

# Medical Technologies



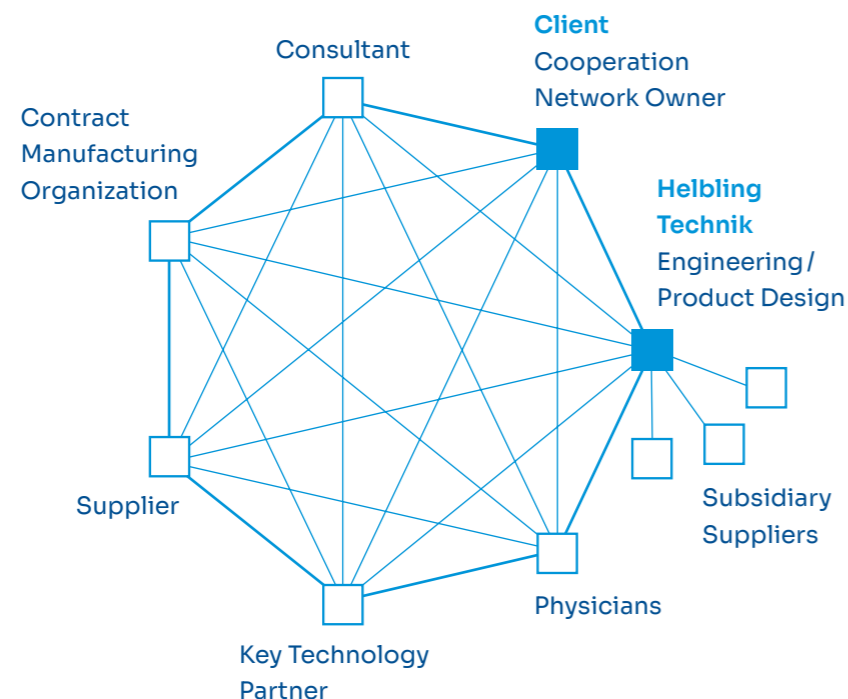
## Innovation, together we do it

The world is constantly changing. New lifestyles, new desires, new insights, and new goals demand effective solutions tailored to market requirements. Long before innovation became a buzzword, we recognized its importance, and began to specialize in working alongside clients as a dynamic, creative, reliable partner, helping them to secure competitive advantage in a changing landscape. Based on your medical requirements, we assist you in designing your technical product and developing it through the stages of design verification, design transfer, and all the way to successful market launch.

### From ideation to market launch

Helbling Technik employs over 500 professionals including engineers, computer scientists, physicists, and human factors experts, with backgrounds from medicine and neurobiology to industrial design. Cross-functional teams develop a wide range of innovative technologies and products for clients worldwide, a key focus of ours for over two decades.

Helbling operates innovation centers in Switzerland, Germany, Poland, the USA, and China to support clients in developing the next generation of medical in-vitro diagnostics devices and instruments from ideation to market launch.



Cooperation Network  
Own illustration

## We are specialized in Medical Technologies

### Innovation, together we do it

Helbling Technik's vision is "Innovation, together we do it". This vision provides a uniform understanding of innovation, even though each of our innovation centers has a different, complementary technological focus. The vision's core theme is that we innovate together and not in isolation. The beginning of the collaborative process involves a wide range of novel ideas to address our client's needs, and then combining these ideas into innovative, promising technologies and product developments. Converting these concepts into successful and profitable products requires an even more collaborative approach that involves us, your network and, of course, our clients. Our project and quality management as well as our execution expertise, enable us to coordinate all of the participating parties effectively, paving the way to success for our clients.

### Innovation emerges from networks

Helbling's size and collective experience allow us to build teams with the right skills and engineering disciplines to develop novel medical technologies and products. In addition, we offer an independent network of partners who complement our know-how, enabling us to cover all aspects of medical technology innovation. Specifically, and in addition to our comprehensive engineering facilities we have established relationships with key opinion leaders, doctors, researchers and scientists, hospitals, and sourcing partners that enable us to quickly build dynamic innovation networks for our clients.



## Benefits for our clients: Why Helbling?

### Experience

Comprehensive portfolio of reference projects. Skilled professionals available for long-term collaboration and/or short-term support.

### Independence

Lower project risks thanks to technology neutral and independent selection of solutions, processes and technologies.

### Network

Independent network of research, vending, and manufacturing partners, providing access to expert panels for executing and reviewing usability and/or pre-clinical studies in medical environments, such as university hospitals or privately-owned medical practices.

### Interdisciplinarity

Holistic approach using the engineering and consulting know-how within the Helbling Group.

### Intellectual property policy

Foreground IP is assigned to the client. Helbling holds no background IP.

### Methods & quality assurance

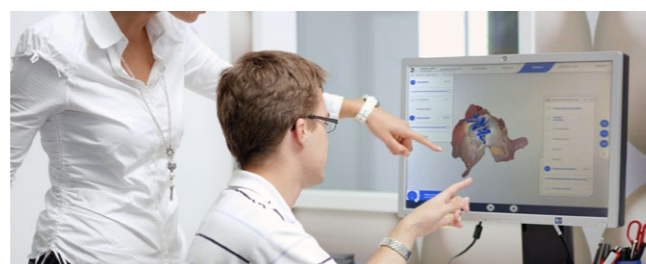
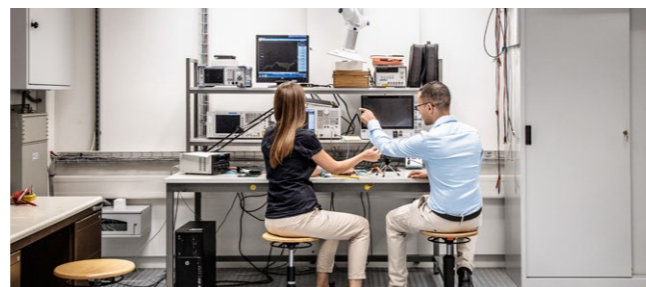
Tried-and-true development methodologies and processes that comply with industry standards (ISO 9001 und ISO 13485). Look beyond established structures and innovate from an independent and neutral standpoint to reduce project risks.

### Resources

Ready-to-go teams that can meet challenging project goals and boost our clients' flexibility.

### Infrastructure

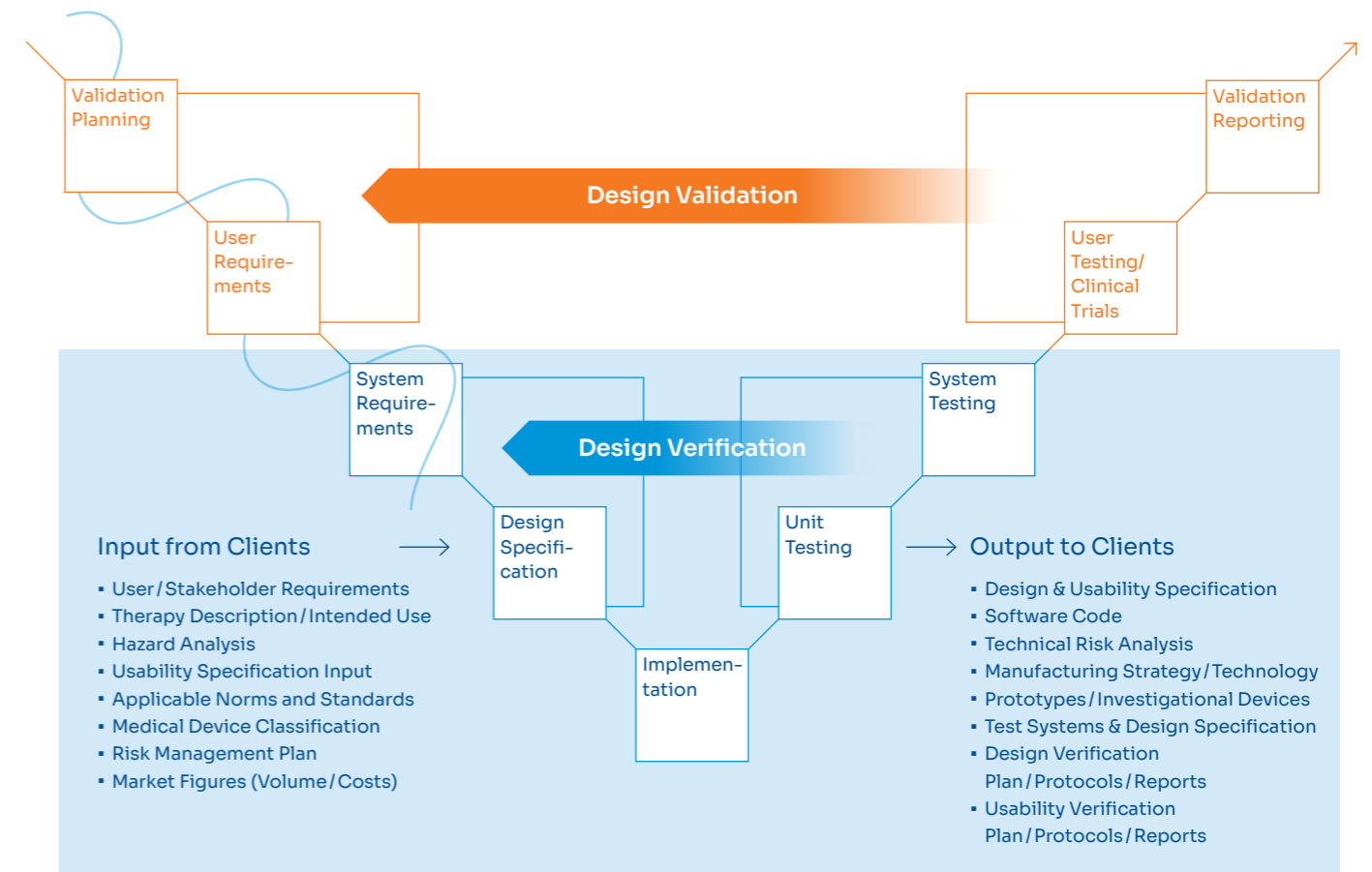
Professional design infrastructure. Qualified in-house lab infrastructure for feasibility demonstration, performance testing, and product design verification.



## We apply the validated development process for MedTech product design

The following diagram depicts Helbling Technik's service offering in the context of the V-Model development process, as commonly adopted in the MedTech industry. Depending on medical, market, and business considerations, by defining validation planning and user requirements. The latter are iteratively defined in collaboration with

Helbling, who specify system requirements. Helbling Technik then implements the design, up to Design Verification, providing the client with means for Design Validation by performing user testing and clinical trials. Typical inputs provided by the client and outputs generated by Helbling Technik are also shown in the diagram.



### V-Model development process

As validated in the Medtech industry, and graphical representation of Helbling's contribution

■ Helbling ■ Clients

# Quality management systems and processes

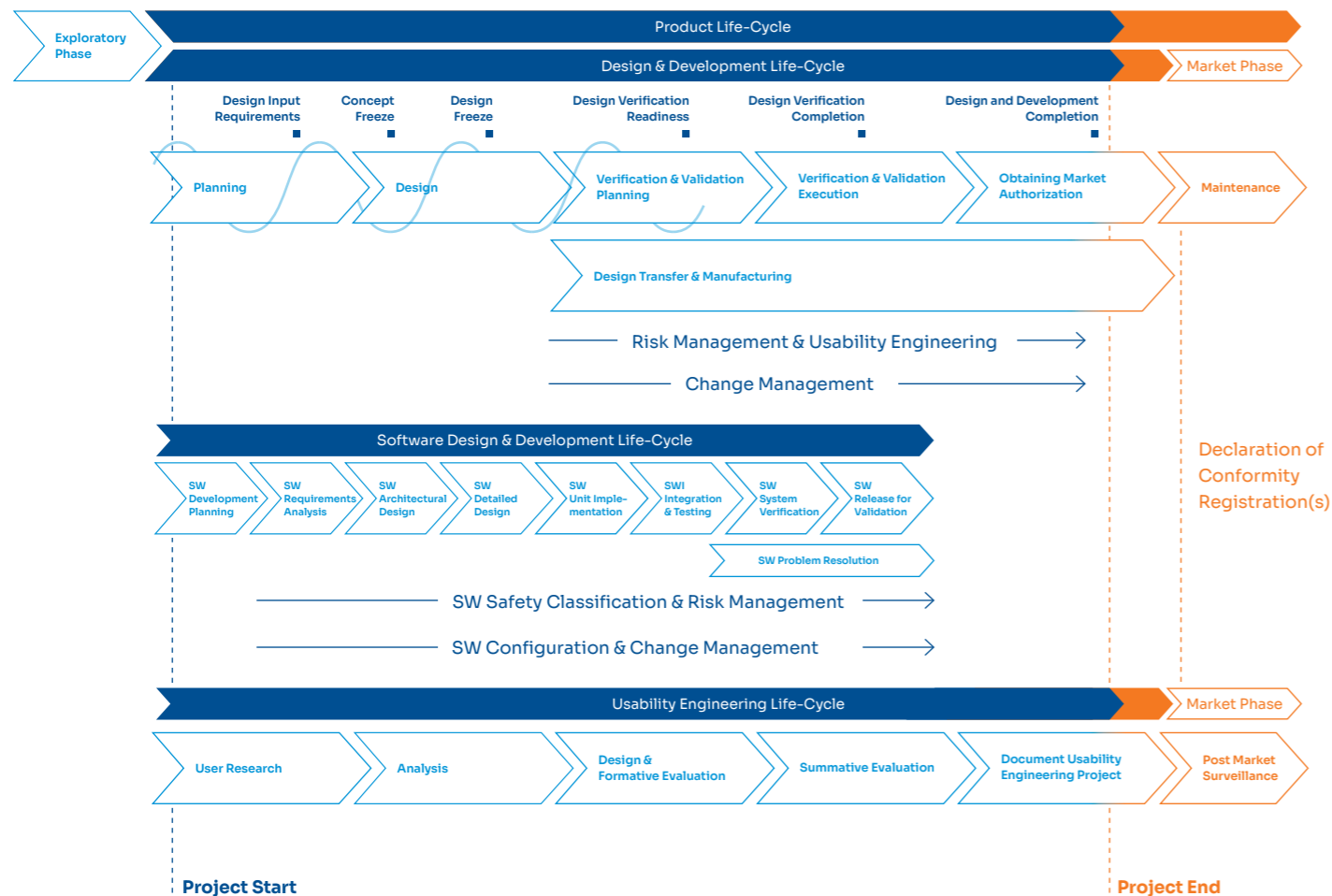
## Proven processes for your project

### Certified quality management system

Helbling Technik is certified according to EN ISO 9001, EN ISO 13485 and EN ISO 14001. Our quality management system guides our project management and development efforts in all our engineering faculties.

### Processes

Helbling operates an EN ISO 13485 and FDA 21CFR 820 compliant quality management system, including IEC 62304 and IEC 62366 compliant medical device software, and usability engineering services. The development processes can either be operated “as is” for full compliance with EN ISO 13485 standards, providing a comprehensive set of documentation for full design control, or adapted to specific client needs.



Development Process Overview

## We know the standards and methods

We incorporate the applicable norms and standards for developing medical devices and instruments for the markets in Europe, the USA, Japan and China. We are working in compliance with the applicable rules, regulations and directives such as EU medical device regulation (MDR), EU in vitro diagnostic regulation (IVDR), EU ATMP regulation, General Data Protection Regulation (GDPR), FDA rules and regulations, as well as specific directives such as GMP Annex 15, EMC, Radio Equipment (RED) and Low Voltage (LVD).

- **ISO 14708 & EN 45502-1** Active Implantable Medical Devices
- **EN ISO 14971 Medical Devices** – Application of Risk Management to Medical Devices
- **IEC/EN 60601-x** Medical Electrical Equipment
- **IEC/EN 61010-x** Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use
- **IEC/EN 62304** Medical Device Software
- **IEC 62366** Application of Usability Engineering to Medical Devices

We are used to integrate multiple norms and standards during product development, including, but not limited to:

- **GAMP 5** Good Automated Manufacturing Practice for Qualification of Test and Production Equipment
- **EN ISO 10993-x** Biological Evaluation of Medical Devices

At the end of a medical technology or product development, we are used to provide to our clients with a technical and design control documentation compliant with the EU and US requirements.



# Systems engineering: Master of collaboration of the disciplines

To provide our clients' projects with the best possible support, Helbling relies on systems engineering – an interdisciplinary field combining engineering and engineering management. Its focus is on how to design, integrate, and manage complex systems over their life cycles. In this way we produce an engineered system comprising a combination of components that work in synergy to collectively perform a useful function.

Requirements and reliability engineering, logistics, coordination of different teams and partners, testing and evaluation, maintainability, and many other disciplines (all necessary for successful system design, development, implementation, and ultimate decommissioning) are more challenging for large or complex projects. We at Helbling use systems engineering to optimize work processes, methods, and risk management tools by combining technical engineering, human-centered thinking, and project management.

Our business model as an independent R&D contract service provider owning no IP, our long-term track record, our engineering resources, and our design and lab infrastructure have made Helbling an established and recognized engineering development and innovation partner. Our sister companies Helbling Business Advisors, Helbling Beratung + Bauplanung, and Helbling PLM Solutions enable us to extend our services to provide all-round solutions, supporting projects all along the value chain with additional services such as planning and implementation of business strategies, marketing and sales.

The MedTech and life sciences industries represent around 30% of our annual revenue, including handheld point-of-care medical devices, and benchtop instruments for diagnostic applications. Our engineering development programs are operated following a systems engineering approach with systematic de-risking. The business model relies on strong project management and development

methodology in combination with a holistic systems engineering approach to deal successfully with critical interdisciplinary challenges.

## Facilities

Helbling relies upon experience, resources, design, and laboratory infrastructure to provide services in the fields of:

- Technical project and medical quality management
- Mechanical construction / design
- Electronics and firmware
- Software engineering / system architecture / app solutions
- Data analytics / AI / algorithmics / IoT / cloud computing
- Microtechnologies / MEMS
- Physics
- Optics
- Microfluidics and acoustics
- Material science
- Biotechnology
- Process development
- Modeling and simulation
- Usability engineering
- Industrial Design
- Requirements Engineering
- Testing (verification)

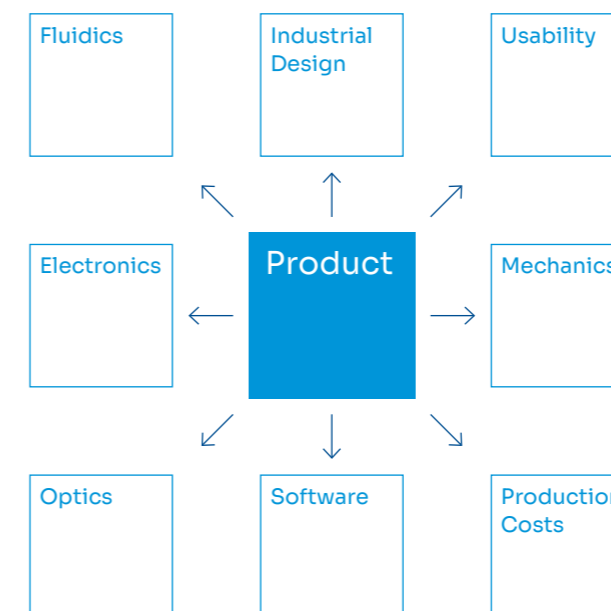
## Scope of work

Helbling Technik covers R&D activities throughout the project life cycle:

- **Ideation** (market/usability/technology)
- **Technology development** (predevelopment, solution search, modeling & simulation, feasibility analysis)
- **Product development** (project management, idea finding & conception, detailed design, industrial- & UX-design, software development, technical risk management)
- **Industrialization** (experimental verification, testing, and proof of performance, design transfer, design verification)

## Infrastructure

To support our work we have our own comprehensive design and lab infrastructure. Although not a certified test house, we have qualified and calibrated test equipment for experimental feasibility investigation, performance evaluation and testing, and formal design verification.



Systems engineering means balancing different stakeholder interests. We offer experience in interdisciplinary collaboration – and keep the product in focus for maximum success.

## Medical devices: Developed for your patients

Medical devices for monitoring, diagnosing, or treating patients reflect the current trend in society toward individualized, mobile, and interconnected products. Designs benefit from fast technological progress in consumer electronics, digitalization, and manufacturing methods. As medical devices are used by untrained patients across a population, ease-of-use and robustness (ergonomics), as well as user de-risking (usability) are equally critical for authority approval, market acceptance, and patient adherence.



**Bluephase G4 – smart polymerization unit for dental applications** – With its built-in reflection sensor, this unit detects incorrect application (movement of the light guide during curing) and discreetly alerts the user by vibrating. Exposure time is automatically adjusted. The assistance system, combined with a tripling of light output and an effective user interface, facilitates more precise application, shorter exposure times, and greater safety.



**Smart sharps bin system** – Home use device with optical recognition of syringes and auto-injectors when disposed into the sharps container. Recognition of hundreds of syringes and auto-injectors is made possible by a machine learning algorithm. BLE communication means for cloud connection to monitor patient compliance and adherence to prescriptions.



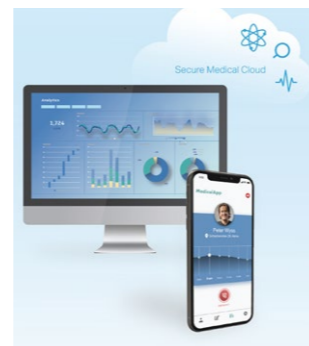
**Injection System for delivery of dermatological products** – A multiuse injector for safe and simple administration of substances such as hyaluronic acid into deeper skin layers for skin rejuvenation and wrinkle treatment (face, neck, neckline, etc.)



**Epinephrine Autoinjector System** – A life-saving product offering ultracompact form, ease of use, and extended shelf life for the contained medication. We developed this device in close collaboration with our client, from ideation to manufacturing transfer to an OEM.



**COMS® One – a portable medical device for treating chronic wounds** – Helbling implemented a highly integrated, compact, and waterproof device design with minimal installation effort. Piomic's COMS® One product made it one of the winners of the W.A. De Vigier Startup Award 2019.



**Secure and scalable cloud and mobile solution** – Used to access medical devices, transmit and analyze medical measurement data, notify physicians in case of emergency, and visualize data to understand trends and patterns.

## Point-of-Care instruments: Providing fast and accurate test results and treatments

The purpose of point-of-care (POC) instruments is to provide patients, physicians and care teams fast and accurate test results (diagnostics) and flexible means of intervention (therapy) at the time and place of patient care. POC instruments reflect the trend towards patient-centered care models, with improved clinical management decisions and lower-cost interventions thanks to greater efficiency and enhanced workflows.



**Retinal Health Monitor – a home-use, cloud-connected device for monitoring the progress of retinal diseases** – The Retinal Health Monitor enables the patient to conveniently monitor the progress of their retinal disease from home. Data is automatically processed with deep neural networks and made available to healthcare professionals so they can optimize the patient's treatment plan.



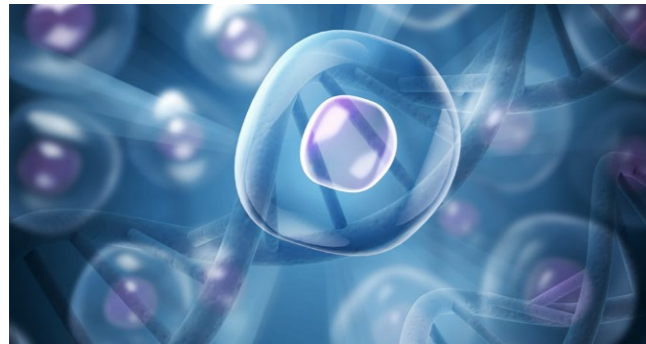
**Novel cross-linking device for the treatment of corneal infections and keratoconus** – The device is mountable on various types of slit lamps, making it possible to perform cross-linking outside an operating theater. This opens up treatment access all over the world, as slit lamps are a basic piece of equipment used by every eye doctor.



**Medical certified software for diagnosis of respiratory diseases** – By measuring and evaluating exhaled nitric oxide (FeNO), inflammation of the airways can be determined precisely and directly. Helbling designed and implemented a user-friendly, efficient software application for clinical use. The comprehensive, certified solution covers the entire process, from patient registration and data collection, to graphical reporting and integration into a hospital information system.

## Diagnostics and lab systems: Performing cutting edge diagnostics

Lab systems include high-performance equipment for automated testing of clinical specimens (blood, tissue, urine) in clinical or centralized laboratories, to which test samples are transferred for analysis. Ease of use, throughput, and cutting-edge diagnostic specifications (accuracy, sensitivity, and selectivity) are key factors for success in terms of healthcare economics and professional user satisfaction.



**Live Cell Processing System** – Enables a process to temporarily disrupt the cell membrane to facilitate delivery of specific materials into cells. We developed multiple versions of a lab system to automate this process and enable faster development of multiple cell therapies for various therapeutic platforms.



**Stem Cell Delivery System** – Fighting the devastating impact of impaired vision has been the driving force of our client's mission. Our contribution was to create a device for accessing the subretinal space without removal of the vitreous, and without making a hole in the retina, for delivery of cells in a targeted manner to the back of the eye.



**Microfluidic cuvette for blood gas analysis instrument** – Roche's Cobas b 123 point-of-care system features an oximetry module to spectroscopically measure total hemoglobin, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, methemoglobin, and total bilirubin content in a single whole blood sample. The cuvette is a key element in the disposable fluid pack.



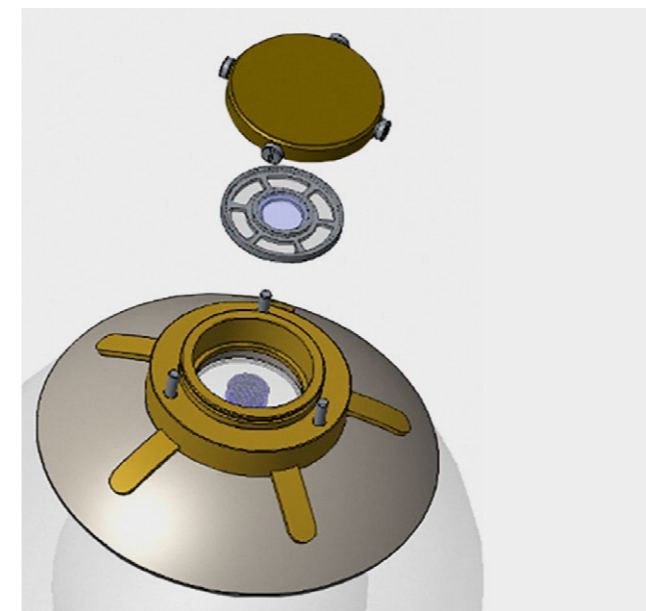
**Lyovapor by BÜCHI Labortechnik AG** – The first freeze dryer with continuous sublimation. The system offers continuous sublimation at  $-105^{\circ}\text{C}$  with two condensers working alternately and automatic hygienic cleaning. Less maintenance is required, and due to the small ice condenser volume, energy consumption is very low.



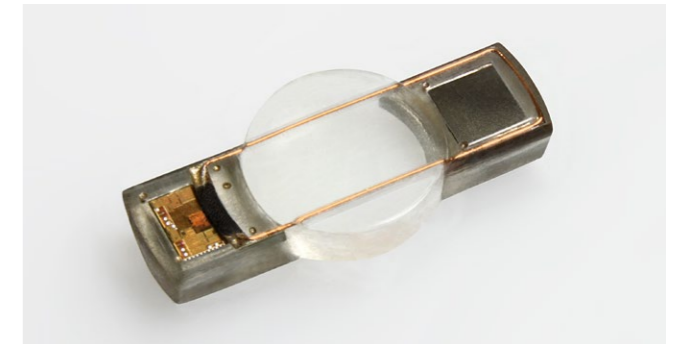
**GeneRead QIAcube – New Generation Sequencing** – The GeneRead QIAcube provides affordable automation for the clonal amplification step of next-generation sequencing template preparation. With a small footprint and intuitive user interface, the GeneRead QIAcube reduces hands-on time to less than 40 minutes, and enables simultaneous preparation of multiple library pools.

## Implants: Enhancing the human body

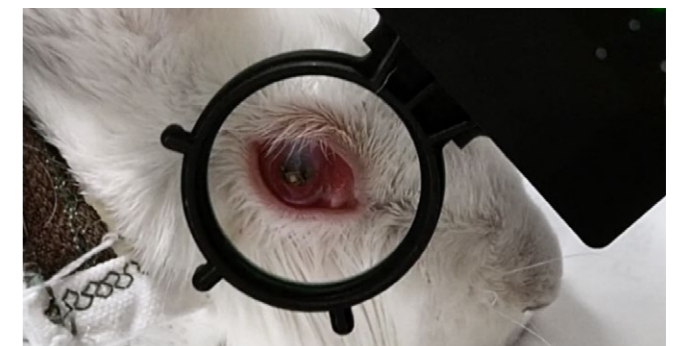
Implants can replace or support biological structures when they are damaged, or enhance them. Active implantable medical devices (AIMDs) are implanted into the human body for sensor, therapeutic, or functional purposes. AIMDs benefit from progress in materials science, miniaturization of electronics, packaging and manufacturing technologies. They satisfy rigorous standards for protection of the health and safety of patients.



**Implantable devices and surgical instruments to stimulate neurons in the cortex of test animals** – A novel and technologically challenging therapy is tested on suitable model animals before use in humans. Some devices are adapted to each individual's anatomy.



**Auto-focal Intraocular Lens** – For cataract patients, the natural lens of the eye has to be replaced by an artificial intraocular lens (IOL), which usually has one fixed focal distance. The active auto-focal IOL has integrated opto-electronics, which enable automatic focus adaptation based on pupil diameter variation gaze direction, without mechanical movements.



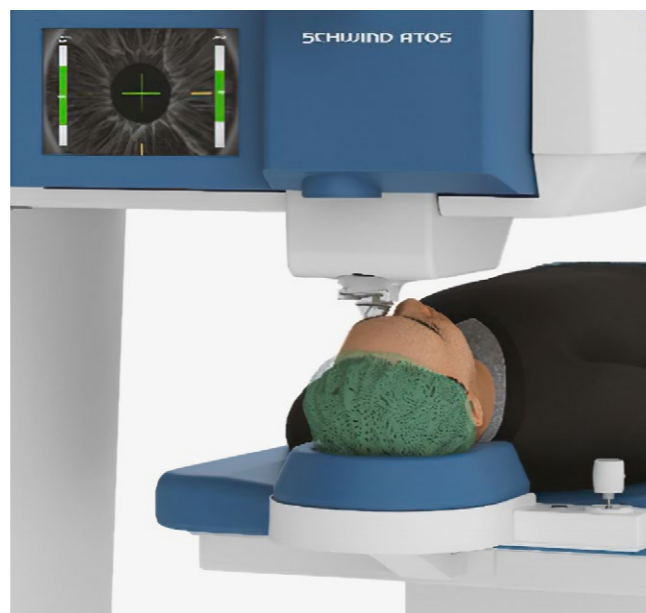
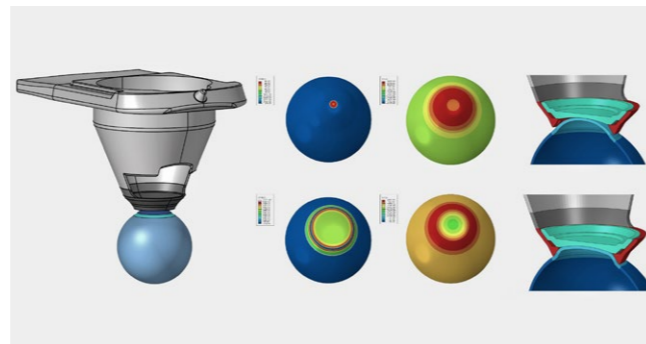
**Wireless Intraocular Pressure Sensor** – Glaucoma is a leading cause of blindness worldwide. The wireless intraocular pressure sensor improves glaucoma monitoring and treatment by means of continuous IOP measurement.

## Surgical tools: High-precision and minimally invasive

Novel medical interventions and implant surgery call for application-specific surgical tools for a variety of medical indications. Recent progress in precision mechanics, real-time data processing and control electronics, scientific informatics (artificial intelligence, AI), and high-speed data communication enable robotics in high-precision, minimally invasive, and telemedicine microsurgery for better medical outcomes and worldwide access to highly specialized surgery.



**Robotic arm system for tool development** – The development of surgical instruments requires extensive testing and evaluation. To help our client evaluate various designs and accelerate the product development cycle, we developed and built a “surrogate” robotic arm system, enabling quantitative evaluation of the performance of new instruments in a pre-clinical environment, with surgeons controlling the arm and trying out the new designs.



**Patient interface for refractive eye surgery** – Reliable positioning and immobilization of the eyeball are vital for providing the highest levels of surgical precision and patient safety. The disposable interface is used to applanate and dock to the corneal surface by means of a suction system. The patient interface not only serves as a reliable position reference for the surgical procedure, but also represents the final optical element in a novel femtosecond laser system used to permanently correct a patient’s vision by reshaping the cornea – one of the most common procedures in ophthalmology today.



**Surgical instrument for placing a tiny electronic implant under the retina of a human eye** – The surgical instrument was developed to match existing implants and facilitate this delicate eye surgery procedure.

## Outlook Personalized medicine: Digital technology for individual health

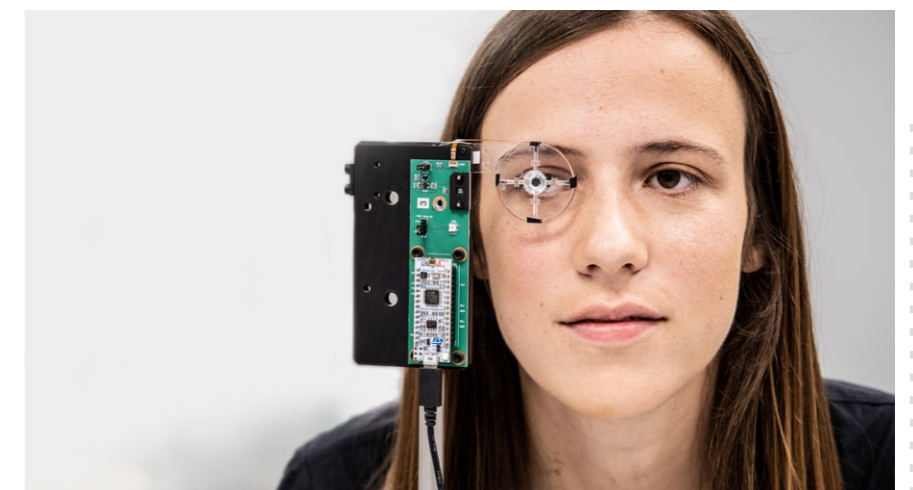
With a strong market position and service offering in a diverse range of medical fields, Helbling is well-qualified to support the development of personalized medicine ecosystems – a general trend in the healthcare industry towards patient-centered, individualized healthcare solutions. Digitalization, scientific informatics, intraoperative 3D bioprinting (prostheses, organs), tissue engineering, regenerative medicine involving stem cell technology, and patient specific drugs are all making key contributions to personalized healthcare.

People are getting older, and yet all of us want to stay healthy and continue living actively. And what initially appears to be contradictory is being made possible by technological progress. The key words here are “personalized medicine” or “precision medicine”. This trend corresponds to the growing need for products and services that are specifically tailored to the user’s personal requirements. Advances in personalized medicine are boosted by technical advances in other industries. For many experts, personalized medicine is the most important medical development of the 21st century.

Examples include new molecular biological diagnostic methods involving gene sequencing, or specific enzymes allowing early detection of disease, or predispositions. Therapies can be tailor-made for the individual patient. Modern diagnostics can record a

patient’s genetic, molecular, and cellular characteristics, and assess the probable effectiveness of a particular therapy. This means that by combining medical technology and electronic data processing, patients can receive targeted treatment appropriate to their individual biological requirements.

Other applications include, for example, regenerative medicine (tissue engineering, stem cells) and biotechnological manufacturing processes. Implants or prostheses can be produced on-site using 3D scanning and 3D printing. Helbling is helping two research groups develop a new optogenetic treatment for people who are blinded by retinal loss, in which specific neurons of the visual cortex are made sensitive to light. We are developing a system that can stimulate these neurons with light to create a detailed, dynamic visual impression.







### Helbling Group

Established in 1963, the Helbling Group has international operations and positions itself as an interdisciplinary nexus of engineering and consulting expertise. With independent ownership, the Group is run by 36 managing partners and employs more than 620 staff at locations in Switzerland, Germany, Poland, the USA and China. The Group's main focus is on providing selected services in the fields of innovation and product development, management consulting, mergers and acquisitions, business turnarounds and financial performance management, IT, real estate, and construction planning.

[helbling.ch](http://helbling.ch)

### Helbling Technik

Helbling Technik is a division of the Helbling Group and currently employs over 500 professionals.

Our vision "Innovation, together we do it" positions Helbling Technik as a trusted long-term partner within the client's innovation network. Helbling Technik's highly trained and skilled engineers, computer scientists, physicists, and human factors experts utilize state-of-the-art development tools, processes, laboratories, and equipment to develop innovative and successful products, and support clients across the globe from ideation to market launch.

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