

JOB DESCRIPTION DEVELOPMENT AND PRODUCTION TECHNICIAN

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. 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.

Position Overview

Reporting through the engineering and product development team, this position will have responsibility for work in both production of devices and in new product development programs. Our medical device products are supported in the field by a unique simulator system used for training and demonstration purposes. The primary role of this position will be to execute the purchasing, component production and assembly of these simulator units. This will involve mechanical and electrical assembly experience. Troubleshooting and quality control of the units in production will be completed by this individual as well. Understanding, modification and creation of work instructions and drawings will be required, including continuous improvement of production process or product design.

This person will also work closely with the engineering team to support new product development efforts. Assembly of early prototype units, production of components with 3D printing, electronics, board soldering, cabling assembly are typical work efforts. Test execution and reporting with engineering team is required in early development efforts. Laboratory organization, safety, efficiency, cleanliness and equipment maintenance and calibration are also part of this position's responsibilities.

The individual who will thrive in this position is a self-motivated and highly skilled in a variety of production and assembly techniques and tools. Since this position will work in support of multiple projects and team members, good communication and organization skills are important. This person should enjoy the fast pace and accountability of a small company and want to make a contribution as we deliver critical medical devices to the market.

Job Responsibilities

- Production of components for products using various equipment and skills, including but not limited to: cutting and sanding of plastics, cable assembly, board modifications, working with moldable and foaming materials, routing of tubing and pumps for water circulation system within the simulator
- Utilize small hand tools and/or precision devices to aid in the manufacturing process
- Strong attention to detail to ensure details of tolerance and design and overall product quality
- Perform inspection of own work of prior manufacturing operations
- Recognize, identify and document problems with availability and variability of parts and materials with an aim toward recommending alternatives
- Disassemble malfunctioning devices and troubleshoot, using standardized testing procedures, to examine using test mechanisms for defects
- Service training and troubleshooting calls with customers or internal clinical/sales users
- Replace or repair defective parts, may require modification or manufacturing replacement components; document all problems and repairs as required for rented units to maintain a rental fleet and internal sales units
- Reassemble device or equipment and test assembly for conformance to specifications

- Able to estimate repair costs (materials and labor) for sold units if repairs requested
- Inventory control, monitoring and purchasing (within company financial procedures) to plan for production of units within planned production schedule
- Work with Supply Chain Quality Manager for production planning and scheduling
- Maintain traceability of product configuration, lot numbers
- Shipping and receiving of finished goods and production materials, R&D prototype components
- Work with the Engineering team through all phases of process development, including prototyping, 3D printed parts production, electronics and cable assemblies
- Creation, execution and reporting of early R&D testing of new products, including creation or programming of test apparatus or data acquisition systems
- Effectively configure and maintain capital equipment and tools for simulator production and general R&D labs; inspect devices and test equipment periodically and adjust calibration to ensure functioning within specified standards
- Follow Standard Operating Procedures (SOPs) and Good Manufacturing Practices (GMPs) within company Quality Management System
- Communicate effectively with co-workers and able to prioritize work across multiple concurrent projects
- Abide by all Company safety and health policies and procedures
- Must use personal protective equipment if required; job requires lifting of products and boxes that may be >40 pounds

Qualifications

- Minimum 5 years of production or technician experience with a hands-on proficiency in mechanical and electrical assembly
- Lead experience in assembly and test in a low-volume manufacturing or product development environment
- Proficiency at soldering, with certification preferred
- Demonstrated proficiency at using hand tools, power tools, and machine tools
- Experience with jigs, templates, guides, and other labor-saving methods (using and developing)
- Familiarity with fault isolation concepts
- Computer literacy
- Preference if any experience has been in medical device R&D, supply chain or quality organizations; regulated environments for production and quality
- Knowledge of supply chain processes and planning for inventory management (limited scale)
- Competent working under Quality Systems, FDA or ISO regulations; experience in regulated production enterprises
- Ability to work independently and in groups
- Excellent ability to multi-task between projects; confident taking initiative
- Excellent interpersonal/communication skills and ability to share knowledge in a team setting

Other Preferred Experience

- Prototype making
- Model making; Silicone rubber molding techniques; mold making
- Selection and use of adhesives and engineered coatings
- Specification and application of vinyl signs/skins/decals
- Assembly of piping and tubing materials and fittings
- Working with a variety of materials: wood, metal, leather, plastics
- Technical Field Service
- Arts and Crafts

Travel: Yes, limited (<10%) to support product development at multiple sites or production supplier visits