FLUIDX
MEDICAL TECHNOLOGY

Fluidx Medical Technology, located in the greater Salt Lake City area, is currently seeking candidates to join our team. This is an opportunity to join a clinical stage medical device company working to develop exciting new medical devices that will change the standard of care for patients.

Senior Regulatory Affairs & Quality Assurance Specialist

JOB DESCRIPTION:

The Senior Regulatory Affairs and Quality Assurance (RA/QA) Specialist is responsible for carrying out Regulatory and Quality efforts to bring novel medical devices to market. The Regulatory activities include participating in all project team RA activities, sharing regulatory expertise, identifying, preparing, and collecting data needed to obtain and maintain commercialization authorization (e.g., FDA, CE Mark, etc.) of Fluidx products. The Quality activities include participating in all project team QA activities, inspection, monitoring, trending, assisting with document control, and reporting quality indicators to upper management, as well as obtaining and maintaining certification (e.g., ISO13485, etc.) authorizations. The Senior RA/QA Specialist will work closely with R&D to ensure alignment. Excellent verbal and written communication skills, detail orientation, and analytical/problem solving skills are a must. Must be a highly motivated self-starter with the ability to achieve results with minimal direction.

JOB RESPONSIBILITIES:

- Demonstrated experience working in a multi-discipline product development team.
- Working knowledge in risk-based product development.
- Responsible for leading all regulatory and quality activities required to receive a PMA (or 510(k)) for a medical device.
- Establish regulatory plan for U.S., Europe, and other relevant markets. Set strategy and manage communications with regulatory bodies (i.e., FDA, notified bodies, etc.).
- Handle all regulatory documentation including pre-IDE submission, feasibility human trial documentation, pivotal trial documentation, FDA documentation, MDR, etc.
- Work with R&D team to ensure planned bench studies and test methods align and support regulatory strategy.
- Ensure company compliance with quality system regulations.
- Prepare for and maintain certification to applicable quality system standards (e.g., ISO13485).
- Prepares reports for management on the effectiveness of the quality management system and any need for improvement, including assembling data for formal Management Review.
- Direct validation programs for existing and new manufacturing processes.
- Function as the gatekeeper for Risk Management and Risk Analysis and champion both.
- Carry out the application of process controls and the assessment and communication of data acquired from process measurement systems.
- Identify tools and methods required to ensure product compliance to specifications and process robustness.
- Generates and maintains metric data required for trend analysis and reporting.
- Carry out or assist with the following quality functions and processes:

- Document control activities – Change control (DCNs), Record retention (e.g., lot histories), and inspection records.
- Quality inspections – Incoming inspections and manufacturing-related inspections.
- Corrective and Preventive Actions (CAPA, Nonconforming material Reports (NCR), and Material Review Board (MRB).
- Internal audits.
- CEA monitoring and testing.
- Assist with qualification of suppliers and supplier audits.
- Calibration.
- Environmental monitoring.

EDUCATION REQUIREMENTS:

- Bachelor's degree.
- General knowledge of the medical device industry.
- General knowledge of quality and regulatory systems including FDA, cGMP, ISO 13485, CE Marking, and QSR.

EXPERIENCE AND SKILL REQUIREMENTS:

- Minimum 5 years of medical device regulatory, quality, and/or R&D experience.
- Experience with taking products from development through the regulatory submission process.
- Well-versed in U.S. FDA and European medical device regulatory processes and documentation, including guidelines, submissions, and communications (CE-Mark, 510(k), PMA).
- Personal experience with implementation and following quality management systems.
- Personal experience with certification audits and regulatory inspections.
- Comfortable communicating with key opinion leaders, physicians/clinicians, FDA and notified body representatives, etc.
- Excellent communication skills (written and verbal). Ability to communicate across business functions and work effectively with executives, managers, and employees.
- Excellent data recording and data organizational skills.
- Good problem-solving skills.
- Ability to teach the use of basic measuring tools used in inspection.
- Strong organizational skills – able to handle multiple priorities/projects in an effective manner.
- Ability to thrive in a fast-paced startup environment.

PREFERRED EXPERIENCE AND SKILL REQUIREMENTS:

- Experience with De Novo and/or PMA applications.
- Peripheral vasculature device experience relating to implantable stents and/or embolic devices.

PHYSICAL REQUIREMENTS:

- While performing the duties of this job, the employee is regularly required to stand, walk, sit, and use hands to manipulate, handle or feel objects, tools, controls, and office equipment. The employee is frequently required to talk and hear. The employee is occasionally required to reach with hands and arms and stoop, kneel or crouch.

APPLY NOW!

Contact us at www.fluidxmedical.com/careers
or email careers@fluidxmedical.com to apply.