Quality Assurance & Regulatory Affairs Manager

About Us

Vivo Surgical is Southeast Asia's pioneering surgical technology disruptor, engaged in developing innovative medical device solutions for better surgeries. An ISO 13485 certified company with international accreditations such as the US FDA and EU CE Mark, our products target the medical needs of the world through innovative applications of science & technology.

Our technologies redefine healthcare accessibility, allowing for widespread adoption of such modalities to improve patient outcomes. These encompass such fields as *in vivo* surgical LED lighting, portable endoscopy and minimally-invasive robotic surgery, which are strategically co-developed with leading healthcare institutions and KOL collaborators in territories such as the USA, UK, France, Germany, Brazil, Vietnam and Singapore.

Join us as we build towards our vision of being the Asia Pacific's leading medical device developer and manufacturer in surgical technology and robotics.

About The Role

We value the importance of having a robust Quality Assurance and Regulatory Affairs team that would serve as a key pillar for sustained commercial success. To that end, we are looking for a **Quality Assurance & Regulatory Affairs Manager** to join us on this journey. You will be part of our fast-growing team and will take ownership of your role from the get-go. You will work on ensuring our company's commitment to comply with regulatory requirements and to maintain the effectiveness of our Quality Management System (QMS). You will also be in charge of our products' regulatory strategies and submissions to various regulatory bodies around the globe. Your role will enable you to work not only with diverse functions within the Vivo Surgical team but also in close tandem with our external partners such as the suppliers, distributors and Notified Body (NB).

Your responsibilities shall include the following:

- Ensuring the company's commitment to the QMS.
- Leading the effort in the ISO 13485 and MDR documentation preparation for submission to NB.
- Preparing and reviewing product regulatory documentation submissions to international health agencies.
- Leading as the person-in-charge of internal audits and external suppliers/NB audits and acting as the person responsible for regulatory compliance (PRRC).
- Managing quality-related issues originating from internally, suppliers and customers.
- Reviewing and contributing to our products' Design and Development process in terms of procedures and documentation.
- Leading the QARA team and working with senior management to define and deliver the company's overall strategy based on quality and regulatory perspectives.

Your Qualifications & Experience

Minimum Bachelor's degree in Engineering or Science with at least 5 years of experience in quality assurance and/or regulatory affairs in the medical device industry.

- Shown a demonstrated understanding of the ISO 13485:2016, MDD 93/42/EEC and MDR 2017/745 requirements.
- Experienced in developing risk management-related documentation (risk management plan, file, report, FMEAs).

- Possess a strategic mindset to organize and prioritize tasks for effective and timely delivery of regulatory goals to meet the company's business objectives.
- Certification as an ISO13485:2016 lead auditor is highly preferred.

Contact

Please send your CV and cover letter to: hr@vivo-surgical.com.

We look forward to receiving your application.

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