Regulatory Affairs/Quality Assurance Associate

COMPANY DESCRIPTION

Ventripoint Diagnostics Ltd is a medical device company that is primarily engaged in the development and commercialization of cardiac diagnostic tools. It sells its products worldwide. We are dedicated to developing quality, smart tools that help solve the immediate needs of our healthcare clinicians, and most importantly improves the clinical experience for our youngest to oldest patient.

Ventripoint offers a great work environment, professional development, challenging careers, and competitive compensation.

JOB DESCRIPTION

The RA/QA Associate supports the RA/QA Manager with various regulatory and quality assurance activities. In this new role on the Ventripoint RA/QA team, you will collaborate with the team to complete and maintain regulatory approval and clearances of products as well as ensure compliance to ISO 13485 standards and applicable regulatory requirements pertaining to the medical device industry (i.e., FDA, Health Canada, and CE).

RESPONSIBILITIES & AUTHORITIES

Regulatory Affairs

- Collaborate with other members of the organization with whom tasks must be completed.
- Assist in preparing and compiling regulatory market submissions and related documents (e.g., application forms).
- Assist in providing guidance and feedback to stakeholders on regulatory activities, (e.g., strategies, registration requirements
- Evaluate and advise on the technical documents for submission.
- Assist with regulatory assessment of new products and changes made to the product.
- Assist in development of regulatory affairs strategies regarding medical device regulatory requirements, risk management, registration, clinical testing requirements, and product safety testing standards.
- Review labeling and promotional materials for adherence to regulatory requirements
- Manage annual license renewals, certifications, and registrations
- Adhere to and promote the adherence to all Corporate, Quality and Health and Safety policies and procedures

Quality Assurance

- Ensure compliance with GMPs, Medical Device Regulations related to product importation, release and distribution in Canada, United States, and Europe.
- Maintain quality documentation and records.
- Assist in preparation and implementation of new SOPs.
- Gathering required documentation from suppliers.
- Perform GMP document review for release of product.
- Support and follow-up of CAPA action plans, deviations, and out-of-specification investigations.
- Support audits with regards to the preparation, conduct and follow-up for annual ISO/MDSAP quality system audit and external audits (e.g., supplier audits).

- Support the preparation and review of validation protocols and reports.
- Assess data and documents to ensure conformance to regulatory requirements.
- Analyze data to identify areas for improvement in the quality process (i.e., quality metrics)
- Perform other duties and projects as required.

QUALIFICATIONS

- Bachelor's Degree in Engineering or related field.
- 1+ years of medical device industry experience in a related role.
- Post Graduate Certificate in Regulatory Affairs or equivalent preferred.
- Knowledge and understanding of Health Canada, FDA, and CE regulations for medical device industry
- Experience with regulatory filings (i.e., 510(k), Health Canada applications, CE marking, and international registrations).
- Proficient in Microsoft Office Suite including Word, PowerPoint and Excel.
- Good problem-solving, organizational, analytical and critical thinking skills.
- Excellent written and verbal communication skills and interpersonal relationship skills.
- Attention to detail.
- Ability to work independently and manage changing and competing priorities in a fast-paced environment
- Ability to adapt and be flexible.
- Ability to work in a team environment.

HOW TO APPLY

Applications will only be considered from candidates eligible to work in Canada without sponsorship.

If you are interested in this position and can demonstrate that you meet the requirements defined in the job description, please email your resume to careers@ventripoint.com. Please include the job title you are applying for in the subject line of the email.

We thank all interested applicants; however, only those selected for an interview will be contacted.

WHAT WE HAVE TO OFFER

- Competitive compensation and benefits package
- Performance bonus plan
- Training and professional development support