Cost-effective and fit-for purpose CER writing solutions for medical devices

WHY CBCC



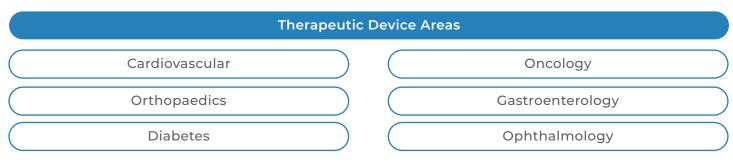
A clinical evaluation is carried out by experts in order to ensure conformity with all requirements.

- We provide expertise in developing new CERs and updating the existing ones
- We tailor our comprehensive CER writing services to match our client requirements
 We train our writers with to be adept with both, technical writing and in-depth device knowledge
- We are capable to conduct literature reviews and analysis across multiple databases with multiple reviewers
- We act independently on all components with the exception of internal data that is required from the sponsor
- We continuously strive to adapt to new technology-enabled DMS tools that are GDPR and ISO complaint

OUR SERVICES

- End-to-end Clinical Evaluation Report (CER) writing support including literature search and handling periodic updates as per MEDDEV 2.7/1 revision 4 and MDD/AIMDD/EU Medical Device Regulation (MDR) guidelines
- > Developing CER template for your organization
- > Developing standard operating procedure for your team to compile PMS data to update CERs
- Identifying, searching, analysing and compiling appropriate scientific literature
- GDPR and ISO compliant DMS tool for your team to collectively contribute to CER writing and integrating PMS data
- > PMS data support for existing devices in the market

EXPERIENCE



With over 10 years of experience in supporting regulatory documents for top 10 medical device companies

Supported 10+ customers for successful submission to BSI, TUV and CFDA requirements

CBCC - THE ANSWERS TO ALL YOUR MDR NEEDS

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