Director, Regulatory Affairs

Location: Rome, Italy

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), EndoOptik® (Endophotocoagulators) and OptiKon (Phaco and Vitrectomy Systems and accessories).

PURPOSE

The Director, Regulatory Affairs will lead the strategic direction and operational aspects of regulatory compliance and submissions for medical devices and diagnostics. The incumbent functions as the regulatory subject matter expert for Technical Documentation filings and global registrations.
This position will be responsible for developing strategic regulatory plans, person with regulatory compliance responsibilities, primary point of communication with global regulatory agencies and with BVI Corporate office.

RESPONSIBILITIES

This position will be responsible for developing a strategic regulatory plan to maintain EU MDD 93/42 EEC documentations as well as transition MDR 2017/745 and other international requirements of the reference markets were applicable.

- Develop strategic direction and priorities for MDR 2017/745, works with R&D, Technical Teams, Marketing and Quality leadership to define clinical development projects including objectives, work plans, milestones and deliverables.
- Work with internal and external parties to design and execute BVI SOPs, applied ISO standards (as applicable), including, identifying risks.
- Review and understand gap assessments on Product Technical Files against MDR requirements. Review all technical documentation, including, but not limited to, design verification & validation protocols & reports, risk management files, usability protocols & reports, manufacturing process information, biocompatibility evaluation of risk reports, labelling content, list of applicable standards, list of general safety and performance requirements, declaration of conformity, and clinical data.
- Provides overall regulatory compliance site management.
- Actively support the regulatory submission process, acting as a point of contact for local and/or global regulatory bodies.
- Supports the collection and provision of data required to submit to EUDAMED.
- Work with EUMDR Program Director lead to determine implementation plan to complete updates to technical documentation.
    - Ensure regulatory compliance of BVI's devices with the EU and other global regions and other applicable regulatory jurisdictions, identifying and assessing regulatory risks.
- Determine issues and problem solves regulatory obstacles; investigate and propose solutions.

- Responsible for promotional materials review and product labeling as they relate to MDR registration and commercialization of medical devices.
- Leads regulatory activities and team, in accordance with MDD 93/42/EEC, MDR 2017/745 and the international requirements of the reference markets, of PMS - PMCF - CER for the product portfolio
- Regulatory SME to support new product development and sustaining engineering teams to assure collection of appropriate data for Product Technical Documentation (regulatory submissions) and compliance related activities e.g. PMS, significant change assessments, regulatory affairs assessments.
- Lead other regulatory workstreams to manage the allocation, implementation and coordination with other company operations.
- Adhere to and ensure the compliance of BVIs Code of Ethics, all Company policies, rules, procedures, and standards.

REQUIRED KNOWLEDGE, SKILLS AND ABILITIES

- Knowledge of certifications/industry regulations (ISO 13485, MDR 745/2017, 93/42/CE, FDA, CFDA, ANVISA)
- Leadership skills, strategic planning, and budget establishment
- Participates in Sr. Level meetings, regulatory authorities and cross divisional peers activities
- Orientation for detailed work with emphasis on accuracy and completeness
- Effective written and oral communication skills in both Italian and English
- Good organizational and planning skills; drives for results
- Effective analytical/problem solving skills and able to make appropriate decisions based on data
- Good interpersonal skills that include working well in a team environment and the ability to lead others
- Proven ability to exercise reasonably independent judgment and discretion within a defined range of policies and practices
- Ability to handle multiple tasks and to prioritize/schedule work to meet business needs
- Working knowledge of international requirements and quality systems
- Intermediate knowledge of the Microsoft Office suite including Word, Excel, Teams, and PowerPoint
- Ability to establish and maintain effective working relationships with coworkers, managers, and clients
- Ability to work independently
- Ability to manage multiple tasks simultaneously and prioritize work

MINIMUM REQUIRED EDUCATION AND EXPERIENCE

- Educational University Masters Degree in Engineering or related field and 10 years' Regulatory Affairs experience; or equivalent combination of education, training and experience
- Regulatory Affairs Certifications (RACs) preferred
- Medical Device Industry Preferred
- Experience with medical device certifications and medical device registrations in EU and non-EU markets
- Experience with US FDA and other outside the EU regulatory experience preferred
- Experienced in the skillful preparation of product technical documentation.

- Assumes the Person Responsible for Regulatory Compliance (PRRC) responsibilities

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.

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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.