Clinical Evaluation Report (CER) Writer/Manager
Job Description
07Dec2017

Frestedt Inc is growing and needs an experienced CER writer and manager. The ideal candidate must have previous experience writing and managing the development of CERs. Frestedt Inc is a small, agile work environment where good people work on good projects with good process. You'll work with a strong internal team and an experienced management team who believes in doing excellent, detailed work. We are proud to deliver our products and services to our clients. We value each employee, we learn from our past experiences, we celebrate our successes and we have a little fun along the way.

General Purpose

To develop and write clinical evaluation reports (CER) for pre- and post-market devices, while ensuring consistency with regulations, quality standards, commitments and goals.

Essential Functions and Responsibilities

- Writing coherent, convincing CERs by organizing and evaluating large amounts of scientific/clinical/medical data
- Managing CER writing by planning, identifying, appraising and analyzing clinical data then writing the CER including conclusions based on expert knowledge
- Ensuring quality by following internal and external SOPs, Work Instructions and Forms/Templates for successful preparation of robust CERs and other documents
- Assisting with other clinical, regulatory, quality and engineering projects as assigned
- Responsible to acquire, interpret, analyze and draw conclusions from clinical data from clinical trials, literature and experiences for a wide variety of medical devices
- Responsible to communicate scientific content in a clear, concise manner
- Other duties as assigned

Qualifications:

- Master's Degree or PhD (preferred) in a scientific discipline
- At least 3 years CER writing experience with solid knowledge of Med Dev 2.7/1, rev 4
- At least 3 years clinical, regulatory, quality and/or engineering work experience
- Advanced computer skills with Outlook, Word, Excel, PowerPoint, etc.
- Able to productively interact with Frestedt Inc. staff and client companies including corporate executives, research sites and research subjects

Requirements:

- Must be focused, efficient, detail oriented and able to work independently
- Able to read, analyze and implement regulations, standards and guidance
- Demonstrated ability to manage projects (take minutes, multi-task, prioritize and ensure reliability and quality while executing projects on time and on budget)
- Strong written and oral communication skills
- Able to travel to client sites as needed (approximately 10% travel)

- Must have excellent critical thinking and problem-solving skills
- Able to reprioritize immediately as new projects arrive
- Passion for clinical research, regulatory, quality and engineering affairs activities for pharmaceutical, medical device and food industries