Role Description: Quality Engineer / Quality Assurance – Fluid Biomed

This is a unique opportunity to join an early-stage company to further the development of a novel implantable endovascular medical device and ensure its readiness for early human use. This hybrid Quality Engineer - Quality Assurance role (QE/QA) will manage design control, risk management and Quality Management System processes at Fluid Biomed. This detail-oriented role will work in a fast paced and dynamic R&D environment where taking initiative and collaborating cross-functionally are critical for success. The ideal candidate is a self-directed learner who willingly works outside a routine comfort zone, seeks out additions to his/her "tool kit" and delights in overcoming barriers and finding creative ways around complex problems.

Key Responsibilities:

- Apply knowledge of Quality Engineering principles to ensure compliance with ISO 13845 and 21 CFR 820. Focus is primarily on design control, product and process verification/validation, failure analysis and compliance with critical Quality Management System requirements
- Maintain technical content of device and delivery system Risk Management files
- Maintain technical content of device and delivery system Design History files
- Develop Device Master File documentation as product and components evolve
- Manage Internal Audit schedule and act as Management Representative for external audits
- Assist in the development of measurable quality objectives and conduct Management Reviews
- Investigate non-conformity root cause and plan and document corrective and preventive actions
- Develop and execute Supplier Quality Agreements with key service providers
- Maintain Quality Manual and QMS Standard Operating Procedures (SOPs)
- Participate in critical review and documentation of engineering changes for consistent fabrication of safe and effective devices
- Evaluate and document potentials risks with design and manufacturing processes and assess efficacy of mitigations
- Develop qualification and verification protocols to provide evidence of conformity to recognized standards or internal specifications
- Participate in the preparation of technical documentation for regulatory submissions.

Education and Experience Minimum Requirements:

- Bachelor's Degree in Engineering and minimum of 3 years' experience in medical device industry
- Direct experience in R&D environment
- Experience leading QMS activities in ISO 13485 certified organization
- Demonstrated experience with Failure Modes and Effects Analysis (FMEA) and ISO 14971
- Demonstrated technical experience with non-conformity and corrective/preventive action activities
- Demonstrated experience conducting equipment qualification, test method and software validation

Additional Skills Desired:

- Hands-on experience with US Class III/Canada Class IV devices including implant/catheter design, materials inspection/testing, and manufacturing processes (cleaning, sterilization, packaging) desired
- Strong technical engineering skills, able to understand device design and function at a practical level
- Experience with contract manufacturers and external testing facilities preferred
- Excellent documentation, communication, and interpersonal relationship skills
- Strong troubleshooting skills and capability in evaluating process changes and/or non-conformances for

risk and development of technical justifications/rationales where needed
- Working knowledge and understanding of statistical techniques and related software
- Strong problem-solving, organizational, analytical, and critical thinking skills
- Ability to review emerging clinical and technical literature and apply findings
- Ability to navigate uncertainty in project scope, timelines, and requirements
- Motivated self-starter who can manage competing priorities in a fast-paced and dynamic environment
- Proven expertise in usage of MS Office Suite
- CQE (Certified Quality Engineer) certification or equivalent appreciated
- Formal training as Certified ISO 9001/13485 auditor preferred.

Role will be located in Calgary, AB and candidates must be legally entitled to work full time in Canada. Flexible work arrangements (e.g. partially remote) may be considered for the ideal candidate.

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.