Regulatory Affairs Project Manager
Req#: 18000MHH

Careers That Change Lives

As a Regulatory Affairs (RA) Project Manager, you will be a member of the Medtronic Respiratory and Monitoring Regulatory Affairs team, working directly with leadership, managers, and individual contributors to plan and execute projects to ensure our devices maintain compliance with changing regulations on a global scale. The focus of this role is to identify the emerging regulatory issues relevant to our product portfolio, analyze the broad scope of implications to the business, and implement long-term solutions to ensure market access is maintained according to the business strategy. This position will oversee these regulatory compliance activities for the Patient Monitoring (PM) and Respiratory Interventions (RI) portfolio within the Minimally Invasive Therapies Group (MITG) of Medtronic. As a leader of regulatory compliance, you will be expected to command influence throughout multiple global facilities and be generally recognized as the expert within the department on managing state of the art product compliance.

A Day in the Life / Responsibilities

- Manage a matrix of programs with well-defined plans and flexible deliverable methodologies to integrate new and changing device regulations enabling product regulatory compliance.
- Establish and effectively communicate program objectives in line the broader MDT strategy.
- Define project resource requirements and negotiate team assignments with functional managers, as required.
- Create and manage project plans, strategies, timelines and budgets to track progress and hold assigned resources accountable.
- Leverage the policies and procedures of the quality system to direct execution of program activities.
- Interface with a variety of management levels and subject matter experts to drive decisions on significant matters, often requiring the coordination of activity across functional groups.
- Maintain oversight of project risks and mitigation plans to ensure business and project objectives are met.
- Challenge teams to meet and exceed project goals and commitments.
- Provide routine project status communications to senior leadership.
- Solve issues through information exchange, influence and active persuasion to gain cooperation of other functions on program objectives.
- Lead in the understanding and awareness of global regulatory requirements to ensure compliance. Disseminate and provide guidance and continuing education, as applicable.

Must Have: Minimum Requirements

- Bachelor's Degree in Business, Engineering, or a technical discipline
- 5+ years of medical device and work experience in regulatory affairs and/or quality assurance with a Bachelor's Degree; or 3+ years of experience with an advanced degree.
- 1+ years of cross-functional project management experience.

Specialized Knowledge Required

- In depth knowledge of regulations and standards affecting the medical device industry.
- Experience with Project Management principles, concepts, practices and standards.
- Experience providing work direction, coaching and guidance to project teams.
- Experience with MS Office, including MS Project.

Preferred Qualifications

- Advanced degree preferred.
- Demonstrated competencies in project management resulting in measurable outputs.
- Experience with 510(k) applications, IDEs, PMA or PMA supplements and US device regulations and/or experience with other international medical device regulations and submissions.
- Experience with EU Medical Device Directive (MDD) 93/42/EEC and exposure to EU Medical Device Regulation (MDR) 2017/245 and industry standards.
- Experience with Corrective and Preventive Action processes and programs.
- Proven success working and negotiating with people from various disciplines, organizations, and cultures.
- Ability to follow scientific arguments, identify regulatory scientific data needs, solve regulatory issues, and define regulatory strategy.
- Strong attention to detail.
- Ability to work in a highly matrixed and geographically diverse business environment.
- Strong verbal and written communications with ability to effectively communicate at multiple levels in the organization.
- Ability to work independently with limited oversight.
- Ability to identify and solve problems in a strategic manner and to manage complex projects.
- Demonstrated ability to understand regulatory requirements and incorporate into business decisions.
- Confident and assertive style, goal oriented, and respectful of others.
- Team oriented and able to adjust leadership style to maximize effectiveness.

Physical Job Requirements

- The physical demands described within the Responsibilities section of this job description are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.
- While performing the duties of this job, the employee is regularly required to be independently mobile.
- The employee is also required to use a computer, and to communicate with peers and co-workers.

About Respiratory and Monitoring Solutions

Our division within Medtronic draws on decades of experience across respiratory care to create innovations that underpin every element of respiratory health. As a member of the RMS organization you'll be part of a business that promotes the best outcome for patients in two key areas: Respiratory Interventions and Patient Monitoring.

About Medtronic

Together, we can change healthcare worldwide. At Medtronic, we push the limits of what technology, therapies and services can do to help alleviate pain, restore health and extend life. We challenge ourselves and each other to make tomorrow better than yesterday. It is what makes this an exciting and rewarding place to be.

We want to accelerate and advance our ability to create meaningful innovations - but we will only succeed with the right people on our team. Let's work together to address universal healthcare needs and improve patients' lives. Help us shape the future.

Link

https://jobs.medtronic.com/jobs/regulatory-affairs-project-manager-respiratory-and-monitoring-54094