Document Control Specialist

Under the direction of the Director of Quality and Regulatory Affairs, (DQRA), the candidate will be responsible for entering document control and quality records and information into ProTom's electronic system; and link them to associated items

Responsibilities

- Assign Part and document Numbers for assembly drawings, SOPs, fabricated parts, etc.
- Process Change Orders (COs); review submitted (COs) for anomalies and completeness and communicate with originator to correct
- Send accepted COs out for approvals
- Close out approved COs; update all document files and part information and release the documents and parts
- Maintain redline and obsolete documents
- Enter multi-level Bills of Material (BOM) in ProTom's Electronic document control system
- Create PDFs of, and enter records of closed change orders
- Enter information in ProTom's item master (parts list)
- Monitor the design control process for missing associated documents, drawings, etc.
- Assist in compiling the Design History File, Device Master Record and the Device History Record
- Associate parts to requirements, specifications, work instructions, etc., as directed by DQRA, and DCM
- Obtain spec/data sheets on existing parts from web sites and attach in item master
- Other clerical tasks as assigned by DRQA

Qualifications

- 5+ years of experience in document control in a medical device manufacturing environment
- 5+ years of experience working with item masters in a manufacturing environment
- Knowledge of document control requirements and procedures in a manufacturing environment

Skills/Abilities/Competencies

- Excellent written and oral communication skills
- Demonstrable ability to work with technical professionals such as Engineers and Physicists
- Detail oriented
- Data entry skills
- Knowledgeable in use of computers and applicable software (MS Windows, MS Office and ERP or MRP systems
- Experience with Document Control Management software a plus

Excellent interpersonal skills

Understand and work within the 'team' concept

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