Regulatory Affairs Manager

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

For a globally known manufacturer of high-quality disposable medical equipment for hospitals and home care, we are searching for a **Regulatory Affairs Manager**.

The purpose of this job is to ensure NME registration/RA, NMEs and environmental compliance. Next to this, the person needs to ensure that NME meets the obligations of the authorized representative described in the Medical Device Directive (MDD) and the importer, distributor and authorized representative obligations described in the Medical Device Regulation (MDR) excluding the activities linked to vigilance and Post Market Surveillance.

ROLE

The role of this function holder is,
1. to ensure NME registration/RA compliance
2. to ensure NMEs environmental compliance
3. to ensure that NME meets the obligations of the authorized representative described in the Medical
Device Directive (MDD) and the importer, distributor and authorized representative obligations described in the Medical Device Regulation (MDR) excluding the activities linked to vigilance and Post Market Surveillance.

YOUR RESPONSIBILITIES

***Registration/RA Compliance* (40%)**

• Distributes the registration activities among direct reports
• Contributes to internal activities and projects (e.g. new supplier selection) and collects technical advice/information from the assigned Sr RA officer and RA Specialist;
• Ensures the local registration requirements and timelines are tracked and documented;
• Ensures the registration projects are assigned and executed within timelines and in accordance with the procedures and work instructions;
• Reports high-level registration status to the RAQA Director;
• Coordinates projects that impact local market access (e.g. Brexit, Swiss exit);
• Ensure updates in company Medical Europe activities (distributor, importer, exporter and authorized representative) are reported to the Belgian Competent Authorities in due time;
• Ensures support in tenders related to regulatory topics
• Manages, guides and coaches the Sr. RA officer and Registration specialist.
• Strive to continuously improve registrations processes and procedures to enhance the collaboration and communication between NME departments for which Registration might have an impact

***Environmental Compliance* (25%)**

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• Maintains a high-level understanding of new and existing environmental regulations (Substances of Very High Concern in SCIP, hazardous substances, eco-design, circular economy, waste) that may impact the organization's products and processes.
• Ensures processes are developed to ensure compliance with environmental requirements (REACH, CLP, WEEE, ,...) for the distribution and import of medical devices and biocides manufactured by company's factories
• Ensures maintenance of data and files for future reference, particularly in the event of an audit by a regulatory agency / company its self
• Ensures company customers/distributors have a point of contact for their environmental related requests
• Escalation of non-compliances to the RAQA Director
• Manages, guides and coaches the RA Specialist – Environment

MDD/MDR Compliance (20%)

Ensures the registration of products with the Belgian Competent Authorities to meet the authorized representative obligations in the Medical Device Directive/Regulation;
• Ensures the maintenance of the certificate library which contains the EC certificates, Declarations of Conformity, and the ISO 13485 certificates.
• Coordinate Risk Management activities on NME procedures
• Ensures NME has access to the technical files for which NME is appointed as the authorized representative;
• Provides non-product related regulatory support to internal and external stakeholders;
• Escalation of non-compliances to the Person Responsible for Regulatory Compliance;
• Reviews external documentation prepared by NME Marketing or other internal stakeholders (Marketing Approval Form)

Change process (PVNC/VNC) 5%

• Review the changes initiated by the LM/suppliers of NME and improve process for change management
• Strive to continuously improve process and procedure to enhance the collaboration and communication.

Marketing RA Approval Process (MAF)/Quality 5%

• Do the Regulatory approval of the marketing material for NME – review the procedure for the process
• To the Regulatory review of the Quality Specifications for NME – draft a procedure for the process

Review of Quality Agreements 5%

• Review of the quality Agreements accompanying Distribution Agreements.

ISO, JSOX and Company Values
The employee performs all tasks in accordance with ISO quality and JSOX requirements, whilst always taking company values into account.