Clinical Evaluations according to MEDDEV 2.7/1 rev. 4

The MEDDEV 2.7/1 3rd revision was replaced with a revised 4th edition in June 2016. With MEDDEV 2.7.1 revision 4, the quality requirements regarding clinical evaluations have increased to such an extent, that many clinical evaluations from medical devices have to be revised and/or compiled anew. This has become indispensable before a CE mark (CE identification) can be issued or the CE mark renewal can be approved by the notified body.

The goal of clinical evaluations according to the Medical Device Directive 93/42/EWG, is to proof that the medical device neither jeopardises the clinical condition of the patient nor the safety and health of users or possibly third parties. For this purpose, MEDDEV 2.7.1 rev. 4, provides extensive methodological and strict regulatory guidelines in fulfillment of these essential requirements, which can be verified and audited by the notified body.To ensure compliance with the regulatory requirements, the notified body will carry out more and more published and unanticipated audits of medical devices of all risk classes in the future. During the audits, the responsible authority reviews whether the technical documentation including the clinical evaluation of the medical device complies with the methodological and technical requirements.

Our task is to help you meet all requirements perfectly, so that your medical device can be in record time on the market or continue to remain on the market.

The quality of clinical evaluation depends on how fast a CE label can be obtained and whether the literature data is considered sufficient with acknowledgeable impact factor. If the literature review is found to be inadequate, the authorised body may require a clinical study prior to bringing the medical device to the market, thus ensuring demonstration of compliance with the necessary requirements. Therefore, we utilize our expertise to avoid unnecessary clinical trials!

Our clinical evaluations team is headed exclusively by a medical director who supervises the work in accordance with MEDDEV 2.7 / 1 rev. 4 as well as German and European standards and guidelines.In addition to regulatory and medical device-specific knowledge, we also have profound know-how gained through many years of experience in bringing medical devices on the market.

Our clinical evaluations include the following contents:

- Draw up the methodology for the clinical evaluation report or clinical evaluation plan
- Detailed description of the product and the medical background taking into account the clinical, biological and technical characteristics
- Analysis of the medical device technical documentation with insight on the risk analysis and

management

- Extensive systematic literature research with PubMed and when necessary, also EMBASE, description and evaluation of the studies according to the PICO classification system as well as evidence levels and degrees of recommendation.
- Search for equivalent reference products according to the requirements of MEDDEV 2.7/1 rev. 4
- Evaluation of the medical device equivalence to the reference product – Here, the equivalence is evaluated clinically, biologically and technically
- Comprehensive data analysis with description of benefits, risks and recommendations
- Evaluation of the unintended side-effects
- Analysis of market-surveillance data
- Search the BfArM and Maude database with analysis of the found medical device or reference products
- Risk-benefit analysis with elaboration on recommendations for granting the CE mark and re-producing the clinical Evaluation

What special characteristic distinguishes your medical device andwhich evaluations can be derived therein? We are looking forward to your product presentation and we are mostly delighted to assist you in the clinical evaluation that brings your device on the market!