Regulatory Affairs CDx Device

Remotely Based

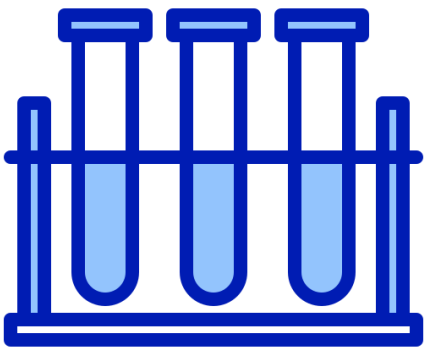
Calling all experts in companion diagnostics!!! We have a fantastic opportunity to get involved in the early phase development of a brand new CDx device.

This company, known across the globe, are continuously working to push the boundaries of possibility in the Healthcare and Life Science industries. They focus on meeting the unmet medical needs of patients across the world by continuously developing new technologies and therapies. Their next focus? A new companion diagnostics device.

This is an opportunity to get stuck in during the early phase of development and work with a global team to bring this product to market. You will be working with IVD partners to define the regulatory strategy and ensure that it is implemented cross functionally throughout the entire project.

In this project you will (not an exhaustive list):

- Work collaboratively in the global development team to ensure that the necessary requirements for CDx registration are met
- Define the regulatory strategy for the project and ensure that it is implemented
- Assist the creation and submission of regulatory documentation to the Health Authorities in Europe and the US
- Outline the timelines for testing and support the clinical team during trials/ patient selection strategy

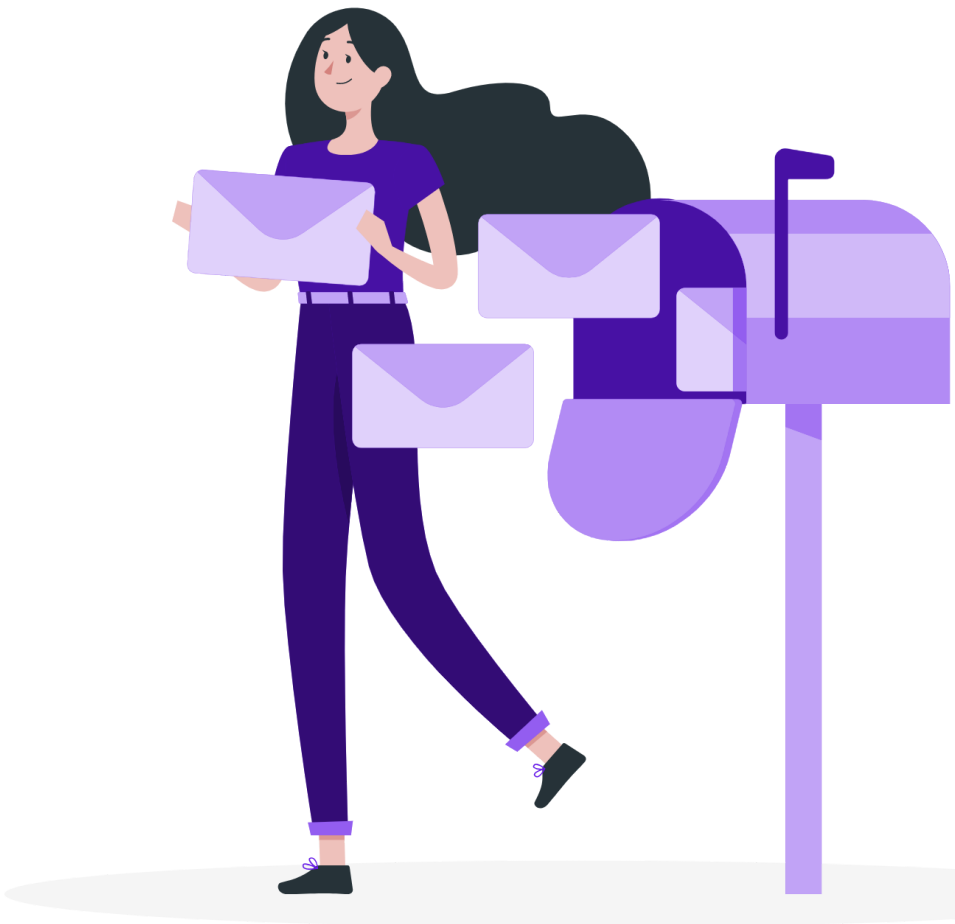


Requirements:

- Extensive hands-on experience and knowledge in CDx products and regulatory requirements in Europe and the US
- Good understanding of the IVDR
- Fluent English; spoken and written
- Experience with Next-Generation Sequencing (NGS) IVDs is a plus

We'd love to hear from you!

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



Only applicants who meet the requirements above will be considered for the role. Unless otherwise stated we are not able to consider applicants without EU work authorization.

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