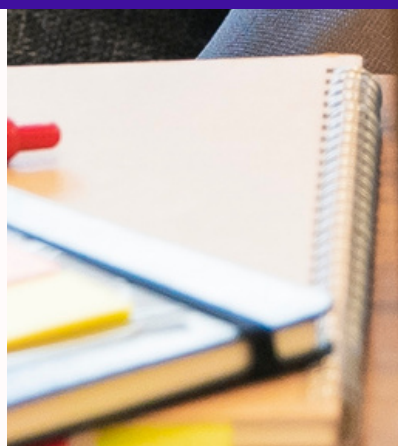




REMOTE FROM UK, ITALY,  
GERMANY, FRANCE, BENELUX,  
PORTUGAL, AUSTRIA OR SPAIN

# NGS/ CD-x/ Embedded Software Expert

VERONICA@ELEMED.EU



eleMed





# The company

Are you an expert in IVD devices? Do you want to be part of the exciting IVDR journey? We have just the opportunity for you!

We are working with a fantastic company that ensures diagnostic and medical device manufacturers meet the requirements set out in European legislation keeping them safe and effective. This is an opportunity to join a growing team and be a key advisor to international stakeholders on all topics surrounding the IVDR.

This company invests heavily in their employees' development and training so you can expect to be onboarded with a state-of-the-art training programme. You will deepen your knowledge within IVDR, get qualified as an accredited auditor, and learn from some of the best IVD experts in the industry.



# The Opportunity

This is an exciting opportunity to be part of a legacy in the development of the IVDR over the coming years.

Join one of the leading companies in the medical devices industry at their exciting point of growth and be their new expert in the exciting field of Next Generation Sequencing, Companion Diagnostics, and devices with embedded software!

As a product expert, you will work to build up the company's IVD business around the EU and ensure that its reputation remains unrivalled. You will analyse and evaluate manufacturer's technical documentation relating to IVD devices. Your primary responsibility is to aid manufacturers seeking CE mark by performing conformity assessment activities across various devices.





# The responsibilities

- Review and assess technical documentation, product dossiers and test results of production batches of in-vitro diagnostic products
- Writing technical reports
- Contribute to the entire certification project through proactive problem-solving and effective management of internal interfaces
- Act as internal EU expert for all questions and queries relating to In Vitro Diagnostic products and providing information to colleagues with regard to standards, regulatory and technical requirements for compliance with standards and the respective regulatory system



# The responsibilities

- Collaborate in an international team for the technical assessment of national and international clients
- Provide product demonstration and ensure compliance with the IVD conformity assessment scheme and applicable Standards
- Prepare product reports and documentation for submission to the certification committee of the Notified Body
- Support customers by coordinating multiple product-related projects and audits, and answering specific questions relating to your area of expertise





# Why this company?

- You can gain invaluable experience in the IVD sector with one of the top market companies
- Be at the forefront of the most cutting-edge IVD technology
- Work alongside a diversified, young, and passionate team
- Build your internal career based on your true interests
- Work from home, anywhere in the UK, Italy, Germany, France, Belgium, Netherlands, Portugal, Austria, or Spain
- Enjoy the international environment, while using English as a main language connecting all



# Qualifications

- Come from a strong educational background - where you have completed at minimum a bachelor's in a scientific discipline
- Minimum 4 years of experience in the design and development of IVD devices or as product assessor of a Notified Body
- 2+ years of experience directly working with IVDs in minimum one of the following areas: embedded software, Companion Diagnostics or NGS
- Fluent communication skills in English

## INTERESTED IN FURTHER CONVERSATION?

IF YOU ARE INTERESTED IN THIS EXCITING ROLE, PLEASE SEND YOUR APPLICATION DIRECTLY TO:

**VERONICA@ELEMED.EU**