SWEDEN

Interim QARA Manager (12-month contract)

VERONICA@ELEMED.EU

elemed

The company

This is a great opportunity to join an IVD company based in the vibrant heart of Sweden at its great point of growth, improving healthcare outcomes through innovative diagnostic solutions in the field of Genetics.

The opportunity

Are you an expert Quality and Regulatory Affairs professional, driven by a deep sense of purpose and a burning desire to make a tangible impact in the In Vitro Diagnostic (IVD) industry? If so, we have an exceptional opportunity for you!

As they navigate the exciting path of growth and innovation, they're seeking a self-starter and results-driven Interim Quality and Regulatory Affairs (QARA) Manager to join their dedicated team available for 50-100% of the week. Your role will be pivotal in shaping the quality and compliance landscape for their IVD products and ensuring their seamless journey to market.

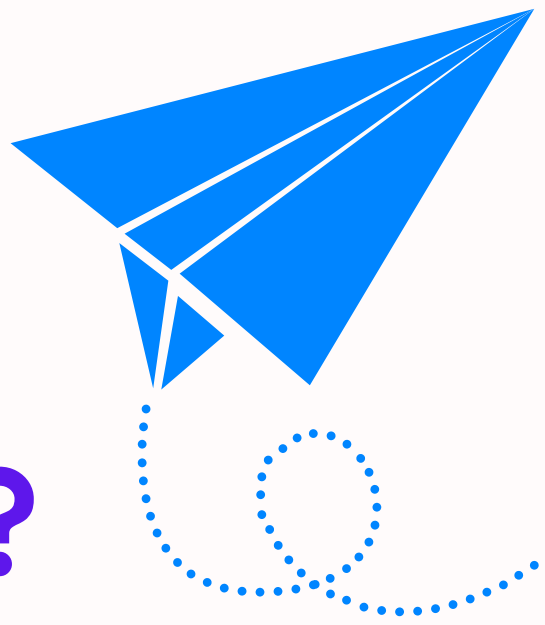
Your responsibilities

- Manage the QARA function, shaping and implementing the quality management system
- Collaborate with the team to ensure regulatory compliance and quality standards
- Update and maintain quality documentation, including SOPs, validation protocols, and update processes for ISO13485
- Keep abreast of evolving IVD regulations and industry trends, providing proactive guidance to the organization
- Participate in quality review meetings every quarter
- IVDR transition: coordinating the team in updating the risk analysis, making sure clinical studies are completed

Qualifications

- Minimum 2 years of experience with QA in the IVD industry
- A deep understanding of IVD regulations, including ISO 13485 and IVDR
- Fluent English

INTERESTED IN FURTHER CONVERSATION?



SEND YOUR APPLICATION DIRECTLY TO VERONICA@ELEMED.EU

elemed