Summary:

Under the direction of the Manager of Quality and Regulatory, the Quality & Regulatory Engineer will be a Q&R generalist that has the capability to be utilized in a variety of Quality & Regulatory functions: such as writing and editing Quality System documents in accordance with ISO 13485, FDA 21 CFR 820 and international standards as well as performing internal and external audits.

Principal Responsibilities:

- The Quality & Regulatory Engineer must have 5+ years of Quality and Regulatory experience to have the ability to be utilized in a variety of Quality & Regulatory functions (e.g. Supply area, Document Control, Quality and Regulatory). It is not necessary to be proficient in every area;
- Demonstrated ability to write Quality System procedures and develop appropriate training required;
- Understands and ensures compliance with appropriate standards, Quality System Regulations, ISO 13485 and company Quality System and project specific procedures.
- Perform internal audits of the effectiveness of Quality Management System (QMS) processes and assist with company audits by the FDA as required. Audit suppliers and their processes using FDA 21 CFR 820 and ISO 13485 requirements (experience is preferable, certification is desirable);
- May perform Document Control duties as required;
- May perform Risk Management activities;
- May provide Supplier Quality duties e.g. inspection, receiving;
- May write, execute and review verification/validation protocols, analyze results and prepare summary reports;
- May provide contributions to regulatory filings and to the Corrective and Preventive Action (CAPA) processes and ensure that appropriate actions taken resolve root cause;
- May ensure that assembly, test and packaging processes meet Device Master Record (DMR) requirements;
- May work with the Document Control Manager to ensure that the Device History Record (DHR) is complete and is maintained to FDA and company requirements;
- May utilize engineering skills to analyze problems with materials and processes and work with internal and external stakeholders to implement effective corrective actions;
- May work with service and installation personnel to resolve issues at field locations as required;
- Will maintain an up-to-date list of standards and regulations and ensure in-house folder contains latest standards and regulations.

☐ Qualifications

- AS or BS degree
- ASQ certifications a plus; Audit certification, a plus
- Five – 10 years' experience in a medical device development and manufacturing environment
- Working knowledge of Quality System Regulations and international standards (e.g. 21 CFR 820, ISO 13485, ISO 14971, IEC 60601) required;
- Design Verification, Design Validation, and Process Validation, CAPA and Records requirements and processes experience desirable;
- No less than 2 years' experience in a capital equipment manufacturing organization (Medical Device Capital Equipment preferred).

Skills/Abilities/Competencies

- Experience in Medical device development environment
- Demonstrated technical writing skills
- Demonstrated competence with Quality System tools and strategies (Data Analysis, Statistical Methods, Problem-Solving, CAPA, Internal and Supplier auditing)
- Detail-oriented
- Excellent data analysis, critical thinking and problem-solving skills
- Ability to manage multiple priorities
- Knowledgeable in use of computers and applicable software (MS Windows, MS Office, SharePoint, MiniTab)
- Excellent verbal and written communication skills
- Working knowledge of computer, office software and general quality tools (such as: Word, PowerPoint, Excel, Visio)

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

- Work is performed mainly in an office environment although some work at device installation sites may be required

- On occasion work may be required in a work environment is in the vicinity of an atomic particle accelerator.
- <30% travel required

Fiscal Responsibilities

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

Training Requirement

- Complete training on, and stay current with, ProTom's Quality Management System and all corporate policies, including specifically Human Resources and Finance policies, and the Employee Handbook.

Other

- Salary range: industry competitive
- Company benefits package to include: health, dental, long-term disability, life insurance
- Bonus potential
- Participation in Company stock option program
- Holidays and paid time off

About ProTom International: ProTom International is a growing medical device company that sells, installs and services its proprietary and patented technology. At ProTom, we work to increase the availability and affordability of clinically advanced proton therapy technology in the fight against cancer for physicians and their patients. We enjoy an innovative and rewarding environment that encourages a sense of ownership and pride in making a difference in the lives of cancer patients. Employee satisfaction is important to us, so we provide: Competitive compensation with bonus potential generous benefits package Participation in the Company stock option program Holidays and paid time off

To Apply: If you meet the required skills and qualifications and want to apply for this position, please send your cover letter and resume in PDF format to Jobs@ProTomInternational.com. Local candidates in the Boston, MA area only, please. ProTom International conducts pre-employment background screenings, and is proud to be an Equal Opportunity Employer. M/F/D/V