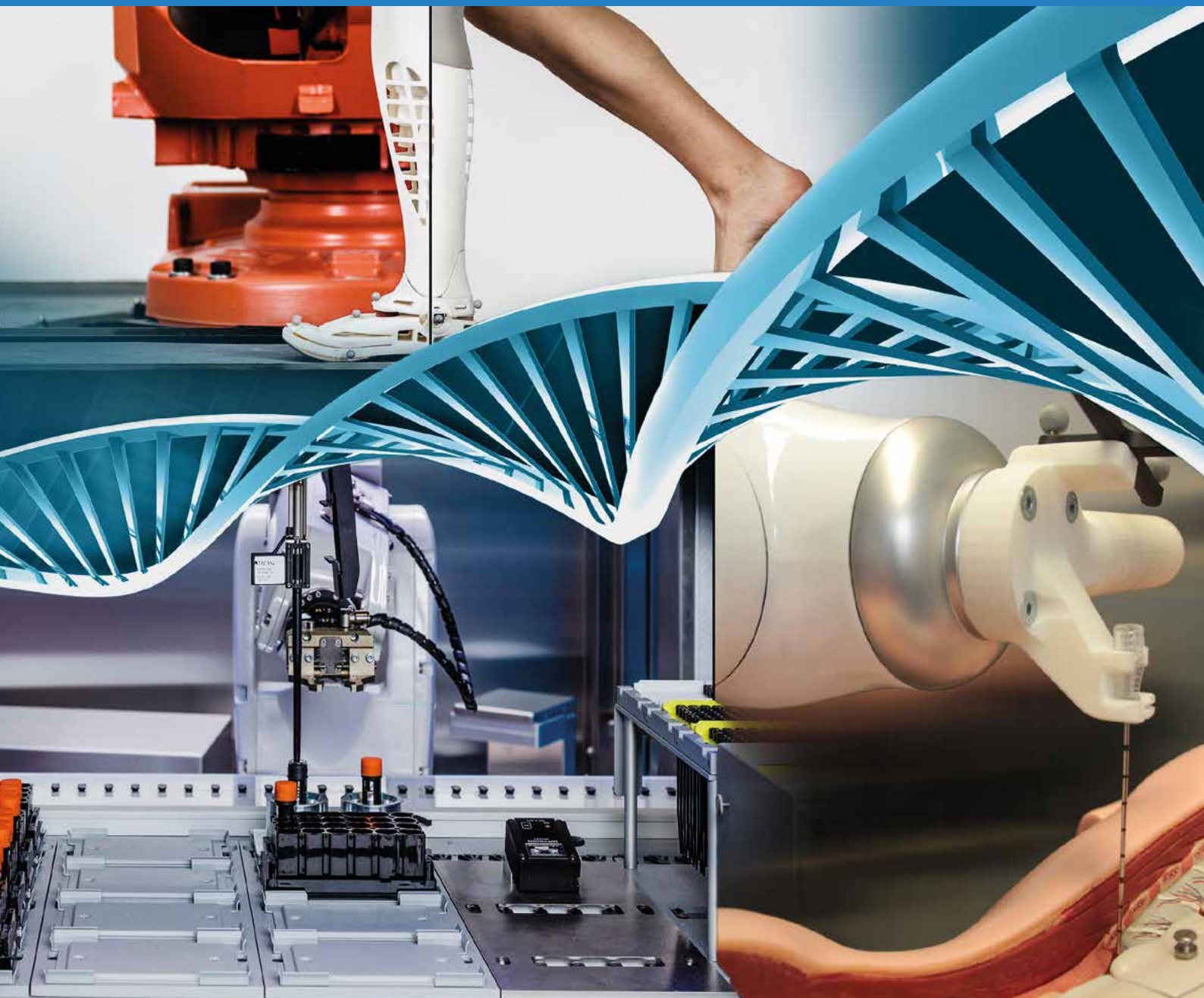
Fraunhofer
IPA

FRAUNHOFER INSTITUTE FOR MANUFACTURING ENGINEERING AND AUTOMATION IPA

BUSINESS UNIT

MEDICAL ENGINEERING AND BIOTECHNOLOGY



OUR MOTIVATION

Biotechnology and medical engineering are two highly complex markets, which can benefit significantly from one another and therefore offer a huge potential for innovative concepts in life science industries. German companies are very well-positioned internationally and world leaders in many areas. Medical products are found in almost all segments of healthcare: in diagnostics, prevention, treatment as well as rehabilitation and care. They contribute extensively towards a better quality of life for the patient as well as enabling older and disabled people to take an active part in social life.

In order to counteract the effects of demographic change and its associated problems, such as a rise in chronic illnesses and care requirements and mounting costs for older people, biotechnology and medical technology need to be successfully combined. The aims are far-reaching: reliable diagnostics, the accurate classification of illnesses and prompt, targeted and consequently optimal patient therapy.

To maintain the position of German companies as innovation leaders in the world market of the future, research has to become more efficient, development rates speeded up, time-to-market shortened and new products brought faster onto a highly-regulated market. With our research competencies and development skills and structures in Stuttgart and Mannheim, we offer application-orientated research that gives direct benefits to companies and research institutions located in the strong medical and biotech region of South-Western Germany and beyond. We cooperate with doctors, biotechnologists, engineers and software specialists to develop innovative solutions. Specialists on cleanroom manufacturing, quality assurance and regulatory aspects complete our teams of experts.

In "Biotech & Pharma" we develop automation solutions from the machine concept to the adapted and validated process. We take our customers' needs into consideration to realize tailormade, integrated automation solutions. We shape our customers' organizational and process capabilities to achieve optimum market flexibility and competitiveness with top quality, short throughput times and minimum costs.

In "Orthopedics & Rehabilitation", we develop innovative solutions to improve mobility in the course of demographic change – from leg prostheses to active exoskeletons.

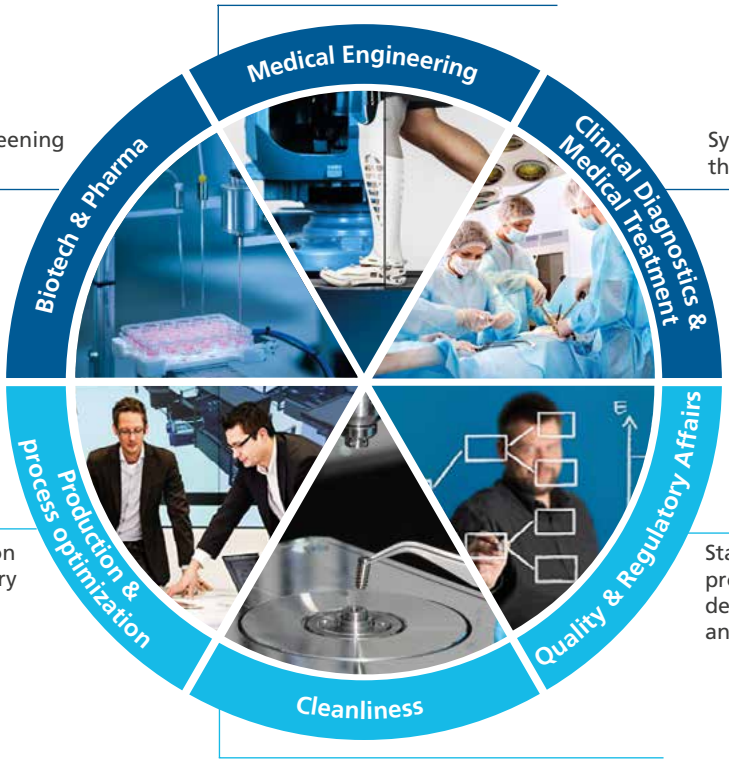
Another focus of our work is on refining intelligent surgical medical devices and instruments to make operations safer and less invasive. Assistive systems in the field of care also help prevent injuries, thus making care tasks more appealing.

The essential link to clinical applications is assured by our Project Group for Automation in Medicine and Biotechnology (PAMB). Located in CUBEX[41] on the grounds of Mannheim university hospital, the group carries out research on application-orientated innovations for diagnostics and surgery. Thanks to its close collaboration with the respective medical and biotechnological institutions on site and in the area, it is able to offer the complete scope of services starting from the product idea right up to clinical evaluations.

Innovative solutions for quality-assured and efficient medicine

Laboratory Automation and development of innovative screening and production technologies

Systems and processes for the future of medicine



Planning, design and realization of value stream-oriented factory planning and organization

Standard-compliant product and process development for medical devices (CE, CE-ivD, DIN EN ISO 14971 and 13485, G(A)MP, ROHS, REACH)

Planning and optimization of measures to develop a successful cleanliness concept

SERVICES AND WORK AREAS

Fraunhofer IPA looks back on many years of experience in medical technology and biotechnology. Our range of services includes consulting services, developing instruments, devices and equipment, and also developing and modifying technologies and processes. Through our project group in Mannheim, which is located on the grounds of the local university hospital, we are in a position to research into automation potentials for the hospital directly where applications are implemented.

Medical Technology

An interdisciplinary team develops innovative technical solutions for interventional medicine and modern rehabilitation. Our skills in medical technology are divided into the following areas:

Orthopedics & Rehabilitation
- Bionic medical technology
- Motion control systems
- Virtual orthopedic lab
- Applied biomechanics

Diagnostics, Intervention and Implants
- Computer-assisted surgery
- Orthopedic implants
- Diagnostic systems
- Surgical instruments
- Micro-implants

Care & Assistance
- Situation recognition using ambient sensors
- Motion capture and analysis using inertial sensor technology
- Assistive robots to help with day-to-day tasks and care
- Mobility and manipulation aids

Biotech & Pharma

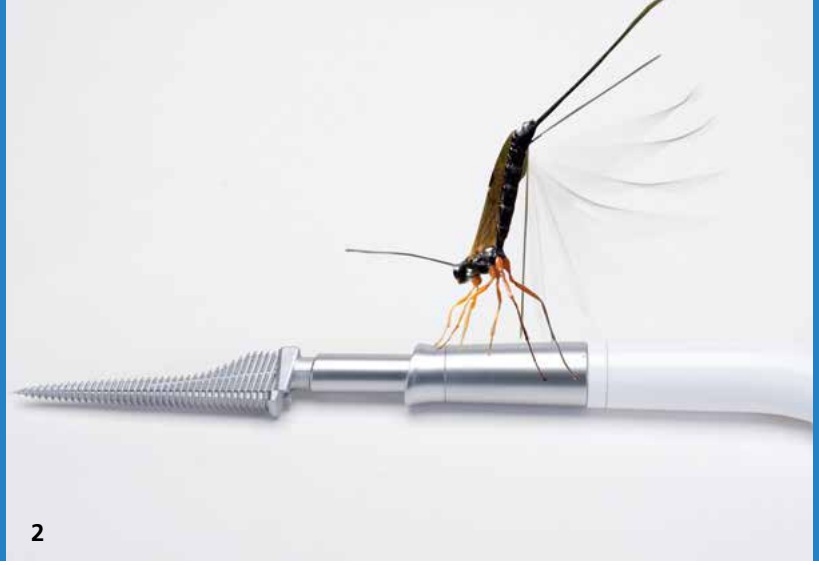
Today, innovative automation solutions in life sciences have become indispensable, especially as a result of the change towards individualized medicine. With our experience, among other things, we can assist you with the following:

Automated Cell and Tissue Culture
- From the product concept to the turnkey solution
- Robust, practicable solutions for cell manufacture, cell therapy medicinal products and tissue engineering

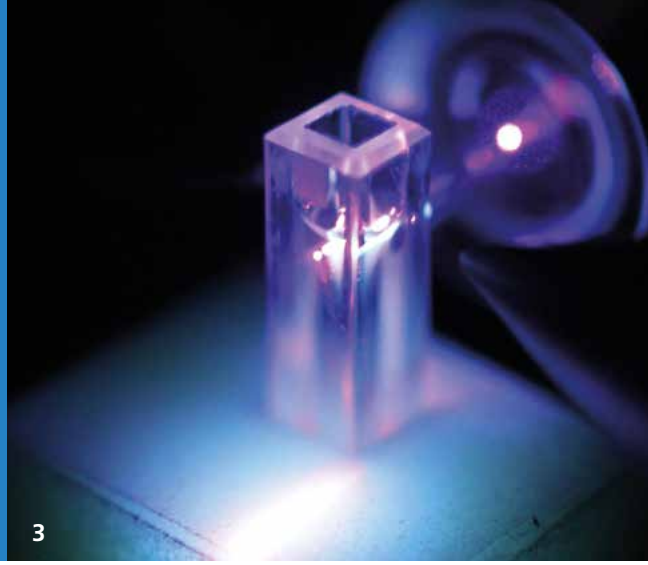
Devices and Equipment for Drug Research and Manufacture
- Special innovative components for "high-throughput screening" and "ultra-high-throughput screening"
- Feasibility studies and technology development
- Support in the planning, development, construction and qualification of devices for use in automated pharmaceutical manufacturing processes (G(A)MP, FDA)

Devices and Equipment for In-Vitro Diagnostics
- Assistance with feasibility studies and product tests
- Development of tailormade device and equipment solutions
- Independent technological consulting services

1 *Cleanroom at Fraunhofer IPA*



2



3

Clinical Diagnostics and Medical Treatment

Our continuous exchange of information with doctors, biotechnologists and users enables us to realize automation solutions designed to meet your specific requirements. Through our longstanding experience, we can advise and help you to develop devices, instruments and software, starting from the product idea right up to clinical evaluation:

Devices and Instruments
- Medical instruments, robots and manipulators
- Active implants
- Sensors and actuators in and on the human body

Systems for Diagnostics
- Analysis, design and realization of customized systems
- Sample processing and analysis
- Multi-spectral imaging and image processing

Software and Control
- Process management systems
- Man-machine interaction
- Device control systems and networked systems
- Development of accompanying tests to develop medical products

Quality & Regulatory Affairs

Maintaining high quality standards is especially important in the development of products and manufacturing processes for medical products. We provide support in the following areas:
- Technical risk assessment in product and process development with the aid of FMEA
- Risk assessment according to DIN EN 14971
- Management of material compliance (RoHS/REACH)

Cleanliness in Life Science Industries

A current development focus is on drafting a guideline to assess the cleanliness of medical products, which will contain methods for deriving acceptance criteria as well as meaningful, reliable standardized analysis procedures:
- Expert analyses to confirm and document the suitability of operating utilities for use in clean manufacturing environments in accordance with GMP, HACCP and EHEDG
- Materials testing, e.g. cleanability, microbiological effects of material surfaces
- Visualization of airflow patterns around or inside devices
- Analysis of cleanrooms to determine airborne microbe concentrations and surface microorganism counts

Production and Process Optimization

Our services include value stream-orientated factory planning as well as value stream-orientated factory operation. The advantages of this are:
- Optimized factory structures through the application of proven methods from "the inside to the outside"
- Integrated design of storage and transport facilities in dependence on optimized production
- Sustained increase in productivity and customer satisfaction through process optimization
- Easy management of fluctuating levels of incoming orders through appropriate production planning and control concepts

2 *Keyhole saw for accurately hollowing out bones*
3 *BeadTRAP system for the sensitive detection of biomolecules*

4

5

OUR INFRASTRUCTURE

New solutions for the quality-assured, efficient patient care of tomorrow – developed together with you. In order to give you a competitive edge in the mid-term, at IPA we offer a spectrum of specific skills ranging from laboratory diagnostics right up to patient care. By cross-networking with our other technical departments, we realize and transfer established solutions as well as the latest developments from other branches of industry.

Biomechatronic Laboratories

In addition to our development facilities containing professional CAD, electronic layout and placement equipment and signal processing and control software, we also have a range of special laboratories at our disposal:

- **Virtual Orthopedic Lab:** Simulation environment for static and dynamic finite-element and multi-body simulations to analyze and optimize biomechanical tasks
- **Navigation Sensory Reference Lab:** Infrastructure for developing and evaluating motion sensors
- **Drive Lab:** Test environment for miniature electrical drives, power electronics, drivetrain dimensioning, components for electro-hydraulic and pneumatic actuators
- **Bionic Lab:** Facilities for performing tests on functional morphological and mechanical structures, development environment for biomimetic medical technology
- **Motion Lab:** Human kinetic and kinematic motion capture for medical, sports sciences and occupational ergonomic tests and also for recording and processing bio-signals
- **Biomechanics Test Lab:** Facilities for testing prosthetic and orthotic components in accordance with EN ISO 22675. Development environment for functional tests in accordance with EN ISO 16955. Individual functional tests on prostheses with the test robot "Gait-to-Robot", dental robotics, tests on structural parts with tensile and compression tests and 3-point /4-point bending tests
- **Polymer Implant Manufacturing Lab:** Evaluation of manufacturing technologies for fabricating biomimetic gradient polymer implants

BioPoLiS

This laboratory has been especially designed for the development of devices and equipment for life science applications and enables engineers and biologists to test them under real laboratory conditions (S2) without having to resort to the use of model systems. Development times are shortened significantly because processes and devices can be developed in parallel and information on device validity obtained much faster.

Care-O-bot Lab

The Care-O-bot laboratory is used to develop and assess new service robot applications for use in the home. The lab is equipped with a living area containing various pieces of furniture and seating and also features a small kitchen area. To implement new application scenarios, several Care-O-bot platforms as well as a total simulation of the robot and laboratory environment are available. The computer infrastructure enables existing robot control software to be accessed both quickly and easily.

Treatment Room in CUBEX[41]

Our project group in Mannheim is located in the innovation center CUBEX[41]. In addition to the various biotechnological, optical, electronic and mechanical laboratories, the center also features a treatment room equipped with Artis Zeego (approved for pre-clinical trials).

Care Lab

In this laboratory, an informative exhibition displays a range of technical assistive systems for aiding people needing care as well as for caregivers. The existing solutions form the basis of discussions on individual requirements and solution approaches for the technical assistive systems of tomorrow.

Liquid Handling Lab

Liquid handling forms the core of many automation solutions. The laboratory contains a range of standard pipetting and dispensing solutions as well as technologies that have been developed at Fraunhofer. By combining "gold standard" solutions with innovative technologies, we can tackle just about any liquid handling challenge.

Cleanrooms

To handle research and development issues related to manufacturing under clean conditions, Fraunhofer IPA has over 300 m² of cleanroom floor space at its disposal. As well as ISO Class 1 cleanrooms, there is also a cleanroom development lab, a photovoltaics test and demonstration center and a heavy-duty cleanroom. Additionally, Fraunhofer TESTED DEVICE® enables cleanroom qualification tests to be performed on devices, components, equipment and environments to assess their suitability for use in contamination-sensitive production facilities.

We help you

– to automate your processes
– to develop devices, instruments and software for clinical, care and rehabilitation applications – starting from the innovative idea up to clinical evaluation
– with feasibility studies, tests and simulations, process evaluation and optimization, and give you independent technological advice
– to develop and realize tailormade device and equipment solutions using established components and Fraunhofer's very own innovative key technologies
– to plan, design and realize value stream-orientated factory operation for companies manufacturing medical and biotechnology products
– to develop products and processes for medical products conforming to the relevant norms (CE, CE-ivD, DIN EN ISO 14971 and 13485, G(A)MP, RoHS, REACH)
– with the cleanliness / sterility of products and manufacturing processes

4 *Automated cell and tissue culture*
5 *Robotic care trolley*
6 *Treatment room in CUBEX*[41]
7 *Software solutions for laboratories*

CONTACT

Tobias Brode
Head of Business Unit "Medical Engineering and Biotechnology"
Fraunhofer Institute for
Manufacturing Engineering and Automation IPA
Phone +49 711 970-1257
tobias.brode@ipa.fraunhofer.de

Dr. med. Urs Schneider
Deputy Head of Business Unit "Medical Engineering and Biotechnology"
Fraunhofer Institute for
Manufacturing Engineering and Automation IPA
Phone +49 711 970-3630
urs.schneider@ipa.fraunhofer.de

Axel Storz
Fraunhofer Project Group for
Automation in Medicine and Biotechnology PAMB
Phone +49 621 17207-366
axel.storz@ipa.fraunhofer.de

Fraunhofer Institute for
Manufacturing Engineering and Automation IPA
Nobelstrasse 12 | 70569 Stuttgart | Germany
www.ipa.fraunhofer.de

Director of Institute
Prof. Dr.-Ing. Thomas Bauernhansl
Prof. Dr.-Ing. Alexander Sauer

Fraunhofer Project Group for
Automation in Medicine and Biotechnology PAMB
Theodor-Kutzer-Ufer 1–3 | CUBEX[41] | 68167 Mannheim | Germany
http://pamb.ipa.fraunhofer.de

122016045