



QUALITY AND REGULATORY AFFAIRS MANAGER (0.6 – 1 FTE)

Plasmacure is a fast-growing commercial stage venture and its goal is to make an impact on millions of lives through 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 you 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:

- Quality Management and Regulatory affairs
- Improvement and implementation of the Company's quality systems, including quality policy and quality objectives
- Prepare QA/RA plans in line with strategic objectives
- Communication with the Notified Body and authorities
- Prepare and lead internal and external audits (ISO 13485)

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 regulation and guidelines pertaining to the medical device industry
- 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, even when under pressure
- Working knowledge in GCP
- Strong ability to assess (updates of) regulatory guidelines
- Project management skills

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 15 November 2022 please e-mail: jobs@plasmacure.nl

Shape your career at Plasmacure. See you soon!