ProTom International Holding Corporation
Job Description: Quality and Regulatory Engineer

Summary:

Under the direction of the Director of Quality and Regulatory Affairs, the Quality and Regulatory Engineer will be a Q&R generalist that has the capability to be utilized in a variety of Quality & Regulatory functions, such as writing and editing Quality Management System (QMS) documents in accordance with ISO 13485, FDA 21 CFR 820 and international standards as well as performing internal and external audits.

Principal Responsibilities:

- The Quality and Regulatory Engineer must have 5+ years of quality and regulatory experience to have the ability to be utilized in a variety of functions (e.g., Supply area, Document Control, Quality and Regulatory);
- Demonstrated ability to write Quality System procedures and develop appropriate training required;
- Understands and ensures compliance with appropriate standards, Quality System Regulations, ISO 13485 and ProTom QMS and project specific procedures.
- Perform internal audits of the effectiveness of QMS processes and assist with ProTom audits by the FDA as required. Audit suppliers and their processes using FDA 21 CFR 820 and ISO 13485 requirements (experience is preferable, certification is desirable);
- May perform Document Control duties as required;
- May perform Risk Management activities;
- May perform Supplier Quality duties, e.g., inspection, receiving;
- May write, execute and review verification/validation protocols, analyze results and prepare summary reports;
- May provide contributions to regulatory filings and to the Corrective and Preventive Action (CAPA) processes and ensure that appropriate actions taken resolve root cause;
- May ensure that assembly, test and packaging processes meet Device Master Record (DMR) requirements;
- May work with the Document Control Manager to ensure that the Device History Record (DHR) is complete and is maintained to FDA and company requirements;
- May utilize engineering skills to analyze problems with materials and processes and work with internal and external stakeholders to implement effective corrective actions;
- May work with service and installation personnel to resolve issues at field locations as required;
- Will maintain an up-to-date list of standards and regulations and ensure in-house folder contains latest standards and regulations.

Qualifications:

- AS or BS degree
- ASQ certifications a plus; Audit certification, a plus
- 5-10 years experience in a medical device development and manufacturing environment

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- Working knowledge of Quality System Regulations and international standards (e.g.
- 21 CFR 820, ISO 13485, ISO 14971, IEC 60601) required;
- Design Verification, Design Validation, and Process Validation, CAPA and Records requirements and processes experience desirable;
- No less than 2 years' experience in a capital equipment manufacturing organization
- (Medical Device Capital Equipment preferred).

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