



Healthcare Engineering

Reliable. Secure. Built for approval.



TOMORROW'S HEALTHCARE TECHNOLOGY



THE TRANSFORMATION OF HEALTHCARE

Digital. Secure. Connected.

Connected devices on the Internet of Medical Things, digital health applications, robotic assistance systems, simulation with virtual reality, digital diagnostics – the digital transformation is in full swing in the medical and healthcare industry. Competitive pressure is high. Developments have to come fast. Systems must be user-friendly, yet secure. We have been rising to these challenges as an ISO 13485- and ISO 27001-certified engineering partner since 1994. Capitalizing on our cross-industry experience and our technology and methodological expertise, we develop innovative medical products with passion and enthusiasm, thus actively shaping tomorrow's healthcare technology.



What sets us apart:

- 30 years of experience in standards-compliant software and system development for medical devices
- Complete OEM product developments
- White box business model
- Holistic systems engineering
- Software, hardware and mechanics from a single source
- Experience in robotics projects since 1996
- Embedded expertise
- Medical consulting born of experience
- Network of industry and research partners



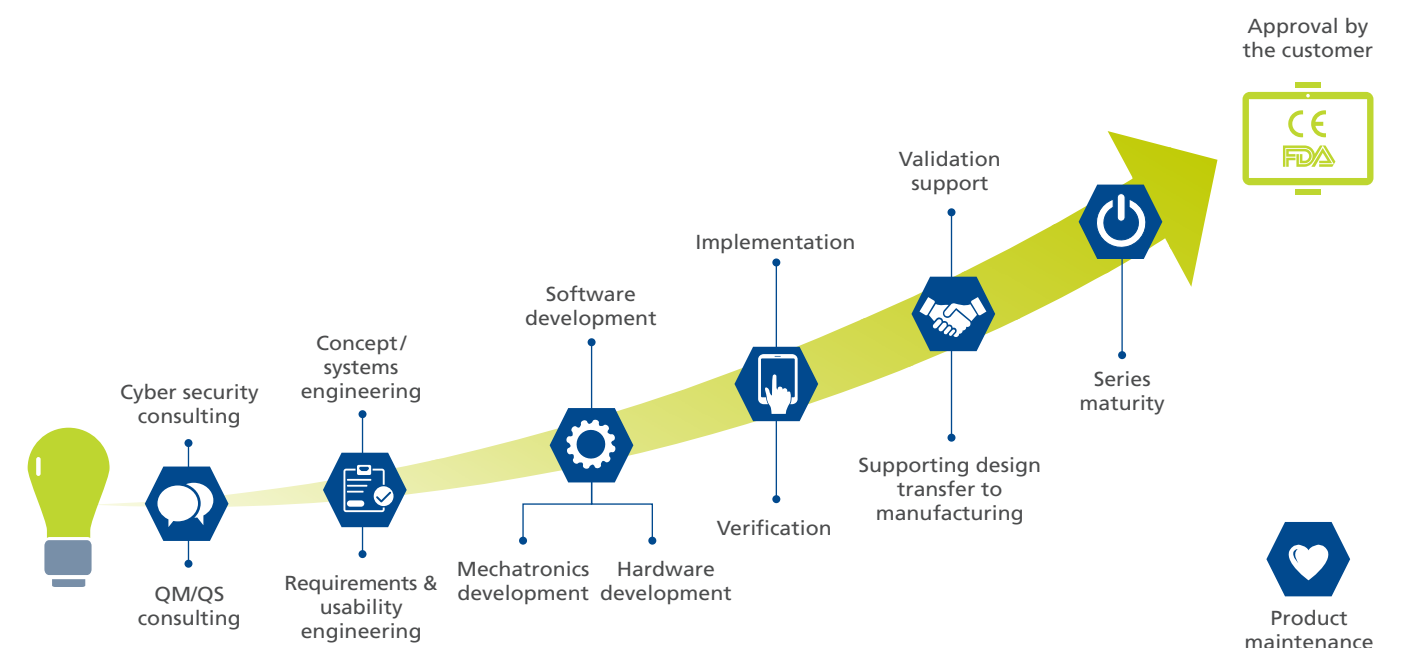
✓ EN ISO13485:2016-certified



FROM THE INCEPTIVE IDEA TO THE APPROVED PRODUCT

Tailor-made. Built for Approval. On schedule.

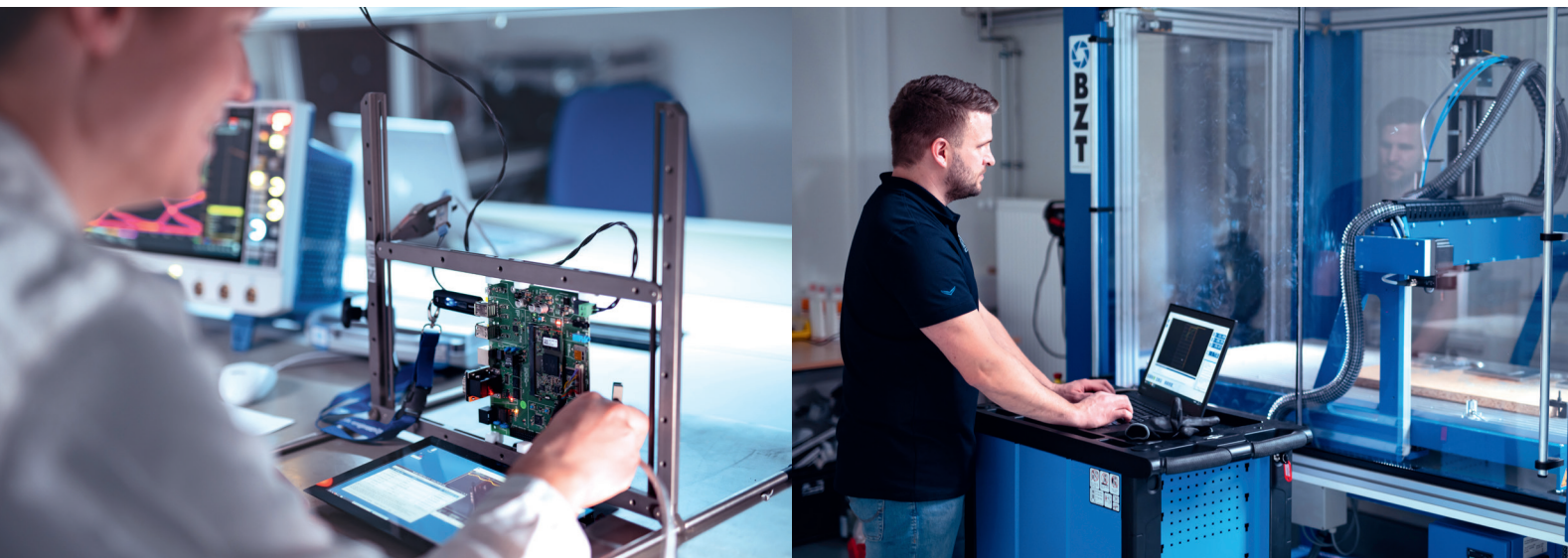
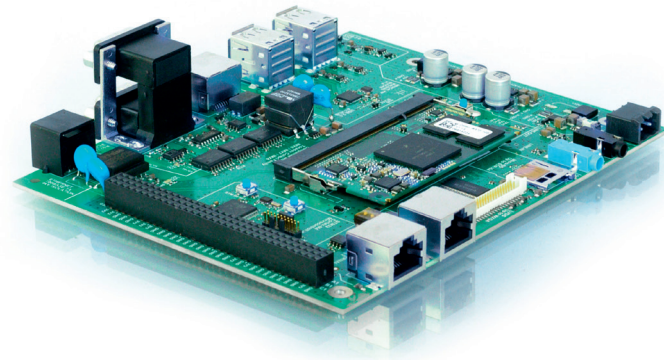
Supporting you throughout the development process, from the inception idea to the product and beyond, we help guide your ideas to real-world success. To this end, we develop full-fledged systems with all the software and hardware and mechanical design tailored to your needs. With full traceability and end-to-end documentation as part of the package, we pave a smooth path to MDR, IVDR, FDA or CFDA approval and your product's market launch.



TAILOR-MADE SYSTEMS FROM A SINGLE SOURCE

Interdisciplinary. Reliable. Approvable.

Medical device, robot, virtual OR or medical cloud – whatever innovative solution you want to put into practice, we make the most of our methods, industry expertise, and firm grasp of trends and challenges to help you do it. What sets us apart: Count on our interdisciplinary teams to deliver turnkey systems from a single source. If you wish, we can handle quality assurance throughout the process, from the drawing board to the manufacturing floor. Our proven and flexible manufacturing partners help us deliver on our performance promise.



Your advantages

- Holistic engineering
- Interdisciplinary teamwork
- Standards-compliant development
- Predeveloped hardware building blocks according to IEC 60601-1
- Flexible manufacturing

Our engineering services at a glance

REQUIREMENTS & SYSTEMS ENGINEERING

- Derive stakeholder requirements
- Develop manageable user stories
- Create proofs of concepts
- Derive system requirements
- System architecture taking usability and risk measures into account
- Design subsystems
- Standards-compliant documentation

SOFTWARE



- Software architecture
- Software design
- Implementation
- Verification and integration
- Tool and/or SOUP validation
- Algorithms, AI, image processing
- User interfaces & user experience

HARDWARE



- Verified building blocks
- Medically safe industrial interfaces
- Embedded controllers and Linux modules
- Connectivity and remote control
- Battery management

MECHANICS



- Design and dimensioning of mechanical precision parts
- Housing, supporting structure, cooling, display integration
- Prototyping
- Production-ready design for manufacturability
- Robotics and assistance systems

MANUFACTURING



- Flexible business model – you manufacture it or have us build it with our flexible partners
- Proven, ISO 13485-certified manufacturing partners
- Manufacturer-independent
- Test bench development

MAINTENANCE



- Lifecycle management
- Product updates
- Maintenance & support

QUALITY ASSURANCE

- EN ISO 13485:2016 QM system
- IEC 62366-1:2020 usability engineering
- ISO 14971:2019 risk management
- IEC 62304:2015 software lifecycle
- MDR, IVDR, FDA regulatory affairs
- DIN EN 60601-1:2020 medical basic safety for medical electrical equipment device safety
- IEC 80001:2021 security
- IEC 61508: 2010 safety





SMART ROBOTIC ASSISTANCE SYSTEMS

Secure. Interactive. Advanced.

Robotics have become indispensable in medical engineering. With our system expertise and our interdisciplinary team with profound competences in control engineering, software development, system architecture, electronics and mechanics, we realize intelligent and user-friendly assistance systems together with you. These innovations are able to extend the range of treatments available to doctors, surgeons and care personnel and to increase the precision of procedures.

Your advantages

- Interdisciplinary team for your specialty applications
- Rapid evaluation of your ideas
- Accelerated time-to-market for your innovations
- Documentation ready for approval



Our services at a glance

CONTROL SYSTEMS



- Kinematics, dynamics and motion planning
- Motor control and sensor technology
- Embedded and real-time systems
- Navigation for mobile robot systems

CONNECTIVITY



- Remote diagnostics and maintenance
- Cloud connectivity, cyber security

MACHINE INTELLIGENCE



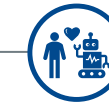
- Image processing
- Cognition, autonomy

SIMULATORS, VIRTUAL AND AUGMENTED REALITY



- Training
- Support for service applications

HUMAN-ROBOT INTERACTION

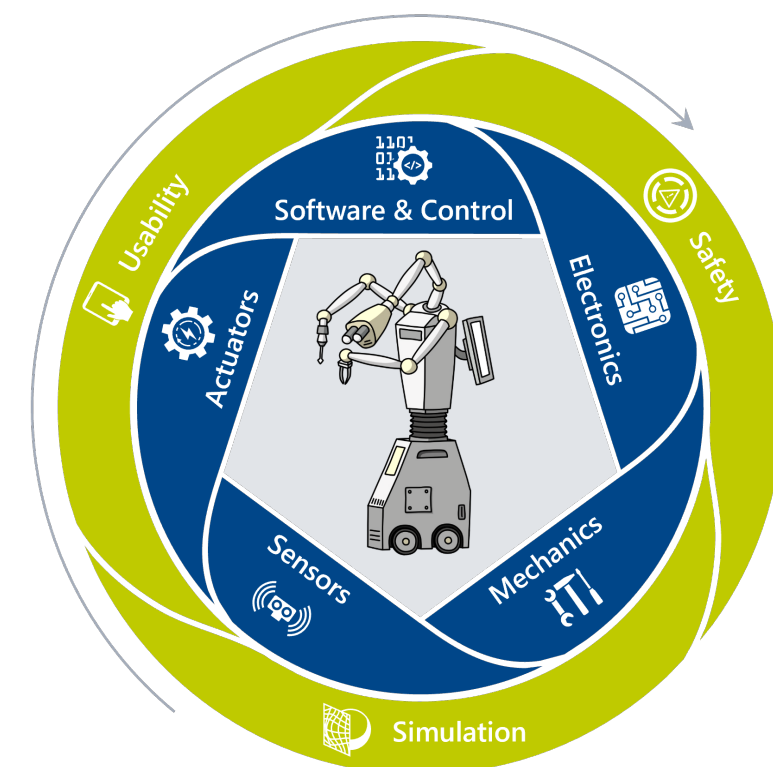


- Collaborative operating concepts
- User interfaces, dialog systems
- Functional safety
- Teleoperation, haptic feedback

PROTOTYPING



- Design, construction and assembly
- Virtual prototyping
- Usability analyses



360° system development



END-TO-END CLOUD SOLUTIONS

Scalable. Highly available. Secure.

Cloud infrastructures and services offer enormous potential for efficiently processing large amounts of data and optimizing business processes to make them future-proof. As a cloud full-service provider, we support you in making the most of your device data. From device development to applications and cloud services, to cloud infrastructure, operations, and support - we provide everything from a single source.

Our services at a glance

CLOUD-NATIVE AND
SERVERLESS DEVELOPMENT



CLOUD INFRASTRUCTURE
AND ARCHITECTURE



DATA ENGINEERING /
ANALYTICS



CLOUD-BASED
AI



IT SERVICE MANAGEMENT
AND IT OPERATIONS



IOT AND
CONNECTIVITY



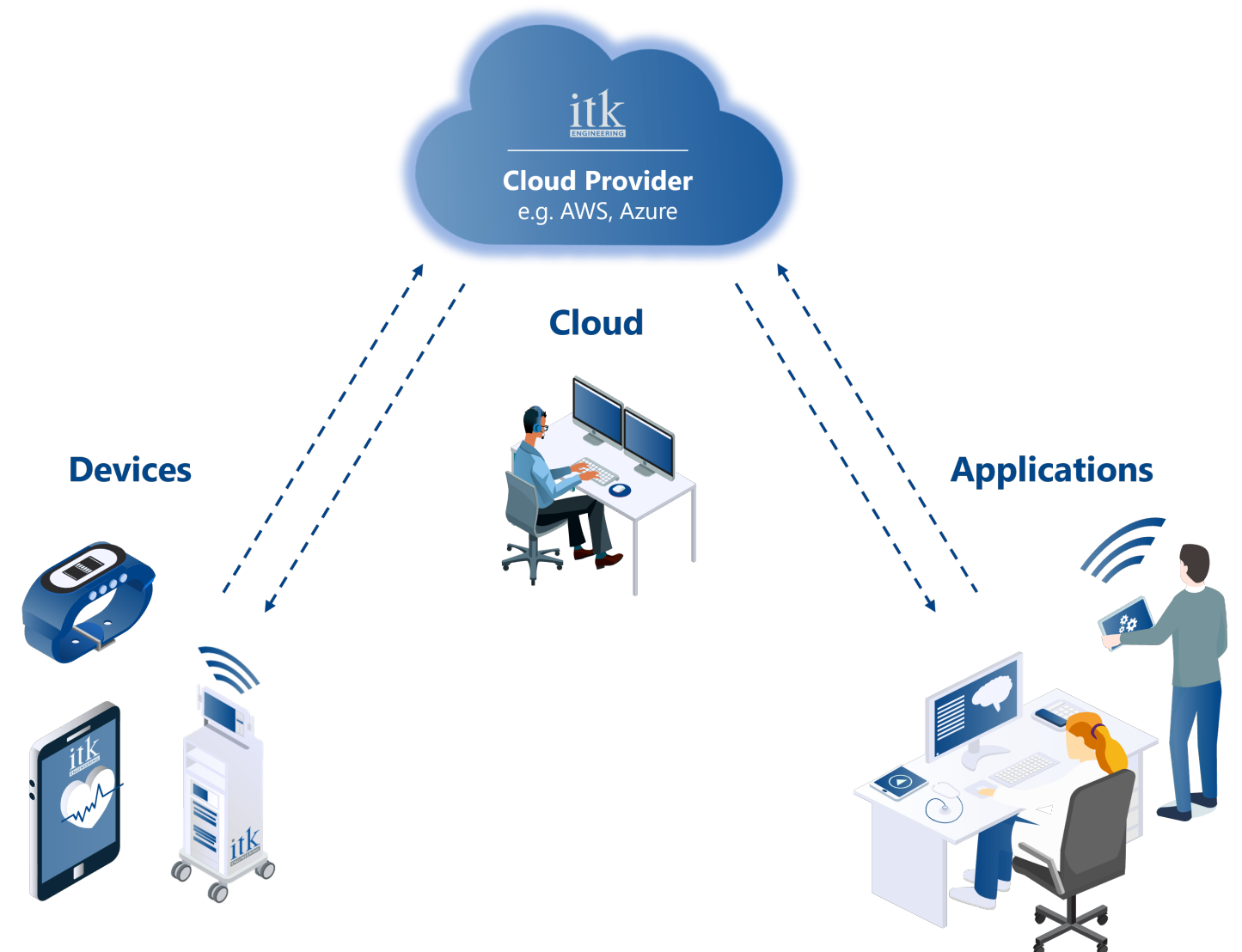
SECURITY AND
COMPLIANCE



DEVELOPMENT AUTOMATION,
OPTIMIZATION, AND PIPELINES



TESTING CLOUD-BASED
SOLUTIONS



Your advantages

- Efficient collection, management, processing, and storage of large data volumes
- Secure storage of health data
- Real-time data analysis
- Cost efficiency
- Reduced time-to-market
- Efficient device management
- Global usability





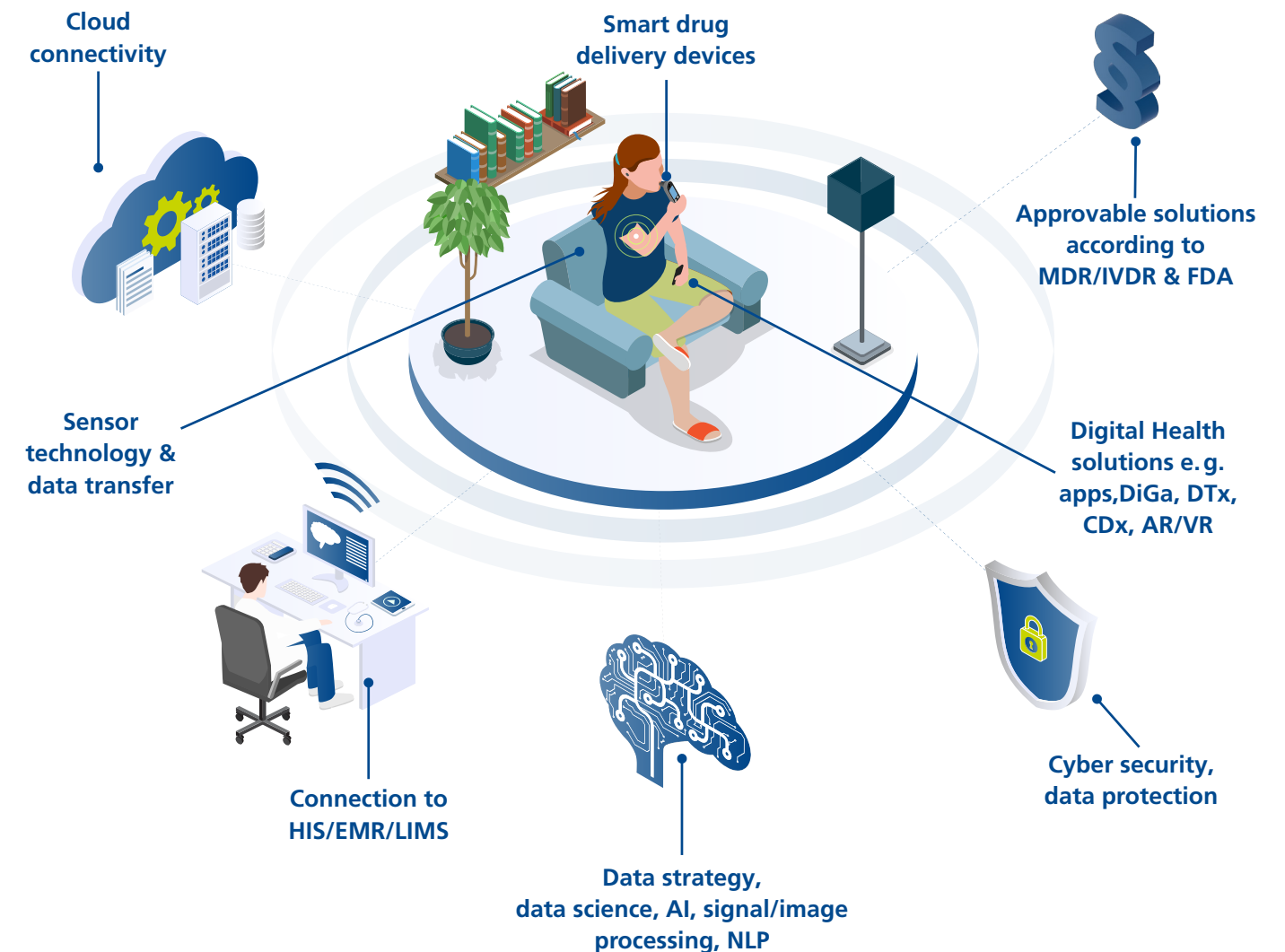
PARTNER FOR DIGITAL SOLUTIONS IN THE PHARMACEUTICAL INDUSTRY

Smart. Secure. User-friendly.

Patient first: New digital solutions such as apps or combination products consisting of an active substance and a smart device enable individualized therapy and increase adherence. Data analytics approaches on the collected data as well as connecting patients and HCPs via platform solutions help to better understand patients and tailor treatment to their needs. Pooling our resources with yours, we develop innovative digital solutions for the pharmaceutical industry.



Our services at a glance



Your advantages

- Digital tools for remote patient monitoring & care
- Smart drug device combination products
- Approvability under MDR & FDA, e.g. as SaMD
- Connecting players through scalable platform solutions
- High usability through innovative UI/UX





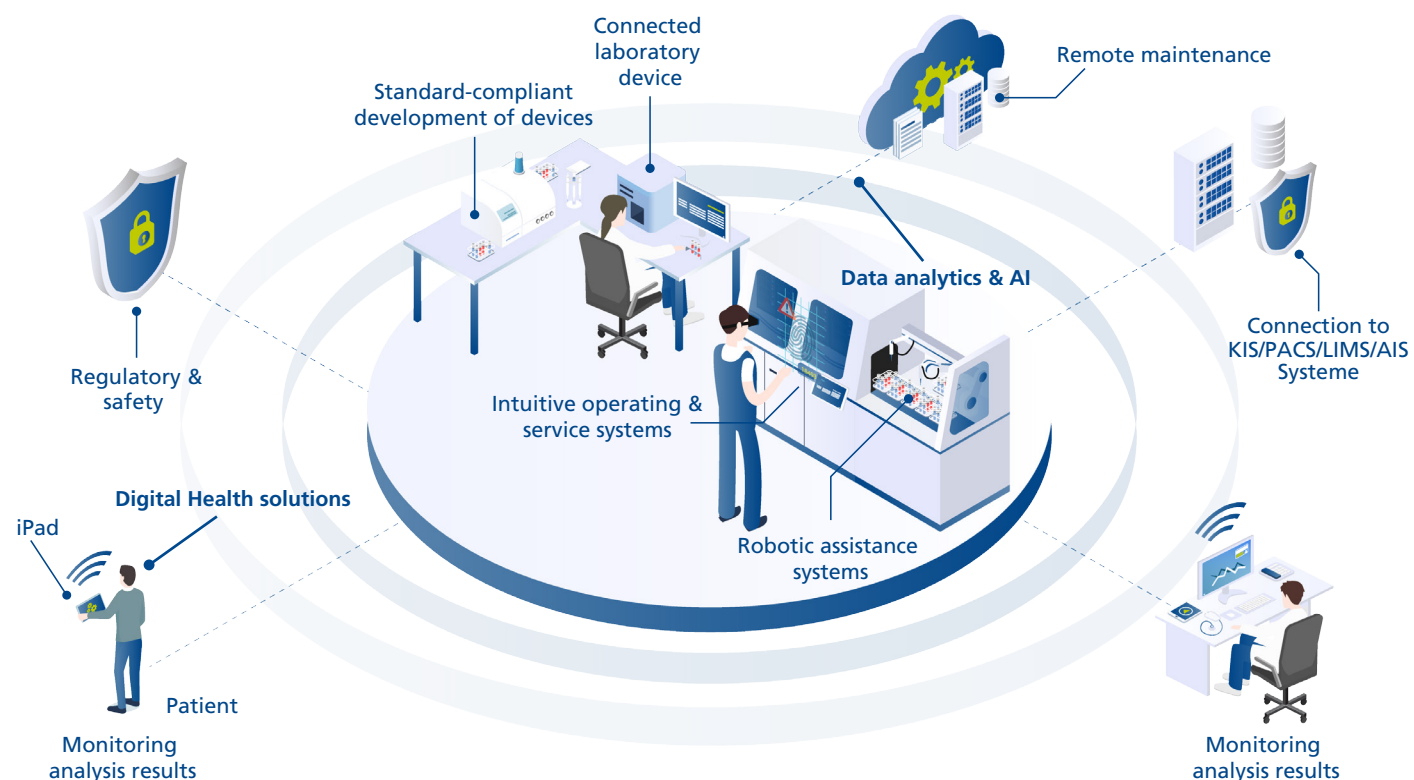
DIGITAL AND AUTOMATED DIAGNOSTICS

Reliable. Innovative. Connected.

As your engineering partner, we are here to expedite your efforts to develop standards-compliant diagnostic solutions for the laboratory, point-of-care, and home care. To this end, we draw on innovative technologies and methods, and take a big picture view that extends beyond the application to encompass risk management.

Your advantages

- Standards-compliant, approvable solutions (MDR/IVDR and FDA)
- Future-proof, connected and easily maintainable systems
- Process automation
- Real-time analysis monitoring



Our services at a glance



REGULATORY AFFAIRS AND SECURITY

- IVDR, MDR, FDA
- QM system
- ISO 13485
- Risk management
- Data privacy
- Cyber security



DATA ANALYTICS

- Data strategy
- AI
- Image processing and analysis
- Signal processing



STANDARDS-COMPLIANT DEVICE DEVELOPMENT

- System, software, hardware, mechanics
- Verification
- Documentation
- Design transfer



ROBOTIC ASSISTANCE SYSTEMS

- Control algorithms
- Human-robot collaboration
- Safety
- Simulation



CONNECTED LABORATORY DEVICES

- Interfaces
- Protocols
- Security
- Cloud
- Integration HIS/PACS/LIMS/EMR systems



INTUITIVE OPERATING & SERVICE CONCEPTS

- UI/UX
- GUI
- Usability engineering
- AR/VR



REMOTE MAINTENANCE

- Device status
- Usage data
- Updates
- Predictive maintenance



ANALYTICS

- Optoelectronics
- Measurement methods
- Imaging and processing
- Data science/AI
- Simulation



PRODUCT DESIGNS, THAT INSPIRE

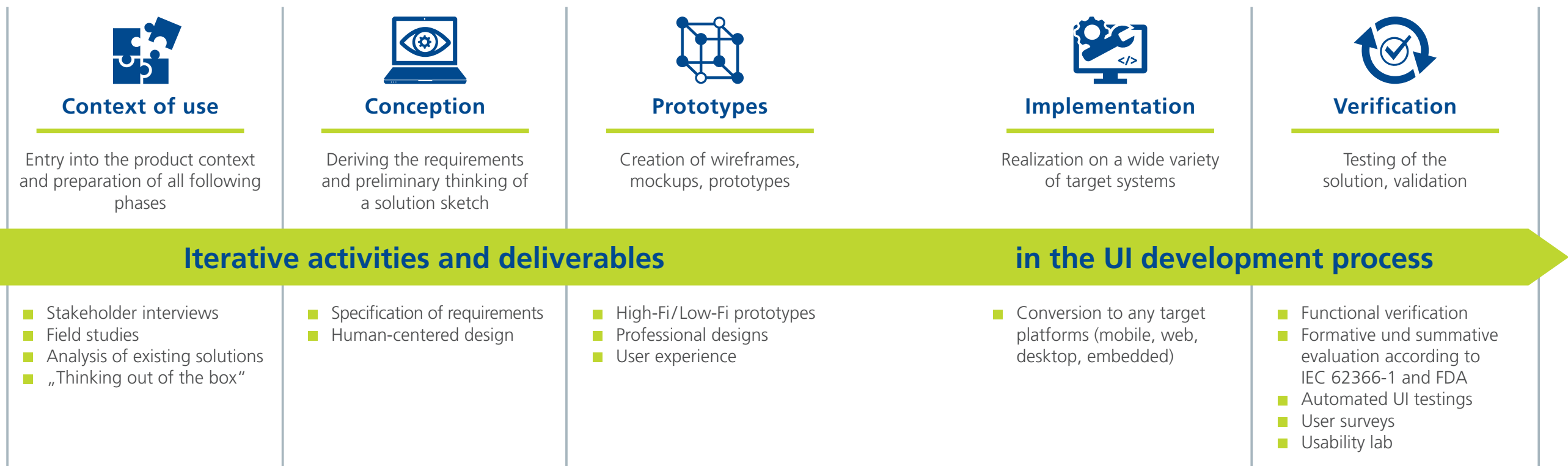
Effective. Efficient. Intuitive.

The world is changing rapidly and with it the way we interact with our environment and our devices. To ensure that users not only use medical devices effectively, but also efficiently and with delight, processes in development are needed that pursue these goals and take into account the needs of real users. The final result of such a human-centered design approach: solutions that are innovative, state-of-the-art and user-friendly. This requires a lot of experience, passion and the right view. Because for the user, the interface is the product!

Your advantages

- Inspiring and innovative solutions
- Developed according to DIN EN ISO 9241 and IEC 62366
- Certified UX professionals
- Professional usability lab

Our services at a glance



CYBER SECURITY FOR PEACE OF MIND

Holistic. Secure. Cross-domain.

Cyber security is not some voluntary exercise, it is a non-negotiable essential of the health-care system's digital transformation. Connected medical devices on the Internet of Medical Things and artificial intelligence (AI) present many unprecedented possibilities, but they also offer many more points of ingress and egress for cyberattacks. Building on our expertise in functional safety and cyber security, we make sure your medical product is protected. We consider a holistic view of cyber security - from conception and risk management to development, verification and approval.

Our services at a glance

Design: Tailor-made security concept

SECURITY RISK ANALYSIS

- Identification of vulnerabilities and derivation of requirements in line with the risk analysis according to ISO 14971 regarding safety



DATA PROTECTION

- Protection of personal data and health data in medical devices according to DSGVO



SECURITY CONCEPTS

- e. g. based on BSI guidelines or on NIST cyber security framework:
 - Protocol design
 - Secure software architecture
 - Secure hardware design
 - Selection of appropriate cryptographic algorithms



CONSIDERATION OF APPROVAL-RELEVANT REGULATIONS

- in a highly regulated healthcare environment (MDR/IVDR, DiGAV, FDA guidance papers, AAMI TIR 57, IEC 81001-5-1, IEC 80001-1 and many more)



Development: Standards-compliant implementation of your security concept

SECURE CODING

- by our software engineering service



BASED ON OUR SEP

- Security Engineering Process and ISO 13485:2016- and ISO 27001 certifications



CODE REVIEWS

- of in-house and third party software based on secure coding guidelines



BASED ON 30 YEARS OF ENGINEERING EXPERIENCE

- in development of safety-critical medical devices & software and robotic telemanipulation systems as well as digital health applications (DiGA)



Verification: Security tests and reviews



- Review of security concepts
- Execution of cross-domain penetration tests: grey box und white box
- Manual and automated tests for verification and validation of security-relevant requirements
- Assessment of impact of known vulnerabilities (CVE analysis)
- Execution as required by independent teams (team red / team blue approach)

Your advantages

- Minimize security risks
- View across domains
- Reveal unconsidered attack vectors
- Rule out unexpected bugs





XR TECHNOLOGY FOR DIGITIZING DEVELOPMENT, TRAINING & SERVICE

Diverse. Efficient. Cross-platform.

Whether as a virtual training system for medical professionals, for the analysis of virtual prototypes in simulated clinical situations, as an assistance function by overlaying image and patient data or in the maintenance of medical devices - the use of virtual and augmented reality technology in healthcare accelerates development and enables innovative solutions and products. With our experienced team of XR experts, we are your partner throughout all development stages: from conception to implementation to system maintenance. In doing so, we rely on state-of-the-art hardware and tools.

Our services at a glance

XR SOLUTIONS FOR YOUR PROBLEMS BASED ON MANY YEARS OF EXPERIENCE IN THE REGULATED HEALTHCARE ENVIRONMENT



- Virtual prototyping for concept evaluation or usability studies
- VR simulators for training and teaching purposes
- AR-based assistance systems for doctors or service technicians

PLATFORM-INDEPENDENT XR SOFTWARE DEVELOPMENT



- Android and iOS tablets and smartphones
- Oculus DK2, Oculus Go, Oculus Quest
- Hololens 1, Hololens 2
- HTC Vive, Pimax, Valve Index, nreal Light



Your advantages

- Shorter time-to-market through accelerated development
- Reduced development costs
- Improved user experience of your medical devices
- Targeted use of XR thanks to many years of experience in the standards-compliant development of medical devices
- Support in all development stages





HEALTH DATA ANALYTICS – MORE THAN MERELY ALGORITHMS

Forward-thinking. Secure. Built for approval.

These days, AI-assisted medical technology is science fact. AI is seeing widespread use in research, diagnostics, drug development and image processing. The machine learning code is but one small piece of the larger puzzle. We support you in your data strategy and analysis and do also implement it for you in your products in compliance with standards. In this way, we make the advantages of AI available to you in a value-adding and sustainable way.

Our services at a glance

CONSULTING



- Explore the possibilities and limits of technologies, ideation and incubation

OPTIMIZE PERFORMANCE



- for deployment in embedded devices

DATA PROCESSING



- Make your datasets usable

CONDUCT FEASIBILITY STUDIES AND ASSESS BENEFITS



- for alternative approaches

SELECT THE RIGHT METHODS AND ALGORITHMS



- for the given application and quality

TRAININGS



- on AI in healthcare

Your advantages

- Tailor-made solutions
- Standards-compliant implementation
- Broad-based expertise
- Practical advice on AI in a regulated environment



MEDICAL CONSULTING BORN OF EXPERIENCE

Hands-on. Holistic. Supportive.

Standards, rules, regulations: The medical industry certainly has plenty of challenges in store for new medical devices. As a certified partner, we have the know-how to rise to the occasion. We accompany you from the beginning to the approval with this motto in mind: What we advise, we can also provide.

Our services at a glance

DIGITAL TRANSFORMATION CONSULTING



- Strategy consulting
- Transformation support
- Technical consulting
- Agile services

USABILITY ENGINEERING SUPPORT ACCORDING TO IEC 62366-1:2015



- Determine use cases from the user's perspective
- Identify and minimize risks for the user

RISK MANAGEMENT SUPPORT ACCORDING TO ISO 14971:2019



- Determine risk policy and risk acceptance
- Conduct FTA to assess system architecture
- Document and link to development artifacts

PRACTICALLY-PROVEN SOFTWARE DEVELOPMENT CONSULTING COMPLIANT TO IEC 62304:2016 + A1:2015



- Efficient implementation of standards, including templates
- Tool support

QUALITY MANAGEMENT CONSULTING COMPLIANT TO ISO 13485:2016



- Tool validation according to ISO/TR 80002-2:2017
- SPICE medical evaluation model
- Practical implementation with templates and artifacts

CYBER SECURITY CONSULTING



- Analyze threats and vulnerability for medical devices
- Define security concepts and protective measures
- Pentesting
- Product life cycle activities according to IEC 81001-5-1:2020

REGULATORY CONSULTING



- MDR, IVDR, FDA

Your advantages

- Consulting rooted in real-world experience
- Entire product life cycle from a single source: design thinking, systems engineering, post-market surveillance
- Holistic hands-on-consulting: From strategy development to implementation





PEOPLE FIRST

Individual. Preventive. Patient-centered.

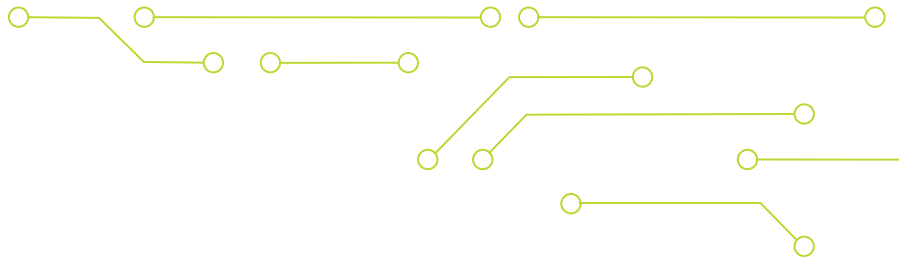
Thanks to the digital transformation and an increasingly connected network of players, it's goodbye volume-based medical management and hello value-based healthcare. The age of the empowered patient and personalized medicine is dawning as the individual gains access to information, greater influence and decision-making options.



A partnership for tomorrow's healthcare tech today

Let us join forces to tap the power of new technologies and develop secure, connected healthcare solutions with smart, patient-centric functions. This way, we can make the most of technology to shape the transition to personalized medicine with a human touch.





ITK ENGINEERING

Stability, reliability and methodological expertise – this is what we have stood for since our founding in 1994. At all times, our customers have benefitted from our dedicated multi-industry know-how, especially in the fields of control systems design and model-based design. Customers can count on us – from conception to deployment, we cover the entire development process.

Our areas of expertise include:

- Software development
- Hardware development
- Electrical & electronic systems
- System integration
- Software as a product
- Turnkey systems
- Customer specific development
- Technical consulting
- Seminars
- Quality assurance

The satisfaction of each of our partners and mutually respectful cooperation shape our corporate philosophy, in which four values are firmly anchored: Read more about this on the web.

We look forward to advise you personally. Contact us at:
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Visit our website to find out how we can help you with your digitalization strategy:
www.itk-engineering.com/healthcare



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Founded in 1994 –
Branch offices throughout
Germany – ITK companies
worldwide.

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