JOIN OUR TEAM, CREATE A FUTURE FOR EVERYONE

Our team is the core of our mission to transform cancer treatment by expanding worldwide access to proton therapy – an advanced form of radiation therapy. We are always interested in hearing from anyone who shares our vision and believes that they can advance our mission.

Director of Quality and Regulatory Affairs

Regular, Full-Time
Wakefield, MA

Summary

ProTom's flagship product is the Radiance 330® Proton Therapy System ("Radiance 330"). This cutting-edge radiation therapy system uses a synchrotron to generate, transport, and steer high-energy protons to treat with sub-mm accuracy. Under the direction of the CEO, the Director of Quality and Regulatory Affairs is responsible for the implementation and continued development of ProTom's quality management system (QMS) and ensuring that these processes are effective for the Radiance 330 – unique accelerator, gantries, beamline, imaging systems, treatment delivery control systems – and that such QMS is in full compliance with FDA and other regulatory agencies as applicable.

Job Functions and Responsibilities

1. Under the direction of the CEO, implements strategic processes and plans for securing FDA, CFDA, TGA, CE mark, and other potential territories, and contribution to the development and realization of business in supporting and implementing global regulatory strategies;
2. 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. Provides regulatory guidance and support to cross-functional team;
3. Lead in the preparation and submission of marketing authorizations (e.g., 510(k), conformity assessment) to governmental authorities;
4. Prepare policies, procedures, and documents, and advise and train others on the preparation of documents needed to implement the quality program;
5. Ensure that post-market activities (e.g., evaluation of design changes, complaint handling, CAPA, risk management) are being conducted in an effective and timely manner;

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6. Responsible for evaluating whether events are reportable to FDA in accordance with 21 CFR Parts 803, 806, 1002, and 1003 (and applicable governmental authorities outside the United States);
7. 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;
8. Responsible for the preparation, oversight and conduct of internal and external audit programs, assess performance, implement and measure effectiveness of corrective actions;
9. Supervise Q&R staff (e.g., document controls specialist, document control manager, quality engineer, CAPA/Complaint Manager, etc.) to ensure compliant, effective, efficient and timely performance; and,
10. Responsible for ensuring that the quality system requirements are effectively established and maintained in accordance with federal regulations, and international regulations as applicable and for reporting on the performance of the quality system to management with executive responsibility for review.

Education and Experience

1. Bachelor's degree in a technical discipline required; MBA preferred.
2. Certifications (a plus):
   a. CMQ/OE – Certified Manager of Quality/Organizational Excellence
   b. CMBB – Certified Master Black Belt
3. Minimum of 20 years' experience in development and deployment of quality management systems, in the medical device environment.
4. Demonstrated knowledge of the applicable national and international standards governing medical device/systems (e.g., FDA; CE; ISO Quality System Implementation & Standardization).

Working Conditions

1. 90% office environment; 10% in accelerator laboratory environment, with little to no natural light.
2. Ability to travel domestically and internationally as needed; must be able to acquire all necessary travel documents.

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