Regulatory Compliance Manager
Location: Liège, Belgium

COMPANY OVERVIEW

BVI® is refocusing the future of vision. As one of the fastest-growing, diversified surgical ophthalmic businesses in the world, our purpose-built portfolio spans more than 115 countries. We've set our sights on touching the lives of millions of patients affected by conditions such as cataracts, refractive error, glaucoma, retinal disease, and dry eye.

Unburdened by legacy or bureaucracy, we have developed our strategy around a simple concept — taking pride in delivering innovative solutions for our physicians and patients, based on their needs. We trust and empower our associates to make decisions and solve problems because collaboration drives us. Valuing agility, simplicity, and transparency, we stay committed to listening to our customers, delivering for our patients, and keeping the future in focus.

PURPOSE

The role will be responsible for the management of people and process for regulatory compliance activities in the post-market phase of the product lifecycle to meet the requirements of the Medical Device Regulation (EU) 2017-745 (EU MDR) and other international regulations and standards.

This role will include:

- Responsible for the strategy, planning and oversight of field actions, including but not limited to regulatory sections of the Health Hazard Analysis (HHA), recalls, Field Safety Notifications (FSN), Field Safety Corrective Action (FSCA), corrections, removals, with possible interactions with regulatory authorities.
- Responsible for timely materiovigilance reporting to legal authorities and follow-up communications.
- Regulatory assessments, reviews and approvals of changes of product and process. Definition of the change notifications strategies to regulatory and auditing organizations.
- Responsible for label/labelling content according to applicable regulatory standards and regulations.
- Oversight of UDI process and reporting to authorities.

- Collaborates with cross functional and global teams such as Regulatory, Quality, Clinical, Marketing, R&D, Operations departments and individual stakeholders and leaders.
- Coordinates and communicates with regulatory authorities and senior management.
- Collaborate with the Quality team on the control of the economic operator as per the EU MDR provisions.

RESPONSIBILITIES

Vigilance, Field Safety Actions, Post-Market Reporting

- Act as subject matter expert for guidelines and regulations regarding field actions, reportable incidence determination, regulatory section of Health Hazard Analysis (HHA)
- Responsible for the regulatory strategy, planning, communications and reporting to competent authorities and to the senior management related to field action and materiovigilance reporting decisions.
- Oversee the timely completion and distribution of adverse experience reports to Health Authorities, distributors, customers.
- Participate in the associated Corrective and Preventive Actions (CAPA) by investigating the root causes, proposing and implementing solutions, monitoring efficiency or other appropriate activities.
- Participate in the risk/hazard assessments associated to the FSCAs and recommend solutions.

Economic Operator regulatory management

- Collaborate with International regulatory, Quality and Legal teams to put under control the framework of operations of the company for its different economic operator roles.

(electronic-) Labelling activities

- Provides regulatory conformity assessment of product labelling content (IFU, Brochure, Web, etc.).
- Supports the implementation of labels/labelling (electronic or paper based) content in compliance with country-specific requirements, considering the packaging and marketing workflows.
- Conducts periodic regulatory labelling reviews to ensure compliance with regulations and standards, to minimize regulatory exposure and to preserve confidentiality of applicable product information, during the product lifecycle.
- Provides UDI guidance, develop SOPs and registers of devices in applicable regulatory databases i.e. EUDAMED, GUIDID

Change management

- Recommend state of the art changes for labeling, manufacturing, promotional/marketing materials for regulatory compliance.

Risk management

- Provides inputs from post-market vigilance and compliance activities for life cycle management.

Registration/Renewals activities

- Responsible for adequate and timely maintenance of EUDAMED or similar regulatory databases for the different Economic operator roles of the business unit.
- Participate in the review significant product change notification with senior management and elaborate action plans for submission issues.
- Support the International regulatory team with inputs for the product change notifications in the countries recognizing the CE mark (e.g. 27 EU countries) and other global jurisdictions (ex. UKCA registration) where product is marketed.

Product technical documentation – inputs and support to the Regulatory product specialists

- Provide inputs to the Technical Dossiers (TD), Technical Files (TF) and other technical documentation in the Design History Files (DHF) according to applicable international regulations & standards (i.e. EU MDR, US FDA) in the post-market phase and as part of the product lifecycle management, and the maintenance/update of the regulatory submissions.
- Provide support to the review of the design documentation (V&V, user needs, design inputs/outputs, claims, risk management) for regulatory compliance matters, provide assessments and signatures as necessary.

Management

- Management of processes related to regulatory compliance in the post-market phase of a medical device product lifecycle.
- Organizes the workload for all projects under direct responsibility, as well as for eventual direct reports and/or external stakeholders.
- Participates in regulatory compliance budgeting process.

Regulatory surveillance

- Participates in the maintainance and verification of the proficiency in worldwide regulatory and normative requirements.
- Completes regulatory effectiveness checks with customers and provide closure reports to authorities.

Activities related to audits and quality assurance aspects

- Responsible to SOPs for processes for which has direct responsibility. Trains stakeholders as appropriate.
- Supports and providing regulatory input for and appropriate follow-up to inspections and audits.

REQUIRED KNOWLEDGE, SKILLS AND ABILITIES

- Ability to lead cross functional, often international teams made up of stakeholders with different, sometimes conflicting, priorities, questions, motives and concerns
- Familiarity with EU Medical Device Regulation (EU 2017/745), ISO 13485:2016, and optionally 21CFR820 or other regulations
- Strong verbal and written communication skills, as well as excellent public speaking skills.
- Ability to work evenings and early mornings to accommodate online meetings with global colleagues.
- Detail-oriented but able to also see big picture strategy
- Uncompromising integrity and professional ethics.
- Ability to travel up to 20% of time, including international travel, in support of compliance responsibilities and initiatives.
- Experience and knowledge on reimbursement policies and Europe, preferred.

MINIMUM REQUIRED EDUCATION AND EXPERIENCE

- For jobs not normally requiring a university graduate, use the phrase "High school diploma or educational equivalent plus BSc+ in Regulatory Affairs or Quality Assurance, Biomedical Engineering or Medical Device engineering, life sciences, or an equivalent combination of education and work experience. Regulatory Affairs Certification (RAC) (optional)
- Minimum of 7 years of progressive experience in quality/regulatory compliance and/or Regulatory affairs in medical device or life science industry, preferably in ophthalmology.
- 3+ years of leadership experience as demonstrated through direct management and/or mentorship/advisory capacity
- Fluency in English (speaking, reading, writing); Good communication and reading skills in French are 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 occasional travel.

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

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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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