Clinical Research Associate

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 Clinical Research Associate will report to the Clinical Trial Manager and is responsible for supporting clinical activities including trial planning, organization, and trial execution. Additional responsibilities include supporting the Clinical Trial Manager with clinical protocol creation, clinical SOPs, and regulatory submissions. The candidate will work with cross-functional teams including chemistry, mechanical, and electrical disciplines, as well as technicians and scientists on in-house and external clinical trials. The candidate will also interface with clinical study subjects and principal investigators.

The ideal candidate will be open to working on a broad range of tasks and to support important deliverables under the Clinical and Regulatory workstreams. After training, the ideal candidate will be able to work independently with subject recruitment, subject consent forms and screening, and with protocol execution during a clinical trial. The candidate will have the opportunity to experience a growing start-up and develop industry experience and skills across a broad range of responsibilities.

Core Job Responsibilities:

- Work collaboratively with the Clinical Trial Manager, multi-disciplinary science and engineering teams to develop clinical trial protocols, plan and coordinate trial logistics, and complete all required documentation and tracking.
- Work collaboratively with external, contracted Clinical and Regulatory to support the regulatory submission strategy and clinical execution strategy.
- Manage multiple tasks and prioritize effectively with limited oversight.
- Identify areas for improvement in the use of the sensor system during clinical trial execution and communicate them effectively to development teams.
- Create protocols to safely clean, set up, test, and run study devices.
- Document clinical trial subject and device information during in-house wear studies and clinical trials.
- Support initial and limited troubleshooting of study devices along with technical team members.
- Maintain clinical device physical inventory and tracking documentation.
- Work hands on with clinical equipment (e.g., autoclave, Keyence microscope, YSI, digital camera, computer software for data collection, laptops, mobile phones, study devices, tools and fixtures).

- Collaborate with Project Managers and the Clinical Trial Manager to create accurate project estimates, schedules, and milestones.

Qualifications:

- BS in STEM discipline or related degree with approximately 2 years' experience working in a clinical environment and working with medical devices or procedures.
- Experience following structured test procedures, running clinical trials, and similar experiences.
- Experience with IRB regulatory submissions.
- Demonstrated ability to work in a start-up or other fast-paced environments.
- Highly motivated, well organized, and able to manage multiple priorities simultaneously.
- Excellent written and verbal communication skills.

Preferred Qualifications:

- Experience with finger stick capillary blood draws for glucose testing
- 3 years medical device experience, preferably with miniaturized portables or electromechanical wearables.
- Experience with FDA IDE, 510k, and PMA processes.
- Experience within the diabetes market.
- Experience with Medical Device Design Control, QSR 21 CFR Part 820, Medical Devices and Regulatory strategies for FDA and 510k along with CE Mark
- The ability to quickly adapt to a fast-paced and fast-changing environment.

Travel: Up to 10% travel may be required

Job Type: Full-time