

helbling



Medical Technologies

Helbling Technik

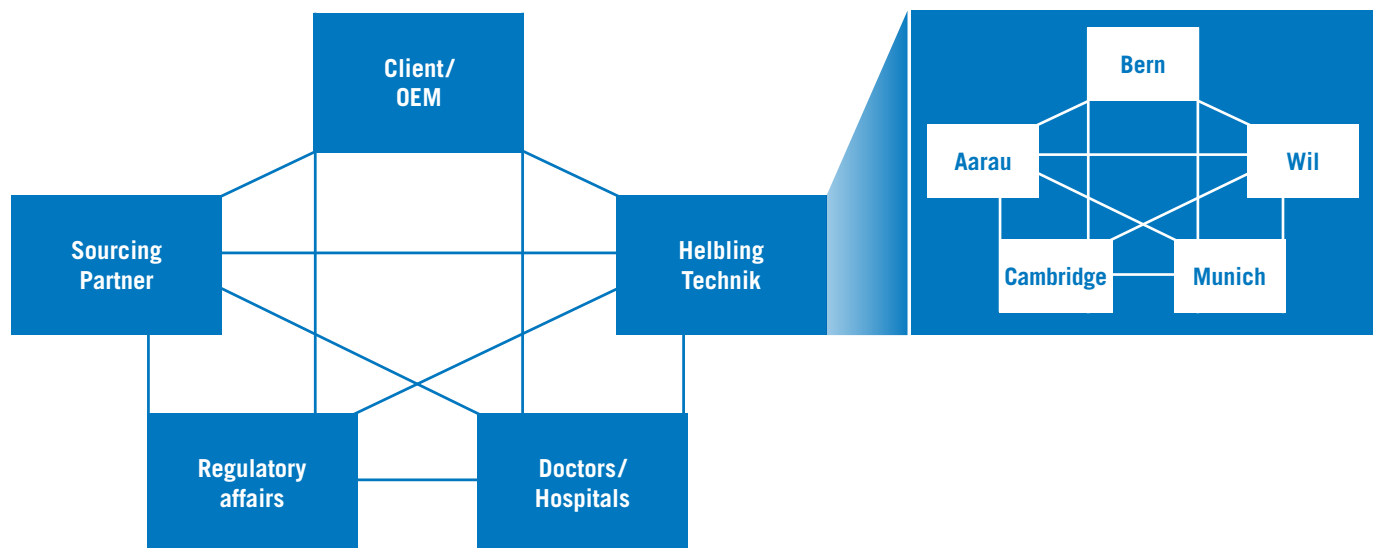
Innovation, together we do it

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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. Consequently, we specialized in helping our clients as an energetic and reliable partner to secure a competitive advantage in this changing landscape.

From idea inception to market launch

Helbling Technik employs more than 350 highly trained and skilled professionals including Engineers, Computer Scientists, Physicists and Human Factors experts. Cross-functional teams develop a variety of innovative products for Medical Technology clients, a key focus for over two decades. Helbling operates innovation centers in Switzerland, Germany and the USA to support clients in developing the next generation Medical Devices and Instruments from idea inception to market launch.



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 our innovation centers have a different yet complementary technological focus. The vision's core theme is that we innovate together and not in isolation. The collaborative process starts by creating a wide range of novel ideas together to address our client's needs and then combining these ideas into innovative and promising technology and product concepts. Converting these concepts into successful and profitable products requires an even more collaborative work approach involving us, our innovation network and, of course, our clients. Our project and quality management as well as our execution expertise enable us to coordinate all participating parties effectively and help bring success for our clients.

Innovation emerges from networks

Helbling's size and collective experience allows for building teams that employ the right skills and engineering disciplines to develop novel Medical Technologies and Products. In addition, we offer a trusted network of partners to complement our skills and knowledge to cover all aspects of Medical Technology innovation. Specifically, we have established relationships with key opinion leaders, doctors, researchers and scientists, hospitals, industrial designers, ergonomists and sourcing partners that enable us to quickly build dynamic innovation networks for our clients.



Benefits of our Clients



Experience

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

Interdisciplinary Teams

Holistic development approach through access to the competencies of engineering and business consulting (Helbling Group).



Resources

Ready-to-go teams to meet challenging project goals and to increase our clients' flexibility.

Intellectual Property Policy

IP developed within a project is assigned to our clients after completion of the project. Helbling Technik does not own intellectual property.



Methods & Quality Assurance

Tried-and-true development methodologies and processes in accordance with industry standards (ISO 9001 und ISO 13485). Look beyond established structures and innovate from a neutral stand point to reduce project risks.



Know-how, Standards and Methods

Certified quality management system

Helbling Technik is certified according to ISO 9001, ISO 13485 and ISO 14001. The quality management system guides our engineering and development efforts in mechanics, optics, electronics and software development as well as in simulation and computation.

State-of-the-art infrastructure

Each innovation center offers a cutting-edge infrastructure and tools to support the development of novel Medical Technologies and to complement the infrastructure of our clients.

Standards

As required, we incorporate the applicable norms and standards for developing Medical Devices and Instruments employed in Europe and the USA including, but not limited to:

- 93/42/EEG European directive on medical devices (MDD)
- 98/79/EG In-vitro-diagnostics directive (IVDD)
- 2004/108/EG EMV-guidelines
- 2006/95/EG Low-power guidelines
- IEC 60601-x Safety and effectiveness of medical electrical equipment
- IEC 61010-x Safety requirements for electrical equipment for measurement, control, and laboratory use
- IEC 62304 Medical device software – Software life cycle processes
- IEC 62366 Usability engineering for medical devices
- ISO 10993-1 Biological assessment of medical devices
- ISO 14708-1 Active implantable medical devices
- ISO 14971 Risk management
- FDA 21 CFR Quality System Regulation (Part 820)

At the end of a Medical Technology project, our clients receive a technical documentation in accordance with the applicable standards.

Labs and infrastructure

- Electronics lab, including EMV test equipment
- Optics labs
- Micro-fluidics labs
- Assembly and test lab
- Prototyping shop
- Metrology labs

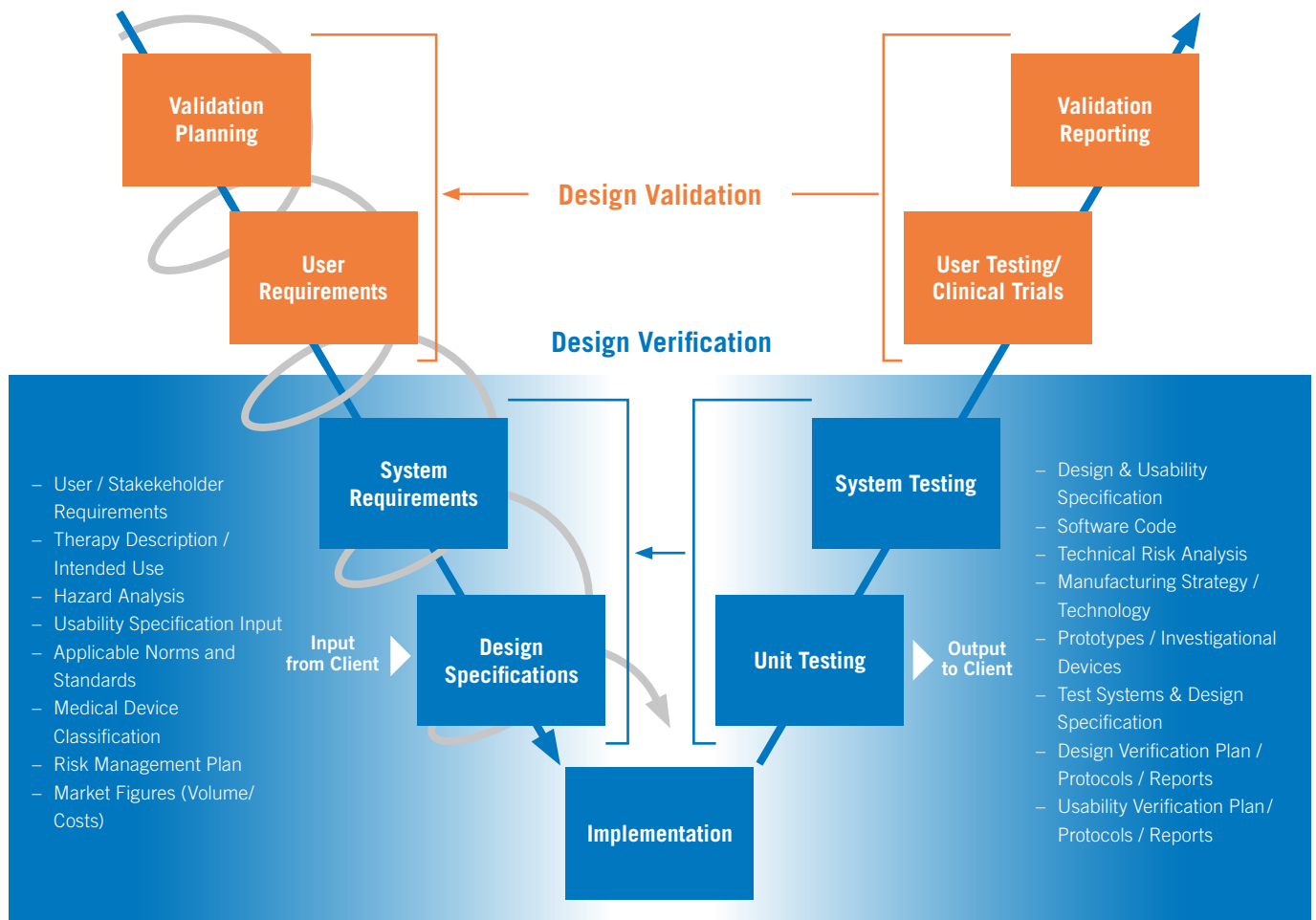
Tools and CAx

- Comprehensive set of engineering simulation software environment to facilitate all steps in the development process including mechanics, electronics, optics, electro magnetics, and multiphysics
- CAx tools
- Software engineering tools
- Microsoft Developer Network
- National Instruments platforms and environments



MedTech Product Design – Service Operations

The following diagram graphically represents Helbling Technik's service offering in the context of the V-Model development process, as commonly accepted in the MedTech industry: depending on medical, market and business considerations, our clients start with the definition of the Validation Planning and User Requirements; the latter being iteratively defined in collaboration with Helbling specifying System Requirements. Helbling Technik then implements the design up to Design Verification providing the client 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 listed on the diagram.



Helbling Client



Medical Devices



Disposable endoscope with opto-electronics and sensor in the tip



Acoustic T30 CR® neurostimulator platform for tinnitus treatment



Electro-active AutoFocal Intraocular Lens (AF-IOL) eye implant providing effective near, intermediate and distance vision



Injection pen for growth hormones



Implantable drug delivery pump

Helbling Technik Bern AG



Service Focus

- Micro instrumentation
- Electro-active implants
- Biomedical optics
- Medical electronics
- Micro-fluidics
- Acoustics
- Micro actuators and systems/MEMS
- Physiological sensors
- Material science
- Cell therapy/tissue engineering
- Human factors/usability engineering

Specialities

- Drug delivery devices
- Hearing aids
- Ophthalmic optics (diagnostics, vision care)
- Optical imaging and therapy
- Neurostimulation
- Mobile devices
- Surgical instruments and tools
- Long term electro-active implants



Medical Devices

Helbling Precision Engineering Inc. USA



Service Focus

- Drug delivery devices and disposable accessories
- Minimal-invasive surgical tools
- Patient monitoring systems
- Laboratory instruments and hospital equipment
- Wireless connectivity

Specialities

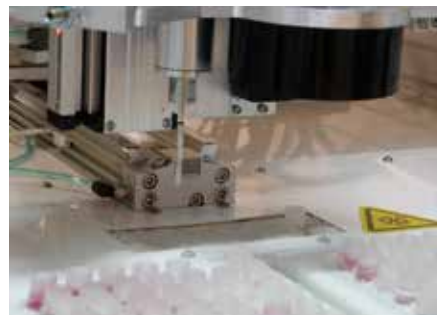
- Devices for diabetes care
- Autoinjectors
- Non-invasive continuous neuromonitoring devices
- Energy-based surgical devices
- Disposables and accessories in high volumes
- Electromechanical systems
- Test and verification of prototypes (in lab and via animal trials)



Automated extraction of multiple frozen aliquots from a single frozen biological sample



Miniature and easy-to-use dual-chamber autoinjector



Pick-and-place and vision system for automated biological sample processing



Wireless indicator development platform for self-injection devices



Diagnostics and Labsystems



Laser based tube inspection unit for clinical diagnostics



Platform for automated sample processing



DensiProbe™ Bone quality measurement device



Multispectral LED based photometer module with lock-in amplifier



Gelcard spinner

Helbling Technik AG, Wil



Service Focus

- Liquid handling, pipetting, dispensing
- Plastics and precision engineering
- Lab robotics
- Optics, measurement technology
- Signal and image processing
- Medical electronics and software
- Usability engineering, human machine interfaces
- Connectivity, improved patient access
- Ultra low cost design

Specialities

- Infusion, injection, medication
- Drug device combinations
- Diabetes care solutions
- Surgery and assistance systems
- Analyzers, readers, microscopes
- Automated sample preparation and processing
- Lab-Equipment
- Consumables and disposables



Medical Software

Helbling Technik AG, Aarau



Service Focus

- Software for controlling, connecting, automating and monitoring of medical processes and systems
- Platforms and portals for the collection, transmission and analysis of medical data
- Usability engineering and ergonomics

Specialities

- Platforms and portals for data collection, analysis and monitoring
- Desktop applications and mobile solutions
- Cloud computing
- Data Analytics and IoT
- Telemetry and machine-to-machine (M2M) communication



Software application for functional testing of lungs



Computer assisted surgery



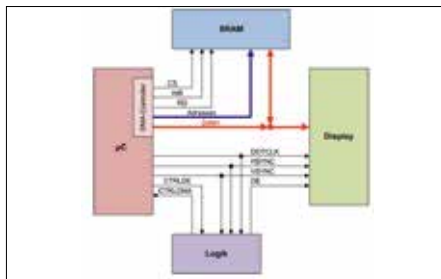
Mobile health platform



Medical Electronics



PCB of a remote control for an insulin pump



Low power display control



Insulin pump with infusion set



Motor Control Board

Helbling Technik GmbH, Munich



Service Focus

- Development of embedded systems
- Power electronics
- Control engineering

Specialities

- Certified requirements engineering
- Embedded software from C to Linux
- Apps for Android and iOS
- Connectivity
- Display technologies
- Motion control
- Battery powered systems (low power)
- Power supplies, filters, inverters
- Digital control and feedback control systems
- Ultra-flat power supplies
- EMC compliant electronic design





Helbling Group

The internationally operating Helbling Group positions itself as an interdisciplinary nexus of engineering and consulting expertise. The independent Group is run by 27 managing partners and employs more than 490 staff at locations in Switzerland, Germany, the USA and China. The Group's main focus is on providing selected services in the fields of innovation and product development, management consulting, merger & acquisitions, turnaround and financial performance management, IT, real estate and construction planning.

Helbling Technik

Helbling Technik is a division of the Helbling Group, which was founded in 1963 and currently employs more than 350 professionals in Switzerland, Germany, the USA and China.

The vision "Innovation, together we do it" positions Helbling Technik as a trusted long-term partner within clients' 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 idea inception to market launch.

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