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

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Our Consulting products

Regulatory Affairs

- Regulatory Affairs/Technical Documentation (MDR, IVDR, FDA)
- International approvals (MDSAP and other countries)
- Biological Risk Evaluation, Material Compliance

Software

- Software life cycle processes/Documentation
- Medical Apps, DiGA, DiPA & Health Software
- Artificial Intelligence & Cybersecurity in medical devices

Clinical Affairs

- Clinical & Market Strategy Consulting
- Clinical Evaluation/Performance Evaluation (MDR, IVDR)
- Clinical Investigations/Performance Studies (MDR, IVDR)
- Post Market Surveillance/Clinical/Performance Follow-up

Regulatory Business & Product Consulting

- seleon Regulatory & IP Due Diligence Services
- Technology consulting (ENG + CON + PROD)
- Taking over the role of the "Legal manufacturer"
- Taking over the role of "EU Authorized Representative"

Life Cycle Processes

- Implementation of QM systems (MDR, IVDR, QSR, ISO 13485)
- Life cycle process consulting
- Risk Management & Usability Engineering Consulting

Digitization

- Digitization of Technical Documentation
- eQMS, ALM & PLM systems, Workflow digitization
- Digital Computer System Validation (D-CSV)

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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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