brighturo

Job Description

Job title: Senior Manager of Clinical Operations

Department: Clinical

Reports to: CSO

☒ **Full-time** ☐ **Part-time**	☒ **Exempt** ☐ **Nonexempt**

Essential Duties and Responsibilities:

The Senior Manager of Clinical Operations is responsible for providing the scientific and operational expertise required to conduct clinical trials in accordance with appropriate regulatory requirements in support of the development and commercialization of the Bright Uro Glean Urodynamics System. The qualified candidate will work with the internal Clinical Team and with clinical investigational sites to properly execute all phases of clinical trials. Responsibilities will include:

- Participates in the development of the clinical strategy, clinical study design, and protocol development.
- Contributes to supporting clinical study documents including study protocols, study amendments, study manuals, Informed Consent Forms (ICFs), Case Report Forms (CRFs), Investigator Brochures (IBs) and other study related documents as required.
- Manages relationship with one or more assigned investigator sites and vendors including facilitating and participating in budget development, contract negotiations and expenditure oversight.
- Contributes to identification and review of potential sites for inclusion in studies.
- Plans, coordinates, and participates in investigator meetings including developing and presenting assigned sections of the meeting agenda/content.
- Recommends strategies for and oversees the execution of activities associated with clinical monitoring, safety, eligibility, and enrollment.
- Conducts periodic review of clinical trial data to ensure timely, consistent, and accurate data flow.
- Maintains study related documents and files.
- Compiles and reviews assigned portions of reports for submission to regulatory agencies and Institutional Review Boards (IRB).
- Addresses and resolves questions from sites and trial monitors regarding trial conduct.
- White paper, journal publication, and grant writing experience a plus.
- Perform related duties as assigned by the CSO.

Education and/or Work Experience Requirements:

- Bachelor of Science or Biomedical Engineering, MD or graduate degree preferred but not required.
- 5+ years of CRA/Clinical Operations experience with relevant FDA regulated industry experience preferably with Class II Medical Device Products.
- Experience with IDE submissions and Clinical Evaluation Reports a plus.
- Excellent verbal and written communication skills, including ability to effectively communicate with internal and external customers including clinical staff.
- Excellent computer proficiency (MS Office – Outlook, Word, Excel, and PowerPoint).
- Must be able to work under pressure and meet deadlines, while maintaining a positive attitude and providing exemplary customer service.
- Ability to work independently and to carry out assignments to completion within parameters of instructions given, prescribed routines, and standard accepted practices.

Physical Requirements:

- High level of personal/professional integrity and trustworthiness with strong work ethic and the ability to work independently.
- Ability to develop and manage a high performance team focused on accountability and meeting and exceeding expectations.
- Proven technical leadership with a strong results orientation, positive “can do” attitude and a sense of urgency to get things done.
- Attention to detail.
- Strong self-organization and documentation skills.

Print Employee Name:

Employee Signature/Date:

Manager Signature/Date: