** University of Potsdam, doctorate degree

Baltaci, Dilek. **Development of a Bead-Based Immunoassay for the Measurement of Complement and Coagulation Parameters in Small Volumes.** Technical University of Berlin, master's degree

Bezold, Veronika. **Development and Optimization of an Enzyme Immunoassay to Detect Secretory Components in Bovine Milk.** Anhalt Köthen University of Applied Sciences, master's degree

Böhm, Christoph. **System Modelling of a Lab-on-a-Chip Test Platform with a Thermal Control Design.** Leipzig University of Applied Sciences, master's degree

Borowiak, Maria. **Cell-Free Synthesis and Functional Characterization of the Channelrhodopsin Variants ChIEF and ReaChR.** University of Potsdam, master's degree

Büchner, Kerstin. **Modification and Characterization of Waveguide Materials for Biosensor Applications.** University of Potsdam, doctorate degree

Djeutch, Audrey M. Ngamga. **Comparison of Different Detection Systems in a Microarray based on the Example of a CRP Immunoassay.** University of Potsdam, bachelor's degree

Ehren, Patricia. **Synthesis of Human Erythropoietin in Eukaryotic Cell-Free Systems: Analysis of Post-Translational Modifications by Mass Spectrometry.** University of Potsdam, master's degree

Ermilova, Elena. **Broadband, Dielectric Characterization of Biologically Relevant Polymers.** University of Potsdam, doctorate degree

Fricke, Stephan. **Development of Preclinical Transplantation Models and Innovative Immunological Therapies to Prevent Graft-versus-Host-Disease (GvHD) while Retaining Anti-Tumor Effect following Hematopoietic Stem Cell Transplantation.** Leipzig University, post-doctoral qualification

Gischke, Marcel. **Developing and Establishing Agglomeration Assays for the Early Recognition of Rheumatoid Arthritis.** Beuth University of Applied Sciences Berlin, master's degree

Hauffe, Robert. **Cell-Free Synthesis and Functional Analysis of the Human Inward Rectifying Potassium Channel Kir6.2.** University of Potsdam, master's degree

Helm, Maria. **Peptide Phage Display with Next-Generation Sequencing: Evaluation of Data and Adaptation of Software-Assisted Evaluation.** University of Applied Sciences Mittweida, bachelor's degree

Hietel, Benjamin. **Isolation and Cultivation of Microglial Cells from Murine Brain Tissue and their Stimulation in order to Generate an Inactive Adult Phenotype.** Brandenburg University of Technology Cottbus-Senftenberg, bachelor's degree

Hoffmann, Marie-Luise. **Establishing and Applying Detection Methods for the Development of an Anti-hn-PY1R Antibody.** Martin Luther University of Halle-Wittenberg, master's degree

Hofrichter, Jacqueline. **The Influence of Plant Extracts on β -Amyloid Induced Pathologies in an APP/PS1 Mouse Model of Alzheimer's Disease.** University of Rostock, doctorate degree

Kacan, Fatih. **Development and Optimization of a Diagnostic Immunoassay for the POC Platform.** Beuth University of Applied Sciences Berlin, bachelor's degree

Larsen, Lena Rebecca. **Characterizing the Epitopes of Beta-Conglycinin and Profilin as Part of Allergy Research using Peptide Phage Display.** Martin Luther University of Halle-Wittenberg, diploma

Lenz, E. **Influence of Iron and Phosphate on the Production of Eicosapentaenoic Acid by an Isolate of the Alga cf. Hormidiospora Verrucosa from Spitzbergen.** Technical University of Berlin, diploma

Meldau, Kathrin. **Manageable Actin Polymerization Initiated by DNA Nanostructures.** Martin Luther University of Halle-Wittenberg, bachelor's degree

Misterek, Maria. **Optimization of an Allergic Asthma Mouse Model for the Preclinical Testing of Innovative Therapeutic Agents.** Otto von Guericke University Magdeburg, master's degree

Möser, Christin. **Engineering Functionalized DNA Nano-Structures for Biomedical Applications.** Friedrich Schiller University Jena, master's degree.

Müller, Claudia. **Establishing an In Vitro Assay to Detect Cytokine Production in Activated T-Cells.** Brandenburg University of Technology Cottbus-Senftenberg, master's degree

Naujoks, Wiebke. **Comparative Analyses of Experimental COPD and Allergic Asthma in Mouse Models.** University of Konstanz, master's degree

Niemeyer, Michael. **Expression and Purification of the Coating Protein with regard to the Human Endogenous Retrovirus HERV-Fc1 SU.** Martin Luther University of Halle-Wittenberg, master's degree

Peters, Ekaterina. **Qualitative HPLC-ESI Single Quadrupole MS Analysis of Uremic Toxins in Blood Plasma Samples of Dialysis-Dependent Patients.** Aalen University, master's degree

Pösel, Claudia. **Efficacy of a Combination Therapy using G-CSF and Mononuclear Cells from Bone Marrow in a Preclinical Stroke Model.** Leipzig University, doctorate degree

Prill, Sebastian. **Real-time In Vitro Toxicity Monitoring in a Microfluidic Bioreactor for Drug and Chemical Safety Assessment.** University of Potsdam, doctorate degree

Quast, Robert. **Synthesis and Site-Directed Modification of Membrane Proteins using Non-Canonical Amino Acids in a Cell-Free System derived from Cultured Spodoptera Frugiperda Cells.** University of Potsdam, doctorate degree

Rapsch, Karsten. **Rational Design of Anti-Microbial Peptides for the Therapeutic Application and Development of Peptide-Based Anti-microbial Surface Coatings.** Technical University of Berlin, doctorate degree

Rautenberger, Paul. **Characterizing the Epitopes of Glycinin and SAM22 as Part of Allergy Research using Phage Display.** Martin Luther University of Halle-Wittenberg, diploma

Riegelsberger, Ute. **Analysis of the Neuroprotective Effect of Human Umbilical Cord Blood Cells following Experimental Stroke in Hypertensive Rats.** Leipzig University, doctorate degree

Römer, Petra. **Studies on the Effect of Short Interfering RNA in Cell-Free Eukaryotic Systems.** Free University of Berlin, diploma

Sachse, Rita. **Biological Membranes in Cell-Free Systems: Characterisation and Functionalisation of Spodoptera Frugiperda Derived Microsomes.** University of Potsdam, doctorate degree

Schlittkuss, Keith. **Creation of a Concept and Prototype for a Dispensing System for Biological Samples to be used in Microarray Production and the Synchronization of Modules used in Parallel and Control of Components in the Nanosecond Range.** Brandenburg University of Applied Sciences, master's degree

Schmidt, Uwe. **Transplantation of Human Umbilical Cord Blood Cells following Experimental Stroke: Evaluation of the Therapeutic Time Frame.** Leipzig University, doctorate degree

Schönbohm, Daniel. **Programming Prototypical Software for the Calculation and Performance of Optimized Process Operations for Parallel Peptide Synthesis.** Brandenburg University of Applied Sciences, bachelor's degree

Spahn, Claudia. **Development of a Purification Strategy for Different β -Amyloid Species.**

Martin Luther University of Halle-Wittenberg, master's degree

Stech, Marlitt. **Investigations on the Cell-Free Synthesis of Single-Chain Antibody Fragments using a Eukaryotic Translation System.**

University of Potsdam, doctorate degree

Strich, Stefanie. **Synthesis of Novel Inhibitors of Bacterial Glutaminy Cyclases.**

Leipzig University, diploma

Tanne, Johannes. **Direct Electron Transfer and Bioelectrocatalysis of Redox Proteins and Enzymes containing Heme to Charged MWCNT/Polyaniline Hybrids in Electrochemical Biosensors.**

University of Potsdam, doctorate degree

Thiele, Maria. **Establishment and Application of Immunohistochemical Detection Procedures for Immune Cells and Cytokines in Chronic Colitis Mouse Models.**

Leipzig University, diploma

Tüting, Christian. **Expression and Characterization of Human Meprin Alpha.**

Martin Luther University of Halle-Wittenberg, master's degree

Westphal, Christina. **Healthy Ageing? Trends and Patterns in Smoking and Overweight and their Impact on the Health Prospects of the Ageing Population in Germany.**

University of Rostock, doctorate degree

Wieczorek, Vivien. **Use of Quantum-Mechanical Methods to Refine Crystal Structures and to Analyze Receptor-Ligand Interaction Patterns.**

University of Applied Sciences Mittweida, bachelor's degree

Wienke, Julia. **Identification and Differentiation of Clinically Relevant Staphylococci using Multiplex PCR and DNA Microarray.**

University of Potsdam, master's degree

Wunderlich, Kai. **Development of a Parallel Multi-Component Analysis of Antigen-Antibody Reactions in Doping Analysis.**

University of Potsdam, doctorate degree

Zhang, Ziyun. **Cloning, Expression and Purification of Coating Proteins of Human Endogenous Retroviruses as Target Proteins in Multiple Sclerosis Research.**

Anhalt Köthen University of Applied Sciences, master's degree

PRIZES

1st prize for the 2015 Summer Semester Poster Presentation awarded by Coburg University of Applied Sciences

to Katharina Pöhlmann from the Cell Engineering / GLP Unit on the topic "Investigation of Ligand-Dependent Transcription Activation of the Aryl Hydrocarbon Receptor with a Luciferase Assay"

2nd prize at the Innovation Academy Biotechnology held by the Federal Ministry of Education and Research (BMBF)

awarded to Dr. Catharina Bertram from the Study and Quality Management Unit for the product idea "3D-Printed Tooth (EverDent)"

Biotechnology Prize 2015 awarded by Anhalt University of Applied Sciences

to Martin Dähne from the Cell Engineering / GLP Unit on the topic "Effect of a Colocynth and Sage Based Phytopharmaceutical on the Gene Expression of Human Immune Cells"

Diploma Thesis Prize 2015 awarded by APFEL e.V.

to Christiane Leovsky from the Ligand Development Unit on the topic "Biodistribution of Transplanted Cells – Effect of Aging"

C-3 Saxony Innovation Award presented by AGIL Leipzig GmbH

to Dr. Arndt Wilcke from the Cognitive Genetics Unit on the topic "LegaTest – Combination of Genetics and EEG in the Early Diagnosis of Dyslexia"

Poster Prize awarded at Fraunhofer IZI Science Day

to Linda Liebe from the Drug Design and Analytical Chemistry Unit on the topic "Design, Synthesis and Structure-Activity-Relationships of Inhibitors of Porphyromonas gingivalis Glutaminy Cyclase as Possible Treatment of Periodontitis" / to Bent Müller from the Cognitive Genetics Unit on the topic "Towards a Genetic Screening Test for Dyslexia: Genetic Modulators of Dyslexia-Related MMR" / to Jessica Lorenz and Christin Möser from the DNA Nanodevices Unit on the topic "Engineering Functionalized DNA Nanostructures for Biomedical Applications"

Travel grant awarded by the GlaxoSmithKline Foundation

to Sandra Mükusch from the Biomarker Validation and Assay Development Unit to travel to an event fulfilling the grant criteria

Research internship in nanotechnology and biomedical engineering

(as part of the Fraunhofer-Delaware Exchange Program) awarded by the Fraunhofer-Gesellschaft to Jadwiga Graczyk from the Ligand Development Unit on the topic "Antibody Engineering"

PATENTS

The patent portfolio of the Fraunhofer IZI currently holds 54 patent families which are available for use in cooperation projects as well as for direct commercialization and licensing.

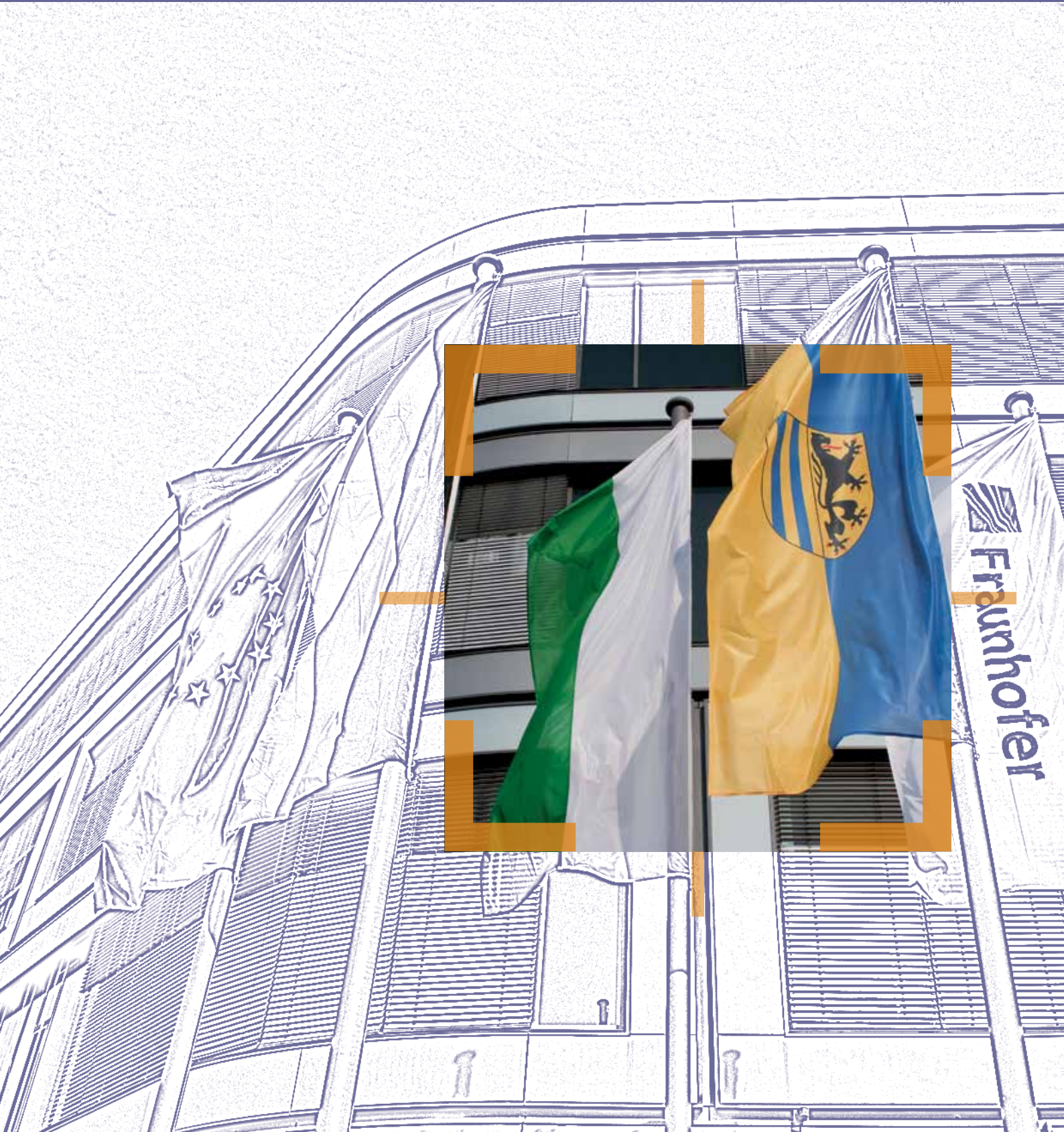
Contact

Dr. Thomas Tradler
Business Development and
Patent Management
Phone +49 341 35536-9305
thomas.tradler@izi.fraunhofer.de

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

FURTHERANCE



SPONSORS AND ADVISORY BOARD OF THE FRAUNHOFER IZI

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

Sponsors

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

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



Bundesministerium
für Bildung
und Forschung



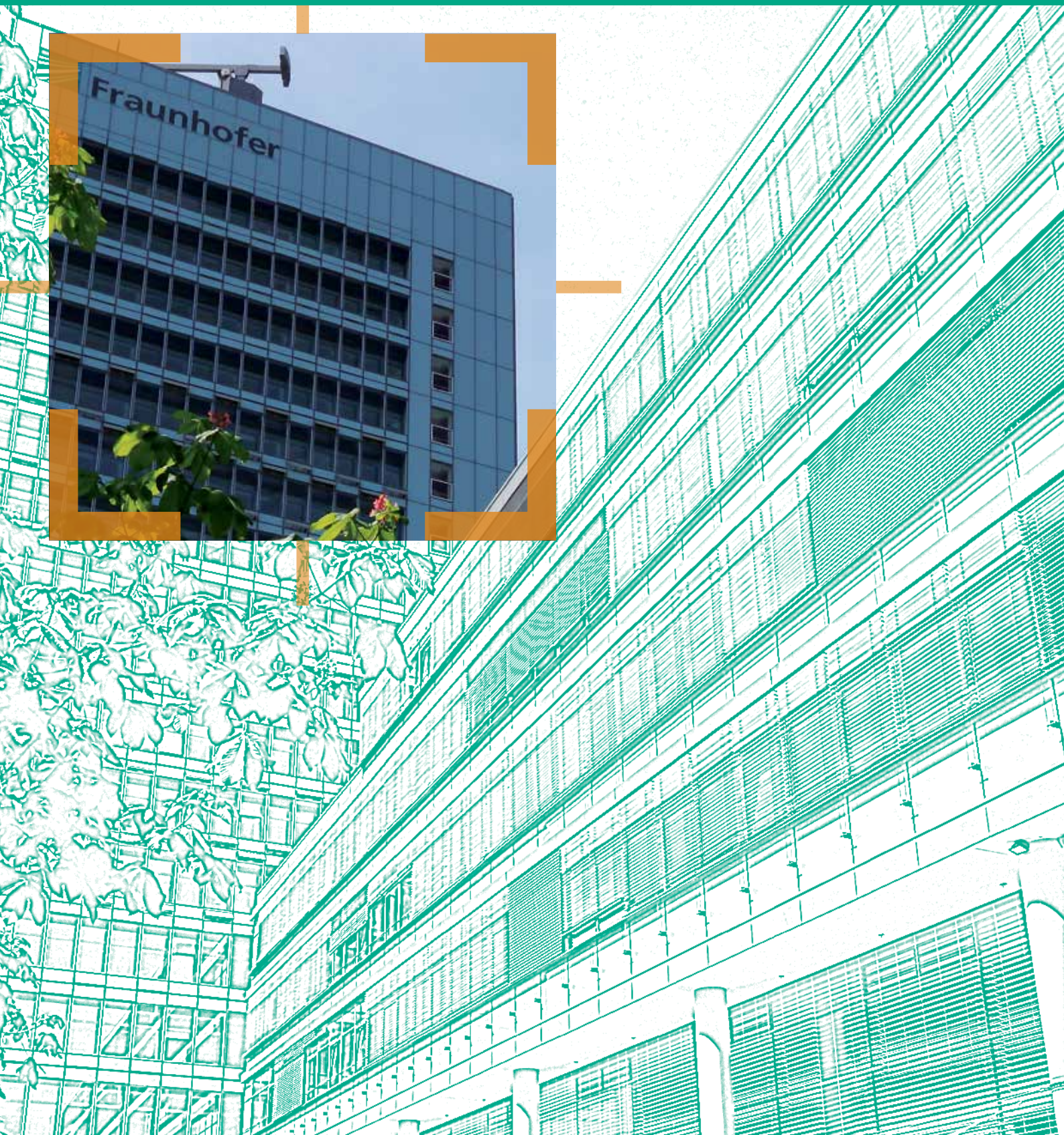
Advisory board

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

Members of the advisory board:

- Dr. Henrich Guntermann (Chair) (President Europe & Immunology Group Nuvo Research Inc.)
- MR'in Dr. Annerose Beck (Saxon State Ministry of Science and the Arts (SMWK), Head of National-Regional Research Centers Administration)
- Klaus Berka (Analytik Jena AG, Chairman)
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- Prof. Dr. Hans-Martin Jäck (University Hospital Erlangen, Head of the Molecular Immunology Department, President of the German Society for Immunology)
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- Dr. Uwe Marx (TU Berlin / TissUse GmbH)
- Prof. Dr. Friedrich-Wilhelm Mohr (Heart Center Leipzig GmbH – University Hospital – Medical Director)
- Prof. Dr. Gerhard Oechtering (Leipzig University, Director of the Small Animal Hospital)
- Dr. Kai Pinkernell (Medigene AG)
- Prof. Dr. Andreas Pinkwart ((HHL Leipzig Graduate School of Management, Dean)
- Dr. Mark Wolters (Bayer Pharma AG)

FRAUNHOFER- GESELLSCHAFT



THE FRAUNHOFER-GESELLSCHAFT IN PROFILE

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

At present, the Fraunhofer-Gesellschaft maintains 67 institutes and research units. The majority of the nearly 24,000 staff are qualified scientists and engineers, who work with an annual research budget of more than 2.1 billion euros. Of this sum, more than 1.8 billion euros is generated through contract research. More than 70 percent of the Fraunhofer-Gesellschaft's contract research revenue is derived from contracts with industry and from publicly financed research projects. Almost 30 percent is contributed by the German federal and Länder governments in the form of base funding, enabling the institutes to work ahead on solutions to problems that will not become acutely relevant to industry and society until five or ten years from now.

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

With its clearly defined mission of application-oriented research and its focus on key technologies of relevance to the future, the Fraunhofer-Gesellschaft plays a prominent role in the German and European innovation process. Applied research has a knock-on effect that extends beyond the direct benefits perceived by the customer: Through their research and development work, the Fraunhofer Institutes help to reinforce the competitive strength of the economy in their local region, and throughout Germany and Europe. They do so by promoting innovation, strengthening the technological base, improving the acceptance of new technologies, and helping to train the urgently needed future generation of scientists and engineers.

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

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

Executive board

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

Head office

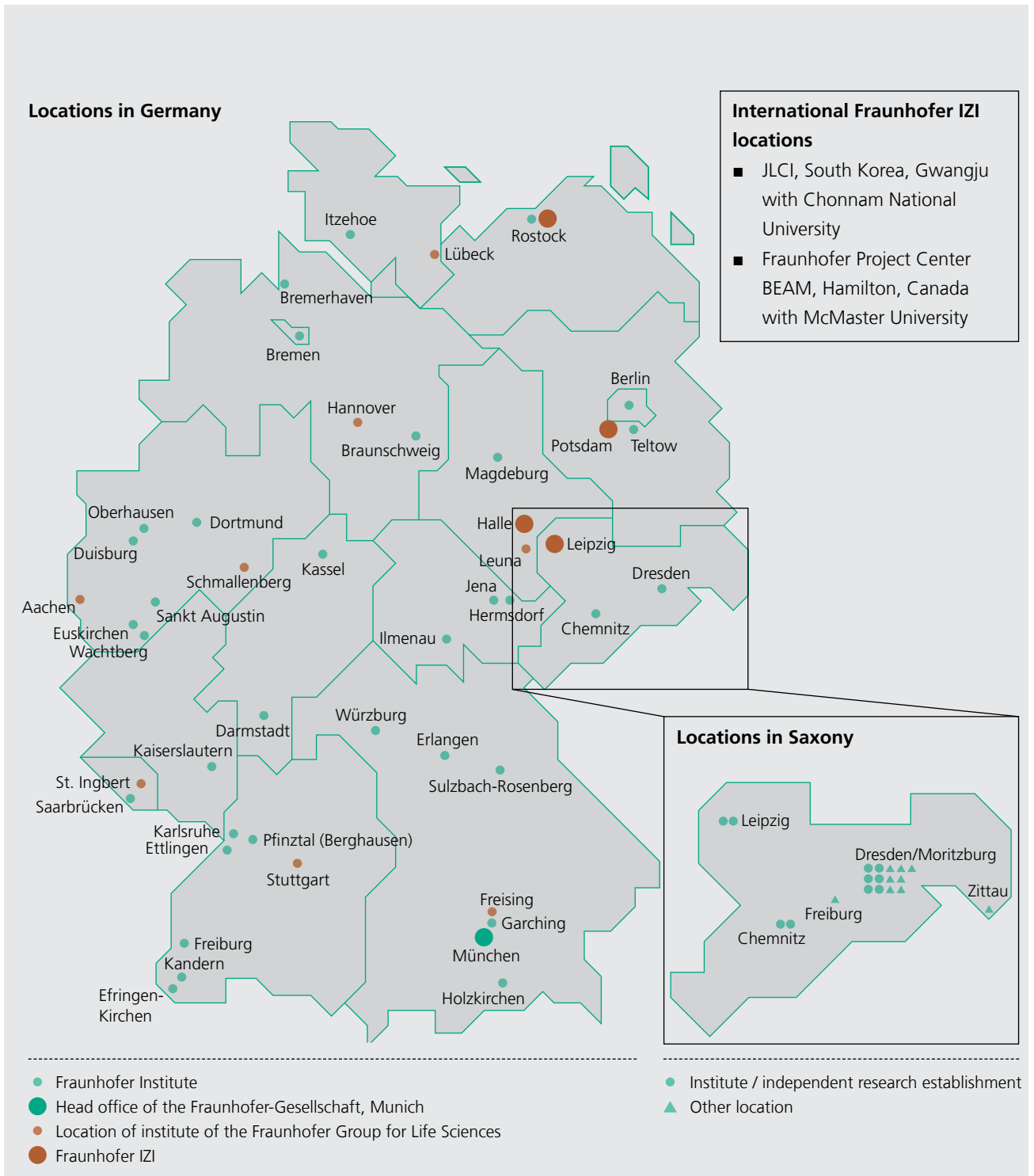
Fraunhofer-Gesellschaft zur Förderung der angewandten
Forschung e. V.
Hansastraße 27c
80686 München
Germany

Phone +49 89 1205-0

Fax +49 89 1205-7531

info@fraunhofer.de

www.fraunhofer.de



FRAUNHOFER GROUP FOR LIFE SCIENCES

The Fraunhofer Group for Life Sciences was founded in 2001 to strengthen the fields of life sciences, biomedicine and biotechnology. It currently comprises seven institutes.

In terms of expanding research revenue as well as business spin-offs, the Fraunhofer Group for Life Sciences is one of the Fraunhofer-Gesellschaft's most dynamic areas of research.

Business units of the Fraunhofer Group for Life Sciences:

- Medical translational research and biomedical technology: The challenge of innovative diagnostics and personalized therapy
- Regenerative medicine: The challenge of qualified biobanking and controlled self-healing
- Healthy foods: The challenge of high consumer acceptance and disease prevention
- The new potential of biotechnology: The challenge to learn from nature for industrial exploitation
- Process, chemical, and herbicide safety: The challenge of environmental and consumer protection

Verbundvorsitzender des Fraunhofer VLS ist ab 2016 Prof. Dr. Rainer Fischer, Leiter des Fraunhofer Institute for Molecular Biology and Applied Ecology IME, Aachen. Deputy spokesman is Prof. Dr. Norbert Krug, director of the Fraunhofer Institute for Toxicology and Experimental Medicine ITEM, Hanover.

Institutes of the Fraunhofer Group for Life Sciences

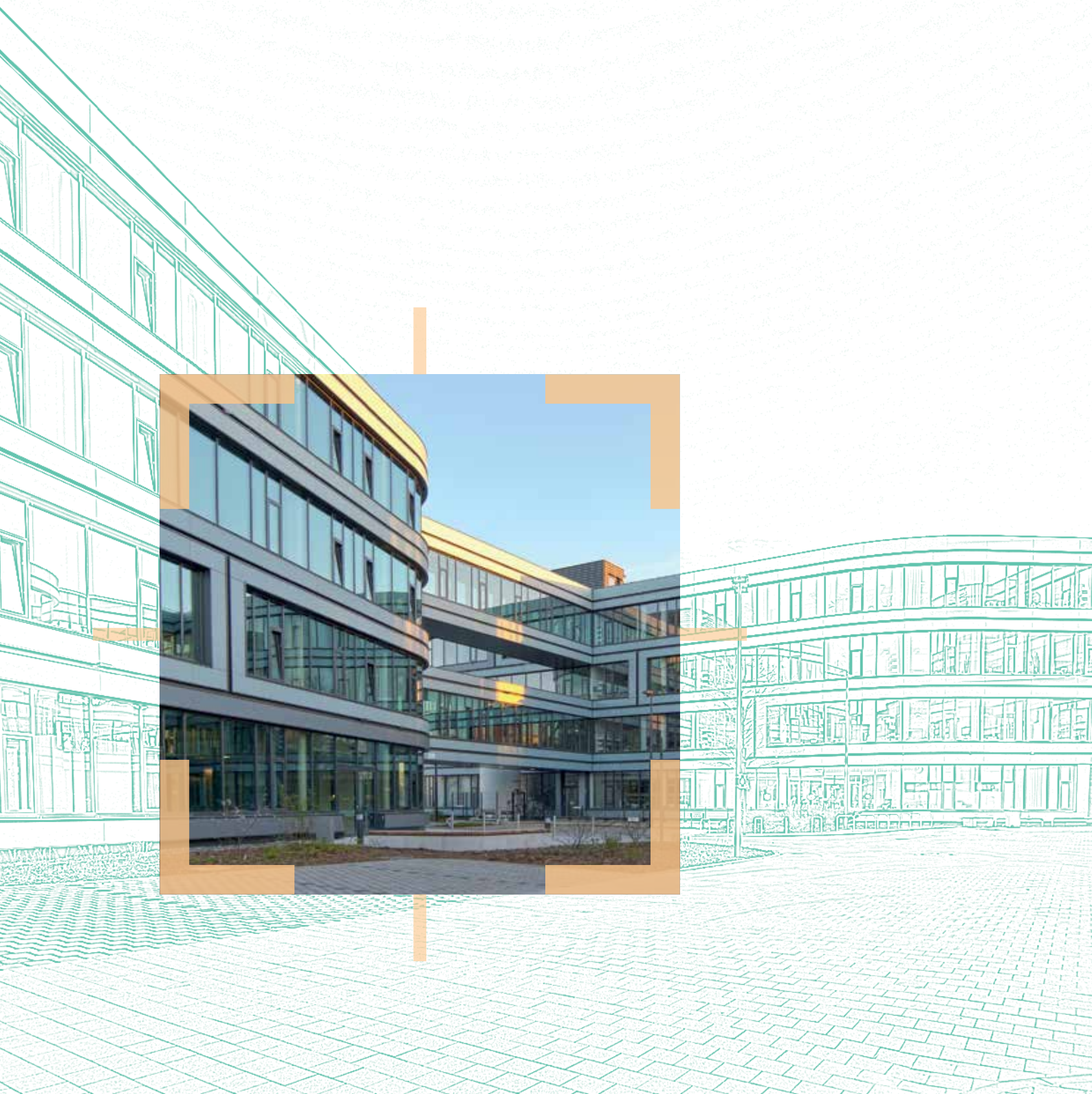
- Fraunhofer Institute for Biomedical Engineering IBMT
- Fraunhofer Institute for Interfacial Engineering and Biotechnology IGB
- Fraunhofer Institute for Molecular Biology and Applied Ecology IME
- Fraunhofer Institute for Toxicology and Experimental Medicine ITEM
- Fraunhofer Institute for Cell Therapy and Immunology IZI
- Fraunhofer Institute for Process Engineering and Packaging IVV
- Fraunhofer Research Institution for Marine Biotechnology EMB

Contact of the head office

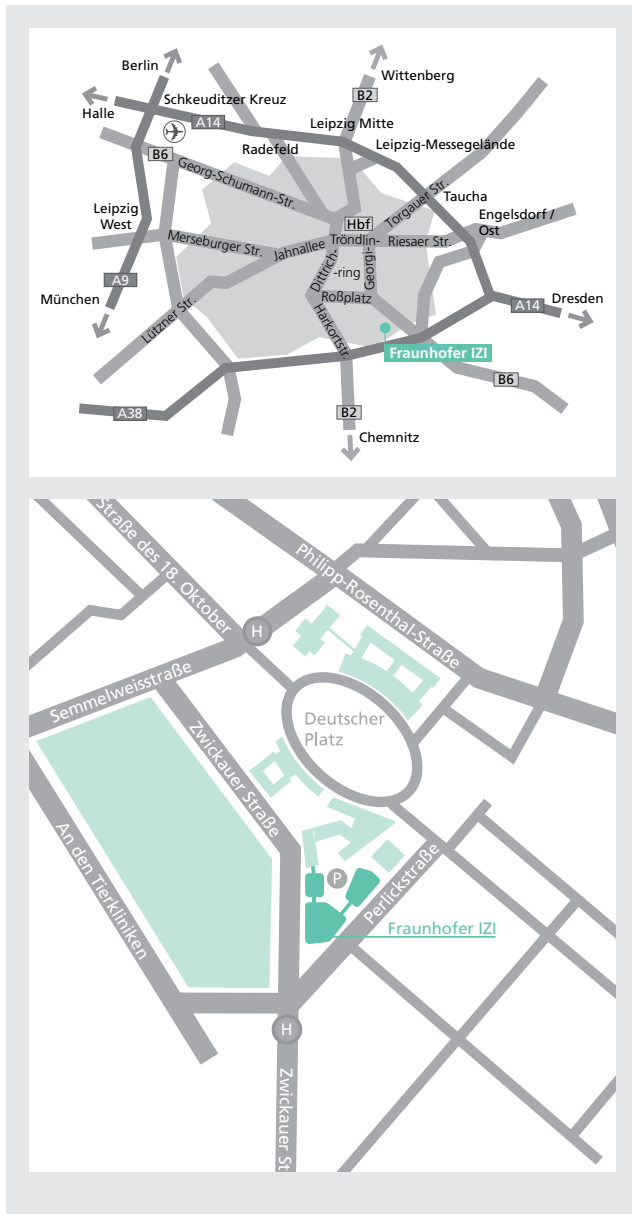
Dr. Claus-Dieter Kroggel
Medical Park Hannover
PHARIS-Haus
Feodor-Lynen-Str. 31
30625 Hannover
Germany

Phone +49 511 5466-440
claus.kroggel@vls.fraunhofer.de
www.lifesciences.fraunhofer.de

FRAUNHOFER IZI CONTACT INFORMATION



HOW TO REACH US



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”.

Address

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

CONTACT

Director

Prof. Dr. Frank Emmrich (executive)
Phone +49 341 35536-9105
frank.emmrich@izi.fraunhofer.de

Prof. Dr. Hans-Ulrich Demuth (executive at the location
Potsdam-Golm)
Phone +49 345 131428-00
hans-ulrich.demuth@izi.fraunhofer.de

Prof. Dr. Ulrich Buller
Phone +49 331 58187-100
ulrich.buller@izi-bb.fraunhofer.de

Administration

Patric Nitz
Phone +49 341 35536-9200
patric.nitz@izi.fraunhofer.de

Press and Public Affairs

Jens Augustin
Phone +49 341 35536-9320
jens.augustin@izi.fraunhofer.de

Business Development and Patent Management

Dr. Thomas Tradler
Phone +49 341 35536-9305
thomas.tradler@izi.fraunhofer.de

Personnel

Anja Bochmann-Seidel
Phone +49 341 35536-9250
anja.bochmann-seidel@izi.fraunhofer.de

INFORMATION SERVICE



Service Catalog (English)

Our service catalog gives you a comprehensive insight into the products and services offered by the Fraunhofer IZI. On the basis of a sorting according to work units you will quickly find your appropriate contact person at our institute and gain insight into reference projects or applicabilities.



Annual Report (German/English)

In combination with past years' issues, our current annual report gives you an insight into the structure of the Fraunhofer IZI, our services, important events and publications, offers, as well as selected project examples.



Homepage (German/English)

An overview of interesting events held at the Fraunhofer IZI as well as further information on our institute can be found on our homepage www.izi.fraunhofer.de.

All our brochures and publications as well as current announcements made by the Fraunhofer IZI can be found on our homepage

www.izi.fraunhofer.de.

You can also mail to presse@izi.fraunhofer.de

and order our brochures as hard copies.

Editorial notes

Editorial team

Frank Emmrich

Jens Augustin

Bettina Hennebach

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Michaela Grunert

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Editorial address

Fraunhofer Institute for Cell Therapy and Immunology

Perlickstraße 1

04103 Leipzig

Germany

www.izi.fraunhofer.de

info@izi.fraunhofer.de

