Agoralaan Abis • 3590 Diepenbeek • Belgium
Tel: +32(0)11/28.69.02 • www.bedal.be

QA/RA Manager

As a Quality Assurance & Regulatory Assurance Manager (QA/RA Manager) you are responsible for the management, development and improvement of the quality management system and the regulatory requirements. You ensure the qualitative aspects of the medical devices and take up this responsibility towards customers, suppliers and official entities. You determine new procedures in order to guarantee the quality of the devices, as well as the registrations of the devices in the different regions.

Your responsibilities:

- You are the management representative for ISO 13485 and MDD and other relevant regulatory requirements
- You demonstrate and develop deep domain expertise in the regulatory requirements for CE marking of medical device products type Class I sterile.
- You serve as a CE marking SME for the product portfolio
- You support the quality aspects of new product development process (such as: technical file set up, coordination of lab tests, sterilization validation)
- You are responsible for the continuous improvement and development of the quality management system and keeping the quality documentation up to date
- You implement Quality Agreements and change agreements with suppliers
- You represent the company in quality audits (internally and externally)
- You serve as a company representative during regulatory inspections
- You manage complaint investigations and corrective and preventive actions

Your profile:

- University degree in a scientific direction (for example biomedical engineering, Bio-engineering, etc.)
- A minimum of 3 years of experience in an ISO regulated industry is required
- Relevant experience in the medical device industry is required
- Knowledge of the Quality system requirements (ISO 13485) is mandatory

- Excellent written and verbal communication skills and interpersonal skills. Ability to advise, persuade and negotiate with colleagues in a supportive and encouraging fashion. Must be able to relate effectively to people at all levels of the organization.
- Expert knowledge of regulatory requirements and the ability to translate regulations into clear data requirements to support CE-marking
- Ability to communicate with notified bodies technical writers and registration officers
- Prior participation in external and third party audit is required
- Experience in compiling technical files is required
- Strong execution capabilities.
- Results driven, business focused, and competitive.
- Ability to work independently under minimal supervision
- Fluency in English and Dutch is required.

Offer

- Young and dynamic work environment with a highly motivated team
- A competitive salary
- Location: Diepenbeek

About Bedal

Founded in 2011, BEDAL is committed to the design and development of novel high-performing solutions that make life easier for medical professionals and better for patients.
Bedal has been developing patent protected medical devices that provide catheter securement and allow patients to maintain daily hygiene while receiving treatment. Bedal has the ambition to expand its catheter securement device portfolio and deliver the best in class catheter stabilization and securement devices.

Contact

Email your CV to info@bedal.be