PRINCIPAL REGULATORY AFFAIRS SPECIALIST (190002VS)

The Minimally Invasive Therapies Group (MITG) strives to enable earlier diagnosis, better treatment, faster complication-free recovery, and enhanced patient outcomes through less invasive surgical solutions. Respiratory, Gastrointestinal & Informatics (RGI) offers technologies to help with early detection and treatment of gastrointestinal diseases and cancers, and focuses on reducing complications through patient monitoring.

Careers That Change Lives

The **Principal Regulatory Affairs Specialist** is responsible for developing strategies for worldwide governmental approval to introduce new products (Class II & III) to market, maintain existing products, provide advice on regulatory requirements, prepares worldwide submissions and negotiates their approval with the agencies. In addition, this position also assists with the training of other regulatory affairs associates and provides work direction on projects of large scale with significant business impact.

A Day in the Life / Responsibilities:

- Team with business unit Regulatory Affair Specialists and international regulatory staffs to provide regulatory support for new products/therapies and changes to existing products. Work with RAS, engineers and technical experts to resolve potential regulatory issues and questions from regulatory agencies.
- Prepare FDA submissions for new products and product changes as required to ensure timely approvals for clinical studies and market release. Review significant product submissions with manager and negotiate submission issues with agency personnel.
- Provide support to currently-marketed products as necessary. This includes reviewing labeling, promotional material, product changes and documentation for changes requiring government approval. Prepare submissions and reports for FDA and support other international agencies as required by product status.
- Review only significant submission decisions/content issues with manager.
- Interact directly with FDA and/or indirectly with international regulatory agencies on most projects/products at reviewer level. All significant issues will be reviewed with the manager.
- Support regulatory compliance activities, including manufacturing site registration, GMP audit, post-market vigilance reporting, product recalls, etc., as needed.
- Maintain proficiency in worldwide regulatory requirements; establish and maintain good relationships with agency personnel.
- Provide business and product information to international regulatory staffs to enable development of strategies and requirements and communicate that information to business teams.
- Provide feedback and on-going support to product development teams for regulatory issues and questions.
- Ensure personal understanding of all quality policy/system items that are personally applicable. Follow all work/quality procedures to ensure quality system compliance and high-quality work.
- May mentor or supervise other RAS, as directed by manager.

Must Have: Minimum Requirements

- Bachelor’s degree
- 7+ years of experience in regulatory affairs or the medical device industry with Bachelor’s degree OR
- 5+ years of experience in regulatory affairs, or the medical device industry with engineering degree and Master's degree
- Experience working with medical device or pharmaceutical regulatory submissions

Nice To Have:

- 9+ years medical device industry experience
- Advanced degree in a scientific discipline (engineering, physical/biological or health sciences).
- Effective interpersonal skills
- Effective team member
- Ability to comprehend principles of engineering, physiology and medical device use. Good analytical thinking skills.
- Ability to effectively manage multiple projects and priorities.
- Proficient computer skills
- Experience with Class II/III medical devices (510(k), PMA, IDE)
- Experience performing advertising and promotion reviews for medical devices
- Medtronic product development experience
- Clinical or statistical experience
- Experience with FDA and international regulatory agency requirements, ISOIGHTF standards
- Project management skills

To Apply:

Please follow this link: http://m.rfer.us/MEDY52rRm

Or visit: https://www.medtronic.com/us-en/about/careers.html and search for Requisition number: 190002vs.

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.

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. For Office Roles: While performing the duties of this job, the employee is regularly required to be independently mobile. The employee is also required to interact with a computer, and communicate with peers and co-workers. Contact your manager or local HR to understand the Work Conditions and Physical requirements that may be specific to each role. (ADA-United States of America)