JOB DESCRIPTION
PRODUCT DEVELOPMENT & SUSTAINING 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-threating 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. We are expanding our team to provide fanatical clinical support to improve outcomes with the launch of these new devices into the trauma and critical care market.

Responsibilities:

- Key role on new product development projects, including feasibility studies, detailed design and pre-development testing. Work may involve CAD design work for mechanical (SolidWorks) and 3D printing of parts, design on tooling and fixtures
- Create product documentation (DHF, DMR) through the Change Order and Releases process
- Create, execute, and document Verification and Validation test methods and technical reports
- Support on-going engineering design and production for sterile and non-sterile medical devices
- Lead smaller sustaining projects relating to design changes, manufacturing process changes and on-going quality work; including creation and control of project budgets, resource plans, development schedules for predictable activity planning across multiple projects in the sustaining portfolio
- As part of development teams or sustaining projects, engineering lead will need to be able to design prototypes, execute tests, and iterate on new designs or changes to existing products
- Review and execute projects related to non-conformities, corrective or preventative actions as assigned by Quality
- Coordinate with contract manufacturing and test organizations in build and testing of product designs
- Provide engineering support for the manufacturing of products at contract manufacturing firms by supplying alternate sourcing advice including vendor or component analysis, alternate manufacturing processes or deviations, and cost improvement design changes
- Develop guidelines for the development of manufacturing inspection/test procedures and equipment
- 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

Qualifications (Primary):

- BS in any engineering discipline (Mechanical or Biomedical preferred)
- Title may include a “Senior” designation if candidate has required minimum 10 years hands-on design and development experience with medical devices; “Staff” level would require 15-20 year experience and ability to mentor other team members
- Strong engineering fundamentals (mechanics, dynamics, electrical, fluids, etc)
- Competent working in regulated design conditions, under Quality Systems, FDA and ISO regulations
- Ability to multi-task between projects; confident taking initiative and ability to share knowledge with teams

- Excellent interpersonal/communication skills

Qualifications (Secondary):

- Experience with Design of Experiments and statistical techniques
- Understanding of clinical and regulatory pathways, IP and internal processes

Regulatory and agency testing experience:

- FDA CFR, MDR, ISO 13485, ISO 14971, IEC 62304, IEC 60601-1, IEC 61010, ISO 10555, ISO 11135
- NRTL experience; Sterilization Validation

Travel

- This job is located in either Denver, CO or Boerne, Texas (San Antonio area)
- Yes, 20-25%