

LABORATORY AUTOMATION AND BIOMANUFACTURING ENGINEERING



LABORATORY AUTOMATION – THE NEXT GENERATION

Automated laboratory devices and systems are indispensable tools for highly-developed modern life science processes. Users, however, face major challenges, such as ever-increasing process complexity, regulatory requirements and enormous development dynamics. In addition individualized production and mass customization are important issues to be tackled. In particular, there is a need for smart, tailor-made, networked solutions. Those are adaptable to constantly-changing operational demands and thus enable complex processes to be controlled cost-effectively in the mid-term. The rising demand for customized solutions can be seen across a broad user range - from developers of major pharmaceutical corporations to operators of small innovative laboratories. However, it has become increasingly difficult for users to select and develop the right automation solution for their needs. Today's laboratory automation market is highly diversified and characterized by a growing number of device manufacturers offering highly-specific uniquely-fitted solutions. In the future, it will be therefore necessary to develop new intelligent automation concepts based on modularization and flexible integration. Due to operational flexibility and sustained extensibility, this strategy not only makes sense for smaller laboratories but also for big pharmaceutical companies.

We bridge the gap between life sciences and automation technology

At Fraunhofer IPA, we design automation solutions from the machine concept right up to the adapted and validated process. Our interdisciplinary team comprises biotechnologists, engineers and software specialists. We develop individual, integrated laboratory automation systems in close accordance to our customers evolving needs.

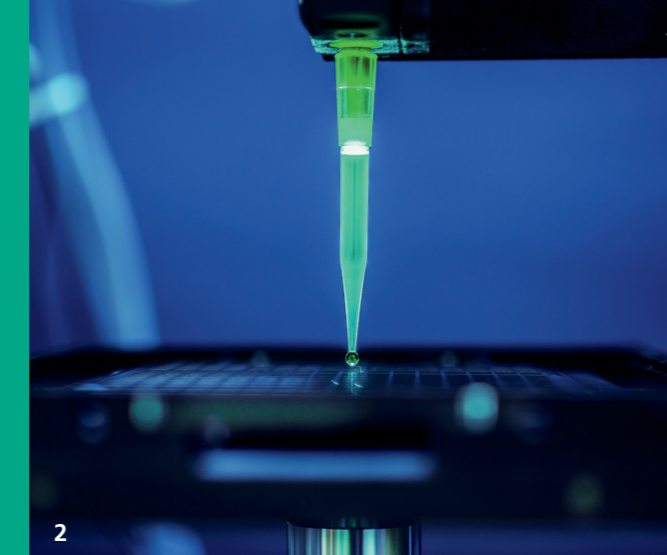
To enable long-term use, devices and system technologies need to be adaptable.

Our automation solutions are based on optimally-adapted process modules which are networked via interface standards. Drawing on a broad network of component and device manufacturers we aim at implementing the most up-to-date and suitable solution for our customers. In those cases where no readily available process module can be identified, we provide a tailor-made OEM development or draw from our comprehensive repertoire of research projects. Fully-automated systems are not always the best solution. We will help our customer to choose the right degree of automation and develop individual concepts. Laboratories are "information and knowledge factories". In the same way as with material flows in a manufacturing company, the administration of data, processes, devices and samples in a laboratory also has to be organized. To do so, we supply integrated software solutions for the networked laboratory of the future. As a driving force in SiLA (Standardization in Lab Automation), we are directly involved in developing the latest standards.

Our paramount goal is to provide our customer with a process that is technically and biologically optimized according to their needs and chosen level of automation. For us, laboratory automation is only completed once the process has been adapted and is running in a reproducible manner.

All projects are therefore supported by technical and biological developers. We carefully map all requirements regarding flexibility, throughput, quality and reproducibility and thus enable an optimum and efficient process design. With this approach even complex processes can be automated reliably. The customer not only receives a technically-refined turnkey system but also support in the process adaption and validation phases.





OUR RANGE OF SERVICES

We realize the complete process chain, or just the areas you need. An interdisciplinary team makes this possible.

PLANNING PHASE

Automation projects are highly complex, making it very difficult for the user to grasp the overall picture. The impact of process modifications and associated sources of error are hard to predict, and the range of possible solutions is extensive. There is also the question of choosing the right time to automate, which also depends on extension potentials and the individual degree of automation required.

Fraunhofer IPA helps you to carry out an initial process analysis and evaluates process adaption options together with you. With a proven portfolio of conception, design evaluation and risk analysis methods, we can identify the right automation solution for you quickly and reliably. This systematically reduces both development times and risks.

Our services

- Detailed process analysis
- Individual modular process and system design
- Pre-tests on implemented process steps and adaption as required
- Assessment and selection of suitable technology providers and solutions
- Process layout according to throughput, in-line quality controls and scope of automation

Your advantages

- Individually adjusted solutions
- Fast project planning and decision to automate
- Extensive knowledge of the bidding market

ADAPTION PHASE

An automated laboratory and manufacturing process does not only consist of the machine and software but, first and foremost, of the biological assay itself. When implementing automation in order to increase efficiency, questions arise about the best way to schedule process sequences or about how to administer and analyze the data generated. We support you during process implementation and adaption and offer services ranging from carrying out methodical analyses to testing your existing processes on the real system. As each assay has its own kinetics and parameters and needs to be specially adapted to end-user specifications, this phase in particular requires interdisciplinary cooperation.

Through the use of suitable needs-based miniaturization technologies, the consumption of reagents and media can be drastically reduced and major cost savings are achieved.

Our services

- Methodical analysis and takeover of manual process sequences
- Identification of key steps
- Analyses of potentials to optimize processes and sequences
- Assessment of chances and risks of process modifications
- Tests on key process steps in real laboratory set-ups

Your advantages

- Maximum of functionality for each solution
- Future-proof business through smart processes
- Early assessment of chances and risks during project implementation

ENGINEERING PHASE

We develop and realize turnkey special solutions that are tailored to customer requirements. Solution options range from handheld laboratory devices right up to complex manufacturing machines for high-throughput operation. We also plan and develop devices from scratch for later serial production right up to pilot series. We attach great importance to an efficient development process. For this reason we choose and integrate components and system modules from commercial manufacturers for device and system development.

Our services

- Manufacturer independent selection and testing of devices
- Layout of process throughput and sequence
- Transfer of the latest research results to real laboratory applications
- Design and construction with documentation in compliance with relevant norms and regulations (CE certification)
- Development of electronics and control units
- Software development and software architectures

Your advantages

- Functional reliability through high implementation quality
- Ability to influence developments due to flexible project milestones
- High quality, state-of-the-art solution and even beyond

1 Every automation begins with an intensive planning and concept design phase.

2 Process adaption and optimization is carried out using the provisional automation setup.

VALIDATION PHASE

The effort to transfer an existing manual process to a machine and execute it is often underestimated and leads to delays when putting the system into operation.

Performing a process in an automated manner not only has to ensure constant product quality but also enable comparable reaction parameters during the process. In accordance with the manual protocol, all process levels and interim steps are included to validate an automated process. We provide services for implementing customer-specific processes both on systems developed internally at Fraunhofer as well as on systems that are commonly available on the market. We analyze your process in detail and help you to define quality criteria, which are subsequently tested in automated operation.

Our services

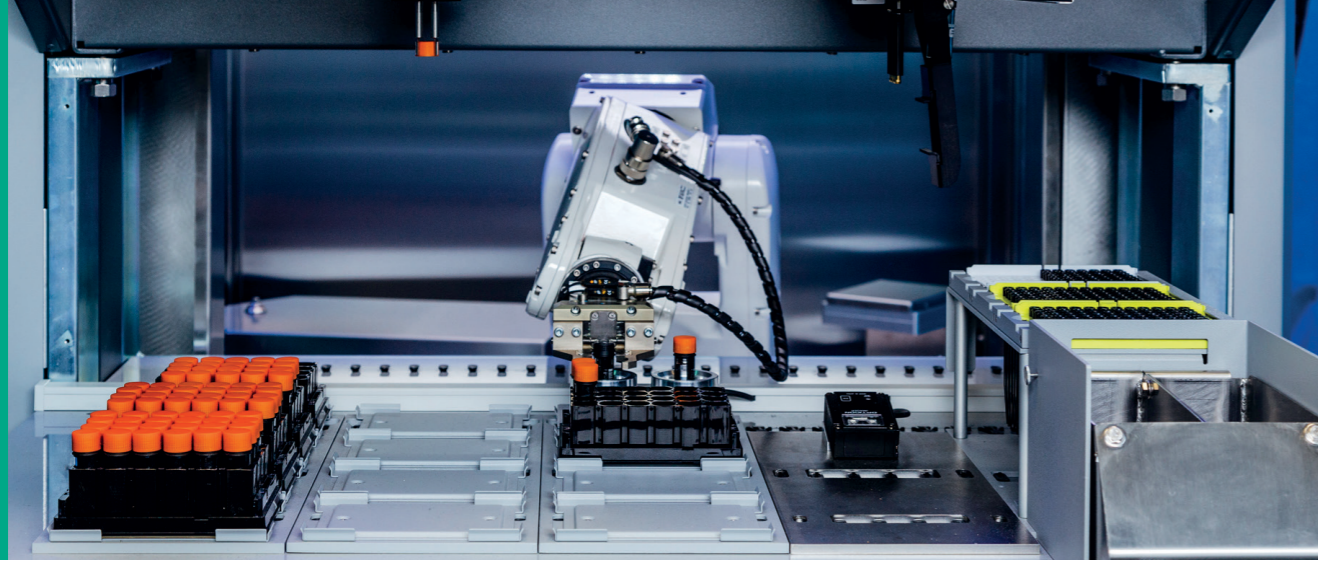
- Definition of quality criteria/minimum requirements
- Establishment of automated processes, taking defined quality criteria into account
- Accompanying molecular biological/biochemical and cell-biological analyses in our laboratories
- Documentation of process implementation and drafting of SOPs

Your advantages

- Fast and functional system implementation
- Identification of sensitive process steps
- Reduced internal establishment efforts

3 We set up all systems in-house and optimize hardware and software components.

4 The final process is validated by us under real conditions.



INFRASTRUCTURE

The bio-production lab in Stuttgart "BioPoLiS" is the main workspace where our developments are carried out. On a surface area of almost 200 m², we can build up complex machines to perform trials under real and even long-term sterile conditions if necessary. We also test the devices for compliance with safety regulations. In the liquid handling competence area, our equipment covers the complete range of leading-edge automated pipetting technology, from low-cost pipettors right up to complex pipetting robots. In our research laboratories we are able to manually prepare samples and perform analyses using a wide range of biological and biochemical techniques.

The development environment is further equipped with ultra-modern CAD, programming and electronic workplaces. These can be adapted to current project requirements at any time.

We also have access to electronic and mechanical workshops as well as our state-of-the-art ISO Class 1 cleanroom facilities, where we carry out cleanliness tests.



At Fraunhofer IPA, we integrate latest system, software and hardware solutions, develop new concepts and advance technological innovations. Our infrastructure enables revolutionary laboratory automation through a strong networking of research and education facilities with suppliers and end-users in one place. Fraunhofer IPA functions as a technology transfer center and campus for a wide range of industries implementing laboratory automation and bio-production engineering.

COMPETENCIES

AUTOMATED CELL AND TISSUE CULTURE

We are technology pioneers regarding automation solutions in the field of 2D and 3D cell culture as well as GMP-compliant cell product manufacturing (ATMPs).

Tissue Engineering on Demand – Automated manufacture of 3D skin models:

- Concept design and process transfer
- Automated cell passage, culture maintenance of primary cells and cell lines
- In-line process control
- Fabrication of in-vitro test systems

Autranomics (Automated Transgenomics) – Systematic analysis and selection of genetically-modified cells:

- Screening unit with integrated microscopic system for long term cell analysis
- Single cell detection and isolation (cell picking)

LIQUID HANDLING AND RELATED ROBOTICS

IPA possesses extensive experience in the areas of pipetting robots, nano dispensing technologies and the handling of solid biological samples.

I-DOT – Immediate Drop on Demand Technology (I-DOT) for liquid handling in the nanoliter range:

- Contact-free nano dispensing systems
- Handling of highly-viscous liquids
- Single cell deposition and cell seeding (single cell handling)

Ribolution – Innovative ncRNA-based diagnostic solution for personalized medicine:

- Development focus on process miniaturization
- High throughput application
- Flexible, modular process automation through SiLA-aided system structure

SYSTEM ENGINEERING

Our automation solutions are characterized by flexible, controlled, functionally-reliable processes with high availability.

Production systems – Automated preparation of active ingredients in accordance to GMP guidelines for a pharmaceutical customer:

- Selection of components independent of manufacturers
- Automation solution from one source, from the first concept to the finished product
- GMP-compliant system planning, software and documentation

LABORATORY IT

The provision of IT solutions for laboratory and manufacturing processes rounds off our portfolio.

SiLA – Standardization in Lab Automation:

- Development of standards for device drivers, communication interfaces and control software
- Accredited SiLA test site
- Simplified driver development via basic library and SiLA wrapper
- Data administration and analysis



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