

Design Quality Engineer:

ProTom International Holding Corporation is seeking a Design Quality Engineer to join the team in the Boston area office location. This individual will be a skilled and experienced Engineer who will work on complex medical device specifications and standards and report to the Director of Quality & Regulatory Affairs.

Responsibilities:

- Execute a risk based approach/procedure/plan of design requirements/specifications, technical standards, test methods, supplier controls and manufacturing controls to the appropriate Regulations, Standards and Guidelines for the Marketing and Sales of the PROTOM Medical Device;
- Work closely with both internal groups (Marketing, Research, Technology, Product Development, Regulatory, Clinical and Management) and external groups (clinicians, consultants, regulatory agencies) to assess and potentially redefine or clarify system level requirements, Use-Conditions and risks for the development of the Device;
- Responsible for the assessment of technical standards against current DHF, labeling and technical file requirements;
- Responsible for the assessment of component and system level specifications relative to customer needs and product performance specifications;
- Perform requirements flow down analysis on critical to quality product performance specifications down to the component level;
- Apply Design for Reliability and Manufacturability tools and techniques to the project as appropriate;
- Provide effective support for multiple projects, balancing priorities and resources appropriately to meet both project and management expectations;
- Prepare or direct the preparation of oral and written reports as required by the project or department management;
- Perform required training and certifications to demonstrate compliance with applicable divisional and corporate policies in accordance with individual training matrix;
- Collaborate with management to ensure effective and robust risk management for products and processes;
- Utilize quality systems expertise by assisting in continuous improvement activities throughout the product lifecycle management considerations;
- Support CAPA Board meetings and assist following-up on open action items until closure;
- Support initiatives to ensure effective reporting of quality improvement program metrics;
- Ensure Regulatory compliance in area of responsibility to GMP of all medical devices regulatory agencies (i.e. FDA, IMB, Notified bodies, etc.);
- Perform other duties as assigned;

Requirements:

- Minimum, Bachelor's degree in Engineering, (Mechanical or Electrical)
- Certified Quality Engineer (CQE) from AAMI
- A minimum of 5 years of experience in Design Quality
- Excellent interpersonal skills

- Ability to work in a small team
- Ability to work with customer's technical staff
- Self-motivated
- Takes initiative and responsibility for professional growth and education/training
- Work is performed mainly in an office environment although some work at device installation sites may be required
- < 10% travel required

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

