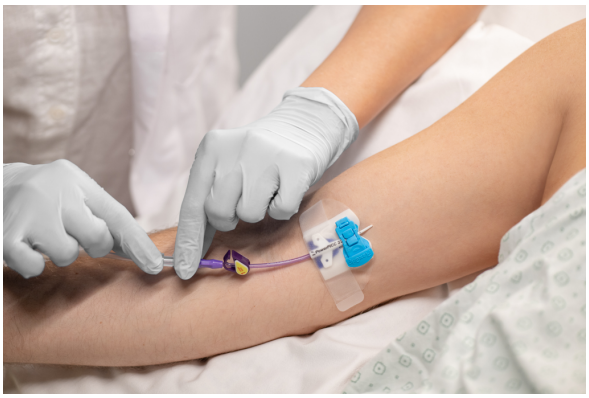
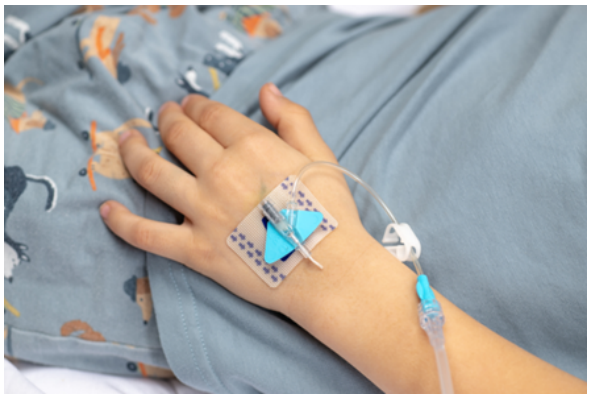
Agoralaan Abis • 3590 Diepenbeek • Belgium
Tel: +32(0)11/28.69.02 • www.bedal.be

Quality Engineer





Meet Bedal, a cutting-edge medical device scale-up of catheter stabilization devices. Our innovations guarantee the safe and secure stabilization of catheters that play a crucial role in long-term medical care. Currently making a difference in the lives of patients across over 30 countries, Bedal is rapidly growing.

As we surge forward, we are not just stopping at our current achievements. Our dynamic team is actively broadening our product line, crafting several new devices, and gearing up for high-volume production.

We are looking for a committed a Quality Engineer who is thrilled to be part of our exciting journey. If you enjoy contributing to the development of medical devices from the initial idea to market launch and large-scale production, this could be the perfect opportunity for you.

Are you passionate about working on products that have a global impact on patients? Do you thrive in a small team environment, engaging with clients and hospitals worldwide? If so, we want to hear from you!

What will you do at Bedal?

As a Quality Engineer, you will be at the forefront of managing and enhancing our quality management system and ensuring compliance with regulatory requirements. You take charge of the qualitative aspects of the medical devices and cover these responsibility towards customers, suppliers, and official entities. You monitor and improve the procedures to guarantee the quality of the devices.

Your responsibilities

- You develop and implement the quality procedures according to ISO 13485 and MDD/MDR along with other relevant regulatory requirements.

- You cultivate in-depth domain expertise in the regulatory landscape for obtaining market approval of medical device products type Class I sterile (CE, FDA, etc.).
- You provide support for the quality aspects of new product development process, including tasks like setting up technical file, coordinating lab tests sterilization validation).
- You drive continuous improvement and development of the quality management system, ensuring all quality documentation stays up to date.
- You implement Quality Agreements and change agreements with suppliers.
- You actively participate in both internal and external quality audits.
- You lead complaint investigations and implement corrective and preventive actions.
- You maintain the thorough documentation of the technical files.

Who are we looking for?

- You have a university degree, and a first experience in a quality role.
- You have relevant experience in the medical device industry and knowledge of the applicable quality system requirements.
- You have the drive and capability to ascend within the organization, taking on more responsibilities within the organization
- You have an affinity with production and assembly of products.
- You have excellent communication (verbal, written, listening) and interpersonal skills. You excel at advising, persuading and negotiating with colleagues in a supportive and encouraging manner.
- You foster a high level of personal and professional integrity and trustworthiness with strong work ethic.
- You work in a diligent and structured way and possess a quality-oriented mindset
- You are a hands-on profile.
- You are comfortable to work independently under minimal supervision.
- Your passion lies in making a positive impact on the lives of patients, contributing to something meaningful, and thriving in a scale-up environment.
- Fluency in English is required, Dutch is a plus
- You are willing to travel occasionally (destinations include EU, US and South America).

Our offer and commitment to you

- Young and dynamic work environment in a highly motivated team
- The opportunity to play a pivotal role in the success of a medical device scale-up company
- A competitive salary
- Location: Diepenbeek, in a hybrid work environment

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Contact

Email your CV to annelies@bedal.be