Companion Diagnostics (CDx) Specialist

Do you want to oversee the newest innovations in companion diagnostic technology?

Think about joining a Notified Body! This company leads the way globally for assessing whether diagnostic manufacturers meet the requirements set out in European legislation, ensuring their products are safe and effective. This is a great chance to really be at the centre of the most cutting edge of companion diagnostics technology entering the market.

This is a newly created role and a unique chance for a companion diagnostics professional with experience in R&D to use those skills in a new context. You will get access to advanced training, learning about the new In Vitro Diagnostic Regulation, as well as the chance to use your technical knowledge to represent the company in stakeholder discussions with the European Medicines Association (EMA) in Brussels. This is a chance to be part of and central to the biggest change affecting the Diagnostics industry in the last 50 years.

Training program

This is a newly created role, and training on the regulations and standards **WILL** be provided for candidates with the following experience:

- Experience in the design, development, manufacture OR testing (use) of In Vitro Diagnostics (IVDs), specifically within Companion Diagnostics (CDx).
- Working experience either within a manufacturer of IVD devices, OR in a testing/pathology lab environment
- Strong project management experience, demonstrated analytical skills, ability to assimilate new information quickly and a critical thinking approach
- A University Degree specializing in appropriate science area or related discipline

Activities associated with this role

As CDx Companion diagnostics expert, you will:

75% of the role

- Technical: Review and assess Technical Documentation for companion diagnostics.
- Perform conformity assessments of regulatory submissions of CDx, to ensure compliance to the IVD conformity assessment scheme and applicable Standards.
- Act as internal EU expert for all questions and queries relating to Companion Diagnostics, and providing information to colleagues with regard to standards, regulatory and technical requirements for compliance with standards and the respective regulatory system.
- You'll have the opportunity to audit your clients (limited travel) as per European Directives, regulations and international standards pertaining to IVDs and CDx.
- Preparing reports and audit documentation for submission to the certification committee of the Notified Body.
- Project management: Supporting customers co-ordinating multiple projects, audits and answering specific questions relating to your area of expertise.
- Providing CDx input on the company's newly developed training program

25% of the role

- Represent the company for matters relating to CDx, including discussions with the European Medicines Agency (EMA) and other major stakeholders

Are you interested in using your experience in a new environment, whilst learning something new? If you have a strong appreciation of different cultures and a desire to really immerse yourself in the field of companion diagnostics, apply to this role!

We'd love to hear from you!

Please send your CV to elena@elemed.eu
for a confidential career discussion.