Open position
QA Manager (32 hours)

About Ventinova Medical

Ventinova Medical BV is an ambitious, dynamic organization. The revolutionary medical products we develop in the field of ventilation enable important new ways of treating patients in the operating room and intensive care unit. With a broad team of developers, clinical researchers, marketers, sales people and anesthesiologists, we work hard every day to bring products that are regularly life-saving on the market.

Thanks to our flexible team, we can quickly respond to new challenges, that we hear from doctors, in patient ventilation.

We are looking for flexible team players with a broad view. Colleagues who are open, thoughtful and energetic. We have an informal and inspiring culture with high standards. Because we are a relatively small team, each of us has a wide range of activities.

Personal development through a varied, challenging and inspiring job is part of our culture. We are convinced that close cooperation is not only valuable for the best operating result, but also for further developing ourselves and having fun in our activities.

Ventinova Medical is looking for a QA Manager to ensure that both our organization and our products comply with legal and customer requirements. We do this by maintaining and monitoring our established and implemented quality management system (QMS) and guiding staff to run the processes in a lean and efficient manner.

The QA Manager is responsible for managing the quality policy and maintaining product approvals. The main tasks are maintenance and improvement of the quality management system, support of the development team regarding reviews and procedure monitoring, preparation and submissions for regulatory approvals, performing quality checks on products, keeping our certificates up-to-date and planning and performing internal and external audits.

You have several years of experience in quality management, quality control, regulatory affairs or in product development in a regulated industry and are you ready for the next step in quality management of medical equipment and regulations? Then this is the ideal position for you.

Activities:

- Maintenance and improvement of the quality management system for MDR/MDD and ISO 13485
- Maintenance and submissions for regulatory approvals
- Support of the development team for all quality and regulatory aspects and reviews
- Monitoring quality data, performing (trend) analyzes and reporting the status to management
- Organizing and conducting internal audits and the management review
- Organizing and conducting supplier audits
- Management of the complaint process and the process for corrective and preventive actions
- Communication with external certification bodies and guiding external auditors

Requirements:

- Experience in a regulated industry with quality systems and procedures
- Responsible and accurate
- Knowledge of quality standards (ISO9001, ISO13485, IEC14971, IEC62304), MDR/MDD or 21CFR820 is a plus
- Experience with internal and external audits is a plus
- Solid in English, spoken and written

We offer:

- The chance to be part of an innovative medical ventilator team
- Working hours to be determined, 32 hours a week (more/less hours negotiable)
- Location: Eindhoven

Interesse?

For more information, please visit our website: www.ventinovamedical.com or contact Rienco Verschelling: +31 (0)40 751 60 20.
Enthusiastic? Send your motivation and resume to info@ventinova.nl

A personality and skills assessment can be part of the selection procedure.

Acquisition in response to this advertisement is not appreciated