



Industry Profile Medical Technology



Konzept
Informationssysteme



Innovation and technology saving lives

The medical technology sector in Germany is strongly characterized by growth, innovation and intensive use of technology. It provides a substantial contribution to efficient health care. However, enterprises are facing ever more government regulations, increasing complexity and growing costs in long-term development processes.

Utilization of technology is welcomed in medical technology as in hardly any other sector. Since these products do not only improve the quality of living but even save and sustain lives in many cases. However, the development of such medical technology products causes difficulties for enterprises owing to the very short product life cycles of less than 3 years required in many cases. The overall development process – from the very first idea to the final medical product – tends to become longer, more complex and often more cost-intensive.

Safety and performance are key aspects

Medical products require comprehensive technical and clinical testing before they are approved for further trials and finally application on patients. The protection and well-being of the patient have top priority. This means for the use of technical products or systems that they are subject to maximum safety requirements and testing as well as a strict quality management system.

Scope of Services

- System and software development in accordance with IEC 62304
- Development of operating concepts for medical technology devices
- Prototype development
- Requirements engineering

Competent support at any stage

This is where we come into play. Our long-term experience in the development of complex systems enables us to support you in any phase of development. We support your complete development process as a competent partner.



Specific Project Experience

- Touch interface product development for users involving user profiles in the lab environment
- Support for use case and stakeholder analyses for product optimization geared to market requirements
- Interfacing / communication with other components of the overall system
- Support for resource optimization in runtime environments
- Preparation and realization of component and system tests
- Product development for minimally invasive surgery using a robot arm
- Low-level software development at microcontroller level
- Implementation and integration of boot loaders
- Runtime optimization
- Working out safety maintenance concepts
- Implementation of various interface protocols
- Validation of computer systems in the biopharmaceutical sector according to GMP
- Software development for minimally invasive surgery

Systems Engineering

- Requirements management at system level
- System architecture and design
- Analysis and consulting for the selection of software components for runtime environments

Software Development

- Software requirements management
- Software architecture
- Software module design and implementation

Verification and Validation

- Preparation of module and unit testing
- Unit- / integration, system tests and test management
- Software integration and system testing
- Preparation of the test documentation for module, integration and system tests
- Creating automated test sequences at module and sub-integration levels
- Validation
 - System requirements
 - Software requirements

Support Processes

- Project management
- Quality assurance
- Configuration management for subcomponents
- Problem and change management
- Documentation

Standards

- V-Model
- IEC 62304
- GMP
- GAMP 5

Tool Experience (synopsis)

- Enterprise Architect
- Qt creator, qt quick and qt widget
- qt QML, C, C++
- MariaDB
- C#, WPF, .NET
- GIT
- Doxygen
- Jira, confluence, Helix ALM
- alfresco
- vera++, cppcheck
- Yocto – ubuntu
- Various microcontroller