RA QA PROJECT MANAGER

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Erkenningsnummer
VG. 1690/BO B-AB10.018.

JOB DESCRIPTION

Are you passionate about ensuring compliance and driving quality in a highly regulated environment? We are seeking a skilled and proactive RA/QA Project Manager to lead projects that uphold the highest standards in regulatory and quality assurance practices. In this role, you will be at the forefront of coordinating cross-functional teams, streamlining processes, and ensuring that every deliverable meets both internal and external requirements.

KEY RESPONSIBILITIES

Regulatory Affairs (RA) Responsibilities:

- Prepare and maintain technical documentation.
- Monitor and implement European and/or Belgian standards and legislation related to medical devices.
- Manage ISO and CE certifications.
- Act as the contact point for Materiovigilance and Post-Marketing Surveillance (PMS).
- Act as the Person Responsible for Regulatory Compliance (PRRC) for the following tasks outlined in Article 15 of the MDR:
    - Overseeing the monitoring and control of:
        - The manufacture of medical devices.
        - The post-marketing surveillance related to medical devices.
        - The vigilance activities related to medical devices.
    - Ensuring that the conformity of medical devices is properly verified before market release, in line with the quality management system.
    - Ensuring that Technical Document`tion and the EU Declaration of Conformity (DoC) are prepred and kept up-to-date.
    - Ensuring that obligations related to Post-Marketing Surveillance are applied and maintained in accordance with Article 83 of the MDR.
    - Ensuring that obligations related to the reporting of serious incidents and FSCA (Field Safety Corrective Actions) are carried out in accordance with Articles 87, 88, 89, 90, and 91 of the MDR.

Quality Assurance (QA) Responsibilities

- Monitor and adjust the Quality Management System (QMS)
- Write QMS instructions and train colleagues accordingly.
- Assess the feasibility of quality-related processes and factors affecting quality.
- Conduct internal audits of the QMS across all departments except proprietary processes.
- Organize and oversee external audits by institutions, organizations, and clients.
- Organize and monitor internal and external validation and qualification processes.
- Implement, monitor, and adjust corrective and preventive actions arising from non-conformities, internal and external process audits, complaints validation, and qualification reports.
- Act as a backup to the QA/QC/RA Manager during their absence.

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QUALIFICATIONS

- Degree in pharmacy, medicine, engineering, or another relevant discipline with a minimum of 1 year of experience in the production, quality control, and distribution of medical devices
- Any other degree with a minimum of 4 years of relevant experience in the production, quality control, and distribution of medical devices.
- Familiarity with the ISO 13485 Quality Management System, the Medical Device Directive (MDD), and the Medical Device Regulation (MDR).
- Familiarity with European and Belgian medical device legislation and standards.
- Ability to independently creare and implement new processes or analyze and improve existing ones.
- Flexible mindset with a willingness to learn in an ever-changing environment where every day brings new challenges.
- Strong communication, analytical, and creative thinking skills.
- Advanced proficiency in Microsoft Office.
- Fluent in Dutch and English.