JOB DESCRIPTION

Position Title: Sr. Electrical Engineer

Reports to: VP of Engineering

Department: R&D Engineering

ABOUT THERANOVA: TheraNova is a medical device start-up incubator developing innovative solutions to some of the most challenging medical problems. We are a dynamic, energetic company in San Francisco, CA, with over 15 incubating and spun-out companies that range in the development cycle from concept through commercialization. We are looking for a Sr. Electrical Engineer to play a key role in device development and manufacturing.

POSITION DESCRIPTION: You will be leading the company's engineering efforts for electrical and electro-mechanical design and development of medical device products. Working with the VP of R&D, VP of Engineering, and Project Managers, you will provide the knowledge, innovation, and design of products from initial concept, through verification & validation, clinical evaluation, production, and commercialization. You will be responsible for ensuring that products are designed in accordance with the Quality Management System and medical electrical equipment standards. This role will include managing work to project budgets and timelines, providing technical expertise, and working with mechanical, software, and quality engineers to drive projects to completion. The right candidate for this role will use a background in developing electrical subsystems to create well engineered, clinically effective, user friendly, and reliable medical products.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Lead electrical engineer responsible for design and development of medical devices.
- Apply engineering knowledge to the design, development and manufacturing of new products as well as process changes and enhancements.
- Collaborate on multi-discipline engineering development and manufacturing including mechanical, electronics and software engineering
- Manage the product design, development, documentation, verification, and manufacturing and assembly activities
- Solve engineering and manufacturing problems at the component through system level.
- Maintain design history folders within full QSR systems throughout the development process including pre-production development, verification, clinical and manufacturing release.
- Generate written test protocols and reports.
- Assign work to junior engineers, technicians, consultants, and temporary workers as needed.
- Manage the supplier and vendors and identification of new vendors for a product development and manufacturing.
- Complete projects (including product enhancements) in a manner consistent with corporate objectives.

This job description is not all inclusive. Incumbents may be required to complete other miscellaneous responsibilities as required.

- Contribute to the intellectual property position of the company via invention and patent applications.
- Maintain accurate documentation of concepts, designs, drawings, and processes.
- Provide engineering and technical support of products introduced into both the domestic and international markets as well as physician in-service programs.
- Provide manufacturing engineering support in the resolution of product complaints and/or safety issues.
- Work with mechanical and software engineering, manufacturing, clinical affairs, sales and marketing, and quality assurance staff to coordinate pilot production of new products.
- Support company goals and objectives, policies and procedures, QSR, and FDA regulations.

EDUCATION REQUIREMENTS: BS in Electrical Engineering or similar. MS preferred.

EXPERIENCE REQUIREMENTS:

- MUST be proficient with Altium PCB Design software.
- 3 to 8 years electrical engineering experience, preferably with medical device design background.
- Knowledge of IEC 60601-1 and its application to electrical medical equipment.
- Experience with analog and digital circuitry, including power control, output monitoring, and wireless communication.
- Working knowledge of layout for grounding, isolation, noise, and size constraints.
- Ability to perform complex calculations and data analysis.
- Management of vendors for fabrication and assembly of electrical circuit boards.
- Documentation of electrical systems, including schematics, layouts, manufacturing packages, electrical specification requirements, verification protocols and reports.
- Preferably have experience with medical device quality system requirements, including FDA CFR and/or ISO 13485.
- Excellent written and verbal communication skills.
- Strong problem-solving skills, ability to work in a fast-paced team environment.

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