

**STYRIA
AUSTRIA**



**IVD
REGULATORY
AFFAIRS
SPECIALIST**

eLeMed

FRANKIE@ELEMED.EU

THE COMPANY

Do you want to use your IVD regulatory experience to bring a new device to market? Do you want to join a dynamic and R&D focused company where you can impact the RA strategy? Do you want to work with both hardware IVD devices and embedded software?

If yes, we have a fantastic opportunity just for YOU!

This is an opportunity to join an Austrian company with a flat hierarchy where your voice is not only heard but also **valued**. You will report directly into the senior leadership team and have the opportunity to impact the business decisions from a regulatory perspective.

This is not a huge, slow-moving corporate machine; there is no “political red-tape” to navigate and projects move from A-Z at a fast-pace.



THE OPPORTUNITY

In this role as Regulatory Affairs Manager you will be responsible for driving the RA technical dossiers and processes for the IVD device to bring it to the market by the end of 2024. You will be working closely with the senior leadership, R&D, commercial and product teams to efficiently integrate Regulatory Affairs into the business.



THE RESPONSIBILITIES

As Regulatory Affairs Manager you will...

- Lead and drive the creation of technical dossiers and internal procedures to achieve product certification
- Craft the roadmap for launching our products internationally. Your strategic thinking will be the key to the company's success.
- Collaborate with and guide cross-functional internal and external supplier teams to create files that are CE-Mark ready
- Guide and communicate with the business and quality departments according to the relevant regulations IVDD/IVDR
- Liaise and build relationships with key internal and external stakeholders i.e. Notified Bodies and Competent Authorities



YOUR QUALIFICATIONS

- Minimum 2 years experience in registering In-Vitro Diagnostic (IVD) devices
- Hands-on experience in all aspects of pre-market regulatory affairs
- Strong written and verbal communication skills in English

IF THIS ROLE HAS SPARKED YOUR INTEREST AND YOU WOULD LIKE TO FIND OUT MORE ABOUT IT, DON'T HESITATE TO GET IN TOUCH WITH:

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