

eleMed



**BERN, SWITZERLAND**

# *Regulatory Affairs Manager*

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# *The Company*

**Do you want to use your experience and skills in the fight against COVID-19? Do you want to join a dynamic company where you can impact decision making? Are you experienced with IVD devices OR with the up-classification of medical devices? If yes, we have a fantastic opportunity just for YOU!**

**This is an opportunity to join a 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 international registrations for the IVD device as well as the transition to IVDR. You will be working closely with the senior leadership and quality teams to efficiently integrate Regulatory Affairs into the business. Worried about where this role goes after the pandemic? Worry not! This company has plans to develop into new areas post-pandemic giving you plenty of opportunities to grow and develop new skills!**



## *As Regulatory Affairs Manager you will...*

- **Oversee and execute international registrations for the IVD device**
- **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**
- **Lead the transition from IVDD to IVDR**





## *As Quality Manager you should have...*

- **Technical / scientific Education:** Biology, Biochemistry, Chemistry, Biotechnology, Engineering or similar
- **3+ years Regulatory Affairs** in the medical device (up-classification of medical device) OR IVD industry
- **Strong written and verbal communication skills** in English and German

## *Interested in further conversation?*

Please send your CV to [kristina@elemed.eu](mailto:kristina@elemed.eu) to arrange a confidential career discussion.

