NO RISK APPROACH

TO KEEP YOUR IDEAS FOR MEDICAL TECHNOLOGY INNOVATIONS FROM BURSTING BEFORE THEY REACH THE MARKET.

MDR
MDSAP

CLINICAL AFFAIRS
CRO

RA
REGULATORY AFFAIRS

CONSULTING IN QUALITY MANAGEMENT AND REGULATORY AFFAIRS

seleon

As an experienced service provider in medical technology, we know all about the complex requirements of demanding medical products that conform to standards. Through our many years of experience in development and in manufacturing services, we have acquired in-depth knowledge of the broad spectrum of underlying requirements, national and international guidelines, laws and standards. Our consultants, who have a great deal of practical experience, will provide additional input from the ever-changing world of requirements and will navigate you safely through global regulatory areas.

rock solid medical engineering.

made in germany.

REGULATORY AFFAIRS

- European, FDA and international approval of medical devices
- Creation and maintenance of technical documentation, as well as OEM-PLM frameworks
- Adaptation of documentation following regulatory or product changes; in particular the conversion of product documentation to MDR
- Preparation of key documents such as risk management files, usability engineering files, biological evaluations, software documentation, and instructions for use

CLINICAL APPROVAL

- Carrying out preclinical and clinical evaluations
- Running clinical investigations and studies
- Organising post-market clinical follow-up (PMCF) studies
- Implementing the required post-market surveillance (PMS) activities
- Support with incidents and the necessary reports (vigilance)

QUALITY MANAGEMENT

- Establishing QM systems for medical device manufacturers in accordance with MDR, ISO 13485, 21 CFR 820 (QSR), etc.
- Implementation of a QM system for distributors and suppliers
- Developing QM solutions for OEM PLM frameworks
- Conducting internal and supplier audits
- Providing preparation and support for audits (Notified Body and MDSAP) and inspections (FDA and state authorities)
- Conduction of MDSAP and FDA mock audits
- Expert Reports on the degree of maturity of products and processes
- Training for process, quality and regulatory matters

DEVELOPMENT PROCESSES

- Process acquisition and structuring, as well as modelling
- Implementation and validation of PLM or ALM tools
- Increasing efficiency and reducing cycle times
- Adapting processes to changed regulatory requirements or the latest development technologies
- Process risk management using a risk-based approach
- Computer System Validation (CSV)

CONTACT

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