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

UL MDT
Medical Device Testing

HISTORY AND MISSION

MDT medical device testing GmbH was founded in 1996 and is specialized in clinical and non-clinical investigations of medical devices for regulatory purposes. UL MDT supports manufacturers in obtaining European and international market authorizations. Since 2012 MDT is part of UL. An experienced team offers all services related to the design, conduct, quality control and evaluation of clinical investigations regarding active and non-active medical devices.

Anerkannt durch/Recognized by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-AP-308.10.29

HIGHLIGHTS

In the consolidated revised AIMDD 90/385/EEC and MDD 93/42/EEC and the revision of the Medical Device Regulation, which came into effect on May 25, 2017, the importance of clinical investigations of medical devices increased considerably. Against this background UL MDT is dedicated to share their extensive knowledge in clinical research and, more widely, in regulatory testing of medical devices. Based upon our long-term experience in the medical device industry as well as the CRO business, we are a strong and reliable partner for our customers.

SERVICES

Medical Writing
UL MDT's philosophy is to offer customer focused high quality services with full compliance to the GCP standard EN ISO 14155. This comprises all paperwork requested by Annex E of the mentioned standard including investigator's brochure, clinical investigation plan, patient information, informed consent form and clinical investigation report.

Project Management
A clinical project manager is the sponsor's "key point of contact" who is responsible for keeping the time lines and targeted budget, and who ensures compliance with both the legal and normative requirements. Furthermore, the project manager coordinates the information flow, as well as all study related activities between all involved parties.

Monitoring and Quality Assurance
The clinical monitor ensures that the whole project is being performed according to the study protocol, that GCP demands, respectively EN ISO 14155, are met and that AEs/SAEs and incidences are adequately documented and reported. The monitor visits the study sites regularly to perform source data verification, clearance of open issues and supporting the investigator in meeting their numerous obligations to the study participants and the manufacturers.

Regulatory Affairs and Training
The regulatory affairs specialist supports compliance with national and international requirements associated with clinical investigations and offers training to clinical investigators in terms of EN ISO 14155, Good Clinical Practice guidelines and national legal provisions for the conduct of clinical investigations.

Data Management & Statistics
The clinical data manager designs the case report forms and supervises the set-up of the clinical database. The data manager is responsible for adequate data processing during the whole project. After study completion numerous quality checks are performed in order to guarantee a valid statistical analysis of the study results.