PRYTIME MEDICAL™

The REBOA Company™

JOB DESCRIPTION – SENIOR/STAFF ENGINEER
PROJECT MANAGER AND MECHANICAL DESIGN LEAD

Mission statement

Prytime Medical's mission is to design and develop rapidly delivered minimally invasive solutions for vascular trauma. The individual who will thrive in this position is a self-motivated, experienced engineer and leader who enjoys the fast pace and accountability of a small company and wants to take high value ideas from concept to commercialization.

Responsibilities include:

- Creation of new innovations and solutions to unmet clinical or business needs, including concept development, invention disclosure and intellectual property protection
- Project planning and execution according to FDA and EU design controls regulations and guidance
- Create and control project budget, resource plans, development schedule for predictable launch planning
- Manage multiple projects concurrently, leading cross-functional team at more than one location
- Interface with contract manufacturer organization and external test groups to complete project
- Lead team to gather correct user requirements, design inputs and validation of final product, interfacing with Marketing, Sales and clinical advisory panel and external customers
- Lead technical teams including mechanical design, electronics, software and system engineers
- Mechanical design lead to design, document, test, iterate, commercialize and support single/multi-use electronic and electro-mechanical medical devices; generate engineering models and drawings in SolidWorks
- Assemble prototypes, iterate design, and support manufacturing
- Create, execute, document verification and validation test methods
- 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

Primary

- BS, MS in mechanical, biomedical engineering
- Minimum 10 years hands-on design and development experience with medical devices; 15 year for Staff level
- Experience on multiple medical devices development projects from concept to commercialization; project or technical lead experience mandatory
- Strong engineering fundamentals (mechanics, dynamics, electrical, fluids, etc); SolidWorks
- Experience molded parts design and manufacturing, fabricating, and testing mechanical designs
- Testing and validation of electro-mechanical, software-controlled systems; sterile medical devices
- Competent working under Quality Systems, FDA and ISO regulations
- Strong experience with Design of Experiments and statistical techniques
- Excellent ability to multi-task between projects; confident taking initiative
- Experience with creating, documenting and supporting intellectual property (IP)
- Excellent interpersonal/communication skills and ability to share knowledge in a team setting

Secondary

- Knowledge of basic human anatomy; clinical settings such as in vivo labs and hospital operating rooms

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, 15%