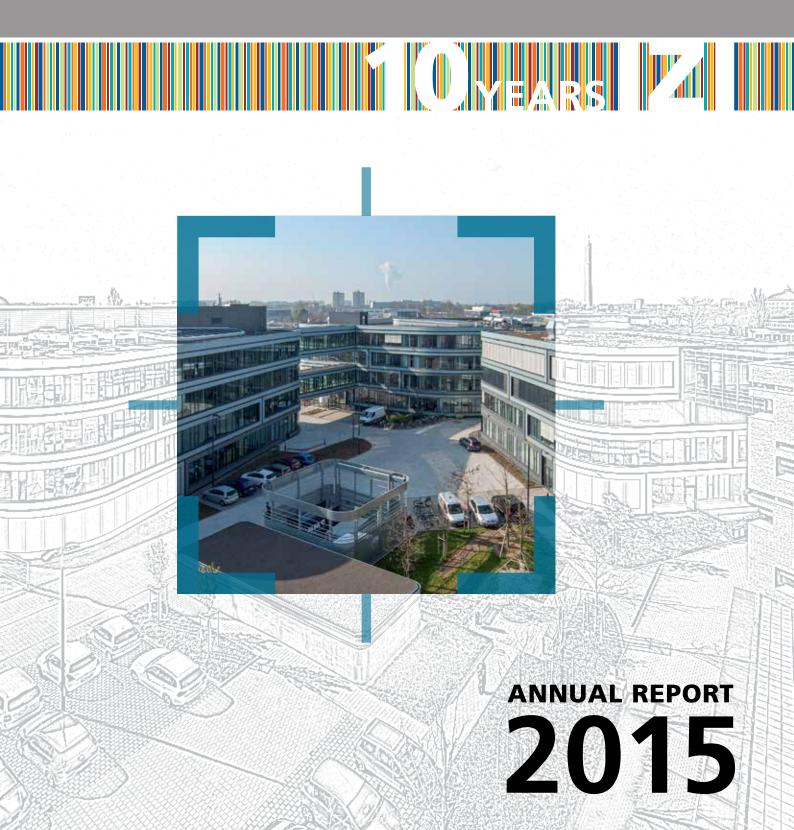


FRAUNHOFER INSTITUTE FOR CELL THERAPY AND IMMUNOLOGY IZI

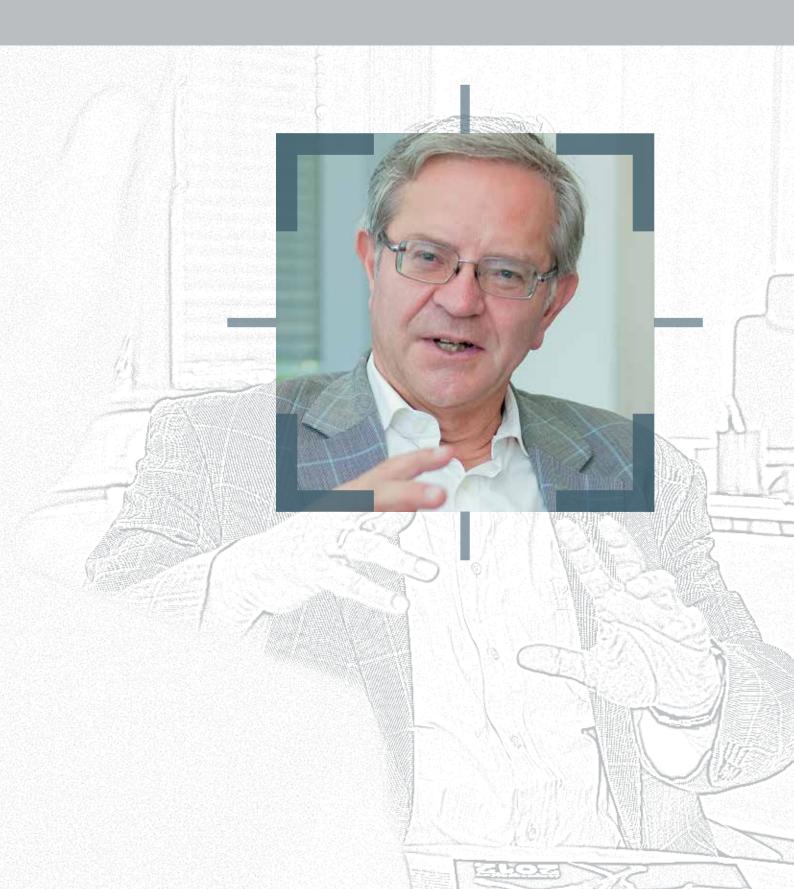


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# **PREFACE**



# **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 m<sup>2</sup> laboratory and office spaces within a main usable floor space of 3,050 m<sup>2</sup>. 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.

Prof. Dr. Frank Emmrich

Flaul Cuis

# **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

McMaster

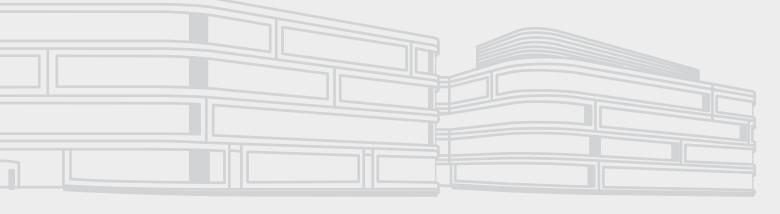
The "Fraunhofer Project Centre for Biomedical Engineering and Advanced Manufacturing" was set up in Hamilton, Canada



Fraunhofer

# April 29, 2015

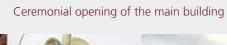
Anniversary and opening of the second extension building



# 2005-2015 IN PUBLIC



Summer of Science





Graduate fair



Open day



Day of Mobility and Technology



Long Night of the Sciences



Movie talk



Children's lecture



Long Night of the Sciences



Pupils' congress



New Year's reception



Girls'Day

# 2005-2015 CONFERENCES



Fraunhofer Life Science Symposium 2006



Research Conference 2014



International Symposium on Albumin Dialysis 2013



World Conference on Regenerative Medicine 2013



International Symposium on Neuroprotection and Neurorepair 2012



International Symposium on Neuroprotection and Neurorepair 2014



Fraunhofer Life Science Symposium 2012



World Conference on Regenerative Medicine 2015



World Conference on Regenerative Medicine 2011



Science Day 2014

# 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

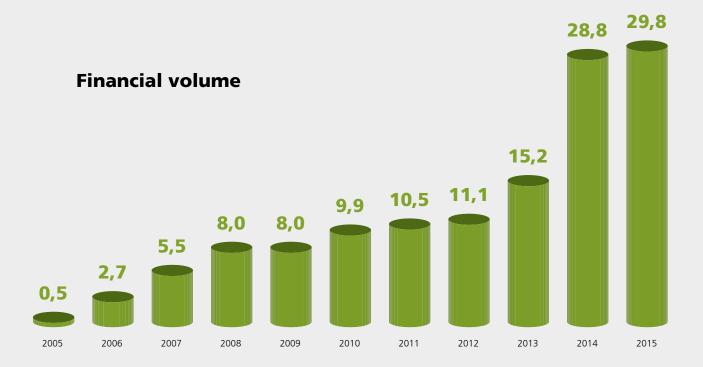


EU Commissioner Dr. Johannes Hahn and Sven Morlock, Saxon State Minister for Economic Affairs and Labour, visiting in 2010

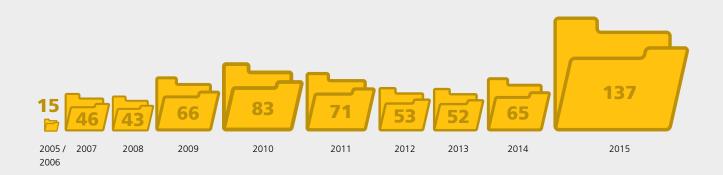


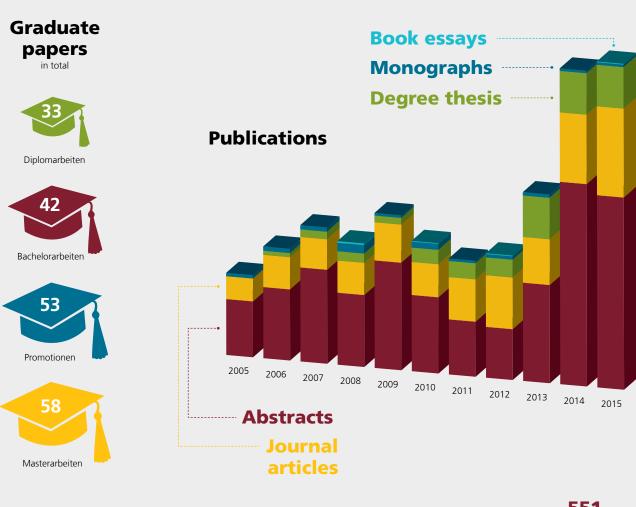
Dr. Reiner Haseloff (3rd from I.) and Stanislaw Tillich (4th from I.), Minister Presidents of Saxony-Anhalt and Saxony, together with the rectors of Halle-Wittenberg University and Leipzig University, Professor Udo Sträter (1st from I.) and Professor Beate Schücking (2nd from I.) as well as Prorector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

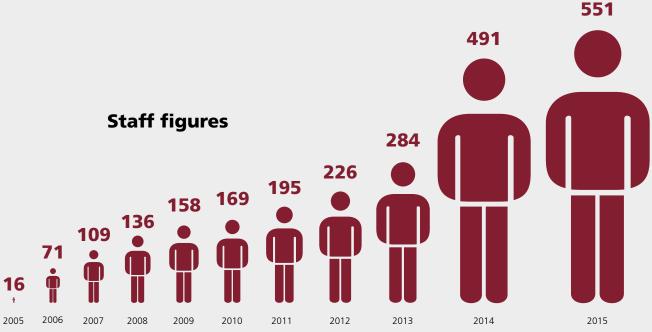
# **2005-2015 DEVELOPMENT**



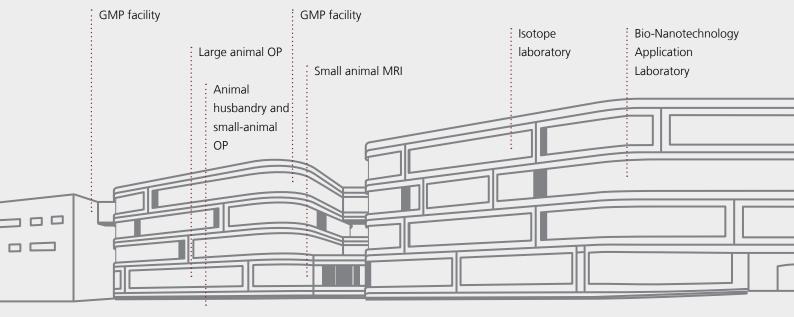
# **Number of projects**







# 2005–2015 RESEARCH INFRASTRUCTURE AT THE LEIPZIG SITE



# First extension building

Start-up operations: 2012 | Usable area: 1568 m² |

Lab space: 470 m<sup>2</sup> | Offices: 142 m<sup>2</sup> |

Clean rooms: 377 m²

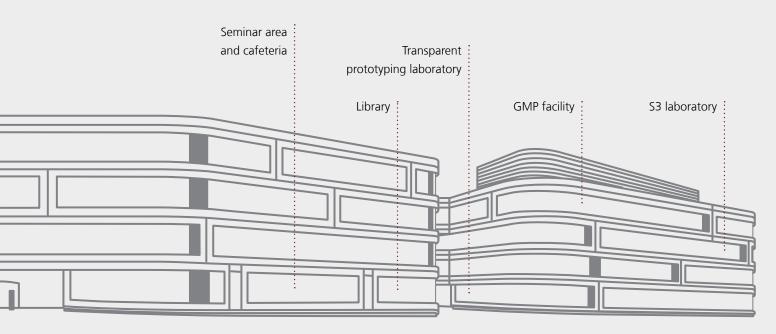
# Main building

Start-up operations: 2008 | Usable area: 4131 m<sup>2</sup> |

Lab space: 1867 m<sup>2</sup> | Offices: 1615 m<sup>2</sup> |

Seminar area: 276 m²





# Second extension building

Start-up operations: 2015 | Usable area: 3 050 m² |

Lab space: 1171 m<sup>2</sup> | Offices: 881 m<sup>2</sup> |

Clean rooms: 408 m<sup>2</sup>



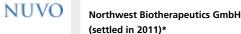
# 2005-2015 **SPIN-OFFS AND COMPANY SETTLEMENTS**

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

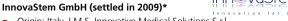


- Origin: USA, Northwest Biotherapeutics, Inc.
- Business model: Developing an immunotherapeutic to treat glioblastomas

- 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

BIOVILLE

PRIMA BIOMED LTD

Business model: Medical device for stroke therapy



oncotrition

Northwest Biotherapeutics

# 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

# **Oncotrition 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



# Tutelacell GmbH (founded in 2014)

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

# **Tutelacell**

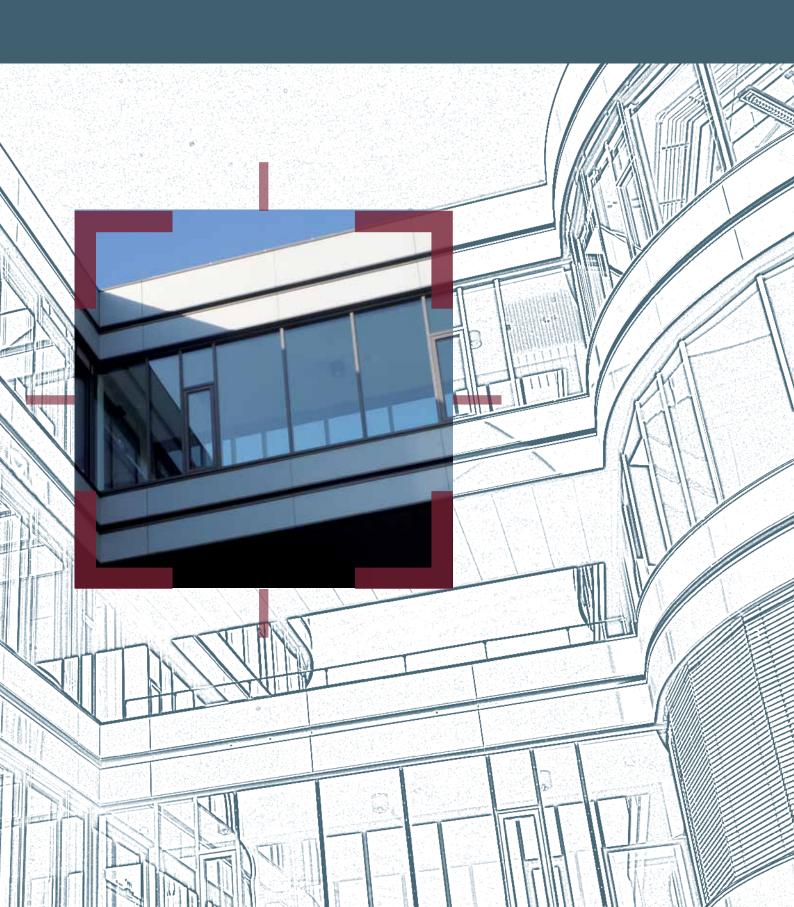
# IPDx Immunoprofiling Diagnostics GmbH (settled in 2015)

- 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 graftversus-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 headquarters. 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.



# **ORGANIZATION (JANUARY 2016)**

Bioanalytics and Bioprocesses Branch of Institute (Potsdam-Golm)

Strategy, Marketing and Administration

iVD-Platform Prof. Dr. Frank Fabian Bier

Biomolecular Nanostructures and Measurment Technology PD Dr. Ralph Hölzel

Biomimetic **Functional Materials** 

Dr. Nenad Gajovic-Eichelmann

Laboratory and **Process Automation** Jörg Henkel

Cellular Biotechnology

Lab-On-Chip Technology

Dr. Claus Duschl

Miniaturized Cell Assays

Dr. Michael Kirschbaum

**Biofunctional** Coatings

Dr. Dmitry Volodkin

Cell-free and Cell-based Bioproduction

Functional Nucleic Acids -**Aptamers** 

Dr. Marcus Menger

**Eukaryotic Lysates** Doreen Wüstenhagen

Extremophile Research and Biobank CCCryo

Dr. Thomas Leya

**Cell-free Protein Synthesis** Dr. Stefan Kubick

Microarray and **Sensor Technology** Dr. Eva Ehrentreich-Förster

**Biomarker Validation and Assay Development** Dr. Harald Seitz

**Molecular Bio Engineering** Dr. Markus von Nickisch-Rosenegk

> Metabiobanks CRIP Dr. Oliver Gros

> > 1 Potsdam-Golm

2 Halle (Saale)

3 Leipzig





# Directors

Prof. Dr. Frank Emmrich (executive)

Press and Public Affairs

**Business Development and Patent Management** 

Administration

**Preclinical Validation** 

Officers

Leipzig Headquarters

# **GMP** Cell and

# Therapy Validation

## **Preclinical Models** Dr. Ulla Schwertassek

**Protein Biomarker** 

## Dr. Jörg Lehmann (komm.)

Immune Diagnostics Dr. Katharina Zoldan

# Antibody Manufacturing

Dr. Jörg Lehmann (komm.)

# Vaccine Technologies

PD Dr. Sebastian Ulbert

# Immune Tolerance

PD Dr. Stephan Fricke

## **Cell-functional Image Analysis**

Prof. Dr. Ulf-Dietrich Braumann

## **Ligand Development** Dr. Michael Szardenings

**Antimicrobial Agents** Dr. Andreas Schubert

# Extracorporeal Immunomodulation **Project Group** (Rostock)

Prof. Dr. Steffen Mitzner

# Immuntherapy -Oncology

Christopher Oelkrug, M.Sc.

# Ischemia Research

Dr. Daniel-Christoph Wagner

# **Experimental Imaging** Dr. Alexander Kranz

**Cognitive Genetics** 

# Dr. Arndt Wilcke

## Clinic-oriented Therapy Assessment

Dr. Antje Dreyer

# **RNA Biomarker**

Dr. Sabina Christ-Breulmann

# Inflammation Models and

**Immunodiagnostics** Dr. Franziska Lange

# Nanotechnology

Dr. Dirk Kuhlmeier

# Tumor Stem Cells Dr. Peter Ruschpler

**DNA Nanodevices** 

# Dr. David M. Smith

**Next-Generation** 

## Diagnostics Dr. Conny Blumert

**Bioinformatics** Dr. Kristin Reiche

# Study and Quality

Management Dr. Catharina Bertram

# Drug Design and Target Validation Halle (Saale)

# Molecular Biotechnology Dr. Holger Cynis

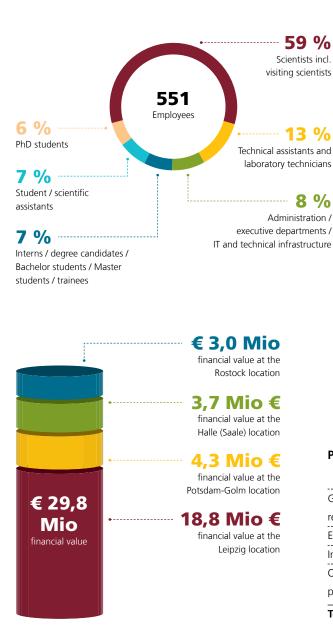
# Protein and Drug Biochemistry

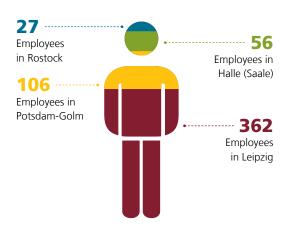
Dr. Stephan Schilling

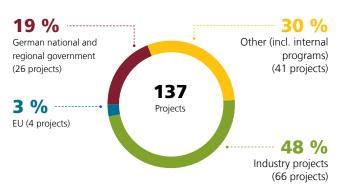
# Drug Design and **Analytical Chemistry**

Dr. Mirko Buchholz

# **KEY INSTITUTE FIGURES 2015\***







# Project revenue 2015 in kEUR

	Leipzig	Halle	Potsdam	Rostock	Total
German national and	2421	3 180	1 970	2 609	10180
regional government					
EU	0	150	260	0	410
Industry projects	7 6 6 9	395	900	376	9340
Other (incl. internal	6345	20	715	0	7080
programs)					
Total	16435	3745	3 8 4 5	2 985	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

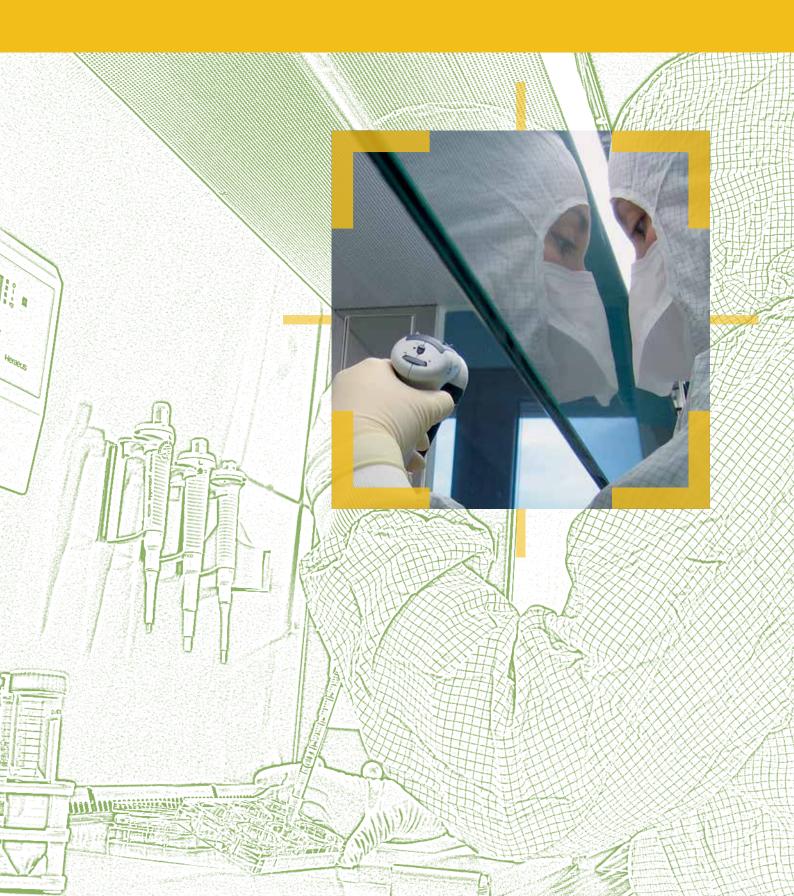
take up a special position among the projects funded by the government and Länder. Due to changes in the accounting procedures, we are now less focused on large EU collaboration projects. The overall value of SAB projects for Fraunhofer IZI amounted to approx. 1.95 million euros for the reporting period.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

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# CELL ENGINEERING



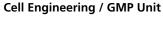
# UNITS

# 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.

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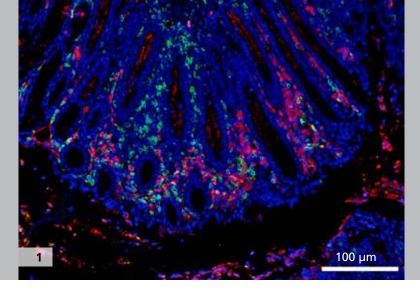


The Cell Engineering/GMP Unit operates Fraunhofer IZI's three modern GMP clean room facilities consisting of ten separate clean room suites (altogether 21 clean room grade B manufacturing rooms) which are optimal for manufacturing Advanced Therapy Medicinal Products (ATMPs). The more than 90 highly qualified staff members specialize in the GMP-compliant manufacturing and quality control of investigational medicinal products. Transfering 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.

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# 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.

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

# CELL ENGINEERING



# 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.

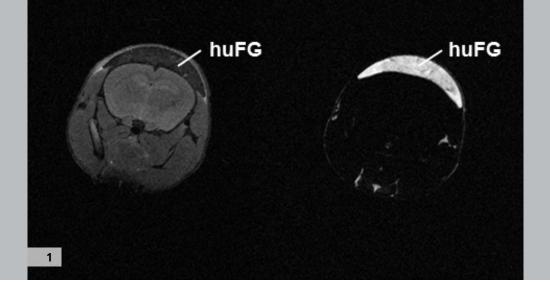
The capacity increases surrounding the new clean rooms and staff, which have been ongoing since 2013, and the regular updates to the submission documents continued to pose a major challenge to the entire group.

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.

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



# 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.

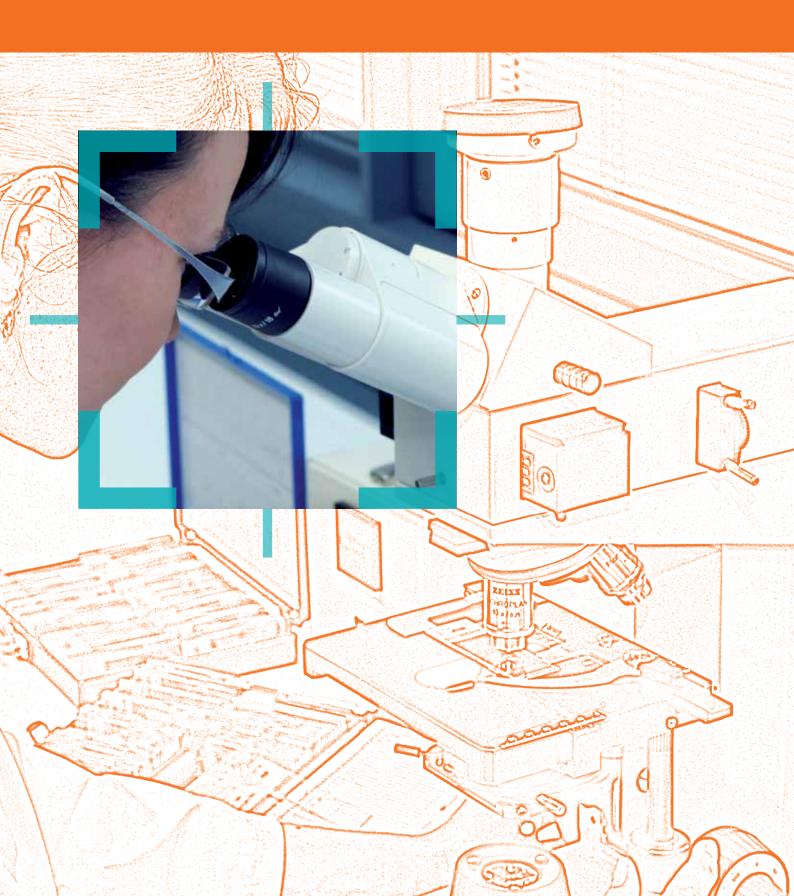
The results obtained so far are impressive: They show that optimally cryopreserved human adipocytes are suitable for the intended purpose. Moreover, MRI has shown itself to be the method of choice for this study.

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> 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 GMPcompliant 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 nutraceutics / 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

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### UNITS

#### **Vaccine Technologies Unit**

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

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#### **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.

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#### **Antimicrobial Agents Unit**

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

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#### **Immune Tolerance Unit**

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

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#### **Preclinical Validation Unit**

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

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#### **Extracorporeal Immunomodulation Project Group**

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

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#### **Image Analysis of Cell Function Unit**

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

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**IMMUNOLOGY** 



# 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.

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1 Vaccinations: Huge demand for vaccines inactivated without formaldehyde



#### 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.

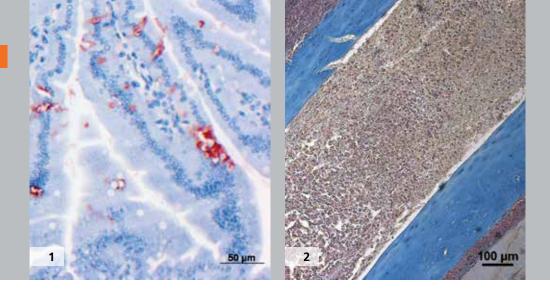
In order to improve the efficacy of the dialysis process in future, further investigations of this kind are vital in enabling the purification efficiency of dialyzers to not only be described in vitro, but primarily in the clinical context. In this regard, much greater consideration is to be given to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

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



#### 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.

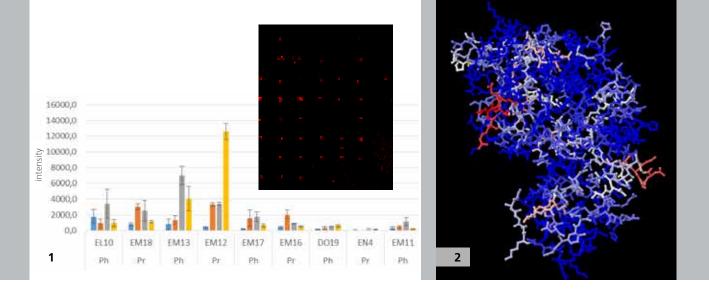
A new approach involves the use of a specific anti-human CD4 antibody. The antibody specifically reduces adverse immune reactions, thus minimizing the chances of aGvHD emerging following stem cell transplantation. The influence of this anti-human CD4 antibody with regard to the prevention of GvHD and under consideration of the graftversus-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).

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<sup>1</sup> 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.

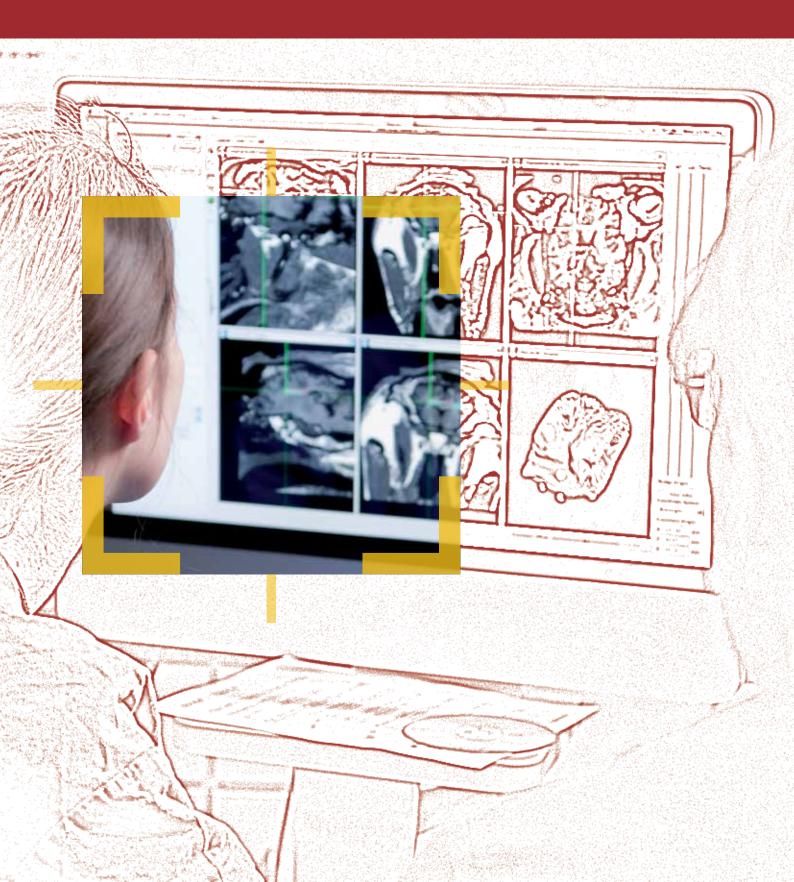
This project is set to be successfully completed in the coming months. Follow-up projects will commence for other allergies and the obtained results will be put into practice in 2016.

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- 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

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## UNITS

#### **Experimental Imaging Unit**

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

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#### Ischemia Research Unit

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

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

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#### 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.

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#### **Cognitive Genetics Unit**

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

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#### **Clinic-oriented Therapy Assessment Unit**

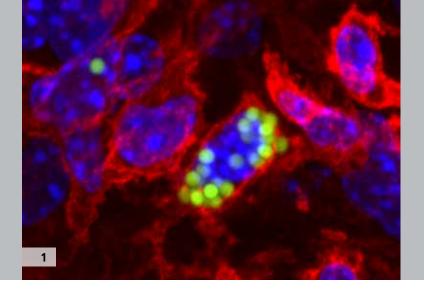
The unit tests and develops innovative diagnosis and therapy procedures for stroke. As the possibility of being able to transfer findings from small-animal models to human patients is sometimes only very limited, a globally unique, large-animal model was established for the translational approach. Using 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.

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**CELL THERAPY** 



# 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.

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> 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 2<sup>nd</sup> 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.

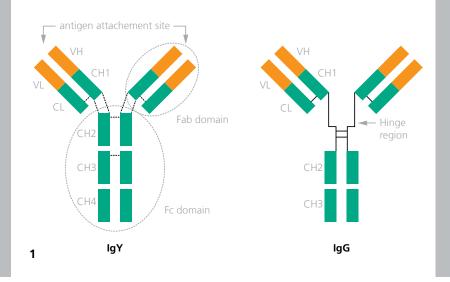
To summarize, the aim of this project is to develop an early screening test for dyslexia which recognizes the respective disposition towards dyslexia long before this can be seen using conventional testing methods. This type of early warning test will be able to considerably improve access to therapy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

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

#### **CELL THERAPY**



#### 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.

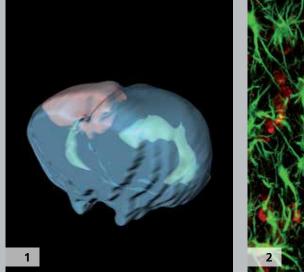
As part of this project, highly specific IgY antibodies will be developed which are effective against multiresistant intestinal bacteria and candida fungi. First of all, suitable immunogenic surface molecules will be identified in these two pathogen groups and used to inoculate chickens, thus stimulating 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.

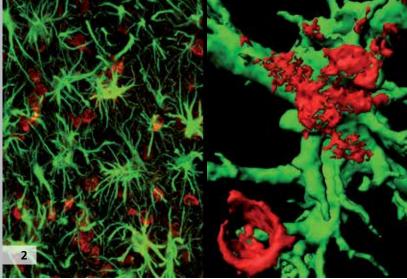
By the end of the project we will have gained IgY antibodies that are effective against multiresistant pathogens and that can be used as pharmaceuticals or in functional food.

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> 1 Comparison between IgY and IgG antibodies





#### 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).

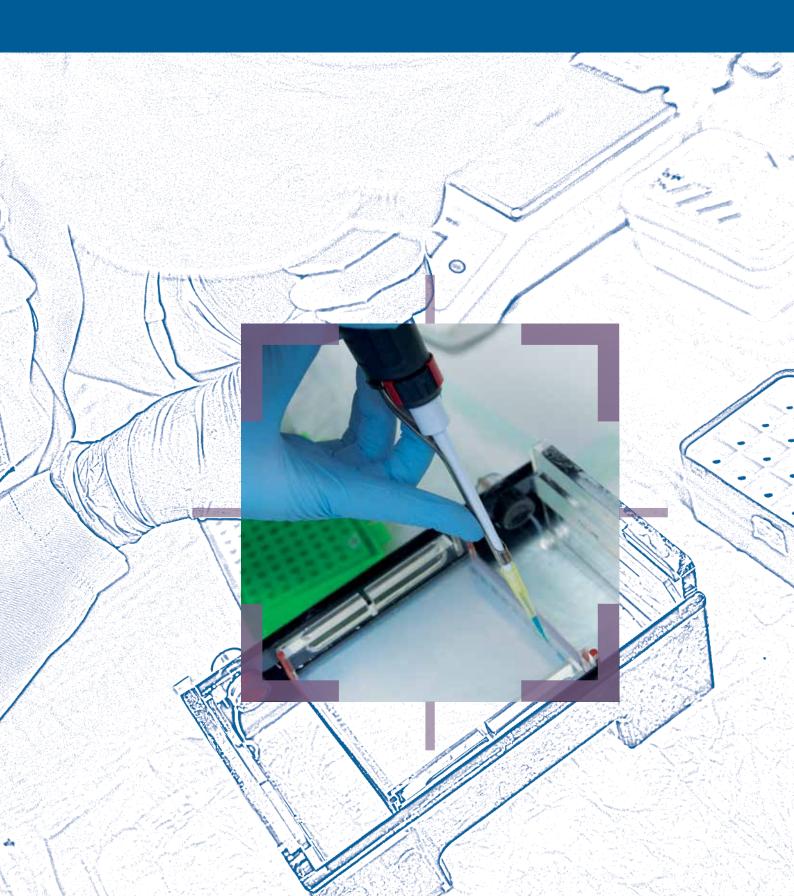
Both processes facilitate the evaluation of pathological changes following brain damage and are therefore suitable for verifying the effectiveness of new therapeutic procedures. The methods used to segment, evaluate, and assure quality are hugely similar here in spite of the different processes. Combining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

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<sup>1</sup> 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

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# UNITS

#### **Inflammation Models and Immunodiagnostics Unit**

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

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**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.

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#### **RNA Biomarker Unit**

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

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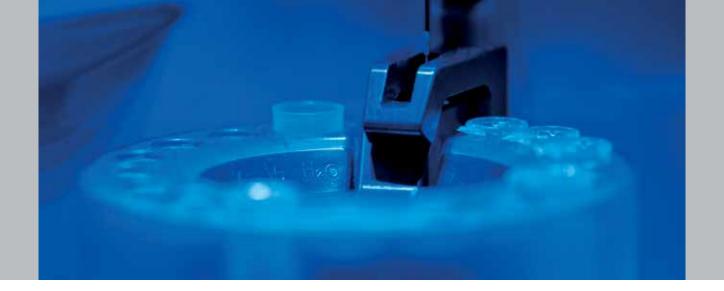
#### **Tumor Stem Cells Unit**

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

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#### **DNA Nanodevices Unit**

This unit focuses on exploring and developing DNA-based tools for biomedical research. In doing this, DNA molecules and their characteristics are used to arrange and structure biomaterials on the nanometer scale. This type of technology is applied to develop biosensors and nanocircuitry for biochips, in addition to being used to develop new procedures to specifically transport molecules in vivo and in vitro. To this end, the unit investigates the biochemical and biophysical characteristics of specific DNA molecules and composite materials in order to deduce concrete applications. The unit has been funded by the Fraunhofer-Gesellschaft's Attract program since 2013.

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#### **Nanotechnology Unit**

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

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#### **Bioinformatics Unit**

The Bioinformatics Unit develops and establishes computeraided ways of identifying and verifying new biomarkers for the personalized diagnosis and prognosis of diseases and for the detection of novel therapeutic targets. The fact that a vast number of RNA molecules are not translated into proteins has only been known for a few years. The latest scientific findings show that these non-coding RNAs (ncRNAs) perform fineregulatory tasks in gene regulation and are therefore suitable as markers for individual disease patterns and progression. The unit develops strategies for 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.

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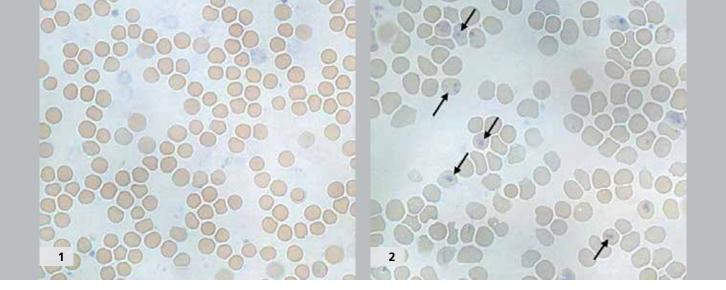
#### **Study and Quality Management Unit**

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

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# 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

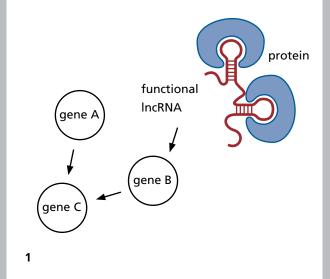
the amount of EPO in the blood plasma during the treatment period. At the end of the study, this dropped back to a normal level.

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.

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- 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 bluecolored 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 (IncRNAs), 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 IncRNAs 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 IncRNAs, 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 lcnRNA gene expression patterns and proteincoding 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 IncRNAs 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.

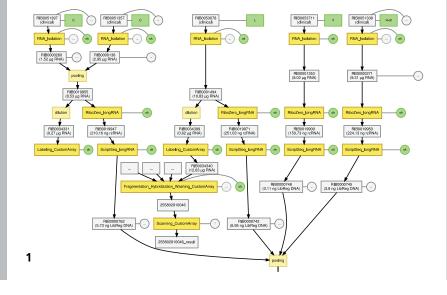
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Supported by the Fraunhofer-Zukunftsstiftung (Fraunhofer Future Foundation) - RIBOLUTION



1 ncRNA-protein complex regulates the activity of various genes



#### 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 userfriendly graphical user interface ensure ease of use.

#### **Contact**

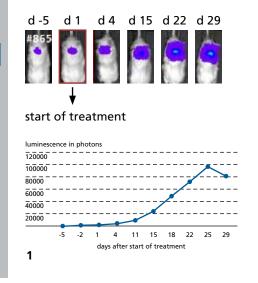
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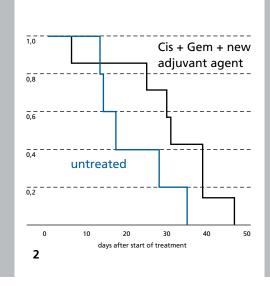
Supported by the Fraunhofer-Zukunftsstiftung (Fraunhofer Future Foundation) - RIBOLUTION



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.

DIAGNOSTICS





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 realtime 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 compoundsensitive 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.

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<sup>1</sup> Documentation of tumor growth using bioluminescence imaging

<sup>2</sup> 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

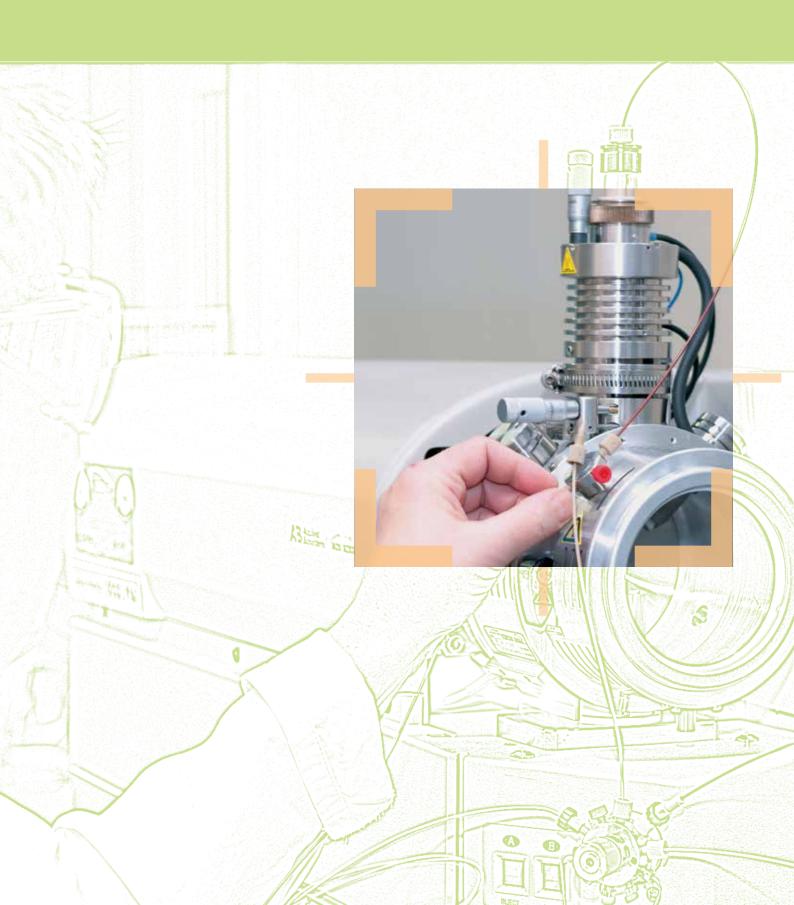
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Europa fördert Sachsen.



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 glutaminyl 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

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### 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.

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#### **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.

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#### **Drug Design and Analytical Chemistry Unit**

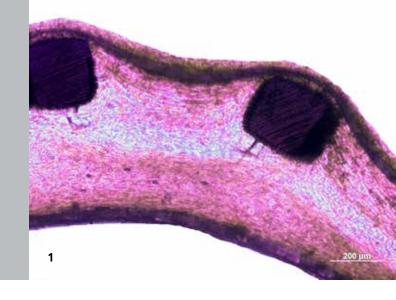
The service portfolio offered by the unit comprises the entire spectrum of medicinal chemistry and analytics required to identify potential, new drug candidates from within the field of "small molecules" and develop them into clinical candidates. New target molecules can be generated in silico with the 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.

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#### DRUG DESIGN AND TARGET VALIDATION



# **PROJECT EXAMPLES**

#### Rabbit model of in-stent restenosis fur drug design

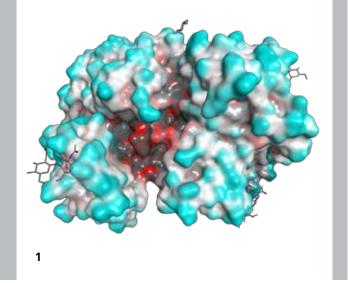
Atherosclerosis is the most common cause of arterial vascular occlusion, which can, among other things, lead to an acute undersupply of oxygen to the myocardium (myocardial infarction). Percutaneous transluminal angioplasty (PTA) with and without stent application is performed as a standard treatment 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.

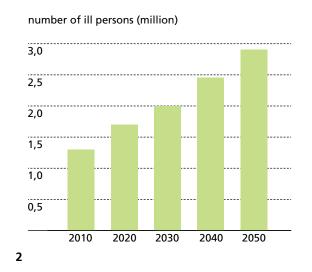
The Molecular Biotechnology Unit has access to an established in vivo model system for ISR. Stent application in the atherosclerotic rabbit model is an effective tool for investigating novel drug candidates, biomaterials and medicinal products.

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





#### 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 (Aβ), initiates this cascade of changes. In recent years it has been successfully demonstrated that various other proteins (enzymes) are responsible for the formation of Aβ. It also became apparent that particularly toxic forms of AB 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.

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- 1 View of the catalytic center of the alternative beta-secretase menrin heta
- 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

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## UNITS

#### ivD Platform Unit

The unit develops procedures and devices for various pointof-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.

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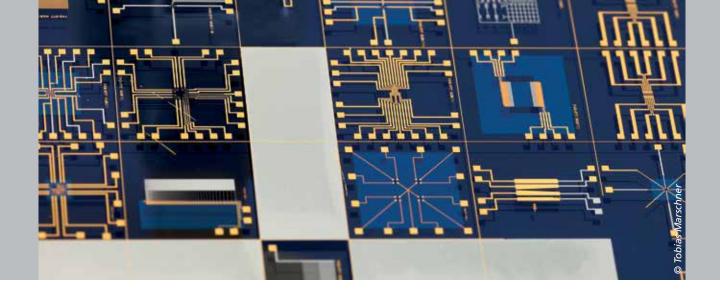
#### **Biomolecular Nanostructures and Measurement Technology Unit**

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

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#### **Biomimetic Functional Materials Unit**

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

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#### **Laboratory and Process Automation Unit**

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

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# PROJECT 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 phasecontrast 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.

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#### 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.

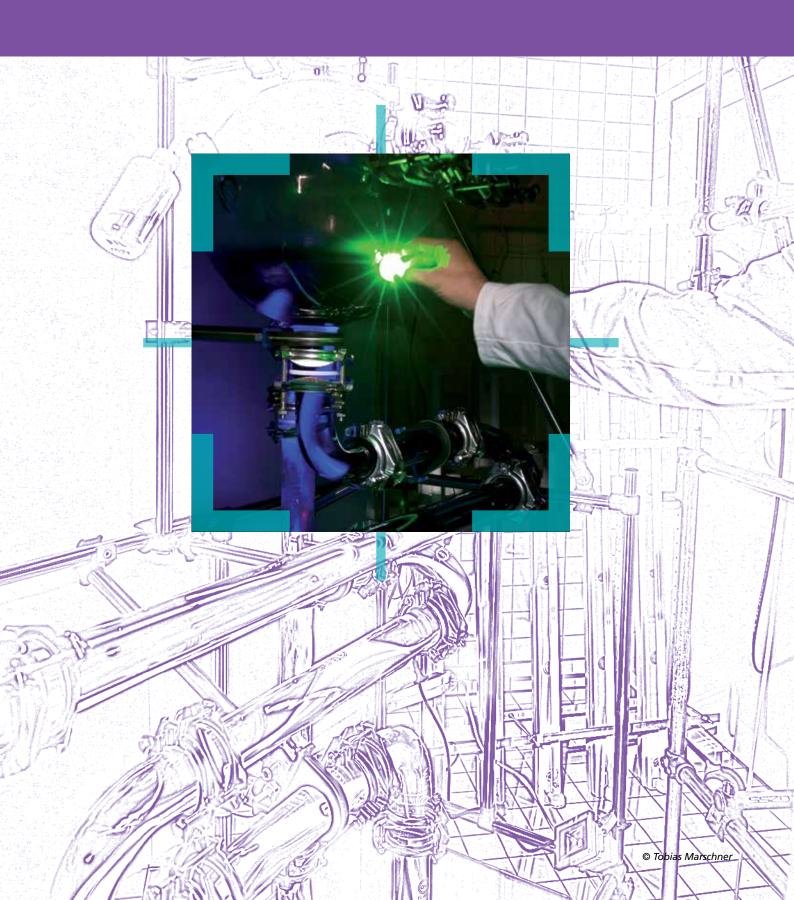
In this project, miniaturized, planar electrode systems made of platinum, gold and graphene were characterized using both cyclic voltammetry and high-speed video microscopy at the same time (with up to 230,000 images per second). The analysis of the video revealed previously hidden properties, e. g.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

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> 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. CLAUS 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 -

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### 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.

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#### **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.

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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.

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#### **Biofunctional Coatings Unit**

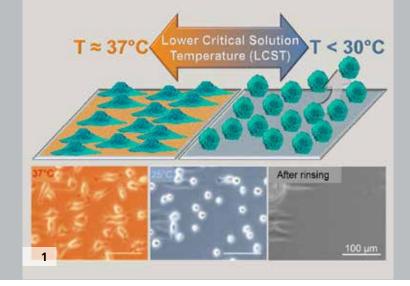
The unit develops novel substrates for cell culture and tissue engineering. The behavior of biological cells is controlled using multilayer films made of biopolymers, which are also externally activated. Planar films and also microcapsules with encapsulated biomolecules are employed. Microcapsules are 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.

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**CELLULAR BIOTECHNOLOGY** 



# 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

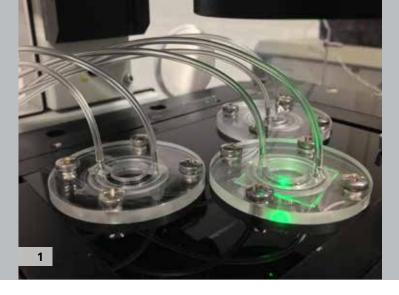
°C, the remaining cells once again migrate to the empty areas. Cell tests such as wound healing or migration assays become greatly simplified through such reversible, local detachment and are thus more user friendly. Structured polymer coatings are also useful for the simple production of cocultures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

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> 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.

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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 cellfree 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 cellfree 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

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### 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.

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#### 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. Sitespecific protein labeling serves as a gentle and easy way of characterizing and detecting the functionality of the synthesized proteins.

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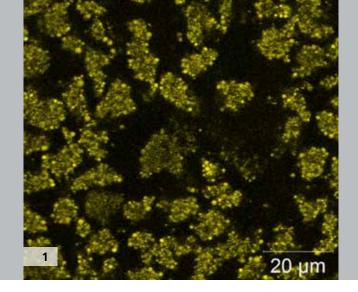
#### **Eukaryotic Lysates Unit**

The unit is developing cultivation systems for eukaryotic cell lines in order to obtain translationally active lysates for cellfree 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

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# 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 timesaving 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 noncanonical amino acids and thus the subsequent chemoselective coupling with the fluorescent dye.

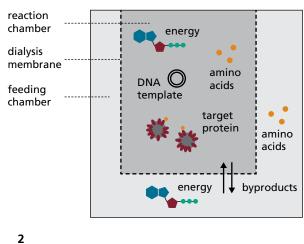
The possibility to manufacture and label antibody formats in eukaryotic lysates in a cell-free manner offers new ways of coupling these molecules with cytotoxic proteins or peptides, which cannot be expressed in cultivated cells due to their toxicity, besides coupling fluorescent dyes or biotin. These 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.

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





#### 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

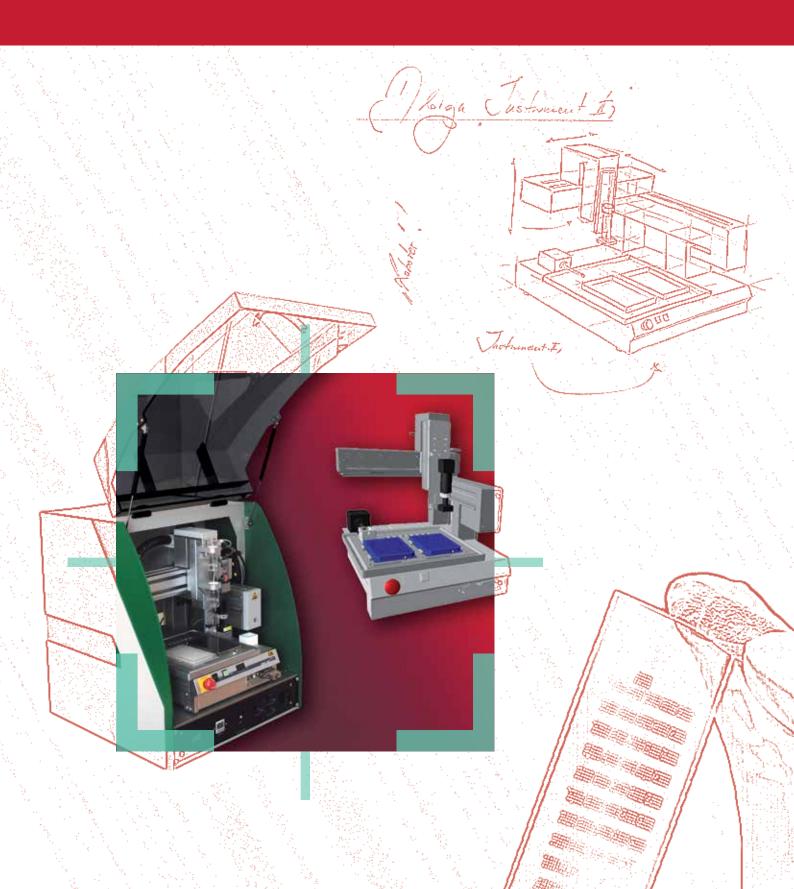
modes, which can be classified as batch or dialysis, allows the cell-free CHO system to be specifically adapted to a respective application. The batch mode is used for fast and costeffective protein syntheses and evaluations. If an application is focused on the high yield of the target protein, cell-free 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.

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<sup>1</sup> CHO cells from a high celldensity fermentation for the production of eukaryotic lysates 2 Schematic depiction of a dialysis system for cell-free protein synthesis

# DEPARTMENT OF BIOANALYTICS AND BIOSENSORS



# 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 immunosuppresive 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**

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## 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.

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#### **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.

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#### **Molecular Bio-Engineering Unit**

This unit converts natural biological processes into isolated artificial architectures and strategies which utilize new perspectives in applications of cellular structures, mechanisms and metabolisms. In former studies, for example, modified synthetic membrane proteins were used to fix extracellular entities.

More recent studies deal with innovative immunodominant antigens taken from cDNA libraries of prokaryotic transcriptomes, which mainly consist of pathogens, besides the development and construction of antimicrobial peptides, especially synthetic and artificial peptides, within the scope of antibiotic resistances.

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#### **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 sampleby-sample basis. Thus, material and data originally collected for health care (e. g. blood, serum, tissue) are swiftly made accessible through stratified, statistically relevant "clinical cohorts" to support research in personalized medicine and disease biomarkers.

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#### **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.

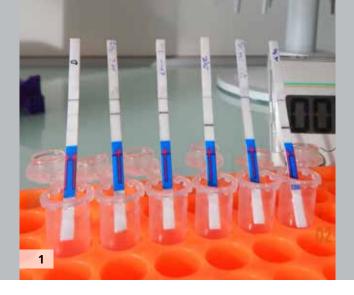
Primarily, aptamers are short, single-stranded DNA and RNA molecules with the particular feature ofbinding high-affine and high-specific targets such as antibodies. The very broad capabilities of aptamers as binding molecules are used in analytical, diagnostic and therapeutic applications.

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.

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# 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.

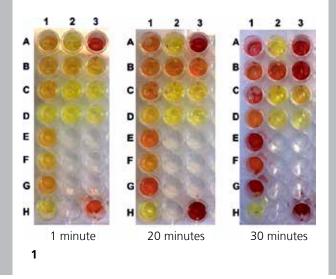
Depending on what is required, this mobile, analytical tool can be modularly adjusted to a specific, diagnostic issue for the simple, device-free detection of nucleic acids. Additional areas of application include environmental, food and agricultural analytics as well as in further investigations in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

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

#### **BIOANALYTICS AND BIOSENSORS**



#### 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.

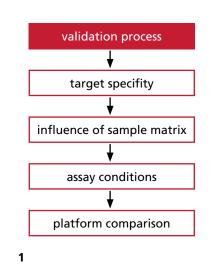
Resistance monitoring for the realistic use in diagnostic, environmental, water and food monitoring

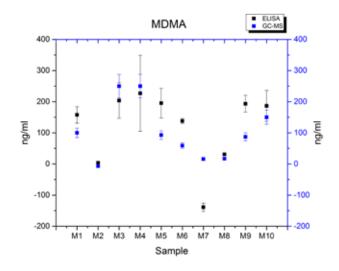
- Sudden change in color from yellow to red seen with the naked eye
- Rapid test within 30 minutes
- Methods not reliant on a laboratory
- Handheld format
- Assessment of germ load with a Yes / No response
- Substrate as kit or strip test
- No germ specification
- Individual resistance mechanisms possible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

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- 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.





#### Immunoassay for quantitative detection of drug abuse in serum

2

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.

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- 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).

#### **BIOANALYTICS AND BIOSENSORS**



#### 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.

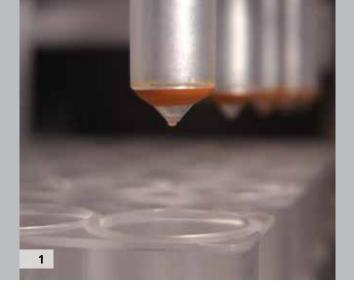
This sample-specific online search ("stratification") gives the Fraunhofer Metabiobank a unique selling point, allowing it to stand out from the masses of national and international biobank registers and portals. The Metabiobank is based on an anonymous dataset that has breadth, depth and can be extended 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.

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> 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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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.

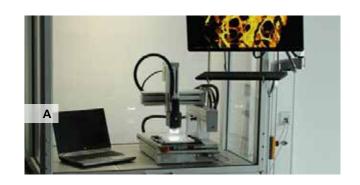
State-of-the-art equipment allows biological and medical issues to be handled in an interdisciplinary manner. BNAL provides research and development services from fundamental biomedical research by process development up to the development and validation of innovative technologies and system solutions.

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

#### **Imaging procedures**

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

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



#### Cell characterization and classification

Diagnosis and mapping for cell biology studies: Non-intrusive way of delivering high-resolution, geometric information from 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, highthroughput analysis of cells and beads in suspension, e. g. for 3D characterization of complex biological structures and precise measurements of cell surface properties.

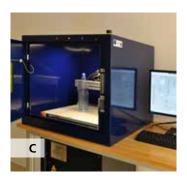


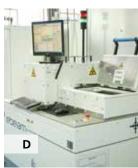


Surface sterilization and modification

Electron beam dosimeter (C): Dose measurement of highenergy 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.





#### Nanotechnology

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

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

Micro-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.

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





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# **CENTER FOR EXPERIMENTAL MEDICINE (TEZ)**

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

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

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

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

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

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

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

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





#### **Equipment and services:**

- Small animals are kept under state-of-the-art standards and permanently monitored
- Animal husbandry under GLP standards
- Animal husbandry with the option to use infecting agents for experimental infection
- Quarantine services
- Standard in-breeding and breeding transgenic lines
- Operation units in various areas including provision of inhalation anesthesia for small and large animals
- Small animal endoscope
- Blood cell meter
- Surgical microscope
- Stereotactic manipulation
- Temperature control during operations

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

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# RIBOLUTION BIOMARKER CENTER

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

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

#### Biomarker screening and validation

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

Illumina HiSeq and Miseq (A): Ultra-high-throughput sequencing platforms

Hamilton Microlab STARlet/STARplus (B): Fully automated preparation of samples for sequencing and fully automated extraction and purification of nucleic acids



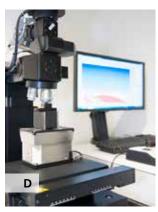


Agilent microarray scanner (C)

EMD (D): Quality and quantity analyses of minimal amounts of nucleic acids with high sensitivity; developed by Fraunhofer FIT

QIAcube (E): Semi-automated extraction and purification of nucleic acids







RiBOT (F): Novel procedure for the automated validation of biomarkers in high-throughput based on complex interactions between actuator engineering and media to be dispensed; developed by Fraunhofer IPA



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

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

#### **Contacts**

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# **IMAGING AND IMAGE EVALUATION**

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

#### In vivo imaging

Magnetic resonance imaging (7 Tesla high-field small animal MRI) (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 contrastenhanced (soft tissue) structures
- Rendered 3D data sets can be used for conformal radiation treatment planning

Fluorescence and bioluminescence imaging for small animals

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

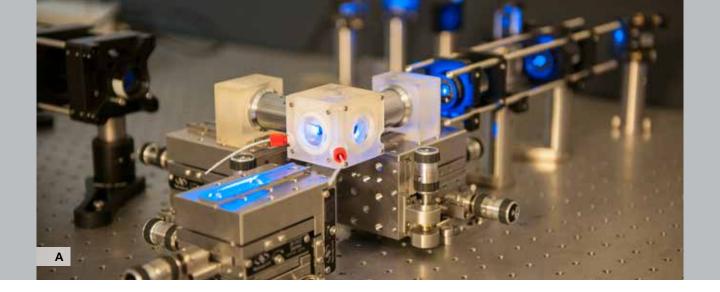
Bedside imaging for small animals

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

#### In vitro / ex vivo imaging

Confocal laser scanning microscope with live cell imaging

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





Light sheet microscopy (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

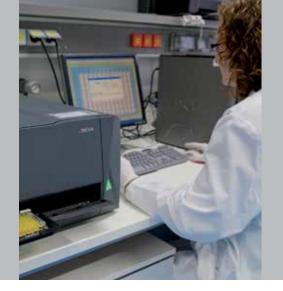
#### Individual image evaluation and analysis

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**

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# **QUALITY MANAGEMENT**

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

#### **GLP – "Good Laboratory Practice"**

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

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

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#### GMP - "Good Manufacturing Practice"

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

#### Contact

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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

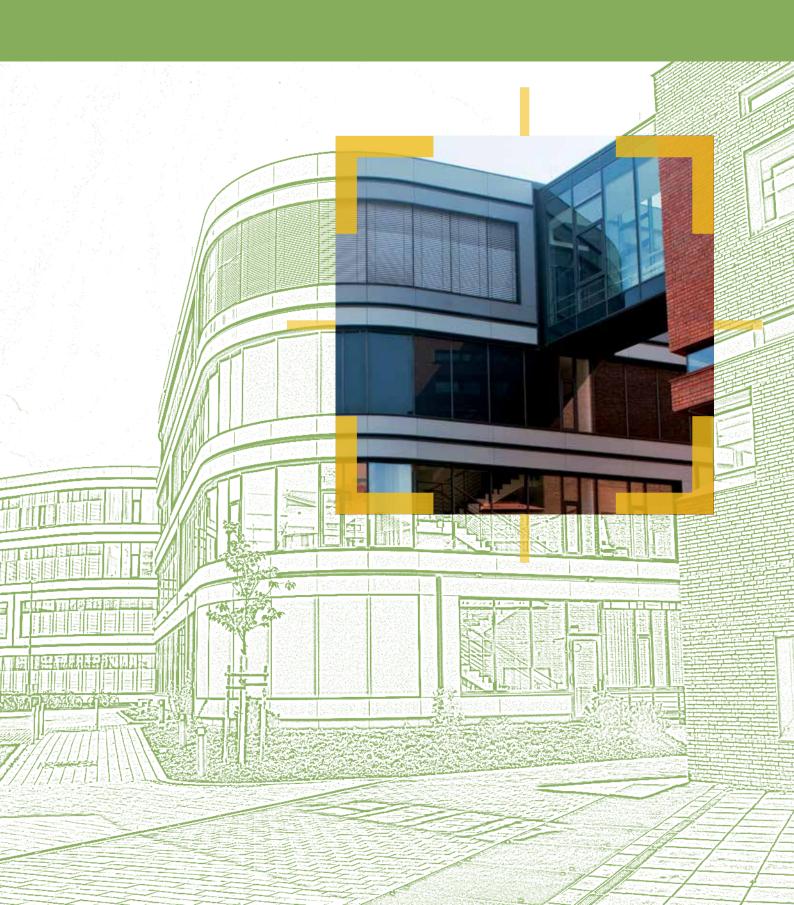
entities involved in the trial including the sponsor, monitor, CRO, primary investigator and ethics committee or intuitional review board and also regulates quality management and adverse event reporting.

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**

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# 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.

**BU** definition **BU** development Business units (BU) workshop workshop Discussions Query STRATEGY PROCESS BU documentation / regarding among unit proposals heads **BU** analysis roadmap 09/14 CC analysis / Query regarding roadmap CC identification core competencies (CC) workshop Fraunhofer IZI Audit

# **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.

**Strategy Meeting** 

Cell and Gene Therapy Drugs Diagnostik Biosystemtechnik **Cell Therapeutics** Analytical Equipment **Drug Testing** In Vitro Manufacturing and **Quality Control Drug Testing** In Vivo **Diagnostic Analytics Proprietary Drugs Imaging** 

### **Diagnostics Business Unit**

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

### **Biosystems Technology Business Unit**

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

## CORE COMPETENCIES

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

Indication-specific **Core Competencies** 

Neuropathology

**Technical Core Competencies** 

Cell Engineering and **Cell Therapy** 

Qualification of Therapeutic Molecules

### **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 GMPcompliant 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**











# **LEIPZIG HEADQUARTERS**

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



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# **BIOANALYTICS AND BIOPROCESSING BRANCH OF INSTITUTE IN POTSDAM-GOLM**

Usable area: 4 096 m<sup>2</sup> Employees: 106

Focal areas: Biotechnology, bioproduction, bioanalytics, automation

Address: Am Mühlenberg 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.



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

Usable area: 1300 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.



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# **EXTRACORPOREAL IMMUNOMODULATION PROJECT GROUP IN ROSTOCK**

Usable area: 700 m<sup>2</sup> 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 inand outpatients. Moreover, the group offers self-developed unique analytic and diagnostic devices including an ex situ intestine model, a cell sensor and novel protein assays.



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LOCATIONS



# 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 m<sup>2</sup>, it will provide joint German-Canadian research units and research subsidiaries of industrial companies with an outstanding, state-of-the-art research infrastructure.

### Contact



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# **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. Micheal 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

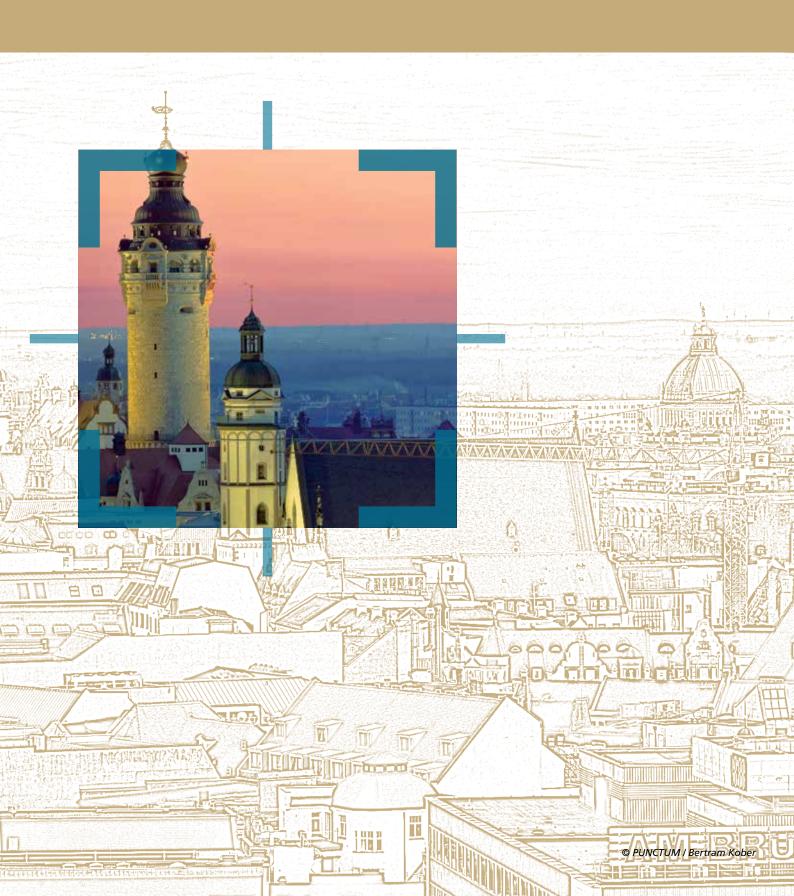


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# SCIENCE LOCATION LEIPZIG



# LEIPZIG AND THE FORMER TRADE FAIR **GROUNDS**

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

#### **Location: Central for interface partners**

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

### **BIO CITY Leipzig: A potent neighbor**

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

### Integrated universities

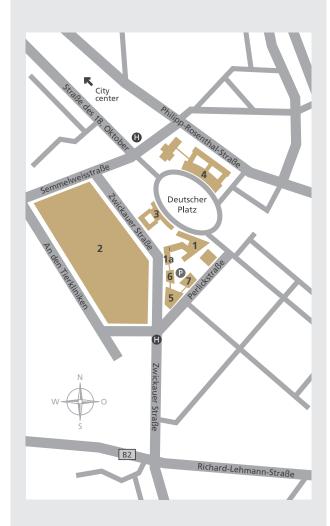
The academic landscape within Leipzig also benefits from cooperation with the Fraunhofer IZI: The Leipzig University, the Leipzig University of Applied Science (HWTK) and the Graduate School of Management (HHL) have found in the Fraunhofer IZI a strong partner for research cooperations and the development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

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

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

### Numerous partners in the immediate vicinity

The neighboring partners of the Leipzig University are, among others, the Medical Faculty, the Veterinary Medicine Faculty, and the University Hospital. Further institutions relevant for cooperation are the Heart Center Leipzig GmbH, the Helmholtz Center for Environmental Research (UFZ), the Leibniz Institute for Surface Modification (IOM), the 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 Congnitive 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

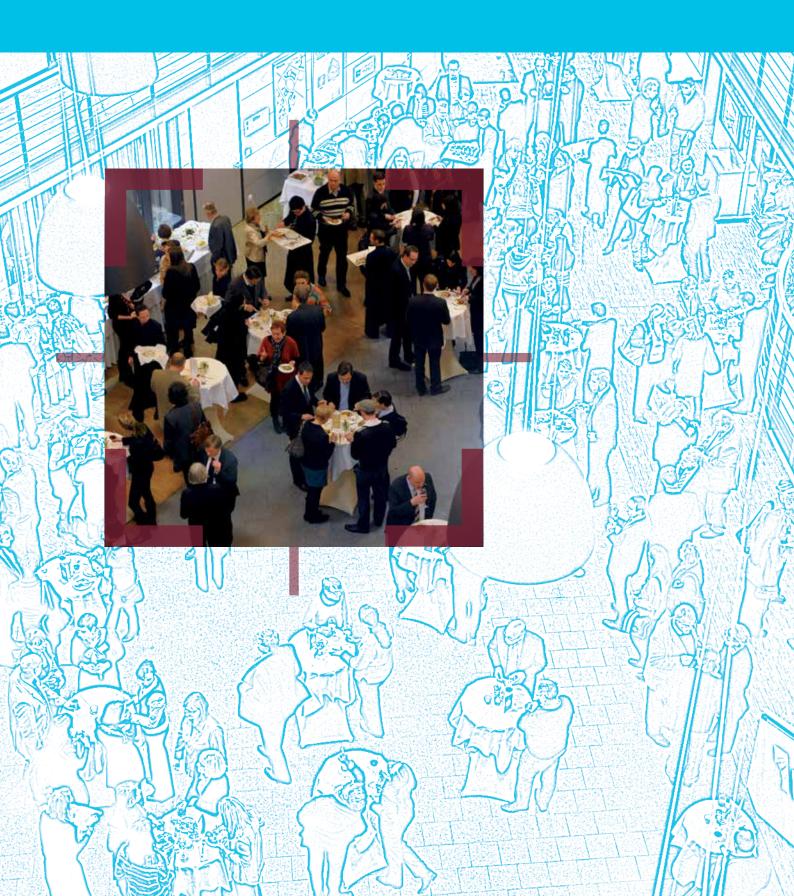
### Leipzig University of Applied Sciences (HTWK)

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.





### 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

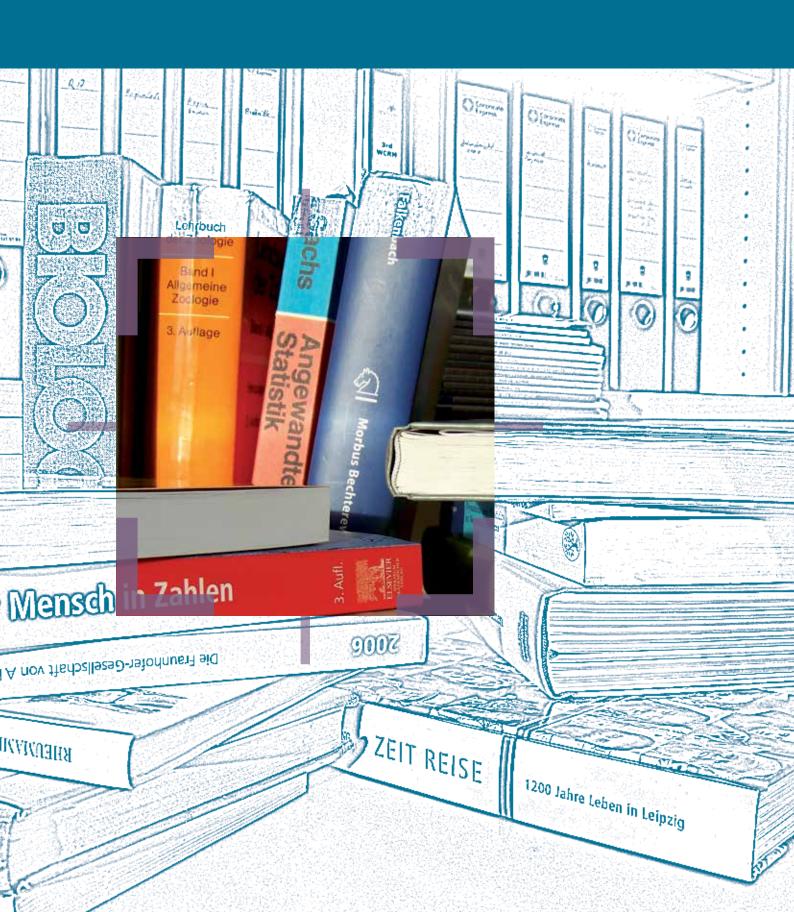
June 26, 2016

**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 Technolo**gy 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 Microbriology 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,

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 Confe**rence, 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, Rauischholzhausen, 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 Bedsite, 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,

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

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

6, 2015, Berlin, Germany

**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

Musicans: 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, Febraury 10, 2015, Frankfurt

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

(Main), Germany

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 immunebrain 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

Anhalt Köthen University of Applied Sciences, Köthen, Germany

Aristotle University of Thessaloniki, Thessaloniki, Greece

Asociación de la Industria Navarra, Cordovilla, Spain

Babraham Institute. Cambridge, Great Britain

**Berlin-Brandenburg Center** for Regenerative Therapies BCRT, Berlin, Germany

**Berlin State Office of Criminal Investigations, Berlin, Germany** 

**Beuth University of Applied** Sciences Berlin, Berlin, Germany

Bielefeld University, Bielefeld, Germany

**Biomedical Primate Research** Centre, Rijkswijk, The Netherlands

**Brandenburg University of** Applied Sciences, Brandenburg, Germany

**Brandenburg University of** Technology Cottbus-Senftenberg, Senftenberg, Germany

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

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

Centre Suisse d'Electronique et Microtechnique CSEM SA,

Neuchâtel, Switzerland

Centro Tecnológico L'Urederra, Navarra, Spain

Charité - Universitätsmedizin Berlin, Berlin, Germany

**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

Dalian Muncipal Hospital, Dalian, China

Danmarks Tekniske Universitet, Kgs. Lyngby, Denmark

École Polytechnique Fédéral de Lausanne, Lausanne, Switzerland

Erasmus MC, Rotterdam, The Netherlands

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

**Federal Institute for Materials** Research and Testing, Berlin, Germany

**Federal Institute for Risk** Assessment, Berlin, Germany

Flensburg University of Applied Sciences, Flensburg, Germany

Fraunhofer Heinrich Hertz Institute, Berlin, Germany

Fraunhofer Institute for **Applied Information Techno**logy 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,

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

Free University of Berlin, Berlin, Germany

Freiburg Institute for **Advanced Studies, Albert Ludwigs University of** Freiburg, Freiburg, Germany

Furtwangen University,

Villingen-Schwenningen, Germany

**German Aerospace Center** (DLR) in the Helmholtz **Association,** Berlin, Germany

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

German Primate Center, **Leibniz Institute for Primate** Research, Göttingen, Germany

**German Prostate Cancer** Consortium (DPKK), Düsseldorf, Germany

**Hannover University of** Applied Sciences and Arts, Hannover, Germany

Harvard Medical School, Boston, USA

**HELIOS Klinikum Berlin Buch,** Berlin, Germany

**Helmholtz Centre for Environmental Research** (UFZ), Leipzig, Germany

**Helmholtz Centre for** Infection Research, Braunschweig, Germany

Helmholtz Centre Potsdam, **GFZ German Research Centre** for Geosciences, Potsdam, Germany

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

Herzzentrum Leipzig - University Hospital, Leipzig, Germany

Humboldt-Universität zu Berlin, Berlin, Germany

Imperial College London, London, Great Britain

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

Institut Dr. Schulze GbR, Markkleeberg, Germany

Institute for Thin Film and Microsensoric Technology (iDM), Teltow, Germany

Instituto Politécnico Nacional, Ciudad de México, Mexico

Jagiellonian University, Krakow, Poland

Jena University Hospital, Jena, Germany

**Johannes Kepler University** Linz, Linz, Austria

Karolinska Institutet, Stockholm, Sweden

Kiel University, Kiel, Germany

Klinikum Rechts der Isar, Technical University of Munich, Munich, Germany

Klinikum St. Georg, Leipzig, Germany

Krankenhaus St. Elisabeth und St. Barbara, Halle (Saale), Germany

**KU Leuven,** Leuven, Belgium

Leibniz Institute for Neurobiology (LIN), Magdeburg, Germany

Leibniz Institute for Plasma Science and Technology (INP Greifswald), Greifswald, Germany

**Leibniz Institute of Photonic Technology,** Jena, Germany

**Leibniz Institute of Surface** Modification, Leipzig, Germany

Leibniz Institute of Vegetable and Ornamental Crops, Grossbeeren, Germany

Leipzig University, Leipzig, Germany

**Leipzig University of Applied** Sciences, Leipzig, Germany

Liverpool School of Tropical Medicine, Liverpool, Great Britain

**Ludwig Maximilian University** of Munich, Munich, Germany

Mahidol University, Nakhon Pathom, Thailand

Manipal University, Manipal,

Martin Luther University of Halle-Wittenberg, Halle (Saale), Germany

Max Delbrück Center for Molecular Medicine in the Helmholtz Association, Berlin-Buch, Germany

Max Planck Institute of Colloids and Interfaces, Potsdam, Germany

**Max Planck Institute for Human Cognitive and Brain Sciences,** Leipzig, Germany

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

Max Planck Institute of **Psychiatry,** Munich, Germany

McMaster University. Hamilton, Canada

Medical University of Graz, Graz, Austria

Medical University of Vienna, Vienna, Austria

Medizinische Hochschule **Brandenburg Theodor** Fontane (MHB), Neuruppin,

Multitel, Mons, Belgium

**National Centre for Scientific** Research "Demokritos",

Athens, Greece

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

Newcastle University,

Newcastle upon Tyne, Great Britain

North German Tumor Bank of Colorectal Cancer, Lübeck, Germany

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

Germany

Saarland University, Homburg,

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,

**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

TU Dresden, Dresden, Germany

Ulm University, Ulm, Germany

**Universidad Autónoma** de Aguascalientes, Aguascalientes, Mexico

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

Università degli studi di Padova, Padua, Italy

Universität Hamburg, Hamburg, Germany

Universitätsklinikum Erlangen, Erlangen, Germany

Universiteit Gent, Gent, Belgium

Universiteit Leiden, Leiden, The Netherlands

Universitetet i Bergen, Bergen, Norway

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 Regens**burg, 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

University of Bayreuth, Bayreuth, Germany

University of Belgrade, Belgrad, Serbia

### **INDUSTRY PARTNERS**

University of Bern, Bern, Switzerland

University of Bonn, Bonn, Germany

**University of California, Los** Angeles / San Diego, USA

University of Cambridge, Cambridge, Great Britain

University of Cologne, Cologne, Germany

University of Erlangen-Nuremberg, Erlangen, Germany

University of Göttingen, Göttingen, Germany

University of Graz, Graz, Austria

University of Greifswald, Greifswald, Germany

University of Illinois at Chicago, Chicago, USA

University of Kassel, Kassel, Germany

University of Leeds, Leeds, Great Britain

University of Oxford, Oxford, Great Britain

University of Potsdam, Potsdam, Germany

University of Rostock, Rostock, Germany

University of Zurich, Zurich, Switerland

Uppsala universitet, Uppsala, Schweden

Wageningen UR, Wageningen, The Netherlands

**Washington University** School of Medicine, St. Louis, USA

Western University, London, Canada

Yale University, New Haven,

2bind GmbH, Regensburg, Germany

A4F, AlgaFuel, SA, Lisbon, Portugal

Achira Labs Pvt. Ltd., Bangalore, India

ACOMED statistik, Leipzig, Germany

Affimed GmbH, Heidelberg, Germany

AJ Roboscreen GmbH, Leipzig, Germany

**AKT Angewandte Kommuni**kationstechnik GmbH, Beucha, Germany

**ALS Automated Lab Solutions** GmbH, Jena, Germany

AMSilk GmbH, Planegg, Germany

Analytik Jena AG, Jena, Germany

AnaPath GmbH, Oberbuchsiten. Switzerland

ANT Neuro HQ, Enschede, The Netherlands

APC AG, Nuremberg, Germany

AptaIT GmbH, Munich, Germany

ASA Spezialenzyme GmbH, Wolfenbüttel, Germany

Baxter Deutschland GmbH, Unterschleißheim, Germany

Bayer AG, Monheim, Germany

Becit GmbH, Bitterfeld-Wolfen, Germany

Befort Wetzlar OD GmbH, Wetzlar, Germany

**BEST-Sabel-Bildungszentrum** GmbH, Berlin, Germany

BioGenes GmbH, Berlin, Germany

BIOSYNTAN GmbH, Berlin, Germany

biotechrabbit GmbH, Hennigsdorf, Germany

BioTeZ Berlin Buch GmbH, Berlin, Germany

BLE GmbH, Potsdam, Germany

Bombastus-Werke AG, Freital, Germany

**BRUKER DALTONIK GmbH,** Bremen, Germany

**BST Bio Sensor Technology** GmbH, Berlin, Germany

CellTrend GmbH, Luckenwalde, Germany

**Charles River Laboratories** International, Inc., Sulzfeld, Germany

Chimera Biotec GmbH, Dortmund, Germany

co.don AG, Teltow, Germany

Cognate Bio Services, Inc., Memphis, USA

Cognate Bioservices GmbH, Leipzig, Germany

**Compart Umwelttechnik** GmbH, Weißenfels, Germany

**CONGEN Biotechnologie** GmbH, Berlin, Germany

Cremer OLEO GmbH & Co. KG, Witten, Germany

DMCE GmbH & Co KG, Linz, Austria

Dr. Michael Himmelhaus -NanoBioAnalytics, Berlin, Germany

E.R.D.E.-AAK-Diagnostik **GmbH,** Berlin, Germany

Enzo Life Sciences (ELS) AG, Lausen, Switzerland

ERT-OPTIK Dr. Thiel GmbH, Ludwigshafen, Germany

EurA Consult AG, Ellwangen, Germany

**EUROIMMUN Medizinische** Labordiagnostika AG, Lübeck, Germany

**Experimental Pharmacology** & Oncology Berlin-Buch **GmbH,** Berlin, Germany

First Sensor AG, Berlin, Germany

Genetic Immunity, Inc., Budapest, Hungary

Geräte- und Vorrichtungsbau Spitzner OHG, Leipzig, Germany

**GESA Automation GmbH.** Teuchern, Germany

GeSiM - Gesellschaft fuer Silizium-Mikrosysteme mbH, Radeberg, Germany

GlaxoSmithKline, King of Prussia, USA

GlaxoSmithKline GmbH & Co. KG, Dresden, Germany

Grünenthal GmbH, Aachen, Germany

**GVG** Diagnostics GmbH, Leipzig, Germany

IBA GmbH, Göttingen, Germany

ibidi GmbH, Martinsried, Germany

Ichor Medical Systems, Inc., San Diego, USA

Idifarma Desarrollo Farmacéutico, S.L., Navarra, Spain

IDT Biologika GmbH, Dessau-Roßlau, Germany ifeu - Institut für Energie- und **Umweltforschung Heidelberg GmbH**, Heidelberg, Germany

IgNova GmbH, Oberursel, Germany

**IGY Immune Technologies &** Life Sciences Inc., Thunder Bay, Canada

ILBC GmbH, Potsdam, Germany

IMT Masken und Teilungen AG, Greifensee, Switzerland

in.vent DIAGNOSTICA GMBH, Hennigsdorf, Germany

Institut für Systemisch-Integrative Lerntherapie, Leipzig, Germany

InstrAction GmbH, Mannheim, Germany

IONERA Technologies GmbH, Freiburg, Germany

**Ipratech SA,** Mons, Belgium

KET Kunststoff- und Elasttechnik GmbH, Radeberg, Germany

Lake Biosciences, Grayslake, USA

**LIMETEC Biotechnologies GmbH**, Hennigsdorf, Germany

Lipocalyx GmbH, Halle (Saale), Germany

Magna Diagnostics GmbH, Leipzig, Germany

MAHLE InnoWa GmbH, Schwaikheim, Germany

MD-5 GmbH, Leipzig, Germany

Medichema GmbH, Chemnitz, Germany

**MEYTEC GmbH Informations**systeme, Werneuchen, Germany

Mibelle Biochemistry, Mibelle AG, Buchs, Switzerland

MicroDiscovery GmbH, Berlin, Germany

microfluidic ChipShop GmbH, Jena, Germany

Nanion Technologies GmbH, Munich, Germany

**NATEX Prozesstechnologie** GesmbH, Ternitz, Austria

Nomad Bioscience GmbH, Halle (Saale), Germany

**Northwest Biotherapeutics** GmbH, Leipzig, Germany

Northwest Biotherapeutics, Inc., Bethesda, USA

Novavax AB, Uppsala, Sweden

NTG Neue Technologien GmbH & Co. KG, Gelnhausen, Germany

Nuvo Research GmbH, Leipzig, Germany

Oncotrition GmbH, Leipzig, Germany

**OntoChem IT Solutions** GmbH, Halle (Saale), Germany

opTricon - Entwicklungsgesellschaft für Optische Technologien mbH, Berlin, Germany

PharmaCept GmbH, Berlin, Germany

PharmGenomics GmbH, Mainz, Germany

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

pluriSelect Life Science UG (haftungsb.) & Co.KG, Leipzig, Germany

PolyAn GmbH, Berlin, Germany

PolyQuant GmbH, Bad Abbach, Germany

Praxis Pharmaceutical, Miñano, Spain

Praxis Prof. Dr. Hoheisel Leipzig, Leipzig, Germany

Prima BioMed GmbH, Leipzig, Germany

Prima BioMed Ltd., Sydney, Australia

Probiodrug AG, Halle (Saale), Germany

qpa bioanalytics GmbH, Berlin, Germany

quartett Immunodiagnostika, Biotechnologie + Kosmetik Vertriebs GmbH, Berlin, Germany

Quimatryx S.L., San Sebastian,

Rathenower Optik GmbH, Rathenow, Germany

RedHill Biopharma Ltd., Tel Aviv, Israel

ReliaTech Receptor Ligand Technologies GmbH, Wolfenbüttel, Germany

RESprotect GmbH, Dresden, Germany

RIPAC-LABOR GmbH, Potsdam, Germany

RS Zelltechnik GmbH, Leipzig, Germany

Sabel-Schülerzentrum, Dresden / Freital, Germany

Sachtleben GmbH, Hamburg, Germany

SCIENION AG, Berlin / Dortmund, Germany

Securetec Detektions-Systeme AG, Munich, Germany

**SelfDiagnostics Deutschland** GmbH, Leipzig, Germany

SensLab Gesellschaft zur Entwicklung und Herstellung bioelektrochemischer Sensoren mbH, Leipzig, 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 Confe-**

rence, 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 FACSVerse 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 Appli-

cants, 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 "Strate**gies - 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 Calori-

metry, 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 Experi**ment Projects, Fraunhofer IZI, Leipzig, Germany

## **Principles of Gas Chromato-**

graphy, 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 **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,

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

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

Radiation Protection Act. B·A·D Gesundheitsvorsorge und Sicherheitstechnik GmbH, Munich, Germany

**Update Course on the** 

**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

# **TEACHING ACTIVITIES**

#### **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 "BioImaging" (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

### **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

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. Sehastian 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

**IO 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 Drever

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

biosaxonv 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 Associa**tion 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

Förderverin 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 Allergology 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 Füldner, 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 Nephro**logy (DGfN), Prof. Dr. Steffen Mitzner

**German Society for Parasito**logy (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-Roseneak. 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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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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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 metabiobanks to translational research platforms: integrating Big Data through CRIP tools. ESBB Annual Conference, 29.9.-2.10.2015, London, UK.

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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.

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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.

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Smith D. Non-genetic programmingof biological systems through nanoscale components. Invited Lecture **Chonnam National University** Hospital Hwasun, 15.9.2015, Gwangju, South Korea.

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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.

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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

Szardenings M. Ultimate peptide phage display in epitope studies. Gwangju Institute for Science and Technology (GIST), 20.11.2015, Gwangju, South Korea.

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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.

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Thoring L. **Future perspectives** for the synthesis of "Difficultto-Express" proteins: development of novel cell-free systems based on CHO cell lysates. PhD Symposium, 26.-27.11.2015, Luckenwalde.

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Wilcke A. Genetics of Dyslexia - an early screening test and its acceptance. Dyslexia and coping behaviour - International Workshop, 8.-9.10.2015, Leipzig.

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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.

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Herrmann S, Seitz H. Personalisierte Medizin und Diagnostika: Der Stand der Dinge. GIT Labor-Fachzeitschrift. 59 (2015), 8, S. 18-23.

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# **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.: III. (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**

# **GRADUATION (CLASS OF 2015)**

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.

Anders, Toni. Development of a Drop Detection Software Module for the Optimization of a Dispensing Platform. Brandenburg University of Applied Sciences, bachelor's

Arnold, Stefanie. Epitope Mapping of PBP2a and Identification of MRSA-**Specific Immunodominant Peptide Sequences.** University of Potsdam, doctorate degree

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

Djeutcha, 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 Patho**logies 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 Antimicrobial 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 dearee

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** Glutaminyl 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 dearee

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 **Ouantum-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 form 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"

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 Glutaminyl 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

Poster Prize awarded at

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

Biomedical Applications"

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
- 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.









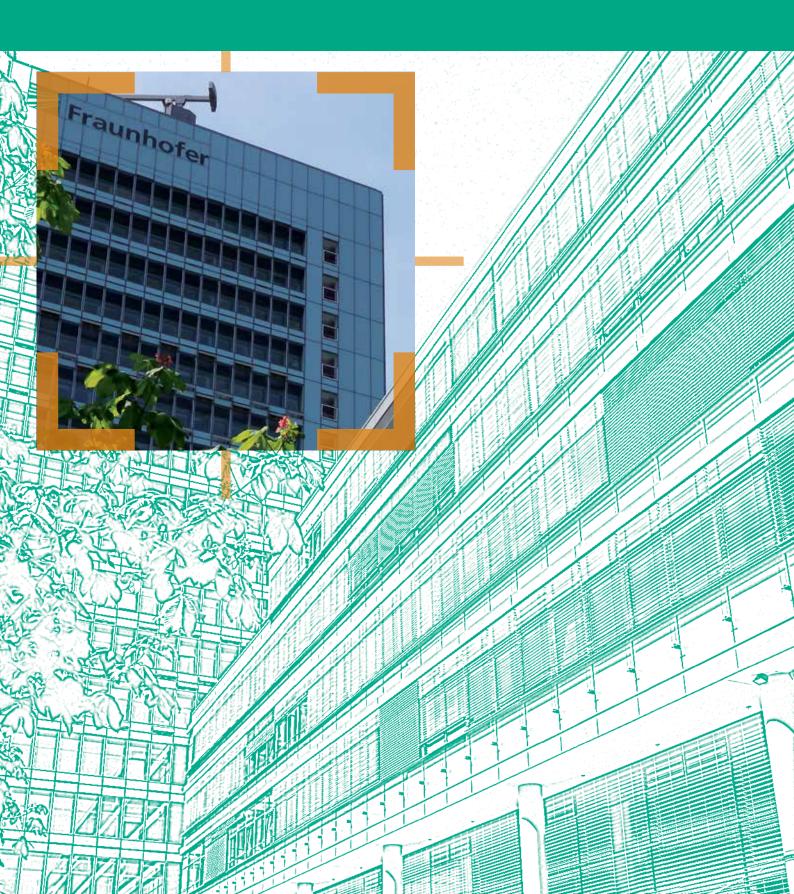
Members of the advisory board:

- 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)
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- Dr. Kai Pinkernell (Medigene AG)
- Prof. Dr. Andreas Pinkwart ((HHL Leipzig Graduate School of Management, Dean)
- Dr. Mark Wolters (Bayer Pharma AG)

# **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.

# 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**

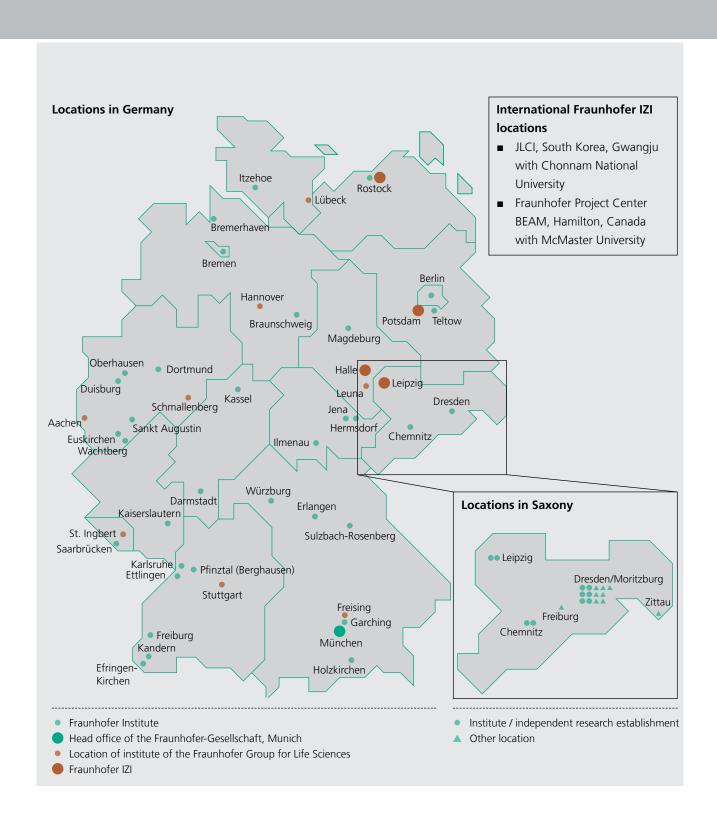
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- Prof. Dr. Alexander Kurz, Human Resources, Legal Affairs and IP Management
- Prof. (Univ. Stellenbosch) Dr. Alfred Gossner, Finance, Controlling (incl. Business Administration, Purchasing and Real Estate) and Information Systems
- Prof. Dr. Georg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

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# 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

### Contact of the head office

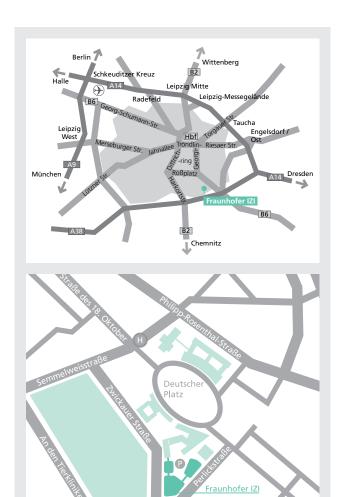
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# FRAUNHOFER IZI CONTACT INFORMATION



# **HOW TO REACH US**



### Address

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

### By car

A9 - Exit Leipzig-West: Take the B181 in the direction of the city center ("Zentrum") and follow the B87 (Merseburger Straße, Lützner Str., Jahnallee). After passing the central station, turn right towards Augustusplatz (Leipzig Opera House). At Augustusplatz turn left and keep to the right, then follow Prager Straße. Turn right at Semmelweissstraße, 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 Semmelweissstraße, 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 Lößnig. 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".

# **CONTACT**

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# **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.

Fraunhofer 10.5...[2] 2015

# 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

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