Regulatory Affairs Manager
Location: US

COMPANY OVERVIEW

BVI® is a global ophthalmic medical device manufacturer with a mission to deliver high quality solutions and innovation for advancing eye surgery and improving the vision of patients. With nine decades of developing leading products and solutions, BVI partners with ophthalmic surgeons to improve the vision of millions of patients across the globe. Our team supports surgical teams, in more than 115 countries worldwide, either directly or through our network of trusted distributors. Our trusted brands include: Beaver® (Knives and Blades), Visitec® (Cannulas), Malosa® (Single-Use Instruments), Vitreq® (Vitreoretinal Surgical Products) and PhysIOL® (Premium Intraocular Lenses).

PURPOSE

The incumbent has Regulatory responsibility for premarket approvals/notifications for specified BVI products. They will oversee the development and implementation of strategic and operational aspects of regulatory strategy and execution for BVI Class I, II and III medical devices. The incumbent functions as the regulatory subject matter expert on the core team, including providing input into the clinical strategy. Responsibilities include developing a strategic regulatory plan through submission and approval in key markets and supporting product regulatory filings and registrations regionally.

RESPONSIBILITIES

New Product Approvals

- Manages development, review and approval of core submission documents, regulatory documents (e.g., Pre-market approval applications (PMAs); Investigational Device Exemptions (IDEs); 510(k) applications; General Safety and Performance Requirements (GSPR) checklists and technical summaries) and label content.
- Supports the design and execution and reporting of pivotal clinical trials in line with Good Clinical Practice, BVI SOPs, FDA guidelines, and ISO standards (as applicable), including prioritizing indications, choosing appropriate populations and endpoints, planning and executing statistical analysis, and identifying Regulatory risks.
- Leads application of regulatory strategy and related activities needed to demonstrate safety and effectiveness and to reach premarket notification and/or approval.

- Assists during Notified Body/ Competent Authorities audits, act as RA Product Subject Matter Expert (SME).
- Participates in the development of strategy for risk-based approaches and in risk analysis meetings.
- Represents Regulatory Affairs in cross-functional teams as needed.

Regulatory Intelligence

- Perform tasks related to integrating and maintaining the requirements of new regulations (including, but not limited to MDSAP, MDR, FDA).
- Contributes to development and utilization of a Regulatory knowledge base that can enable continuous improvements and drive efficiencies through regulatory processes, including registration management.

LCM / Change Control

- Provides support to the Quality department. May serve as the backup of the QA Project Leader for the role of Independent Person (who has no direct responsibility for the project) during product design reviews.
- Provides Regulatory support for experimental tests within the framework of R&D projects.

REQUIRED KNOWLEDGE, SKILLS AND ABILITIES

- Excellent written, verbal communication, and presentation skills. Strong medical and technical writing skills with an ability to share information in a standardized format to convey complex concepts to a variety of stakeholders
- Strong working knowledge of FDA and EU MDR requirements, including PMA, IDE, and/or 510(k) applications
- Excellent analytical skills, with keen attention to detail
- Ability to plan and deliver against project deadlines
- Ability to balance multiple priorities simultaneously
- Ability to resolve complex issues with a high degree of initiative
- Ability to work independently as well as collaborate across the organization
- Ability to establish and maintain effective working relationships with coworkers, managers and clients
- Positive, self-motivated, detailed, and hands-on

MINIMUM REQUIRED EDUCATION AND EXPERIENCE

- Bachelor's degree in engineering, biology, or related field. Advanced degree and/or RAC preferred
- 5 years regulatory experience in a medical device organization with Class I, II and III medical devices

PHYSICAL REQUIREMENTS

- Extensive use of keyboard requiring repetitive motion of fingers.
- Extensive use of telephone and face-to-face communication requiring accurate perception of speech.
- Regular sitting for extended periods of time.
- May require travel up to 15%

Interested? Submit a cover letter and C.V.
to TalentAcquisition@bvimedical.com

BVI is an Equal Opportunity/Affirmative Action employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability, or protected Veteran status.

The above information on this description has been designed to indicate the general nature and level of work performed by employees within this classification. It is not designed to contain or be interpreted as a comprehensive inventory of all duties, responsibilities and qualifications required of employees assigned to this job.

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