



RA/QA MANAGER

Work from home with quarterly travel to site in Berlin, Germany. Open to candidates EU Wide.

Contact: tamanna@elemed.eu

THE COMPANY

Join a company that puts women's health at the forefront of its vision. This company is at an exciting point of growth and is now looking to hire its next RA/QA Manager to be part of an exciting roadmap to bring a new product to market globally. Be part of the think tank of a business that empowers its employees to develop key strategies and provides you with the support and environment to do so. With exciting prospects of their product developing within the US and Europe within the next two years, you will join at the perfect time to develop your career within RA and QA and be part of a business where you will leave your legacy.

This company really puts their people at the forefront with excellent benefits for all their employees, including (this list is not exhaustive):

- Shares within the business
- Flexible four day week, where Friday is considered a wellness day
- Home office flexibility, with the chance to be totally remote if you wish



RESPONSIBILITIES

As the Regulatory Affairs and Quality manager you will report directly into the Head of RA/QA.

Your responsibilities will cover:

Be part of a team that will be developing and driving key regulatory strategy for all products internationally; with a key focus on the USA.

Work with local and international notified bodies to ensure product approval

Be part of a regulatory team where you will be part of a FDA approval process

Play a key role within QMS and technical file management

Prospect to mentor and manage work students that join the business

Work closely with the engineers to process design and development technical files

(not an exhaustive list)



REQUIREMENTS

- 5+ years experience within regulatory affairs and/or quality assurance for medical devices. Any experience within software medical devices or women's health would be an advantage
- Experience of working to ISO 13485
- Previous CE marking experience would be a bonus
- FDA experience would be a bonus for this position
- Willing to be part of the business as a whole, working in close collaboration with multiple departments from the CEO and senior management team to the scientific engineers.
- Excellent communication skills in English

Interested to explore this further?

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