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 R&D Engineer

JOB DESCRIPTION:

Responsible for carrying out R&D efforts to bring novel medical devices to market. This position requires hands-on engineering that leverages medical device development / quality / manufacturing / project management experience in new product and process development. Responsible for both the technical aspects of product design and development as well as developing final product specifications, in conjunction with polymer science team. 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:

- Carry out design and development activities, as directed by management.
- Guide product development projects through the design control process.
- Develop and execute all essential R&D activities for product launch.
- Manage the activities of product development project team, composed of R&D engineers and technicians.
- Work closely with polymer science team and with any consultants performing essential R&D activities.
- Interface with other departments within the company (e.g., quality, regulatory, operations, etc.) to ensure that product designs meet quality objectives and long-term requirements, including any essential regulatory requirements needed to receive regulatory clearance.
- Develop and execute appropriate project design control documentation (including design requirements, risk analyses, verification, validation, etc.).
- Develop and execute bench studies, preclinical studies, and clinical trials.
- Develop and execute design verification and validation protocols. Document results in verification and validation reports.
- Develop and execute validation studies on manufacturing and testing equipment and processes.
- Help coordinate manufacturing scale-up.
- Interface with physicians to ensure that developed products meet requirements.
- Develop detailed project timelines. Ensure that timelines are adhered to.
- Perform other related duties and tasks, as needed.

EDUCATION REQUIREMENTS:

- Bachelor's degree in a related engineering discipline.
- General knowledge of the medical device industry.
- Familiarity with quality and regulatory systems including FDA, cGMP, ISO 13485, CE Marking, and QSR.

EXPERIENCE AND SKILL REQUIREMENTS:

- Minimum 5 years of medical device engineering experience.
- Demonstrated experience developing technological solutions for medical device products.
- Demonstrated experience managing a multi-discipline product development team.
- Working knowledge in risk-based product development.
- Experience with project planning and management tools.
- General understanding of biocompatibility.
- Preclinical and clinical trial experience.
- Experience developing validation activities (IQ/OQ/PQ) required for product launch.
- Strong organizational skills – able to handle multiple priorities/projects in an effective manner.
- Ability to thrive in a fast-paced startup environment with a willingness to take on a variety of tasks and roles.
- Background demonstrating strong self-motivation – able to independently achieve results with only minimal direction.
- Excellent communication skills (written and verbal).
- Generate and implement detailed project timelines.

PREFERRED EXPERIENCE AND SKILL REQUIREMENTS:

- Peripheral vasculature device experience relating to implantable stents and/or embolic devices.
- Demonstrated proficiency in product design and IP, as demonstrated by being named primary on at least one issued medical device patent.

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.