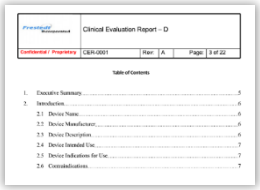
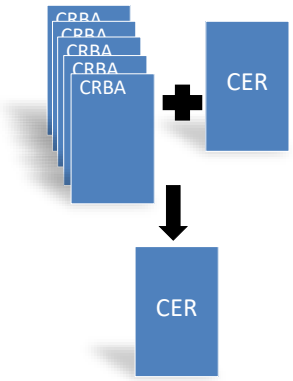
Clinical Research · Regulatory Affairs · Quality Systems · Biomedical Engineering

CALL US TO HELP WITH CLINICAL EVALUATION REPORTS (CERS)

Frestedt Incorporated has authored 100+ CERs using a proprietary preparation process with a proven track record of consistently delivering CERs in compliance with Notified Body requirements (European Union's Council Directive 93/42/EEC and Medical Device Directive (MEDDEV) 2.7.1). The Frestedt process guides the necessary scope, provides structured direction to identify equivalent devices, delivers expert analysis focused on the safety and performance of the device and integrates a stage-gate system to ensure timelines are met and client feedback is incorporated into the CER.



Case Study 1:



A large, fast-growing company had multiple engineering-driven tasks including over 20 clinical risk benefit analyses (CRBAs) and a separate clinical evaluation report (CER) which did not link to their risk-management processes. Frestedt combined the CRBAs and the CER to incorporate risk management reporting into one CER process, which led to a reduced regulatory gap to be compliant with international standards (e.g. ISO 14971 and MEDDEV2.7.1). Frestedt further revised the company's Quality Management System to merge CRBAs and CERs and link them to the risk-management processes in the engineering department.

A streamlined, integrated, interdepartmental system is now in place supported by updated/revised standard operating procedures, work instructions and forms. Frestedt completed dozens of CER/CRBA and trained numerous staff team members. The implementation of the strategy led to over a four-fold reduction in costs.

Case Study 2: A mid-sized medical device company required a CER to remediate Notified Body findings. Frestedt reviewed Notified Body findings and supporting documentation. Systematic literature searches were conducted and the findings were integrated into the CER. Frestedt completed the CER and the CER was cleared by the Notified Body without further remediation. Client costs were reduced by allocating expert resources at each level of the CER development process.

Services offered

Frestedt offers full life-cycle clinical, quality and regulatory assistance.

- Literature Search/Abstraction
- Post-Market Experience Analysis
- Competitor Evaluation
- Risk-Benefit Analysis
- Clinical Trial (CT) Preparation
- CT Protocol Development
- CT Monitoring/Data Collection
- Clinical expert consulting
- Regulatory Submissions
- GRAS Panel Meetings
- Claim Substantiation
- Auditing (on/off site)
- SOP Development
- Work instructions/Forms

FRESTEDT, YOUR FIRST CALL FOR HELP (952) 426-1747

9445 Minnetonka Blvd. St. Louis Park, MN 55426
www.frestedt.com Email: info@frestedt.com Tel: (952) 426-1747 Fax: (952) 426-1757