PRODUCTS REVIEWER - AIMD PRODUCTS

Home-based anywhere in Europe

THE COMPANY

Calling all regulatory affairs, quality, and R&D professionals! Do you want to oversee the newest innovations in active implantable cardiovascular or neurovascular 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 active cardiovascular or/ and neurovascular products.

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THE COMPANY

As a products 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 products review team and ensure their reputation remains unrivalled. You will analyse and evaluate manufacturer's technical documentation relating to implantable medical devices.

Your primary responsibility is to aid manufacturers seeking CE mark by performing conformity assessment activities across a range of different implants. You will report directly to the head of the notified body.

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THE RESPONSIBILITIES

As Products 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 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.

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EXPECTATIONS

- Bachelor's, Master's or PhD in relevant science or engineering
- 4+ years regulatory affairs experience
- Must have experience in active medical devices products
- Fluent in English

INTERESTED TO EXPLORE THIS FURTHER?

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