Remote, Europe

SENIOR REGULATORY AFFAIRS IVD

Get in touch with kristina@elemed.eu

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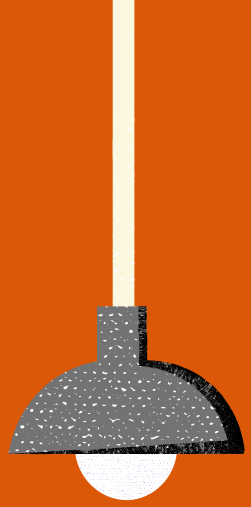
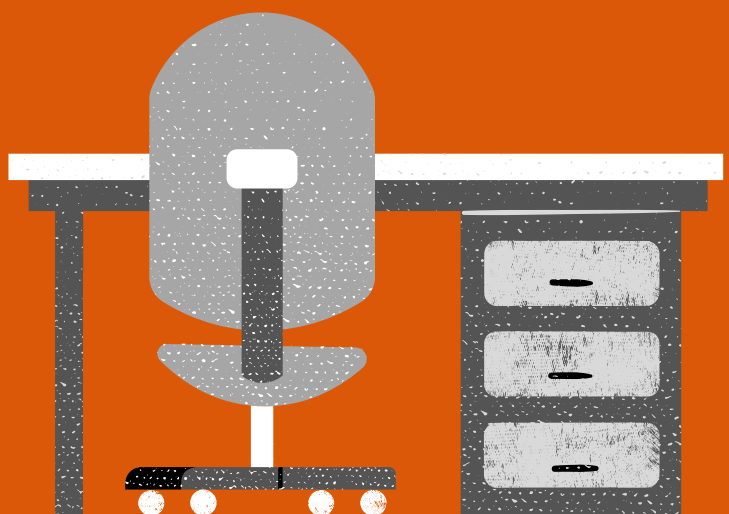


If you are an expert in Regulatory Affairs for In-Vitro Diagnostics and thrive on variety and complexity, we have just the opportunity for you.

THE COMPANY

This company is a big player in supporting IVD manufacturers across Europe, US and China with their Regulatory, Quality and Clinical challenges. Working with a range of companies from small IVD start-ups to large multinationals, their aim is to improve patient health and safety by supporting their clients to advance medical technology.

This large, diverse and international team understands the importance and value of their employees and their families. They encourage a strong work-life balance by offering flexible working days and home-office setups and ensure that you will have the opportunity to take the development pathway that most interests you. You will be surrounded by knowledge and expertise within your team, at conferences and at training events.



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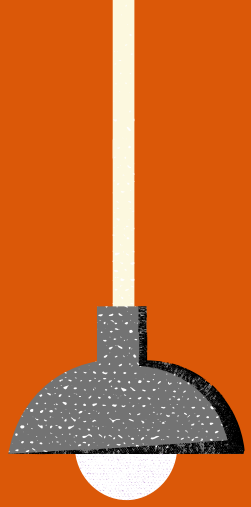
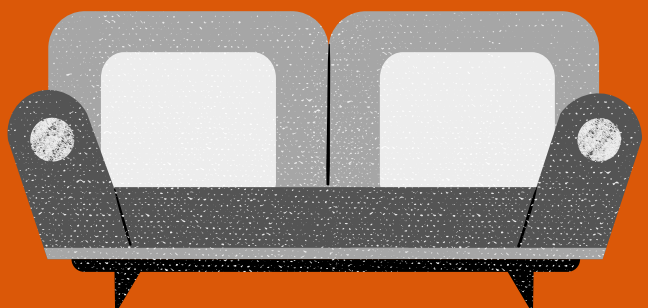


THE OPPORTUNITY

Due to continuous growth within the company and the demand for IVD Regulatory expertise, a new role has been created. This would be an opportunity to support a range of manufacturers on their regulatory projects and be at the forefront of some of the most cutting-edge IVD technology in the market. You will hone your already established technical skills whilst learning and developing yourself in new areas and technologies.

You will provide specialist support and advice to customers on various complex regulatory topics such as IVDR, CE marking, FDA clearance and approvals, as well as navigating and interpreting “the grey”. If you enjoy being in a position where no two days are the same, this is the role for you!



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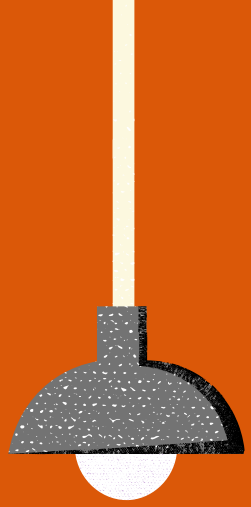
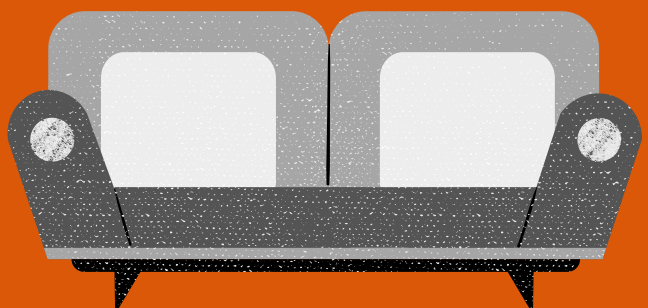


THE RESPONSIBILITIES

As Senior Regulatory Affairs IVD you'll have the following responsibilities

- Support customers on various IVD topics such as IVDD/IVDR, CE marking, FDA clearances and approvals OR new market approvals in China
- Build technical files for regulatory submissions in Europe, US and other global approvals
- Develop and execute regulatory strategy for manufacturers where needed
- Review performance evaluations and risk management data
- Perform gap analysis on various procedures to support customers to improve their quality systems
- Create and review quality management system policies and procedures
- Support internal and supplier audits



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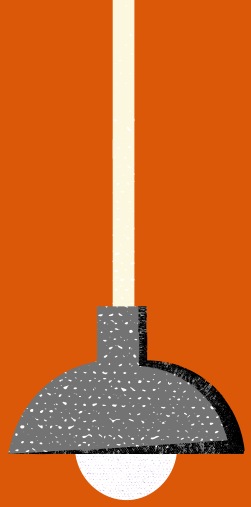

THE QUALIFICATIONS

As Senior Regulatory Affairs IVD you should have

- 5+ years experience in Regulatory Affairs for IVD devices
- Hands-on experience with technical file authoring OR CE marking OR 510(k) for IVD devices
- Fluent speaking, reading and writing in English (second language is a bonus)

ARE YOU INTERESTED IN THIS POSITION?

Please send your application directly to
kristina@elemed.eu