Independent clinical evaluation of medical devices according to (EU) 2017/745

Every manufacturer of a medical device has to demonstrate compliance with the General Safety and Performance Requirements according to (EU) 2017/745 (MDR, Medical Device Regulation) both during the approval process as well as in the post-market phase. A clinical evaluation has to be created and maintained for each device that is CE marked as a medical device.

With certain exceptions, the clinical evaluation is based on clinical data from clinical trials, clinical data from the scientific literature and from post-marketing surveillance feedback. In principle, however, all data that allow conclusions to be drawn about the clinical performance and safety of the medical device must be considered. This means that the clinical evaluation requires not only a thorough, systematic literature search, but also the inclusion of other data sources such as databases of the authorities on recalls or field safety actions, or data of the manufacturer from post market surveillance.

The preparation of a clinical evaluation report according to (EU) 2017/745 and MEDDEV 2.7/1 Revision 4 places increased demands on resources and competence. The MEDDEV 2. 7/1 Revision 4 and the MDR require

A sound plan for clinical evaluation

The clinical evaluation, as a process over the entire product life cycle, must be represented in a plan. This plan shall specify, among other things, the intended purpose and expected benefits of the medical device, the applicable General Safety and Performance Requirements and the methods for evaluating safety and risks. An integral part of the clinical evaluation plan shall be a clinical development plan.

Increased quality of clinical data that can be used for conformity assessment

The MDR lists in article 2, 48 the possible sources of clinical data. These include clinical studies, publications as well as market surveillance activities - on the one hand from the company's own or an equivalent device. The narrow definition of clinical data in combination with increased requirements for the use of an equivalent device means that there is often no way around a clinical study.

A very high similarity and sufficient access to the technical documentation to rely on data from equivalent devices

Equivalency can only be claimed if a device is clinically, technically and biologically equivalent. Thus, a potentially equivalent device must be carefully selected and comprehensively documented. The equivalent device must also provide sufficient clinical data as defined in Art. 2, 48. To make matters worse, the MDR requires sufficient access to the technical documentation of the equivalent device; for implantable devices and Class III devices this must be contractually regulated.

Comprehensive and cross-linked argumentation

All documents of the manufacturer, which accompany and describe the medical device to be evaluated, must be included in the clinical evaluation and assessed (IFU, surgical technique, marketing documents, risk documents, biocompatibility reports, transport validation, mechanical tests and many more). The documents have to be checked against the current state of knowledge as well as against the scientific literature. Post market surveillance (PMS) must be planned and justified.

Competent authors and reviewers

The authors as well as reviewers of the clinical evaluation reports must meet high standards. The MDR requires that the requirements are defined and deposited in writing by the manufacturer. The suitability of the authors and reviewers must be verified.

We offer sound experience in writing clinical evaluation reports for medical devices of all classes. The people who write the clinical evaluation reports in our company have successfully completed a university degree and have worked scientifically, and in some cases published their own research.