

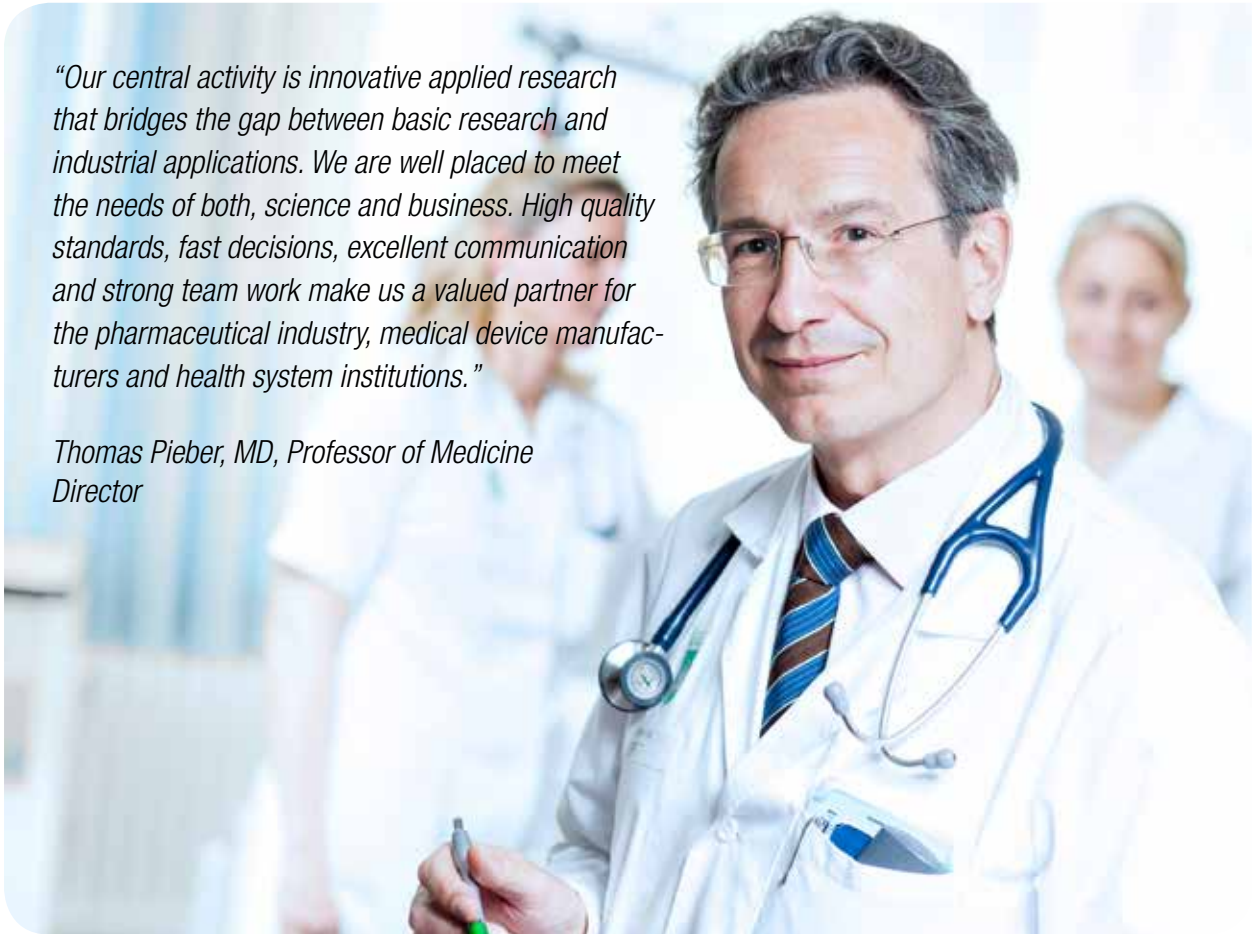
# HEALTH

Institute for Biomedicine  
and Health Sciences



*“Our central activity is innovative applied research that bridges the gap between basic research and industrial applications. We are well placed to meet the needs of both, science and business. High quality standards, fast decisions, excellent communication and strong team work make us a valued partner for the pharmaceutical industry, medical device manufacturers and health system institutions.”*

*Thomas Pieber, MD, Professor of Medicine  
Director*



## Contact

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# HEALTH – Institute for Biomedicine and Health Sciences

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## BRIDGING BOUNDARIES

No other field is as dependent on interdisciplinary collaboration to bring new ideas to market as medicine.

We work in a close strategic alliance with the Medical University of Graz and our director, Prof Thomas Pieber MD, is also the director of the clinical department for endocrinology and metabolism at the University.

Our team consists of around 70 technical and scientific employees. We work closely with a further 120 medically oriented specialist personnel from the Medical University of Graz.

Together, we work to translate ideas and technologies from medicine, pharmaceutical science and health services research into marketable products and services.

## Research services

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- Tissue-specific pharmacokinetic and pharmacodynamic studies
- Bio- and pharmaceutical analysis
- Metabolomics/Biomarker research
- Medical device development & evaluation
- Health economics & outcome research
- Integrated health care concepts and planning

## Quality

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We set high quality standards for our services and products. As our partner, you can rely on the application of international quality standards right from placing your order up to delivery of the final product/service. We operate according to the following guidelines:

- EN ISO 9001:2008
- EN ISO 13485:2012
- GLP

Our customers are welcome to assess our facilities and quality standards on-site at any time.



## Tissue-specific pharmacokinetic and pharmacodynamic studies

We examine pharmacokinetic (PK) and pharmacodynamic (PD) profiles of new drugs as well as the bioequivalence of new pharmaceutical formulations. We carry out biomarker-based and metabolomic studies to pinpoint the causes of inflammatory diseases. We have the capacity to perform pre-clinical ex vivo and in vivo, as well as clinical in vivo studies, using microdialysis and our patented Open-Flow Microperfusion method.

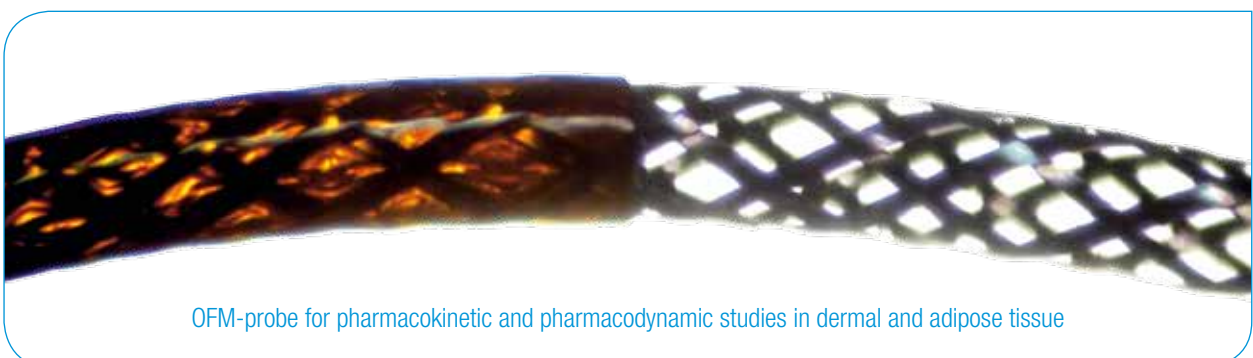
### Our services

- preparing study protocols
- submitting ethical applications

- executing pre-clinical and clinical studies
- performing and validating bioanalytical procedures
- statistically analyzing the data

### We focus on the target tissue level

- **Dermatology:** Transport routes and effects of drugs within the dermal layer after topical or systemic administration (e.g., topical glucocorticoids or systemic antibodies in the case of psoriasis)
- **Endocrinology:** Transport routes and effects of drugs in adipose tissue (e.g., insulin)
- **Neurology:** Transport across the blood-brain barrier (BBB), dose-response effects when the BBB is bypassed, monitoring of BBB function (e.g., highly lipophilic and psycho- and neuropharmaceuticals)





#### Advantages of Open-Flow Microperfusion (OFM)

- Direct in vivo access to the interstitial fluid and to the interstitium's whole biochemical information
- continuous sampling of diluted, unchanged tissue interstitial fluid
- no limitation in substance size (even cells), lipophilicity or protein binding effects
- continuous multi-analyte sampling and PK-PD analysis

#### OFM-material

CE-labeled catheters and small, wearable, multi-channel pumps for (pre-)clinical PK and PD-studies

#### High-end laboratory – GLP certified

We are specialized on microliter sample volumes and picomolar analyte concentrations with state-of-the-art mass spectrometry.

#### Study planning, electronic data capture and management and statistics

Having a profound understanding of medical research, we combine electronic data capture and management with long-term expertise in reliable and stressable statistical analysis – according to GCP and 21 CFR Part 11.

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## Bio- and pharmaceutical analysis

We develop, validate, optimize and automate innovative bioanalytical methods for high-throughput analyses that can be used by medical researchers and in the pharmaceutical industry. We can analyse microliter sample volumes and picomolar analyte concentrations with state-of-the-art bioanalytical methods. We offer our services GLP compliant - if required.

**GLP certified**

### Our services

- **Sample Preparation** from various biological sample matrices (serum, plasma, interstitial fluid, tissue, cell cultures) and drug formulations.

- **Bioanalysis**

From innovative analytical methods to quality controlled analysis of human and animal blood and tissue samples.

- **Pharmaceutical analysis**

is performed on pharmaceutical raw materials and formulations, e.g. drug analysis, cleaning validation, quantitative testing and testing for impurities.

- **Cleaning validation**

From optimizing sampling methods, the development of high sensitive and selective analytical methods and validation according to international standards.

- **High-throughput analysis**

### High-end metabolomic wetlab

- Metabolites including acyl-CoA enzymes, products of energy metabolism, isotope-labeled tracer molecules, etc.
- Drug analysis
- Polyamines





## Metabolomics/ Biomarker research

The application and optimization of innovative analytical services for the investigation of metabolic processes is our focus. We combine medical, biological, biochemical, bioanalytical, information technology and statistical expertise for basic research, drug development, diagnostics and personalised medicine.

### Our services

- **Study design**  
medical as well as biological and statistical expertise
- **Sampling**  
Freeze clamp tissue samples, serum, plasma, cell culture, yeast

- **Sample storage, sample preparation**
- **LC/FTMS-analysis**
- **Data analysis**  
data conversion, peak detection, alignment, grouping, data filtering
- **Statistics**  
multivariate statistical methods, regression models, neural networks
- **Metabolite database**
- **Determination of unknown substances**

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## Medical device development and evaluation



We are ISO 13485:2012 certified and develop technologies relevant to medical sensors, clinical decision support and minimally-invasive in vivo sampling.

We also support the development of medical devices through all stages of the medical device life cycle. We aim to help you develop products that meet medical needs, high demands of medical staff and patients as well as stringent regulatory, safety and quality requirements.

### Our services

- Assessment and evaluation
- Design-Development-Verification
- Clinical data and evaluation
- Market launch & production
- Market and technology surveillance
- Quality and risk management







## Medical sensors

We focus on implementing various sensor technologies into applications for the clinical environment. We drive the development of new sensing methods from fundamental ideas to experimental models and prototypes for preclinical and clinical testing.

- Optical and electrochemical sensors for in vivo and ex vivo monitoring
- Point of care systems
- Home monitoring
- Evaluation of sensor systems



## Clinical decision support systems

We develop smart software systems to support complex clinical processes focussing on usability. It is our aim to support professional medical decision making and adequate patient care.

- Work-flow management and decision support for mobile devices, focusing on optimum usability
- Implementation of clinical protocols and algorithms
- Information extraction from medical free-text documents
- Usability studies with patients and clinical professionals
- Clinical studies for software validation

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## Health economics & outcome research

We support you by offering our unbiased, evidence- and science-based expertise in the areas of health care and pharmacoconomics, market analysis, horizon scanning, regulatory affairs and reimbursement, as well as in the scientific and economic evaluation of health care programs.

### Our services

- Early assessment of new technologies and products
- Health economics and reimbursement
- Market analysis and horizon scanning
- Medical and economic evaluations of health care

### Know How

- Comprehensive analyses and solutions
- Interdisciplinary approaches
- Information about decision-making processes and requirements within the health care system
- In-depth knowledge of the health care system and services
- Expertise in specific diseases and indications
- Application of a wide range of scientific methods and study designs

### Code of conduct

In our work, we place the highest value on the use of methods that have been scientifically established and supported, as well as on unbiased results derived by applying principles of both scientific rigor and objectivity.

We work toward the continuous improvement of health care in Austria and other countries and, for this reason, we feel that we are obliged to the interests of our society. We are particularly keen to represent the interests of patients insofar as possible, with the ultimate goal to benefit the whole of society with our concepts, expertise and analyses.



## Integrated health care concepts and planning

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We assist healthcare decision-makers and service providers in the development, implementation, monitoring and evaluation of integrated health care operations. We increase the visibility of your services in therapeutic, diagnostic and nursing settings and help you to unlock your full potential as a healthcare provider, support organization, hospital, insurance agency, association, clinic or doctor in a private practice.

### Our services

- Structural planning
- Procedural planning
- Development of care management programs
- Medical and economic evaluations in the health care system

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