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QA/RA Manager

Full-time - Antwerpen, Belgium

Bingli is an innovative healthcare technology company dedicated to advancing medical software solutions. We are committed to delivering software as a medical device (SaMD) solutions that ensure the highest standards of quality, safety, and regulatory compliance.

Bingli is a digital health start-up, located in Antwerp. Based on Artificial Intelligence, a digital medical interview is conducted with the patient, prior to their medical consultation. Bingli then proposes a highly accurate differential diagnosis to the physician to support the clinical decision-making. This innovative application contributes to a more qualitative and efficient consultation, brings back more empathy during the consultation and creates more comfort for the patient. Bingli works together with doctors, hospitals as well as pharmaceutical companies.

Bingli is rapidly expanding and has big ambitions. To support this growth, we're looking for a (m/f/x):

Role Overview:

We are seeking a dynamic and experienced QA/RA Manager to join our team. This role involves a hands-on approach and a deep understanding of the software development lifecycle, as well as the regulatory requirements specific to SaMD for both European (MDR) and American (FDA) markets. Reporting directly to the CEO, the successful candidate will be instrumental in maintaining our compliance and enhancing our quality assurance strategies.

Key Responsibilities:

- Oversee and maintain the Quality Management System (QMS) documents, ensuring compliance with MDR class 2a and ISO 13485 standards.
- Manage the technical file for MDR class 2a compliance.
- Lead continuous improvement efforts in change control, CAPA management, and document control.
- Provide QA guidance throughout the software development phases to R&D teams.
- Serve as the Management Representative for the organization.
- Manage the customer complaint system and prepare monthly reports.
- Analyze product failures and generate detailed evaluation reports.
- Oversee software verification and validation processes, maintaining accurate records.
- Conduct internal audits and manage external ISO audit schedules, including correspondence and resolution of findings.
- Ensure that labeling and advertising are in compliance with regulatory standards.
- Manage Documentation Control Process and Documentation Change Control Process.

Qualifications:

- 5-10 years of experience in Quality Assurance and Regulatory Affairs specifically in software medical devices (SaMD).
- Strong expertise in MDR (class 2a) and ISO13485.
- Comprehensive knowledge of risk management and compliance regulations related to SaMD.
- Proven track record in software verification and validation specific to SaMD.
- Experience conducting internal audits and writing standard operating procedures and work instructions.

What we offer:

- Competitive salary and benefits package with home-working policy.
- Opportunity to work in a cutting-edge field of medical technology.
- Contribute to the growth of a start-up and the healthcare of the future.
- A challenging position in a rapidly growing environment, that provides you with numerous opportunities to learn new things and to take on new challenges and responsibilities.
- A dynamic and supportive work environment where you can take initiative and show leadership.
- Professional growth and advancement opportunities.

Application Process:.

Interested candidates should submit a resume and a cover letter outlining their qualifications and why they are a good fit for the position to jobs@mybingli.com

Join Bingli where you can make a significant impact on our products and help shape the future of medical software solutions!