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

Summary:

Responsible for the implementation and oversight of ProTom's Quality Management System (QMS) and ensuring that the processes are effective for the Company's ***Radiance 330***® Proton Therapy System- unique accelerator, gantries, and beamline, imaging systems, treatment delivery control systems – and that such QMS is in full compliance with FDA and other regulatory agencies as applicable. Lead and manage FDA (QMS), ISO (QMS), TGA (Australia), CFDA (China), CDSCO (India), CE mark, MDSAP (One-Audit), etc. (as applicable) applications and clearances.

Principal Responsibilities:

- Under the day to day supervision by the CEO, manage the further refinement and implementation of the quality processes necessary for a safe and effective product, compliant with the 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.

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Qualifications:

- Bachelor's degree; Master's Degree a plus
- Minimum of 3 years experience in development and deployment of quality management system, ideally 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)

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