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

CBCC GLOBAL RESEARCH

WHY CBCC

- **CBCC has capabilities and resources to meet all your needs**
- 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

Therapeutic Device Areas

Cardiovascular	Oncology
Orthopaedics	Gastroenterology
Diabetes	Ophthalmology

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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