CRO: NO RISK MORE FUN

REDUCED RISK TO MAKE SURE NEITHER CLINICAL APPROVAL PROCESSES NOR POST-MARKET SURVEILLANCE MAKE YOUR INNOVATIVE IDEAS IN MEDICAL TECHNOLOGY BURST.

CLINICAL RESEARCH ORGANISATION

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. Here, special attention needs to be given to the increasing importance of clinical data and market observation for medical devices.

Follow the low-risk product approach with us together – so that your product ideas do not run out of breath that fast.

rock solid medical engineering.

made in germany.

PRECLINICAL AND CLINICAL EVALUATION

- Analysis of relevant clinical risks and the degree of innovation of your products
- Feasibility study for product development
- Identification and evaluation of equivalent devices
- Creation of a Clinical Evaluation Plan and a market approval strategy
- Implementation of clinical evaluations according to MEDDEV 2.7/1 rev.4 and MDR
- Scientific literature research
- Inclusion and evaluation of post-market surveillance data
- Sound standing consultation for the decision to conduct a clinical investigation/study

POST MARKET SURVEILLANCE (PMS), VIGILANCE, POST MARKET CLINICAL FOLLOW-UP (PMCF)

- Fulfilment of market observation obligations
- Analysis and update of the clinical evaluation, the risk management files and the usability engineering file
- Analysis and evaluation of incidents, support in reporting them, as well as the implementation of corrective actions
- Market observation research via international databases
- Support in deciding on the need for post-market clinical follow-up (PMCF) studies

CLINICAL INVESTIGATION/STUDY

- Formulation of the objectives and hypotheses of the clinical investigation/study
- Conduction of different types of studies
- Obtaining initial approval for a clinical investigation/study
- Project management of the clinical investigation, including budget management
- Continuous monitoring as well as the supervision and coordination between the involved parties
- Ensuring study documentation, data management and data safety
- Evaluation of data from clinical investigation/studies according to statistical, biometric and other aspects
- Drafting or reviewing the clinical investigation report

CONTACT

seleon gmbh
Im Zukunftspark 1
74076 Heilbronn, Germany

Fon +49 7131 2774-40
regulatoryaffairs@seleon.de

regulatory-affairs.org
seleon.de

CONSULTING ALSO IN QUALITY MANAGEMENT AND REGULATORY AFFAIRS

As of: 10/2018