Quality Assurance & Regulatory Affairs Executive

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 Executive** to join us on this journey. You will assist the QARA team to ensure that the company complies to quality and regulatory requirements. You will also support our products' regulatory submissions to various regulatory agencies 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:

- Assist in maintaining and ensuring compliance to the company's Quality Management System.
- Support during internal and external audits, and management review meetings.
- Responsible for quality control checks and batch release of incoming/outgoing parts and products.
- Facilitate response to quality-related feedback (internal, suppliers and customers).
- Aid in updating quality-related records, technical files and document releases.
- Help prepare the documentation for regulatory submission to the NB and international health agencies.

Your Qualifications & Experience

Minimum Bachelor's degree in Engineering or Science.

Fresh graduates are welcome to apply.

1-2 years' experience in quality assurance and/or regulatory affairs in the medical device industry would be advantageous.

Contact

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

We look forward to receiving your application.

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