ai6 SOLUTIONS

Consulting



Compliance made easy

Services
Consulting

ai6 supports medical device manufacturers in navigating complex regulatory, clinical, and quality requirements – from early product development and regulatory strategy to technical documentation, market access, and post-market activities.

Our interdisciplinary team combines expertise in Regulatory Affairs, Clinical Affairs, Quality Management, Medical Device Software, Cybersecurity, Digitalization, and Sustainability. We bridge the gap between regulatory requirements and the technical realities of product development, providing practical, solution-oriented support throughout the entire product lifecycle.

From start-ups and small and medium-sized enterprises (SMEs) to international medical technology companies, we support our clients with European and international market access, clinical and performance evaluations, and the implementation and improvement of quality management systems. We help our clients successfully bring innovative, safe, effective, and compliant medical devices to market and maintain regulatory compliance throughout their lifecycle.

Our services include support with:

- Product definition, intended purpose, regulatory and market access strategies, and reimbursement strategies
- Regulatory requirements throughout the product development process
- Preparation and maintenance of technical documentation
- Regulatory requirements for medical device software and cybersecurity
- Clinical evaluations and performance evaluations
- Planning and conducting clinical investigations and performance studies
- European conformity assessment procedures and international regulatory approvals and registrations
- Implementation, optimization, and certification of quality management systems
- Assumption of regulatory roles and responsibilities, subject to applicable legal requirements
- Digitalization of documentation and business processes

From Regulatory Strategy to Successful Market Access

Our Consulting products

Regulatory Affairs

- Product adaptations to changed regulatory requirements
- Creation and maintenance of technical documentation
- European and international approval of medical devices
- FDA approvals and coaching

Clinical Research Organization – CRO / Clinical Affairs

- Preclinical and clinical evaluations
- Clinical trials / studies
- Post Market Surveillance (PMS), Vigilance, Post Market Clinical Follow-Up (PMCF)
- Performance evaluations according to IVDR
- Post Market Surveillance (PMS), Vigilance, Post Market Performance Follow-Up (PMPF)

Product Life Cycle Management / Quality Management

- Setting up QM systems for medical device manufacturers
- Introduction of a QM system for dealers and suppliers
- Process adaptations to changes in regulatory requirements or modern development technologies
- Process recording / structuring and modeling
- Increased efficiency and shorter cycle times
- Holistic process approach for hardware/software development, risk management, usability and associated documentation

Startup Consulting

Medical Software

- Establishment and adaptation of software life cycle processes
- Support in ensuring product security / cybersecurity
- Post-documentation of software for existing medical devices
- Approval of medical apps / health software
- Approval as digital health application (DiGA) and digital care application (DiPA) in Germany
- Approval of medical devices with artificial intelligence

Digitization

- Support with your digitalization strategy
- Digitization of your technical documentation
- eQMS, ALM & PLM systems and digitization of workflows
- Digital Computer System Validation (D-CSV)

Assumption of regulatory roles

- Assuming the role of the legal manufacturer
- Assumption of the European Authorized Repre-sentative (according to MDR, IVDR, Article 11)

Regulatory & IP Due Diligence Services

- Expert reports and evaluation of products and processes

Sustainable Medical Technology

- Product Lifecycle
- Regulation and Reporting
- Corporate Management

Training courses

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Contact

Discuss your project with us:
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Engineering
Consulting
Production

Also ask about our services engineering and production. We show you, how high quality products from your ideas arise.

WE UNCOMPLICATE MEDTECH FOR OUR CUSTOMERS