QmedConsulting
Enabling Better Health

Clinical Evaluation Report (CER)

MDD 93/42/EEC and MEDDEV 2.7/1 ver. 4 Compliance

QmedConsulting
Enabling Better Health

Welcome

We provide full-service medical device CRO expertise to people who change healthcare.

Qmed Consulting is a global full-service Contract Research Organization (CRO) based near Copenhagen, Denmark. We provide strategic consulting services in connection with medical device approval as well as best-in-class expertise in clinical affairs, regulatory affairs, quality management and commercial healthcare.

CLINICAL AFFAIRS

REGULATORY AFFAIRS

QUALITY MANAGEMENT

COMMERCIAL HEALTHCARE

CONCEPT AND PRODUCT DEVELOPMENT

EU AUTHORISED REPRESENTATIVE

Founded in 2006, **Qmed Consulting** is a privately owned CRO with offices located near Copenhagen, Denmark

Purpose
To pave the way for new medical device approvals that enable more efficient healthcare procedures while improving patient safety, outcomes and quality of life, thus helping inventors and investors achieve success.

Proposition
We offer strategic consulting services based on best-in-class knowledge, experience and competences from a result-oriented and highly motivated team of international medical device advisors, CRO specialists and commercial healthcare experts.

Promise
We help create success for our clients based on international best practices, close personal collaboration, and device approval solutions that serve their best interests.

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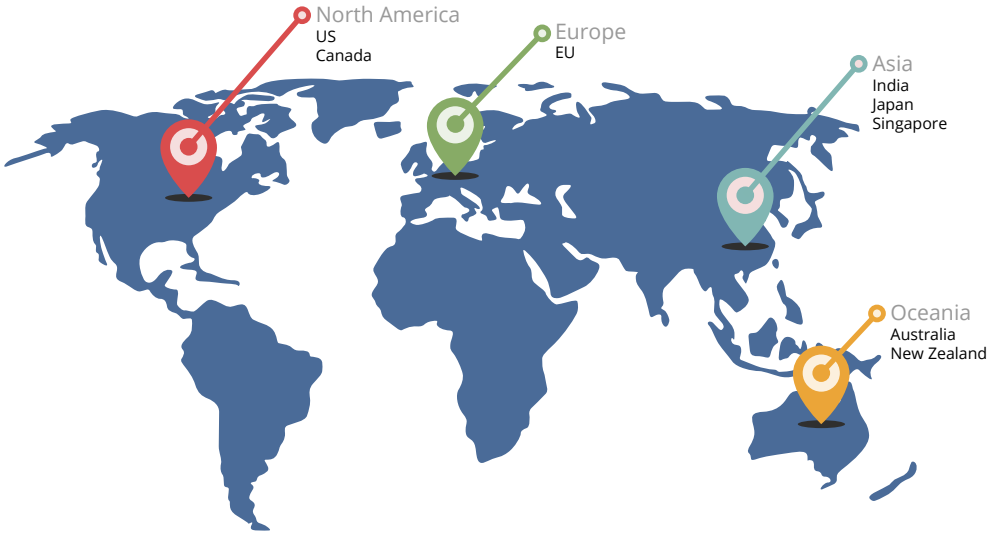
Our Expertise

Global expertise when and where you need it.

Global Alliance
Qmed Consulting has learned that success comes with working closely with other organizations.

Trusted Subcontractor
Qmed Consulting is the Scandinavian subcontractor to Top 40 medical device companies and global CROs since its establishment in 2006.

Trusted Partner to Hospitals and Investigators
It is of high importance to Qmed Consulting to build trusted relationships with hospitals. Our employees have daily contact with healthcare personnel. We have a working relationship with more than 100 hospitals globally.



The Clinical Evaluation Report (CER)

Introduction

A new version of the European Guideline MEDDEV 2.7/1 rev 4 was issued in June 2016 affecting all companies that market medical devices in Europe.

The MEDDEV is a guidance document and therefore there is no implementation period. Therefore, it is important to start using the new version. The general principle in performing a clinical evaluation report remains the same. The manufacturer must use clinical data to demonstrate compliance with relevant Essential Requirements. Such data still has to be based on investigations done with the subject device and data from post-market surveillance (PMS) activities and vigilance activities where appropriate.

Unchanged fundamentals

The Clinical Evaluation Report is a four-legged table: leg one represents any newly-conducted clinical investigations on your device. Leg two reports your unpublished data, such as biological safety data, bench testing data, post-marketing surveillance data, or complaint and experience records. The third leg includes a literature review of clinical investigations published on own or similar devices. Leg four is the risk analysis.

Furthermore, the literature review may serve as the primary source of clinical evidence to support commercialization and may justify the decision not to conduct clinical investigations.

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Clinical Evaluation Report (CER)

New emphasis

When writing a Clinical Evaluation Report you are required to ensure the essential requirements for safety, performance and risk-benefit (respectively numbers 1, 3 and 6 in Annex I of the MDD) are supported with adequate clinical evidence in the Clinical Evaluation Report. Depending on the nature and risk level of the device, demonstrating conformity to other essential requirements may also necessitate clinical evidence in the Clinical Evaluation Report.

Any gaps in showing conformity to the essential requirements require a clinical investigation. If you have not performed a clinical investigation a justication is necessary to assure that risk, claims, biocompatibility and non-clinical data is sufficient to ensure compliance with the essential requirements.

Sufficient clinical evidence

Sufficient clinical evidence is necessary to support the intended use, the clinical performance and benefits, the usability aspects for the intended users, the risk avoidance and mitigation information and the suitability of the IFU for the intended users.

Databases

PubMed is a free, online database from the US National Library of Medicine, which includes over 24 million citations dating back to 1948. PubMed is widely used as a tool for performing literature searches. The new guideline emphasis that PubMed searches are not sufficient as failed studies are not published in high profile journals, therefore searches in other databases will have to be performed and a justification for choice will have to be assessed, the databases below show some examples:

EMBASE, owned by Elsevier Publishing, gives access to PubMed citations in addition to the other 2,000 global medical journals, using full-featured Boolean logic under the product name of EMBASE.com. Ovid and Dialog are simply alternate services with different front-ends to access the same data.

Prospero, includes protocol details for systematic reviews relevant to health and social care, welfare, public health, education, crime, justice, and international development, where there is a health related outcome. Systematic review protocols on PROSPERO can include any type of any study design. Reviews of reviews and reviews of methodological issues that contain at least one outcome of direct patient or clinical relevance are also accepted.

Cochrane, is a global independent network of researchers, professionals, patients, care-givers, and people interested in health. Cochrane provides accessible health information that is free from commercial sponsorship and other conflicts of interest.

Clinical Equivalence

The concept of Clinical equivalence has been clearly defined and the room for interpretation has become smaller (Appendix A1 of the MEDDEV covers equivalence).

The comparator used to show clinical equivalence must be equivalent on **all** criteria: Clinical, Technical and Biological. The comparison has to be with a single comparator (you are not able to use composite construction) and all three groups of characteristics need to be fulfilled.

In practice, the use of equivalence will be limited to devices of the same manufacturer, and qualifying devices must be part of the same device family. Only CE-marked devices are admissible to show Clinical equivalence.

Qualification of evaluators of clinical evaluation reports

Clinical evaluation should be conducted by a suitably qualified individual or a team. The manufacturer defines what is required by the evaluators to be in line with the nature of the device.

The evaluators should possess knowledge of research methodology, information management, regulatory requirements, medical writing, the device technology, diagnosis and management of the conditions intended to be diagnosed or managed by the device.

The evaluators should have a higher degree education in the respective field and 5 years of documented professional experience or 10 years of documented professional experience if a degree is not a prerequisite for a given task. If the level of expertise by the evaluator is less, this has to be duly justified. The manufacturer has to assure that a declaration of interests for the evaluators are available.

Post-Market Surveillance

The frequency to update the CER should be justified by the manufacturer taking into account the risk classification of the device.

Medical devices which have a high-risk classification or are not well-established should be updated annually.

Well-established medical devices or low-risk devices should be updated every 2-5 years with a justification for the frequencies.

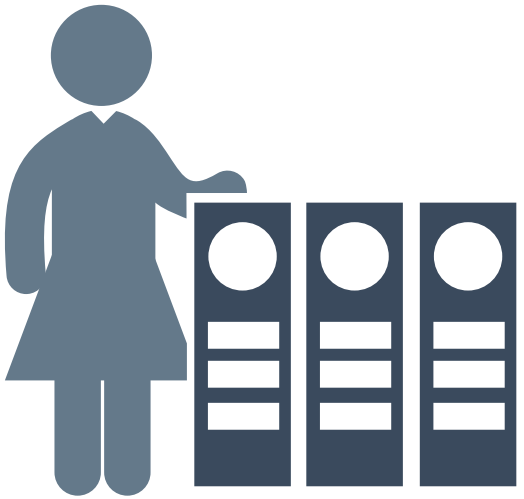

Table of Contents for a CER (example)

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How can Qmed help

Clinical Evaluation Reports are more important in Europe today than ever before. If conducting a well-designed report seems daunting and time-consuming, especially with Notified Bodies demanding updates on commercial devices, let us help you performing an initial GAP assessment of your existing CERs and what needs to be done. With trained global professionals (we have experts in Asia, the EU, and the US), we have the capability to address all four legs of the Clinical Evaluation Report on your behalf. Please contact us with your request.

CERs written within all classes in cardiology, radiology and imaging, gastroenterology, general surgery, neurological devices, anaesthesie and other class I products.

STED reports reviewed including CER for NB within aortic intervention, neurology, gastroenterology, fertility, dental, dermatology, gynecology, IVD, wound care, urology, and general surgery.

Our experts

Helene Quie: Conducted several Clinical Evaluation Reports on all classes or products and numerous indications. She also conducted training on how to compile and write CER for Notified body and companies worldwide.

Pierre Pelletier: Experience writing Clinical Evaluation Reports in dentistry (class IIa), diagnostic imaging (class IIa & IIb), radiology (class IIb & III) and geriatrics (class I). Reviewer for Clinical Evaluation Reports in audiology.

Merete Hansen: Experience writing Clinical Evaluation Reports for high-risk class medical devices (class IIb and III) and accessories for a large medical device company.

Stephanie John: Extended knowledge writing Clinical Evaluation Reports within all classes and several indications. Stephanie has a detailed knowledge on Notified Body requirements to content of the Clinical Evaluation Report.

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www.qmed-consulting.com

Qmed Consulting A/S - Ørnevej 2, 4600 Køge, Denmark
Tel.: +45 56 64 10 10 Email: info@qmed-consulting.com