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JOB DESCRIPTION

Position Title: Clinical Research Associate II

Reports to: Clinical Research Manager

Department: Clinical

FLSA Status: Exempt

PURPOSE OF JOB: Assist in the design, planning and execution of clinical research trials by effectively managing investigational sites, assisting with the development of study protocols, preparing CRFs and IRB submissions, and ensuring compliance with study protocols, FDA regulations, IRB requirements and company clinical strategy.

MAJOR DUTIES AND RESPONSIBILITIES:

- Assist in planning, designing and executing clinical research trials
- Manage several investigational sites from trial start to finish with limited supervision
- Act as a company representative at clinical cases by traveling to investigational sites, observing and preparing reports as required, and ensuring proper collection of data
- Train and advise clinical study coordinators on the collection of clinical data, data entry into electronic database system (EDC) and good documentation practices
- Conduct regular visits at investigational sites to monitor study activities and assure adherence to study protocols, company's SOPs and compliance with GCP guidelines, FDA regulations and IRB requirements
- Work with investigational sites on discrepancy resolution, protocol deviations
- Conduct study qualification, initiation and closeout visits. Prepare site visit reports as required
- Participate in developing and managing trial budgets
- Train, mentor and advise junior and consultant CRAs
- Attend relevant scientific and/or medical meetings as directed
- Support company policies and procedures for compliance with FDA regulations

EDUCATION REQUIREMENTS: Minimum of BS degree preferably in Life Sciences or related field. RN or other professional degree highly desirable. Certification in clinical trial conduct is preferred.

EXPERIENCE: 3-5 years of experience in conducting industry-sponsored clinical trials, preferably with medical devices in the Ear, Nose and Throat space involving surgery. Demonstrated experience managing at least 2 trials from start to closure. Experience with data collection and monitoring using EDC. Working knowledge of clinical research methodology, GCPs and ICH guidelines and FDA regulations. Experience in clinical quality assurance and/or participation in clinical study audits preferred.

OTHER QUALIFICATIONS: Excellent interpersonal, managerial and organizational skills. Excellent writing and presentation skills. Ability to complete tasks independently and efficiently with attention to detail and in a timely manner. Ability to travel 50- 80% of time.

This job description is not all inclusive. Incumbents may be required to complete other miscellaneous responsibilities as required.