Regional Regulatory Operations Manager

Location: Latin America

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 works with the Senior Director, International Regulatory and Operations to design appropriate strategies in support of all BVI product registration activities, regardless of origin, and is responsible for their oversight and execution. This includes tracking and ensuring timely renewals, planning and management of license-holder and distributor relationships, and leading company interactions with Health Authorities and agencies across the region.

The Regional Regulatory Operations Manager r has deep knowledge of the strategic and operational aspects of regional regulatory compliance and registration requirements for BVI Class I, II and III medical devices.

RESPONSIBILITIES

- Leads the development of regulatory strategy for the region and plans the resourcing and activities necessary to advance the business in the region.
- Serves as the regional regulatory subject matter expert and contributes to development of global regulatory affairs strategy and plans
- Ensures regulatory performance is conducted in accordance with procedures, internal guidelines, and industry / regulated standards and requirements.
- Works with Quality to plan and manage interactions with regulators; assists during notified body/ competent authorities audits, may act as RA Product Subject Matter Expert (SME).
- Determines appropriate requirements and balance of Licensing and Distributor agreements and relationships in the Region
- Manages the company's relationship with Distributors and License Holders in the Region; oversees their performance, budgets, resourcing and ROI to BVI.
- Other duties as required

REQUIRED KNOWLEDGE, SKILLS AND ABILITIES

- Strategic and operational planning strengths; able to convert high level concepts to actionable plans, confident in the selection and assignment of appropriate tools and resources.
- Active participation in leadership and executive-level environments; confident to advocate and negotiate from a strong point of view.

- Highly skilled at building and maintaining effective and productive relationships with key stakeholders; ability to engage with multiple stakeholders while ensuring alignment, commitment, and compliance.
- People management and oversight capability, both with direct reports and influencing colleagues from other teams.

  Positive, self-motivated, detailed, and hands-on, with the ability to work independently as well as collaboratively across the enterprise.

MINIMUM REQUIRED EDUCATION AND EXPERIENCE

- 5-7 years of industry experience in regulatory affairs functional leadership role, or in a related area such as quality, technical or clinical research.
- 10+ years of operations experience in a medical device setting.
- Bachelor's degree or higher in an appropriate discipline.
- Proven knowledge of regulatory requirements, and prior experience working with regulatory agencies; Latin America regional knowledge a plus
- Experience with Class I, II and III medical devices.
- Demonstrated experience supporting major regulatory submissions (ANVISA, Cofepris)
- Project management and leadership experience.

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 occasional travel.

Beaver Visitec International 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.

Important notice to Employment businesses/ Agencies
BVI does not accept referrals from employment businesses and/or employment agencies in respect of the vacancies posted on this site. All employment businesses/agencies are required to contact BVI's human resources department to obtain prior written authorization before referring any candidates to BVI. The obtaining of prior written authorization is a condition precedent to any agreement (verbal or

written) between the employment business/ agency and BVI. In the absence of such written authorization being obtained any actions undertaken by the employment business/agency shall be deemed to have been performed without the consent or contractual agreement of BVI. BVI shall therefore not be liable for any fees arising from such actions or any fees arising from any referrals by employment businesses/agencies in respect of the vacancies posted on this site.