Notified Body

Product Reviewer : Software

Home-based anywhere in Europe!

The company

Calling all regulatory affairs professionals!

Do you want to oversee the newest innovations in medical software, embedded and standalone software as a medical device, machine learning and artificial intelligence?

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 non implantable/active device team, and this is your chance to be part of that! We are looking for Regulatory affairs professionals with experience in SOFTWARE.

As a product reviewer you will assess some of the most innovative software 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 manufacturer's technical documentation relating to medical software. Your primary responsibility is to aid manufacturers seeking CE mark by performing conformity assessment activities across a range of different medical device software - standalone and embedded. You will report directly to the head of the notified body.

eleMed

The activities

As Product Reviewer / Auditor 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 a **regulatory affairs role**, or with a **software development background** and 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

The requirements

Expectations:

- Bachelor's, Master's or PhD in relevant science or engineering
- 4+ years regulatory affairs experience with medical device software

Interested in this position?

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