Supplier 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:

- Provide support for all Supplier Quality related activities. Assist in Receiving Inspection operations, supplier survey/audit responsibilities, and new product development operations;
- Technical understanding of manufacturing prints and tolerance GNDT;
- Basic understanding of manufacturing processes;
- Ownership for supplier quality performance and measurement including KPI’s and participate in supplier performance reviews;
- Enable reporting of metrics for monthly reviews;
- Lead quality issues with suppliers & partner with Internal Customers;
- Lead effective supplier containment and corrections/corrective actions;
- Act as point of contact for Internal/ External Customer groups on key compliance issues related to assigned suppliers;
- Participate in External Audits and Internal Audits as needed;
- Ensure Regulatory compliance in area of responsibility to GMP of all medical devices regulatory agencies (i.e. FDA, IMB, Notified bodies, etc.);
- Responsible for accuracy and integrity of supplier data that ensures compliance with documented procedures & processes;
- Ownership and reporting on all quality issues associated with the assigned suppliers;
- Ensure all assigned supplier related material quality issues are effectively communicated to key stakeholders;
- Participate in the supplier material related processes which include:
  - Material Review Board to ensure Coordination of MRB activities with the business unit to ensure the timely assessment of potential non-conforming products;
  - Maintain structured communication channels with strategic sourcing, identifying responsibility by commodity / supplier;
  - Liaising with the Manufacturing and Quality groups, in assessing and addressing material quality issues with assigned suppliers;
  - Maintenance of the Approved Supplier List (ASL) in conjunction with the Global Sourcing, Supplier Controls and Audit functions;
- Deliver continuous improvement activities focusing on supplier quality;
- Participate in supplier audit program – planning, execution and closure Participate in supplier reviews for assigned suppliers as required;
- Participate in cross functional projects both locally & globally as required;
- Partner with SQM functions and Strategic Sourcing on the developments and approval quality assurance agreements with suppliers.

Requirements:
Minimum, A Bachelor’s Degree in Engineering (Mechanical or Electrical)
Certified Quality Engineer (CQE) from AAMI
A minimum of 5+ years of experience in Supply 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