Regulatory Affairs Manager

Location: China

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. He 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 in China. The incumbent functions as the regulatory subject matter expert on the core team, including providing input into the clinical strategy.

RESPONSIBILITIES

New Product Approvals

- Adherence to BVI credo and industry code of conduct、ethics and good regulatory practices, comply with local legislation and global regulatory policies.
- Responsible for the life-cycle management for key new product registration projects, make strategic registration plan for each high priority registration project per set registration timeline per project team, execute regulatory submission and monitor related post market surveillance activities.
- Responsible for product change impact assessment per applicable NMPA regulation and implement change registration accordingly.
- Responsible for NMPA extension registration within the set timeframe.
- Establish strong relationship with related authority agencies to better support BVI product registration and achieve regulatory compliance to meet China panel and industry standard/technical requirement.
- Actively monitor& analysis any update about NMPA regulation and clearly communicate with global HQ to avoid negative impact for BVI regulatory compliance together with other cross function stakeholders.
- Responsible for product labelling management including RA data、IFU、label template etc.
- Support tendering and commercial team's business events related to regulatory materials.

- Represents Regulatory Affairs in cross-functional teams as needed.

Regulatory Intelligence

- Perform tasks related to integrating and maintaining the requirements of new NMPA regulations.
- Contributes to development and utilization of a Regulatory knowledge base that can enable continuous improvements and drive efficiencies through regulatory processes, including registration management.

REQUIRED KNOWLEDGE, SKILLS AND ABILITIES

- English fluent in 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 NMPA、FDA and EU MDR requirements
- 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. Ophthalmology experience and CER practice preferred.

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%

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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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