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Quality Specialist

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Company: Nipro Europe Group

Location: Mechelen

Category: other-general

About the job

As a total solution provider of medical devices and pharmaceutical packaging, Nipro Europe Group Companies is continuously committed to improving patient outcomes and quality of life. We are part of a large global network headed by Nipro Corporation Japan, an industry-leading healthcare company with over 35.000 employees worldwide. Our European headquarters in Mechelen, Belgium covers a wide geographical reach (Europe, Africa, India, the Americas) and is home to Nipro Medical Europe, Nipro PharmaPackaging International, and the Institute for Medical Practice (iMEP) Belgium."

Join our dynamic team at **Nipro Medical Europe**, a leading innovator in the medical device industry. We are committed to improving patient outcomes and transforming healthcare through our cutting-edge technologies. As we continue to expand, we are seeking a talented **Quality Specialist** to ensure the highest standards of quality and compliance in our products and processes.

About the Role

As a **Quality Specialist**, you will play a vital role in maintaining and enhancing our quality management systems. You will collaborate closely with cross-functional teams to implement and maintain quality processes, drive continuous improvement initiatives, and ensure adherence to regulatory requirements. This role offers an exciting opportunity to contribute to the development of life-saving medical devices and make a meaningful impact on patient care.

What you'll do

Complaints handling

Responsible for reviewing complaint documentation & ensure all information is timely available to the manufacturer for investigation.

Ensure a timely registration and closure of complaints according to internal procedures.

Organize shipment of samples and continuously improve the process

Master and improve the IT tools used in complaint handling.

Effectively manage the goods return and quarantine procedures in closed collaboration with Operations team.

Contributes to trend analysis.

Quality Management System

Maintaining relevant documentation in place in accordance to MDR and ISO 13485:2016.

Support the QA Manager in preparing reporting and management review reports.

Support specific improvement projects.

Maintain and improve the Quality Management System under the supervision of the QA Manager.

Internal and external audits

Perform internal audits, write reports, register NC as per the relevant procedure.

Support the Quality Manager during external audit and take care of the logistics.

Ensure CAPA documentation and follow up

Vigilance activities

Responsible for starting the discussion about reportability with NME team members.

Proactive request reportability to the legal manufacturers.

Ensure that the timelines set by the applicable regulations are met.

Draft Manufacturer Incident Reports and handle submission to the health authorities.

Leading or supporting FSCA and recall as needed.

What You'll Need

Bachelor's degree in engineering, science, or related field.

Minimum of 3 years of experience in quality assurance or regulatory affairs within the medical device industry.

Strong knowledge of quality management systems, and regulations applicable to Medical Devices (MDR, ISO 13485).

Experience managing complaints and vigilance activities is preferred.

Ideally, experience conducting internal audits and managing corrective and preventive actions.

Excellent communication and interpersonal skills, with the ability to collaborate effectively with cross-functional teams located in different time zones.

Detail-oriented mindset with strong analytical and problem-solving skills.

What We'll Offer

To the right candidate, we will offer the ability to develop and grow in a fast-paced international business setting. In addition to a competitive salary and benefits package, you will land in a friendly and dynamic workplace environment where people enjoy autonomy and taking initiative. Together with you and the team, you will be part of a "Nipro family network" that draws upon talent from around the globe.

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