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/

Regulatory Affairs

- Regulatory affairs/technical documentation (MDR, IVDR, FDA, etc.)
- International approvals (MDSAP and other countries)

Regulatory product and business consulting

- seleon Regulatory & IP due diligence services
- Technology consulting (engineering and consulting and production)

Clinical Affairs

- Clinical evaluation/ performance evaluation (MDR, IVDR)
- Clinical examination/ performance studies (MDR, IVDR)
- Post market surveillance/ clinical follow-up (MDR, IVDR)
- Clinical & market strategy consulting

Digitalisation

- Digitisation of technical documentation
- Digitisation of regulatory workflows
- Digital Computer System Validation (D-CSV)
- Cybersecurity and data protection consulting

Life cycle processes

- Development/adaptation of QM systems (MDR, IVDR, QSR, ISO 13485)
- Life cycle process consulting
- Usability engineering consulting

Take on regulatory roles

- Assumption of the role of “Legal manufacturer“
- Assumption of the role of the “Regulatory host“
- Assumption of the role of “Authorised representative“

Medical/Health Software

- Software Life cycle processes/ documentation
- Medical Apps, DiGA & Health Software

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Contact

Discuss your project with us:

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Engineering
Consulting
Produktion

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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