QUALITY & REGULATORY AFFAIRS MANAGER (0.6-0,8 FTE)

Job Description

In this role you have the opportunity to join a fast-growing venture, break into a billion dollar industry and impact on millions of lives by introducing a unique medical device solution in chronic wound care.

You are responsible for all activities in Quality and Regulatory Affairs, such as managing the ISO 13485 certified Quality Management System and assuring compliance with all other relevant standards, guidelines and legislation. You will be member of the management team and also have an advisory role towards the entire internal organization.

This role offers the unique opportunity to be part of our journey. Location office: Nijmegen.

You are responsible for:

- All activities in Quality and Regulatory Affairs
- Defining the QA/RA strategy and follow up on the annual QA/RA plan
- Managing and improving the company's quality management system
- Performing the internal and external audit planning and monitoring the follow-up of findings
- Advising and monitoring the internal projects regarding Quality Assurance and Regulatory Affairs
- Preparing and submitting documents for medical device registrations worldwide
- Together with management, ensuring implementation of the quality policy and quality objectives
- Communication with the Notified Bodies globally
- Training of the team on the quality management system (SOPs), guidelines and protocols and monitoring the adherence
- Active maintenance of the change control and CAPA processes.

Competences:

- Proactive and flexible attitude with a hands-on mentality
- Team player, and able to work independently
- Fluent and written communication skills in English, open and clear communicator (and Dutch is a pre)
- Project management skills

To succeed in this role, you should have the following experience:

- Bachelor or Master's degree, preferably in life science or background in technology.
- 4-5 years experience working in quality affairs in the medical device industry

- Knowledge of and experience with legislation, guidelines and standards pertaining to the medical device industry, including ISO 13485, ISO 14971, MDD and MDR, and FDA regulations

Are you interested in joining the Plasmacure team? For questions related to this opportunity and to send your application please email: jobs@plasmacure.nl

Shape your career at Plasmacure. See you soon!