tecurat

English Version

When Medical Device Development Gets Complex, We Keep You Moving Forward

Medical device executives face mounting pressure: shorter development cycles, stricter regulations, and rising market demands. At tecurat, we've guided a wide range of medical devices through development and market approval. Our practical experience helps companies navigate regulatory hurdles and technical challenges before they impact timelines.

Deep Expertise When You Need It Most

Many consulting firms claim medical device expertise. We live it daily. Our team includes managers, quality system architects, and medical device engineers who have shepherded products from initial concept through market success. This practical knowledge means we spot critical issues early and guide you toward efficient solutions.

Quality Management and Regulatory Compliance That Makes Business Sense

Medical device companies need efficient processes that support both business goals and regulatory requirements. We specialize in creating streamlined solutions that improve productivity while ensuring compliance. Our approach integrates regulatory requirements with your business processes, resulting in faster development cycles and reduced overhead. We focus on practical, automated solutions that support rapid growth without constant revision or manual work. Whether you need process optimization, compliance strategies, or digital solutions, we help identify and implement the right approach for your specific challenges, even if you're not yet sure what those challenges are.

Strategic Testing Support and Coordination

Medical device testing requires sophisticated facilities typically found in specialized aerospace and automotive testing labs. Our experienced engineers guide you through these complex testing requirements, leveraging both our hands-on testing background and established partnerships with leading test facilities.

We provide comprehensive testing support across all key areas:

- Usability evaluation (IEC 62366-1)
- Electrical safety testing (IEC 60601-series)
- Biocompatibility assessment (ISO 10993 series)
- EMC testing to international standards

Additionally, we support comprehensive design verification and validation, including all mechanical hardware, electronics, and software testing. Our experienced team can assist as interim managers, project managers, or engineers throughout your V&V process.

Our role can be tailored to your needs - from strategic consulting and test planning to project management and engineering support. While we don't operate testing facilities ourselves, our team's direct experience with these tests allows us to effectively coordinate with testing labs, manage projects, and support your engineering teams throughout the process.

tecurat

Technical Development That Saves Time and Money

Early-stage development decisions have massive downstream impacts on costs and timelines. While most companies excel at defining clinical applications, the deeper technical requirements often create expensive challenges later. Both our expertise and data shows that requirement errors caught in early development cost a fraction to fix compared to issues found during final testing.

We create development structures that get it right from the start. Our engineering team specializes in detailed requirement engineering that goes beyond basic user needs to capture the full technical scope. This comprehensive approach prevents the cascade of rework and extra costs that typically hit engineering and testing departments late in development.

Our test management solutions go far beyond basic protocols. We implement complete testing structures that not only improve current efficiency but dramatically reduce effort for future product updates. Through smart regression testing strategies and robust test management, we help companies cut testing time and costs while maintaining complete compliance coverage.

Digital Innovation in MedTech

As medical device development grows more complex, digital tools become essential. Beyond offering our own proven solutions, we guide companies through their digital transformation. Our experience spans critical business systems including eQMS (electronic Quality Management Systems), technical documentation and design control systems, and DMS (Document Management Systems) for versioning and approval workflows

We provide comprehensive digital solutions that integrate company-wide processes. While most businesses have established digital tools for sales and accounting, we extend this same efficiency to all operational areas. Our solutions cover the full spectrum of medical device processes - from complaint management and product management to production documentation and verification/validation. This integrated approach creates a cohesive digital infrastructure that supports both compliance requirements and operational efficiency.

Building Your Internal Capabilities

We believe in true partnership. While we can handle complex tasks directly, we also excel at building your team's expertise. Through targeted training, hands-on workshops, and guided implementation, we help your staff master quality processes and regulatory requirements. This approach gives you the flexibility to handle routine tasks internally while calling on our expertise for specialized needs.

Flexible Support Models

Every medical device company has unique needs. We tailor our support to match your stage of growth and specific challenges.

For established manufacturers, we focus on optimizing existing systems and processes. Our services include:

- Development process improvement
- Technical file maintenance
- Post-market surveillance programs
- Market expansion strategies
- Expert team augmentation

For growing companies, we provide structured development support:

- Efficient development processes
- Design control implementation
- Regulatory pathway planning
- Compliance strategy development
- Process optimization

For startups, we establish foundational frameworks that scale:

- Initial development structures
- Documentation systems
- Regulatory planning
- Process implementation
- Growth-ready solutions

Our software development support includes:

- Project and team management
- Requirements engineering
- Product architecture
- Implementation oversight, full implementation, and testing
- Developer coaching
- Technical leadership

tecurat

Complete Solution Through Partnership

Our established partner network complements our services across every aspect of medical device development and commercialization. In engineering and testing, we coordinate with specialists in EMC, electrical safety, biocompatibility assessment, mechanical construction, and electronics engineering. Our partners provide advanced sterile production capabilities when needed.

For certification and registration, we work with qualified notified bodies and registration specialists. These partnerships ensure smooth quality management system certification and efficient product registration across international markets.

Clinical expertise comes through our network of research partners, including leading German hospitals like Charité Berlin, who conduct clinical studies, prepare evaluations, and perform literature research. For usability testing, we work with specialized laboratories worldwide, including FDA-compliant facilities in the U.S. and China, ensuring your device meets regional regulatory requirements across different user groups.

Beyond technical requirements, our commercial partners help drive market success. They provide targeted sales strategies, marketing solutions, and distribution networks. This support proves especially valuable when entering new markets or expanding existing ones.

This comprehensive network means we can deliver complete solutions while maintaining our focus on efficient, practical approaches to medical device development.

Maintaining Market Success

Success continues well beyond initial market approval. Our support extends to existing products through continuous regulatory monitoring, quality system maintenance, and strategic improvements. We assist with product changes, new market registrations, and when needed, remediation projects. Our post-market surveillance and clinical follow-up programs help protect your market position while meeting evolving requirements.

Comprehensive Audit Support

External audits represent crucial moments for medical device companies. Our certified auditors provide complete support before, during, and after audits by notified bodies and authorities like the FDA. We conduct internal audits and MOCK audits to ensure preparedness, and can extend this expertise to supplier audits. This comprehensive audit support helps prevent findings and ensures smooth interactions with regulatory bodies.

Let's Discuss Your Needs

Contact our team to explore how we can support your medical device success:

+49 (0) 331 600 87 640

info@tecurat.de
www.tecurat.de

tecurat