

CONSULTING IN REGULATORY AFFAIRS

As a provider of development and production services to the medical technology sector, we know all about the complex demands made on sophisticated and standards-compliant medical products. Our many years' project experience has given us an in-depth understanding of the vast range of requirements, national and international directives, legislation and standards applicable to this field. We also want to pass on this knowledge to you independently of any product development, since delays caused by uncertainties in approval processes can prove to be extremely expensive. Profit from our considerable wealth of experience – to make sure you reach your goal quicker!

rock solid
medical
engineering.

SERVICES AND EXPERTISE

- » Consulting and training on current process and approval-related issues
- » Research / monitoring of international directives, legislation and standards
- » Drawing up of requirements and testing concepts
- » Creation or preparation of product and approval documentation
- » Support with international approvals such as CE, FDA, CMDCAS

BENEFITS FOR THE CUSTOMER

- » Benefit of many years' experience of processes and approvals
- » Rapid access to the latest know-how in regulatory affairs
- » Straightforward and rapid processing within your teams or at our premises
- » Use of our established relationships with testing agencies and notified bodies

AREAS OF ACTIVITY

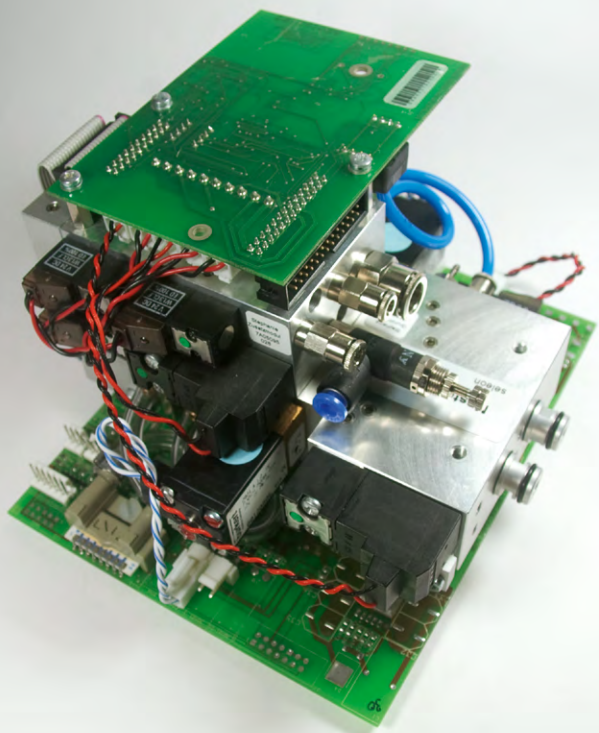
- » Quality management to ISO 13485 and 21 CFR 820 (FDA)
- » Software development, verification and documentation as per IEC 62304
- » Software validation to IEC 60601-1-4, IEC 60601-1:2005, FDA Guidance
- » Usability engineering as per IEC 60601-1-6 and IEC 62366
- » Risk management as per ISO 14971
- » Product update to IEC 60601-1:2005 (3rd Edition)

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REFERENCES

Setup and support for the certification of a QM system for various companies, including:

- » a newly founded business unit of the Siemens Healthcare Sector,
- » an operator and service company for proton therapy systems,
- » a company using naturopathy-based medical products,
- » a company selling cardiology products.

Revision, auditing and documentation as per EN 62304 or FDA requirements on software:

- » for a contrast medium injector,
- » for a tracheal respiration system,
- » for a novel endoscope,
- » for a major cleaning and disinfectant system.

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Companies are keen to primarily focus on the development of new and innovative products. We help them do this by taking care of the testing, documentation and approvals that accompany the development process. Since the company was first founded in 1998, seleon gmbh has provided advice and support to major, SME-sector and small medical technology companies.

