



QUALITY AND REGULATORY AFFAIRS MANAGER (0.4 – 0.8 FTE)

Plasmacure is a fast-growing venture and its goal is to make an impact on millions of lives by introducing a unique medical device in wound care. Complex wounds are a serious health problem with major consequences for patients. In this role you have the opportunity to strengthen the Plasmacure team and in doing so making a difference for patients. You will share responsibility with your colleague QA/RA manager to ensure our company is adhering to rules and regulations, while supporting our growth strategy. We have offices in Nijmegen and Eindhoven, you will mostly be working from the office in Eindhoven.

You are responsible for:

- Preparation of QA/RA plans in line with strategic objectives
- Communication with the Notified Body and authorities
- Preparation of regulatory submissions (e.g. FDA)
- Preparation and leading internal and external audits
- Support of the CAPA process by approving all the CAPA plan, and the completed actions. Ensure review and approval of effectiveness check.
- Update management on the following:
 - The company's Quality Systems, including appropriate vendor relationships
 - Adherence to SOP's, guidelines and protocols
 - Any issues that may arise
- Review Technical Documentation

The following competencies and experience are necessary/recommended:

- Bachelor or Master's degree
- 4-5 years' experience working in quality systems in the medical device industry
- Knowledge and experience in regulations (FDA, MDR, ISO13485)
- Knowledge in guidelines pertaining to the medical device industry
- Working knowledge in GCP
- Proactive and flexible attitude
- Team player, but also able to work independently
- Strong verbal and written communication skills (Dutch and English), open and clear communicator
- Conscientious and structured way of working
- Project management skills
- Auditor certificate ISO13485 or ISO9001 (optional)

What we offer:

- Energetic and inspiring work environment where you are a part of making a difference for patients.
- Market conforming salary and good secondary conditions.
- Flexible hours/days and total number of hours can be discussed.

Are you interested in joining the Plasmacure team? For questions related to this opportunity and to send your application before 31 August 2022 please e-mail: jobs@plasmacure.nl

Shape your career at Plasmacure. See you soon!