

Are you passionate about innovation and groundbreaking development? Do you want to join an organisation where you can really make an impact? Have you got experience in EU and US regulatory submissions?

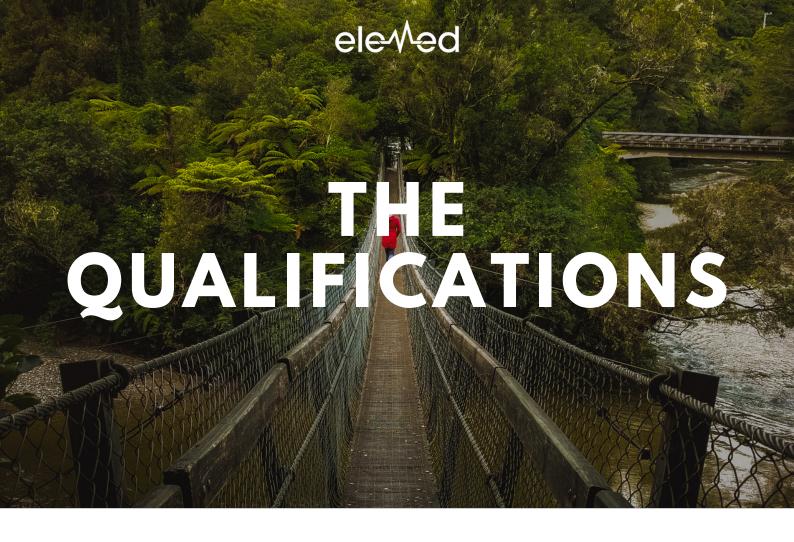
If yes, we have a fantastic opportunity for you!

This is a chance to join an extremely well funded, early commercialisation stage company with over 1000 patents - a huge innovation portfolio. Right now they are developing and bringing to market not one, but FOUR Class III active and (non active) implantable medical devices that are about to totally change the status quo.

With the continuous growth and development, the company is looking for a strong RA/QA Manager to manage the portfolio of products from cradle to grave and register them in key markets such as EU and US. This is an opportunity to step into a brand new position, no old shoes to fill here, reporting directly to the VP QA/RA and really make an impact on the Regulatory and Quality processes in the company, working with some of the most innovative and life-changing products.



- Manage, review and support the creation of technical documentation and the submission process to key notified bodies on an international scale
- Manage your portfolio of products through development and lifecycle management processes globally
- Work on Innovation projects as the regulatory representative, providing input regarding risk management, standards and guidance documents
- Work closely in supporting the VP RA/QA and Head of RA/QA with creating and maintaining regulatory and quality processes
- Closely collaborate in multi-disciplinary teams from Regulatory, Quality, Technical, Marketing & R&D on new product development projects and international product launches
- Support key relationships with European Authorities, notified bodies and International competent authorities



- 5+ years regulatory affairs experience in Europe OR US
- Experience with active OR implantable medical devices
- Fluent speaking, reading and writing in English

INTERESTED IN FURTHER CONVERSATION?

PLEASE SEND YOUR CV TO <u>KRISTINA@ELEMED.EU</u> TO ARRANGE A CONFIDENTIAL CAREER DISCUSSION.