ProTom International Holding Corporation
Job Description: Director of Quality and Regulatory Affairs

Summary:

Responsible for the implementation and oversight of ProTom International Holding Corporation's Quality Management System (QMS) and ensuring that these processes are effective for ProTom's ***Radiance 330***® state-of-the-art proton therapy system and is in full compliance with FDA and other regulatory agencies as applicable. Lead and manage FDA (QMS), ISO (QMS), TGA (Australia), CFDA (China), CE mark, MDSAP (as applicable) applications and clearances.

Principal Responsibilities:

- Under the day-to-day supervision of the CEO, manage the further refinement and implementation of the quality processes necessary for a safe and effective product, compliant with regulations noted above;
- Under the direction of the CEO, implement strategic processes and plans for securing FDA, CFDA, TGA, ISO 13485, and CE mark and contribution to the development and realization of business in supporting and implementing global regulatory strategies;
- Develop and maintain quality strategies driving excellence across the Quality and Regulatory Affairs department and throughout the organization. Provide oversight of all quality-related activities. Direct quality programs ensuring GMP compliance along with continuous quality improvement. Provide regulatory guidance and support to cross-functional teams;
- Develop and manage department budget;
- Continually revise and improve the comprehensive risk-based QMS for ProTom's ***Radiance 330***;
- Responsible for ensuring that the QMS is effective and in effect, including defining, coordinating and recording QMS internal and external senior management reviews (as appropriate);
- Act as the Management Representative, chair the management review, validation, and CAPA initiatives with respect to ProTom's QMS;
- Prepare documents, and advise and train others on the preparation of documents needed to implement and refine the QMS;
- In concert with senior operations and information technology leadership, establish mandatory electronic policies and procedures governing the maintenance, transfer, security, and user–friendly functionality of document control; ensure compliance and measure effectiveness with medical device design controls and other QMS policies. Establish process improvements and/or recommend alternatives;
- Remain current on applicable regulations governing the ***Radiance 330*** system; alert CEO, Quality Leadership Committee and key departments/individuals impacted by changes;
- Develop and/or review all job descriptions of staff associated with the production and use of the ***Radiance 330*** system for compliance with applicable regulations;
- Responsible for the preparation, oversight and conduct of internal and external audit programs, assess performance, implement, and measure effectiveness of corrective actions;

PROTOM
proton therapy technologies

- Manage and maintain the Company's quality inspection and product release programs for incoming and in-process materials and components, processes;
- Supervise Q&R staff to ensure compliant, effective, efficient, and timely performance.

Qualifications:

- Bachelor's degree in a technical discipline
- MBA (a plus)
- Certifications (a plus)
  - CMQ/OE – Certified Manager of Quality/Organizational Excellence
  - CMBB – Certified Master Black Belt
- Minimum of 20 years' experience in development and deployment of quality management system, in the medical device environment
- Demonstrated knowledge of the applicable national and international standards governing medical device/systems (e.g., FDA; CE; ISO Quality System Implementation & Standardization)
- Ability to engage with and teach to a variety of professional staff, internal and external, customers, federal agencies, etc.
- Comfortable in a fast-paced environment
- Ability to self-motivate and work independently

Contact: ProTom International, 500 Edgewater Drive, Suite 522, Wakefield, MA 01880
Jobs@protominternational.com