Role Description: Quality Specialist – Fluid Biomed

This is a unique opportunity to join a start-up company focused on the development of a novel implantable medical device. The Quality Specialist will administrate elements of the Quality Management System (QMS), control inventory, and support the Engineering and Operations team. The role will work within the Quality Department in a fast paced and dynamic environment where attention to detail, ability to multi-task, taking initiative and collaborating cross-functionally are critical for success.

Key Responsibilities include:

- Under an established QMS, manage processes including Supplier Qualification, Training programme, Materials Receiving, Non-conformities/Corrective and Preventive Action, Engineering Change Orders, etc.
- Manage company document control activities including revision control, document routing for review and approval, obsolete revision archiving, document retention, electronic and hardcopy filing, etc.
- Maintain Engineering Drawings library
- Manage physical and electronic inventory control of product, delivery components, and supporting equipment
- Conduct internal audits under ISO 13485 requirements and host external audits
- Prepare annual QMS Management Review materials and present to team and executives
- Complete receiving documentation for incoming parts, components or equipment
- Support the preparation/editing of reports or presentations for internal and external discussions and projects
- Assist in the preparation of request for quotes (RFQs), shipping documentation, regulatory submission technical documentation, etc. as requested.
- Maintain training files for all staff
- Maintain quality documentation including Certificate of Analysis, Calibration Reports, Maintenance Reports, etc. and coordinate ongoing equipment service or testing.
- Execution of Non-Disclosure Agreements (NDAs) for external service providers
- Other Quality Department support activities as required.

Education and Experience Requirements:

- Bachelor's degree and minimum of 2 years' experience with QA/document control in industry required
- Experience working in ISO 9001 or 13485 certified organization required
- Demonstrated experience with document control activities including revision control, document routing for review and approval, obsolete revision archiving, etc.
- Demonstrated attention to detail and excellence in written communication

Additional Skills:

- Experience as lead resource with document control software preferred
- Certification as Internal Auditor preferred
- Some previous R&D/technical industry exposure, able to understand company technology at a practical level
- Excellent documentation, communication and interpersonal relationship skills
- Strong problem-solving, organizational, analytical and critical thinking skills
- Ability to navigate uncertainty/fluidity in role scope, priorities, and timelines
- Ability to manage competing priorities in a fast-paced and dynamic environment
- Proven expertise in usage of MS Office Suite

Role is on-site in Calgary, AB and candidates must be legally entitled to work full time in Canada.

Please send your resume to hr@fluidbiomed.com and include the position you are applying for in the e-mail subject as well as main body.