



Job Title: Quality Technician

Initial Date: 04 January 2012

Job Location: Middleton, MA

Status: FT

Department/Unit/: Quality

Reviewed By: N. Corbett / E. Rule

Reports To: Director of Quality Control

Revised: 07November 2011

Summary:

Under the direction of the Director of Quality Control, the Quality Technician will work to improve and/or maintain elements of the Quality Management System (QMS) in accordance with ISO 13485 and FDA 21 CFR 820 requirements as well as company protocols. In addition, the Quality Technician will inspect components and assemblies and perform other Verification and Validation activities, write procedures, perform testing on components and assemblies and assist Quality personnel in completing their job assignments.

Occasionally, the Quality Technician will perform or assist in quality audits of processes.

Principal Responsibilities:

- Perform and document the verification and validation of components and processes in accordance with ISO 13485 and FDA 21 CFR 820 requirements and company protocols
- Document assembly, test, packaging, delivery, installation and servicing processes
- Perform internal audits of the effectiveness of Quality Management System (QMS) processes
- Assist with company audits by the FDA as required
- Provide contributions to regulatory filings and to the Corrective and Preventive Action (CAPA) processes
- Write verification procedures, validation protocols, perform inspections and/or tests and prepare summary reports
- Perform part and process validations
- Test hardware and software using test protocols to demonstrate conformance with requirements
- Inspect mechanical, electrical and electro-mechanical components and assemblies for conformance to specifications
- Audit suppliers and their processes using FDA 21 CFR 820 and ISO 13485 requirements
- Ensure that assembly, test and packaging processes meet Device Master Record (DMR) requirements
- Working with the Document Control Manager, ensure that the Device History Record (DHR) is complete and is maintained to FDA and company requirements

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- Utilize technical skills to analyze problems with materials and processes and work with the Quality Engineer, Quality Director and other stakeholders to implement effective corrective actions
 - Work with service and installation personnel to resolve issues at field locations as required
 - Implement solutions to Corrective and Preventive Actions (CAPA) and ensure that the actions that were taken were effective in resolving root cause
 - Work with internal and external stakeholders to identify improvement opportunities, develop corrective action (C/A) plans, and work to implement those plans
 - Prepare summary reports of verification, validation and improvement activities, goals and plans
 - Assist field personnel in their Verification and Validation (V&V) activities.

Qualifications

- Associates degree in a technical field required
- 5+ years experience in a manufacturing role in a Medical Device setting
- Experience with equipment manufacturing requirements
- Knowledge of 21 CFR 820 and ISO 13485 requirements
- Experience performing Verification and Validation of materials and processes
- Experience in quality system auditing (internal and supplier audits) a plus

Skills/Abilities/Competencies

- Detail-oriented
- Data analysis, critical thinking and problem-solving skills
- Ability to manage multiple priorities
- Schedule-orientated (able to consistently maintain schedules and meet deadlines)
- Knowledgeable in use of computers and applicable software (MS Windows, MS Office, SharePoint, MiniTab)
- Technical writing skills
- Process auditing techniques
- Proficiency with metrology and mechanical inspection tools (Digital height gage, surface plate, hand tools)

Mental/Physical Skills:

- Excellent technical and interpersonal skills
- Ability to work within the 'team' concept
- 20/20 eyesight (with/without corrective lenses)
- Ability to read/write/comprehend English (some fluency in Russian a plus)
- Ability to lift 50 pounds on occasion

Working Conditions

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- Work is performed mainly in an office environment although some work at device installation sites may be required
 - Work environment is in the vicinity of an atomic particle accelerator
 - <20% travel required

Fiscal Responsibilities

- Responsible for using ProTom resources in an efficient manner and identifying opportunities for savings

Training Requirement

- Must complete the in-house Quality and Regulatory Overview Training (Modules 1-3)

Other

- Salary range: \$45,000 - \$65,000 annually
- Company benefits package to include: health, dental, vision, long-term disability, life insurance
- Bonus potential
- Participation in Company stock option program
- Holidays and paid time off

To apply for the this job, please send your cover letter and your resume in PDF format to:

QTReviewer@protominternational.com