

CER Writing

What is Clinical Evaluation?

Clinical evaluation is a set of ongoing activities that use scientifically sound methods for the assessment and analysis of clinical data to verify the safety, clinical performance, and/or effectiveness of the medical device.

What is the Process?

The clinical evaluation process involves identifying and generating the clinical data needed to address questions of safety, clinical performance, and/or effectiveness of the medical device. The results of this process are documented in a Clinical Evaluation Report (CER).

What is the Primary Purpose of CER?

The primary purpose of this document is to provide manufacturers with guidance on how to conduct and document the clinical evaluation of a medical device as part of the conformity assessment procedure prior to placing the device on the market, as well as to support its ongoing marketing.

With CER Rev 4 in effect already, developing and maintaining Clinical Evaluation Reports (CER) has become a very high priority for medical device companies.

Current Challenges in CER Writing

In the EU, the medical device conformity assessments dwell on the technical documentation and clinical evaluation. A clinical evaluation is needed for medical devices of all risk classes, and it is vital in determining the clinical study requirements.

The Clinical Evaluation Assessment Report template has recently been published by the Medical Device Coordination Group (MDCG). The requirements in CER Rev 4 differ significantly compared to the previous versions, making it highly unlikely that updating the CER solely with literature will be accepted. The rules for planning and updating clinical evaluations have been substantially tightened.

What is the Solution?

As Rev 4 has a different outlook for equivalence and predicate devices, assembling the right team, bringing together expertise from medical, regulatory, technical, and scientific disciplines, is essential to ensure higher-quality CERs that meet notified body standards and communicate accurate, meaningful information to the healthcare community.