JOB DESCRIPTION: EXEMPT	DATE: 09-February-2024
Title: Clinical Site Manager (CSM)	**Reports to:** Sr. Director, Clinical Field Support

FUNCTION

The CSM primary responsibility is to support enrollment, ensuring patients meet eligibility criteria and our device is utilized per the instructions for use. Will support multiple activities for the conduct of clinical research studies, operations, and special projects in compliance with applicable regulatory standards, IRB/EC policies and procedures and internal requirements. This position works directly with study management and the study team.

PRINCIPLE RESPONSIBILITIES

- In person support for all clinical trial enrollments for assigned sites.
- Responsible for driving enrollment in assigned study sites.
- Responsible for coordinating field activities with clinical sites, enrollment, and study execution.
- Assist with overall successful conduct of assigned clinical studies consistent with applicable regulations, guidelines, and policies.
- Interface with and ensure training of Investigators and site staff.
- Assist in follow-up and resolution of site issues.
- Assist in device allocation, reconciliation, accountability, and retrieval.
- Assist with reporting, compliance, review, and conclusion of device events/complaints.
- Able to refer to Standard Operating Procedures (SOPs) for guidance on everyday study tasks.
- Participate in training to enhance knowledge base.

CANDIDATE MUST HAVE / BE:

- Strong verbal and written communication skills, technical and problem-solving skills.
- Prior relationships in the PE thrombectomy space
- Able to read, analyze and interpret general business documents, technical procedures, and standard operating procedures.
- Able to work effectively, independently and on cross-functional teams.
- Able to write reports, business correspondence and procedure manuals effectively.
- Able to frequently use general knowledge of industry regulations, practices, techniques, and standards.
- Develop solutions to a variety of problems of moderate scope and complexity.
- Able to refer to policies and regulations for guidance.
- Able to travel by air and car extensively (up to 80%) including overnight and weekends as necessary.

The above statements are intended to describe the general level of work being performed by people assigned to this job. They are not intended to be an exhaustive list of all responsibilities.

JOB REQUIREMENTS *(The minimum qualifications required to adequately perform the job.)*

Minimum Experience:

- Prior PE Thrombectomy or equivalent experience preferred in a commercial role or a clinical background (RN, Tech).

- Must have prior experience working and managing cath labs and clinical areas of the hospital.
- Familiarity with clinical trial operations desired.

Education:

- Bachelor's Degree and 1+ year of experience in clinical / clinical research setting.
- Knowledge of ICH and GCP Guidelines
- Strong computer literacy with Microsoft Office

Additional Requirements:

- Must have a valid driver's license
- Must become vendor credentialed with all applicable credentialing services.

Environmental Situation:

- General office environment
- Laboratory environment
- Extensive travel required
- Medical device research and manufacturing environment

Physical Functionality:

- Includes varying work schedule
- Prolonged periods of sitting, standing and walking
- Up to 80% overnight travel by automobile, train and aircraft
- Occasional travel on weekends

ADDITIONAL SKILLS

- Flexible and able to work with deadlines.
- Team player who can also operate alone.
- Solution-oriented and problem-solving attitude.
- Good project management and organizational skills. Ability to prioritize work.
- Excellent verbal and written skills, good organizational, interpersonal, and team skills.
- Hands-on team player with the ability to work in a fast paced, dynamic start-up environment.
- Experience working with small cross-function product/process development teams.