Senior Clinical R&D Engineer

Laxmi Therapeutic Devices – Pasadena, CA

Job Description:

Laxmi started in 2016 with an idea and a mission to improve individual care with improved Continuous Glucose Monitoring Technology. Laxmi Therapeutic Devices is applying cutting edge advances in sensing, microfabrication and electronics to create the next generation of wearable diagnostic devices. We are connecting and empowering consumers, healthcare professionals and treatment providers with personalized medicine. Our versatile biosensor platform enables rapid, inexpensive, and dependable screening of important analytes, with a focus on glucose sensing for our first product.

The primary duties of the Senior Clinical Engineer is to manage clinical testing, both internal as well as external from study start-up activities through the follow-up phases of clinical trials. Tasks would involve, but not be limited to: the overall management of all aspects of the site regulatory process, clinical data collection, investigator and research coordinator relationships and maintenance, conducting site visits for initiation, site monitoring and closeout, maintaining device accountability, maintaining study records and communicating with appropriate site staff and investigators for the successful completion of clinical studies.

In addition, this person will be able to work as a part of the R&D team as an engineer. While this portion of responsibilities will not be primary, this position will support the R&D team with not only clinical insight but product development capabilities (systems, mechanical, electrical, or software engineering are all acceptable).

Core Job Responsibilities:

- Design, manage, and conduct internal simulated use studies and other functional testing
- Development and execution of clinical protocols
- CRO and PI primary interface
- Clinical site(s) primary engineering contact
- Interface with clinicians and KOL's on behalf of the company
- Key person coordinating all aspects of clinical trials
- Support enrollment at specific clinical sites if necessary
- Accurate and complete data collection during clinical trial procedures
- Work collaboratively and effectively with investigators, coordinators, and site staff
- Assist in the management of clinical site monitoring plans/procedures
- Oversee and/or conduct site initiation, staff and investigator training
- Assist in maintaining clinical site compliance with company policies and other appropriate regulatory guidelines
- Serve as the clinical trial and protocol expert, ensuring each site's protocol compliance
- Provide feedback to management on the ongoing progress of trials and study related activities
- May be required to manage resources (including people) who are internal or external to the company
- Must be comfortable working with medical equipment

- Provide R&D engineering and/or engineering support in a chosen discipline for the development of the Laxmi product when not supporting trials

This person will be required to work independently, but will also understand how to impact company objectives from product development to the clinic and will need to be comfortable influences overall project goals. We expect all of our employees to be collaborative team players, demonstrating open-mindedness and flexibility while having the ability to stand up for what is right in a cross-functional setting.

Qualifications:

- 5+ years of related experience and a Bachelor's degree in a scientific/engineering discipline or equivalent combination of education and experience (advanced degrees a plus)
- Ideally 3+ years of experience in the diabetes field
- Knowledge of medical device regulations including clinical trial practices and regulations
- Ability to work with electronic data systems and clinical trial management tools
- Demonstrated problem-solving abilities in managing clinical sites and demonstrated tactfulness and diplomacy in dealing with study coordinators and physicians
- Excellent organizational skills and ability to juggle assignments without losing efficiency
- Detail-oriented, well organized, self-motivated, and independent work style with the ability to initiate and follow through on assignments
- Leadership capabilities; teamwork oriented; ability to work in cross-functional environment
- Analytical, planning, and communication skills in a dynamic startup environment
- Well-developed interpersonal skills; strong in providing education on complex scientific/clinical issues in a crisp and clear manner to both a peer and larger audience
- Anticipates and provides solutions for challenges
- Exercises good judgment when working independently
- Strong verbal and written communication skills with the ability to produce accurate, punctual reports/information, as required and thoroughly share information with others. Must be able to read, write and speak effectively
- Ability to seek (and give) constructive feedback, build relationships, promote teamwork
- Able to quickly adapt to change in a startup environment

Job Type: Full-time