Principal Systems Engineer

R&D

Laxmi Therapeutic Devices – Goleta, CA

Job Description:

Laxmi Therapeutic Devices is changing the world, 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 product platform enables rapid, inexpensive and dependable screening of important analytes, with the focus of glucose sensing being our first product.

The primary duties of this Principal Systems Engineering position are to drive the architecture of a Continuous Glucose Monitoring System from early development through commercial release. This includes input documentation such as User Needs, Market Needs, and Product Requirements. Leadership of cross functional teams with a vision for continuous integration of various functional systems. Exceptional understanding of medical device regulatory path, balancing product development and adherence to the quality system and standards, and communication skills to bring alignment

Responsibilities will include working with a cross-disciplinary team to architect and implement devices and systems in line with company goals. Additionally, organization and prioritization of deliverables with clearly communicated responsibilities in conjunction with project management team and involvement in project planning will also be responsibilities in this position.

This position supports the future growth of the company as we seek to commercialize a cutting-edge new device that will significantly improve quality of life for our customers.

Core Job Responsibilities:

- Articulate long-term product vision and Develop actionable strategies for early technology development as it pertains to the business and business drivers.
- Break-down complex business needs and translate them into actionable system level projects to address those needs.
- Develop and foster internal relationships with functional teams.
- Manage interdependencies and coordination between the various technology efforts, driving all key system-level decisions.
- Provide SME support through development as technologies are transferred beyond Phase 0.
- Develop Technical Solutions in keeping with system requirements and business goals in collaboration with Chemistry, Electrical, and Manufacturing teams.
- Identify systems needs at the team and company level and provide proposals to fill those needs.
- Write and/or review technical documentation to drive system inputs/outputs and complex integration.
- Present work to cross functional teams in technical design review meetings for critical deliverables

- Collaborate with cross-functional stakeholders to develop requirements for new product development, electro-mechanical test systems, and test fixtures.
- Engage in conceptual idea generation and intellectual property development
- Other duties as assigned

Qualifications:

- Previous direct involvement in Medical Device product and/or technology development
- Track record of and ability to run self-directed projects, maintain timelines, transfer technology and execute projects in an early-stage technical environment
- Proven ability to organize, analyze, and interpret data to generate insights and conclusions
- Proven ability to deal with ambiguity/uncertainty and a willingness to try new/challenging things
- Command of statistical analytical methods including reliability allocation & prediction
- Proven ability to work hands-on and independently in a fast-paced environment
- Strong interpersonal and teamwork skills
- Ability to communicate complexity in a simple and straightforward way
- Proficiency with Microsoft Office Products
- BS or higher in Engineering and/or related disciplines
- 10+ years' experience in industry
- Experience in commercialization of advanced technology preferred
- Small-part, high-volume product design experience with high proficiency in Design for Manufacturability preferred
- Knowledge of ISO13485/FDA 21 CFR Part 820 Quality Systems, and FDA requirements

Preferred Qualifications:

- Previous experience in the design and development of small electromechanical systems for high volume (100M+/year) production.
- Previous experience working in a start-up or early-stage environment
- Specific SME knowledge in one or more of the following technology spaces: wearables, needles/micro-needles, patch/adhesives, batteries, sealing technologies, flexible circuits, electronics packages, sensor technologies.

Workplace Type

- The Workplace Type for this role is on site. Based on the nature of your role you will have an assigned desk or office located at a Laxmi site and should plan to be onsite approximately 4-5 days per week.

Travel

- Up to 10% travel may be required.

Background Check

- Candidate may be required to submit to background and/or reference checks.

Salary Range

- $140,000 – $150,000 annually

Job Type: Full-time