Title: Senior Regulatory and Compliance Specialist

Monarch Medical Technologies, a high-growth healthcare technology firm providing the leading solution for inpatient diabetes care, is seeking a Sr. Regulatory and Compliance Specialist. This individual should be an independent thinker with a "can-do" attitude that can skillfully leverage regulatory expertise to improve efficiencies and compliance across the organization.

The qualified individual will be a member of the Regulatory Affairs and Compliance department, working collaboratively to ensure compliance with quality control, risk management and product life cycle requirements as prescribed by the U.S. FDA, E.U. CE and ISO.

Principle Responsibilities

- Provide cross-functional support to assure regulatory compliance and appropriate business planning across the organization, including working with Quality Assurance, R&D, Professional Services and Marketing.

- Direct the establishment, implementation and maintenance of the company's quality system to ensure compliance with internal, customer and regulatory requirements, including:
    - Implementing and maintaining policies and procedures to ensure compliance with Quality System Regulations (QSR), as well as the International Organization for Standardization (ISO) quality system requirements.
    - Creating and monitoring CARs, CAPAs and MDRs as required, including assisting manager with evaluating feedback, measuring data and developing consistent with risk management goals and periodic review requirements.
    - Supporting generation of QMS documentation using Electronic Document Management System (EDMS).
    - Supporting managers with troubleshooting, root cause analysis, design control, supplier selection and evaluation, etc. to address risk control and quality issues.

- Manage and maintain medical device submissions and product compliance across all applicable jurisdictions, including:
    - Developing project timelines and managing regulatory submissions, to include 510(k) and international submissions, for new products as well as changes to software functions or indications.
    - Supporting product development projects by reviewing proposed changes to software functions or uses, to determine if the change requires pre-market clearance or Letter to File.
    - Preparing and maintaining Technical Files for Europe (CE Mark) for new products, new indications, and significant product changes.

- Participate in the development, review and approval of product labeling and promotional materials.

- Perform other duties as needed.

Required Skills and Experience

- Bachelor's degree (B.S.) from four-year College or university and a minimum of 5 years Medical Device Regulatory Affairs experience; or equivalent combination of education and experience.
- Experience with stand-alone software medical device preferred.
- At least 5 years' experience with FDA medical device regulations, ISO 13485, CMDR and/or EUMDD/MDR requirements.
- Must be skilled in Microsoft Word, Excel and Power Point, Salesforce and EDMS.

About Monarch

Monarch Medical Technologies is a privately held medical technology company founded by clinicians with a vision of improving hospital-based glucose management. Providing the safest option on the market, Monarch is replacing traditional linear protocols with individualized and predictive computer-based solutions. With its flagship product, the EndoTool® Glucose Management System, the company pioneers the field of predictive therapeutic control technologies for managing drugs.

Monarch provides a degree of personalized care that results in lower readmission rates, reduced lengths of stay, reduced risk of hospital-acquired conditions & infections, and dramatically improved patient outcomes. Monarch's technology is doing more than changing the conversation in more than 300 hospitals throughout the United States — it's helping providers achieve the coveted triple aim: better health, better care, at a lower cost.

Our team is passionate about improving the delivery and safety of patient care. We are quickly growing and seeking individuals who thrive in a fast-paced, entrepreneurial environment.

To apply for this apposition, please submit a cover letter and resume to Ann Marie Gaitan at AnnMarie.Gaitan@monarchmedtech.com.