Title: Director of Regulatory Affairs and Compliance

Monarch Medical Technologies, a high-growth healthcare technology firm providing the leading solution for inpatient diabetes care, is seeking a Director of Regulatory Affairs and Compliance to join as a key member of the team. This position will be responsible for creating, planning and implementing solutions for regulatory approvals and compliance of Monarch Medical Technologies products and standard operating procedures.

This position reports to the CEO.

Location: Charlotte headquarters preferred, but not required.

Principle Responsibilities

- Ensures compliance with U.S. Food and Drug Administration (FDA) and international regulations, other regulatory requirements, company policies, operating procedures, processes and task assignments
- Provides regulatory leadership to company departments and teams
- Acts as a liaison with other departments, including Quality Assurance, R&D, Product, Legal, Professional Services, Marketing and Clinical Affairs
- Leads regulatory strategy formulation, submission preparation and development
- Develops global regulatory strategies for new and modified medical devices
- Maintains Standards of Practices (SOPs) and provides training and updates on new FDA guidance, communications, and competitive cleared devices.
- Prepares submissions for new devices and manufacturing or device changes
- Provides definition, direction and support of regulatory activities, including complaint handling and standard documentation, as required by FDA
- Ensures that complaints are investigated and documented thoroughly in compliance with the FDA medical device regulations
- Conducts audits of and compliance of complaint management system
- Reviews product and manufacturing changes for compliance with regulations (change control)
- Reviews protocols and reports to support regulatory compliance for product changes and submissions
- Reviews device labeling and advertising materials for FDA submissions and applicable regulations
- Builds partnerships and mutual respect with regulatory authorities (e.g., FDA, Notified Body)
- Support all company initiatives in QMS, EMS and other regulatory requirements
- Maintains positive and cooperative communications and collaboration with all stakeholders
- Performs other related duties and responsibilities, as assigned

Required Skills and Experience

- Bachelor's degree (BS, BA). Master's degree preferred
- Degree in regulatory affairs and/or a science-related field or equivalent experience
- Minimum six years' medical device regulatory experience (US FDA Class II and EU MDD/MDR)
- Extensive experience with US and global medical device regulations and 510K submissions

- Experience writing Clinical Evaluation Reports (CERs) that are compliant with MEDDEV 2.7.1 revision 4
- Knowledge of the impact that the transition from the Medical Device Directive (MDD) to the Medical Device Regulation (MDR) will have on manufacturers and notified bodies
- Experience working in a broader enterprise/cross division business-unit model preferred
- Ability to work in a matrixed and geographically diverse business environment
- Strong leadership skills, including the ability to set goals and provide positive and constructive feedback to build relationships and improve business results
- Ability to work effectively within a team in a fast-paced changing environment
- Multi-tasks, prioritizes and meets deadlines in timely manner
- Regulatory Affairs Certification (RAC) from the Regulatory Affairs Professional Society strongly preferred. American Society for Quality (ASQ) certifications also desirable
- Strong organizational, planning, and follow-up skills and ability to hold others accountable
- Ability to travel approximately 20%, including internationally

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 Melissa Tindall at melissa.tindall@monarchmedtech.com.