seleon

Consulting

Safely through the regulatory jungle of medical technology

High-Class Medical Technology. First-Class Service.

Services
Consulting

We are not “THE CONSULTANTS“, but engineers, clinical and approval experts as well as quality managers whose in-depth specialist knowledge is based on a large number of international development, manufacturing and approval projects for medical devices.

Our customers benefit from this expertise – startups, small and medium-sized companies as well as corporations – with consultative and executive support:

- for all development-accompanying regulatory topics,
- for writing technical documentation,
- for clinical or performance assessments and studies,
- for European and international approval,
- for corporate processes and certifications,
- for taking on regulatory roles (manufacturer, authorised representative),
- when digitising your documentation and processes.

Regulatory Affairs Blog

NO RISK MORE FUN

seleon.com/en/regulatory-affairs/

Medical Product Development, Consulting & Production

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 Represen tative (according to MDR, IVDR, Article 11)

Regulatory & IP Due Diligence Services

- Regulatory & IP Due Diligence Services

Sustainable Medical Technology

- Product Lifecycle
- Regulation and Reporting
- Corporate Management

Training courses

For more information please visit our website: www.seleon.com/en/service/consulting..

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Contact

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Engineering
Consulting
Production

Also ask about our services engineering and production. We show you, like high-quality products from your ideas arise or how your medical devices be produced perfectly.

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