CER Writing

CBCC GLOBAL RESEARCH

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 a medical 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 been on 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 estimating the clinical study requirements.

The clinical evaluation assessment report template has been recently published by the Medical Device Coordination Group (MDCG). The requirement in CER Rev 4 are very different compared to the previous versions that make updating the CER just with literature highly unlikely to get accepted. The rules for planning and updating clinical evaluations have been tightened.

WHAT IS THE SOLUTION?

- As Rev 4 has a different outlook for “Equivalence / Predicate”, right team comprising expertise from medical, regulatory, technical and scientific disciplines is essential to ensure higher quality of CER that meet standards of notified bodies and communicate right information to healthcare community.

USA
6501 Truxtun Avenue,
Bakersfield, CA 93309

India
2nd Floor, Skoda House,
S G Highway, Ahmedabad-382210,
Gujarat

bd@cbcc.global
www.cbcc.global