Job Description
Electrical Engineer

Company Overview:

At Prytime Medical Devices, we have a bold vision: No one should bleed to death, and the sooner you stop bleeding, the better. We are working to revolutionize the care of severely injured patients by enabling trauma teams to gain control of life-threatening bleeding as a bridge to definitive repair. We partner with leading trauma centers to enable endovascular bleeding control through innovative devices and fanatical customer support. In support of our vision, we design, develop, and commercialize minimally invasive solutions for hemorrhage control. Our flagship product is the ER-REBOA-PLUS™ Catheter, the market leader for endovascular aortic occlusion in trauma. In addition to our national roll out of the ER-REBOA-PLUS™ catheter, Prytime was recently granted FDA clearance on a next generation partial REBOA catheter designed specifically to reduce ischemic insult and reperfusion injury called pREBOA-PRO™. We are following a very selective, data intensive approach to releasing this product. In doing so, Prytime is poised to create additional strategic opportunities and to lead the introduction of these devices in trauma and adjacent specialties. Concurrently, we are expanding our product line to include internet enabled embedded systems to provide advanced physiological monitoring and decision support. We look forward to continuing to improve patient outcomes and improving the physician experience as we build and launch of these new devices into the trauma and critical care market.

Position Overview

Reporting directly to the Senior Vice President, Research and Product Development.

Working within a team to develop real-time embedded software systems for new products, from early concept and feasibility work through complete development, testing, release and sustaining of systems and final product.

The individual who will thrive in this position is a self-motivated professional who is a good communicator, technically proficient, detail oriented, and not afraid to learn new skills. This individual enjoys the fast pace and accountability of a small company and wants to make a contribution as we deliver critical medical devices to the market.

Job Responsibilities

- Creation of new innovations and solutions to unmet clinical or business needs, including concept development, invention disclosure and intellectual property protection
- Input to overall project planning and ownership of major portions of development efforts, leading electrical design as a part of project team
- Execution of design and testing according to FDA and EU design controls regulations and guidance
- Part of creation and control to project budget and development schedule for predictable launch planning
- Participate in multiple projects concurrently, as part of cross-functional team at more than one location: working with Work mechanical design, software and system engineers, design quality engineers
- Interface with contract manufacturer organization and external test groups to complete development activities
- Gather correct user requirements to drive creation of engineering design inputs and validation plans for final product, interfacing with Marketing, Sales and clinical advisory panel and external customers
- Electrical design lead to design, document, test, iterate, commercialize and support single/multi-use electronic and electro-mechanical medical devices; generate systems architecture (with software and systems engineers), electrical system design, board schematics and final documentation in Altium
- Demonstrate knowledge of microcontroller-based systems: architecture, software development, synthesis, analysis, problem solving, troubleshooting and testing of embedded software and hardware
- Assemble prototypes, iterate design, and troubleshooting
- Create, execute, document verification and validation test methods

- Design for system sustainability over device lifecycle and provide engineering support for the manufacturing of products
- Assure that product quality and performance targets are appropriately implemented, suitable quality tools are deployed and utilized on projects, and that project schedules are being met
- Lead smaller projects or sub-projects within a program in project manager role

Qualifications

Primary - Required

- BS in electrical engineering
- Minimum 5 years hands-on design and development experience with medical related software-electronic devices
- Experience creating, developing and maintaining system architecture design for complex electro-mechanical medical devices
- Experience designing electrical schematics including fabricating, and testing PCBAs
- Testing and validation of electro-mechanical, software-controlled systems; sterile medical devices
- Competent working under Quality Systems, FDA, ISO regulations including Cybersecurity guidance, IEC 60601 series (general medical electrical safety) and IEC 62304 (Medical Device Software)
- Strong experience with Design of Experiments and statistical techniques
- Excellent ability to multi-task between projects; confident taking initiative
- Excellent interpersonal skills and ability to share knowledge in a team setting

Secondary - Desired

- Experience on multiple medical devices development projects
- Project or technical lead experience which would then allow role to expand to include some project management or design lead ownership
- Experience with creating, documenting and supporting intellectual property (IP)
- Experience using electrical design software Altium
- Excellent interpersonal/communication skills and ability to share knowledge in a team setting
- Knowledge of basic human anatomy; clinical settings such as in vivo labs and hospital emergency or operating rooms

Specific Electrical Engineering skills:

- Safety critical systems engineering, redundancy, FMEA, etc.
- Digital signal processing
- PCB design / Functional prototype / rapid PCB
- EMC mitigation design
- Application specific integrated circuits
- Analog and digital design / simulation
- Spice modeling and simulation
- Broad array of microprocessor experience: CISC, RISC, DSP, PIC, PSoC, TI MSP430, Atmel AVR, Motorola HC05/12/16, 56000DSP, ARM Family single and multi-core, Thunderbolt, Freescale IMX etc.
- High-end Field Programmable Gate Array (FPGA) experience: Xilinx Spartan, Virtex, Artix families; Altera/Intel Cyclone, Stratix families

Regulatory, agency testing & support experience:

- FDA CFR, MDR, ISO 13485, ISO 14971, IEC 62304, IEC 60601-1, IEC 61010, ISO 10555, ISO 11135
- NTRL experience (UL, CSA, ETL, TUV); EMC, EMI, FCC Testing; Sterilization Validation

Travel: Yes as needed per project plans (estimated 10% to other R&D sites and to manufacturing partners)