Job Title:	Clinical Safety Specialist
Reports To:	Director, Clinical Affairs
Location:	900 Long Lake Road, Suite 300, New Brighton, MN 55112
Date:	2017 December 8

Purpose/Role

A brief description of the primary responsibilities for which the employee is accountable

The Clinical Safety Specialist will have primary responsibility for coordinating death and adverse event collection, assessment, adjudication and analysis in collaboration with other members of the Clinical Affairs Team and ensure Regulatory Affairs is notified of events that require reporting in compliance with applicable regulatory standards and internal requirements.

Position Description

A listing of the deliverables to be accomplished, including specific duties/activities that make up the job

PRINCIPAL DUTIES AND RESPONSIBILITIES:

- Provides review, evaluation of, and tracking of incoming adverse events (AEs) including follow-up of ongoing events
- Collaborates with sites/monitors/CRO to ensure comprehensive information is available for full review of adverse events
- Collaborates with Regulatory Affairs, Clinical Affairs, and the Medical Director on events requiring expedited review or reporting
- Assists with preparation of safety reporting for annual reports, clinical study reports, investigator brochure updates, and other documents as required
- Drafts AE narratives
- Coordinates, participates in the preparation for, and attends (as applicable), CEC and DSMB meetings
- Ensures consistency and compliance in application of protocol definitions for adjudication outcomes
- Provides ongoing updates regarding adverse event management including trending and signal detection including weekly review of AEs with applicable study teams
- Ensures appropriate distribution and notification of AEs to appropriate personnel and clinical sites, as needed
- Liaison for safety-related questions from Clinical Affairs, CRO, monitors, Field Clinical Specialists, etc.
- Maintains knowledge of current FDA, ISO, competent authority, IRB, REB, and EC regulatory rules and policies affecting AE reporting
- Provides input to the development and management of study related documents including clinical protocols, case report forms, monitoring plans, study manuals, and other study tools related to adverse event reporting and definitions
- Provides input into the planning of, preparing materials for, and presenting of adverse event information at investigator and coordinator meetings
- Assists in training of study personnel regarding the adverse event definitions per protocol
- Assists with training of AE definitions per study protocol for investigators, research coordinators, and other study personnel, as requested by the study team
- Collaborates on additional Clinical Affair's activities, as required

Qualifications

Represents the desired qualifications but may not reflect the employee's existing qualifications

Education:

- RN or equivalent healthcare experience with a Bachelor's degree

Experience:

- 3-5 years of clinical research experience, including clinical safety events management
- Experience in cardiovascular/heart valve disease
- Experience with medical device clinical studies
- Experience with patient care in a hospital setting is highly desired

Skills:

- Advanced communication skills, both orally and in writing
- Expertise with medical terminology, acronyms, and ability to communicate effectively with medical personnel
- Proficient computer skills (Microsoft Word, Excel, PowerPoint, etc.)
- Good organizational and problem-solving skills
- High attention to detail and degree of accuracy
- Familiarity with electronic data capture (EDC) systems
- Works independently and in a team environment
- Experience coordinating, prioritizing, setting timelines, and multi-tasking
- Expertise with medical device regulations and compliance guidelines for clinical studies including Good Clinical Practice (GCP) and other relevant Guidance documents (ICH, ISO, FDA, etc.)
- Professional demeanor and appearance

Other:

- Position requires approximately 10% travel
- Sit or stand for 8-10 hours per day
- Use of hands to manipulate office equipment including continuous computer use with repetitive motion to wrists, hands and fingers
- Required to see, speak and hear
- Occasionally required to bend, lift, reach, or stoop

Please note that only applicants local to the TWIN CITIES will be considered for this position.

The purpose of this description is to provide a concise statement of the major responsibilities of this position in a standardized format. It is not intended to describe all the elements of the work that may be performed and should not serve as the sole criteria for personnel decisions and action.

Approvals:

_____ _____

Employee (signature) Date

_____ _____

Manager (signature) Date