Principle Regulatory Affairs Specialist

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 Sr. Regulatory Affairs Specialist will be responsible for preparing gap assessments and preparing updates to BVIs product technical documentation that are required to meet the requirements of Medical Device Regulation (EU) 2017_745 and international registrations. The incumbent will interface with, and assess documents from, various departments such as local and global Regulatory Affairs, Medical/Clinical Affairs teams, R&D, Quality Engineering and Manufacturing. Works in a fast-paced Cross-Functional Team to develop and support EUMDR compliance and helping to global ensure business continuity.

RESPONSIBILITIES

- 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.
- Support 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.
- Work with regulatory affairs and MDR program work stream leads to ensure technical documentation update timelines are aligned.
- Participate in regulatory impact assessments as it relates to the MDR and relay the information to product specific RA team member and/or design teams.
- Identify use of appropriate International standards.
- Work in coordination with MDR program and monitor MDR government agency laws and regulations through websites and publications.
- Provide global registration documentation as applicable to the business i.e. renewals and new registrations.
- Bring MDR Regulatory Affairs questions/issues to the attention of MDR Project Management team.
- Review and coordinate vigilance reporting and communication with Notified Body and/or local authorities.

- Interact with Notified Body reviewers and auditors during product technical file active reviews.
- Determine issues which may create regulatory obstacles; investigate and propose solutions.
- Serve as MDR Regulatory Affairs team member for promotional materials review and product labeling as they relate to MDR registration and commercialization of medical devices.
- Participate in the regulatory activities, 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
- 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.
- To participate in the activities of managing the allocation, implementation, updating and archiving of medical device UDI, in 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)
- 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 with routine supervision
- Working knowledge of international requirements and quality systems
- Proficient Microsoft Office suite of applications, 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
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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.

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.