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.

Director, Regulatory Affairs and Clinical Affairs

JOB DESCRIPTION:

The Director of Regulatory Affairs and Clinical Affairs will manage Regulatory Affairs (RA) and Clinical Affairs (CA). The Director will lead regulatory and clinical efforts to commercialize a novel embolic device in the U.S. and other regions. This position requires both high level leadership and strategy setting, as well as hands on work in regulatory and clinical documentation. In this role, the Director will create the RA/CA strategy in multiple regions and execute to that strategy. The Director will design and manage all clinical trials including early feasibility trials and the U.S. pivotal trial, as well as all associated documentation. The Director will work closely with R&D to ensure alignment. Excellent verbal and written communication skills, and detail orientation are a must. Must be a highly motivated self-starter with the ability to achieve results with minimal direction.

JOB RESPONSIBILITIES:

- Lead regulatory and clinical efforts to bring a novel polymer embolic to market.
- Responsible for leading all regulatory and clinical activities required to receive a 510(k) or PMA for a medical device.
- Establish regulatory plan for U.S., Europe, and other relevant markets.
- Set strategy and manage communications w/regulatory bodies (i.e., FDA, notified bodies, etc.).
- Handle all regulatory documentation including pre-IDE submissions, IDE submission, feasibility human trial documentation, pivotal trial documentation, FDA documentation, MDR, etc.
- Design and manage early feasibility clinical trials.
- Design and manage the U.S. pivotal trial.
- Manage work with a CRO.

EDUCATION REQUIREMENTS:

- Bachelor's degree.
- Well-versed in U.S. FDA and European regulatory processes and documentation for medical devices (e.g., CE mark, 510(k), PMA, etc.)

EXPERIENCE AND SKILL REQUIREMENTS:

- 8-10 years of medical device regulatory, clinical affairs, R&D, and/or quality experience.
- Experience with taking multiple products from development through the regulatory submission process.
- Well-versed in regulatory documentation including guidelines, submissions, communications, etc.
- Created detailed project timelines.

- 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.
- 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:

- 4 years of regulatory and/or clinical affairs experience.
- Experience in planning and managing a U.S. clinical trial, including working with an outside CRO.
- Experience with 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.