JOB DESCRIPTION

Position Title:	Clinical Research Associate
Reports to:	Clinical Research Manager
Department:	Clinical
FLSA Status:	Exempt

PURPOSE OF JOB: Assist in the design, planning and conduct clinical research trials by effectively managing investigational sites, coordinating the activities of study coordinators and investigators and by ensuring compliance with study protocols, FDA regulations, IRB requirements and overall clinical objectives.

MAJOR DUTIES AND RESPONSIBILITIES:

- Under review of Clinical Research Manager, plan design, and implement clinical research projects, or portions of research projects.
- Act as a company representative at clinical cases by traveling to investigational sites, observing and preparing written reports on procedures as required, and ensuring proper collection of data.
- Monitor patient screening and enrollment rates at assigned investigational study sites.
- Monitor ongoing compliance to study protocols. Ensure adherence to FDA and IRB requirements.
- Work with investigators and site coordinators to quickly and effectively resolve discrepancies.
- Review source documentation, case report forms, and data reports for accuracy and ensure the timely submission of such documentation.
- Develop materials and perform site training and in-services during clinical studies.
- Coordinate meetings with site coordinators and investigators.
- Identify and prepare written reports for serious or unexpected adverse events.
- Manage investigational device accountability according to SOPs (receipt from manufacturing, distribution to study sites, monitoring site's device accountability records, tracking returned devices back to inventory).
- Prepare accurate and timely reports (e.g. site qualification reports, site initiation reports, monitoring reports, site closure reports) to management.
- Attend relevant scientific and/or medical meetings as directed.
- Support company goals and objectives, policies and procedures, Good Clinical Practices, and FDA regulations.

EDUCATION REQUIREMENTS: BS in Life Sciences, or related field. Certification in clinical research preferred.

EXPERIENCE: Minimum 3 years' experience as CRA conducting industry-sponsored medical device or pharmaceutical clinical trials related experience; strong working knowledge of Good Clinical Practices and FDA regulatory requirements. Experience in clinical quality assurance and/or participation in clinical study audits preferred.

OTHER QUALIFICATIONS: Must possess excellent written, verbal communication skills, excellent organizational skill and detail-orientation. Position requires domestic travel 30 to 50% of time, with periods of more frequent travel (up to 80%).

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