Dr. Dietmar Falke
Head of CRO
dietmar.falke@ul.com

History and Mission

Emergo by UL's CRO specializes in clinical investigations of medical devices for regulatory purposes. Our experienced team offers all services related to the design, conduct, quality control, and evaluation of clinical investigations regarding active and non-active medical devices. We contribute to our clients' success by delivering high-quality clinical data.

Highlights

By May 26, 2020, when the Medical Device Regulation becomes enforceable, the need for medical device clinical investigations will drastically increase. Our strong experience in the medical device CRO business makes us a strong and reliable partner for our customers.

Emergo by UL
Baumgartenstraße 16
89231 Neu-Ulm, Germany

Tel. +49 731 725 582 0
Fax +49 731 725 582 88

BVMA member since 2005
Audits passed in 2005, 2006, 2009, 2012, 2016 and 2019

EMERGO by UL

www.emergobyul.com

Services

Project Management and Quality
The Project Manager is responsible for adherence to timelines and targeted budget. She/he ensures compliance with legal and regulatory requirements, and coordinates information flow and activities between all involved parties.

For Clinical investigations with medical devices, we offer reviews of documents, systems, and procedures. The intent of these reviews is to ensure the capture, analysis, and reporting of data is in accordance with the study protocol and other approved documents, and in compliance with ISO 14155 and GCP, regulatory requirements, and the Sponsor's Standard Operating Procedures (SOPs).

Monitoring
Our Clinical Monitor(s) ensure(s) that data is collected according to the study protocol, ISO 14155, and GCP. She/he performs on-site and remote source data verification, and ensures that adverse events and incidents are adequately documented and reported.

Data Management
Our Clinical Data Manager designs the case report forms and supervises the set-up of the database. She/he is responsible for data processing in accordance with the data management plan (DMP).

Biostatistics
Our Biostatisticians provide valuable input regarding the design of your clinical study. He/she will conduct a thorough assessment of the scientific requirements to ensure your study is planned with the proper sample size (number of patients included) and design as well as the evaluation methods. A proper protocol design and analysis will improve the quality of the medical device clinical study submission for approval, contribute to cost efficiency, and help accelerate the introduction of your product to market.