



SEQLY X M&M FOR MEDTECH

UNDERSTAND
MEDTECH.
SHAPE THE
FUTURE.



**From idea to certified, secure
medical device.**

- Regulatory clarity.
Technological leadership.
- Digital solutions & software
that truly deliver.
- Together, we accelerate your
scale-up and market entry.

MedTech consulting and MedTech software solutions

Future-proof MedTech through Digitalization, AI, Data & Regulatory Excellence. We empower MedTech companies with compliant, innovative and scalable digital solutions, from concept to market launch.

- ✓ 360+ dedicated experts
- ✓ 38+ years of experience
- ✓ 4 locations worldwide (DE, CN, IN)

Contact

M&M SOFTWARE GMBH x SEQLY
Industriestr. 5
78112 St. Georgen
Germany

+49 7724 / 9415-0
info@seqly.de | seqly.de
info@mm-software.com | mm-software.com



#MedTechBySEQLYxMM

>> DIGITAL TRANSFORMATION & REGULATORY EXCELLENCE IN MEDTECH

Learn more:



01. DIGITAL TRANSFORMATION

- Clear status analyses and actionable digital transformation strategies leads to company-wide digitalization roadmaps
- Strategic concepts for selecting, implementing, and optimizing PDM, ALM, PLM, RIMS, and other systems
- Use Case Factory: Fast PoC sprints delivering quick, measurable digital wins
- **Ensuring compliance with ISO 13485**

02. REGULATORY COMPLIANCE, APPROVAL AND IP STRATEGY

- Workshops on software, security, AI-related regulatory requirements and on IP strategies in the software sector
- Implementation of product, software, security, and regulatory lifecycle processes
- Workshops on MDSW/SaMD concepts, software verification and validation, and tool validation (CSV)
- **Ensuring compliance with ISO 13485**

03. AI STRATEGY FOR MEDICAL DEVICES

- AI potential workshops to identify suitable initial use cases (e.g., AI agents)
- Analysis of product and process status regarding AI governance & compliance (MDR, AIA)
- Extension of lifecycle processes to include AI-related requirements in an AI management system (AIMS)
- Use Case Factory: Fast PoC sprints for measurable data and AI wins
- **Ensuring compliance with the AI Act and ISO 42001**

04. CYBERSECURITY FOR MEDICAL DEVICES

- Analysis on process- and product-related cybersecurity status
- Integration of regulatory product security requirements into product, software, and security lifecycle processes
- Moderation of safety and/or security risk analysis workshops
- Use Case Factory: Fast PoC sprints for tangible cybersecurity improvements
- **Ensuring compliance with IEC 81001-5-1, IEC 62443, ISO 14971, AAMI TIR57**

>> BUILDING THE NEXT GENERATION OF CONNECTED MEDTECH SOFTWARE

Learn more:



M&M
software

01. DEVELOPING DIGITAL PRODUCTS

- End-to-end custom software solutions across embedded, web, cloud, and mobile
- Discovery → Delivery → Launch & Run, including UX/UI preparation and comprehensive software quality assurance
- Implementation, scaling, continuous development, and long-term operation

→ **Accelerates the launch of secure, user-centered software by combining clear architecture, quality assurance, and security-by-design from idea to scalable operation.**

02. MODERNIZING APPLICATIONS

- Assessments and potential analyses for existing applications
- Modernization strategy and roadmap development including evaluation of business value and ROI
- Security and compliance review
- Cloud readiness assessments and migration support
- UX redesign for improved usability and performance

→ **ROI-driven modernization while improving performance, usability, and maintainability.**

03. CONNECTING SYSTEMS AND PRODUCTS

- IoT, connectivity, and cloud enablement for smart, networked solutions
- Integration of medical industry-specific device protocols such as HL7 FHIR, DICOM, IHE, and SDC (IEEE 11073 Series)
- Ensuring data quality, system security, and suitable data formats

→ **Securely networked medical devices, accessories, and data platforms ensure high data quality as well as service and automation use cases.**

04. DEVELOPING PLATFORMS AND SMART CONNECTED ECOSYSTEMS

- Development of a target vision and platform strategy
- Definition of architecture, data, and integration principles
- Implementation of scalable, modular cloud, hybrid, or on-premise architectures
- Connecting data, products and partners through data rooms and digital twins for internal and cross-company value creation

→ **Building scalable, regulatory-compliant platforms for data-driven services and partner ecosystems, enabling new MedTech business models and continuous innovation.**