Product Reviewer - Cardiovascular

Home-based anywhere in Europe

clarisse@elemed.eu

The Company

Calling all regulatory affairs, quality, and R&D professionals! Do you want to oversee the newest innovations in implantable cardiovascular medical technology?

Have you ever thought about joining a notified body? We are offering a great chance for professional development in a notified body where you will have your voice heard and be more than just a number. You can expect an excellent work-life balance, working from home. The role is uniquely structured so that there is very limited travel. This notified body is growing its cardiovascular implantable device team, and this is your chance to be part of that! We are looking for Regulatory affairs professionals with experience in cardiovascular medical devices (Active OR non active devices).

As Product Reviewer, you will assess some of the most innovative products coming to the market: from startups and global corporations alike. You will add technical competence to this Notified Body in their product review team and ensure their reputation remains unrivalled. You will analyse and evaluate the manufacturer's technical documentation relating to implantable medical devices. Your primary responsibility is to aid manufacturers seeking a CE mark by performing conformity assessment activities across a range of different implants. You will report directly to the head of the notified body.

Responsibilities

As Product Reviewer you will:

- Plan, identify milestones, and oversee the entire conformity assessment project plan
- Assess manufacturer documentation for CE marking according to MDR 2017/745, caring out conformity assessment
- Provide input/recommendations to the audit team on areas of focus for QMS audits, based on your experience of reviewing the technical documentation
- Manage compliance and regulatory activities related to the notified body

This is a great opportunity to be at the forefront of the newest, cutting-edge technology. If you have previously worked in industry in regulatory affairs, quality, and/or R&D role, want to widen your product scope instead of being limited to one company, and work from home with limited travel then this could be the perfect opportunity for you.

Expectations

- Bachelor's, Master's or PhD in relevant science or engineering
- 4+ years regulatory affairs, quality and/or R&D experience
- Fluent in English
- Cardiovascular experience is necessary

Interested in this role?

If you are interested in this exciting role, please send your application directly to **clarisse@elemed.eu**

Would you like to find out more about our open opportunities? Visit https://www.elemed.eu/vacancies/