

Cardiovascular Systems, Inc.
Position Description

Title: Senior Quality Engineer

Reports to: Director, Quality

Summary

The primary focus of this role is Quality Engineering within and in support of CSI manufacturing operations to ensure products manufactured at or for CSI meet specifications and all applicable product quality and manufacturing process requirements. This will require in-depth involvement in process development, qualification, daily operations, and ongoing performance monitoring. This position is also expected to provide leadership in areas of product quality assurance and quality engineering for continuous process and product improvement. This position may also include engineering activities in design assurance and internal process quality system processes.

Qualifications

- BS in Engineering with minimum 3 years of work experience in a FDA/ISO regulated Medical Device manufacturing environment. Certified Quality Engineer (CQE) preferred.
- Working knowledge of and experience planning and performing quality engineering duties in compliance with medical device regulations and standards including 21 CFR 820, ISO 13485, ISO 14971, and MDD
- Strong background in application of statistical methods and quality engineering techniques and tools. Mini-Tab experience preferred.
- Excellent analytical and problem solving skills
- Must be self-motivated, able to work independently and take full ownership of assigned responsibilities
- Excellent organizational ability, capability to manage multiple, dynamic projects simultaneously
- Working knowledge of sterilization methods, sterilization validations, and biocompatibility testing methods preferred
- Effective interpersonal and people management skills
- Strong technical writer

Responsibilities

1. Process Owner for Manufacturing Related Corrective Actions. Lead root cause analysis investigations and provide corrective and preventive actions based on sound engineering analysis and review. Provide effective solutions that will drive continuous and measurable improvements.
2. Act as a primary resource to Manufacturing Operators and Engineers on all quality related issues. Participate in manufacturing process development, manufacturability analyses and transfer to manufacturing.

3. Create and or review & approve process, equipment, and test method validation plans/protocol and reports that are comprehensive, clearly written and technically sound for execution.
4. Manage process and equipment change to maintain product quality attributes.
5. Review and approval of controlled documentation including drawings, manufacturing work instructions, plans/protocols, reports, NCMRs, and RGAs. Review and monitor key quality records for completeness and accuracy.
6. Process Owner for Process Risk Management. Create and maintain pFMEAs and other applicable risk management documentation for commercial products.
7. Provide QE support for the equipment calibration and preventive maintenance programs.
8. Demonstrate and educate others in the use of quality engineering tools and techniques within the organization to drive a methodical approach to design and process development, implementation and improvement including process capability, analytical statistics, advanced statistical engineering, and other proven tools (see list).
9. Collect, analyze, and monitor quality data from production. Identify, prioritize, plan, and lead the execution of continuous improvement projects based on process quality data monitoring and analysis results to proactively identify potential quality problems.
10. Play a leadership role in the Quality Engineering team at CSI. Coach others and assist in their professional development.
11. Work as an integral member of the Quality Engineering team to complete other key activities and projects as needed.

Please contact Jim Murray at jmurray@csi360.com to submit resumes or inquire about the position.