

Senior Director Quality EMEA

Vaud, Switzerland

Contact: elena@elemed.eu



The company

Are you

- ... a strategic Leader with a background in quality or post market regulatory affairs?
- ... excited by the prospect of a quality role overseeing a region worth **billions of dollars**?
- ... interested in using quality to its maximum potential to automate and simplify processes?

Then we have something great for you, working for a world leader in the healthcare industry. This is a BIG quality role, where you will be on the succession plan of the VP Quality.

As part of a global strategic initiative of quality, a new role has been created as Senior Director Quality (complaints & vigilance). This is a brand new role so you'll not be stepping into anyone else's shoes, and you'll have the chance to directly make your mark! The Senior Director Complaints & Vigilance is a strategic, senior level role within the organisation, overseeing quality for the EMEA and leading a team of 8 senior managers/associate directors, with an overall team scope of 35 people.



The opportunity

As Senior Director of Quality, you will have the chance to oversee quality for all products from the company sold across EMEA. So, you will have the opportunity to use quality where it can really add value: simplifying end to end processes, looking for opportunities for improvement and building automation into workflows; to maximise human value and potential.

You will also be responsible for direct dialogue and negotiation with competent authorities and industry opinion leaders relating to post market quality topics. In this role you will be the strategic quality partner of the senior regional leaders across EMEA and leaders within the company's global business units, partnering also with senior management, including the president of EMEA and Chief Quality officer.



Your responsibilities

- You'll be responsible for leading the complaint management, vigilance and field action execution across EMEA for all products across all divisions for the company (worth billions of dollars)
- Partner with senior level strategic leaders across all areas of the business unit and the EMEA region.
- Seek opportunities for simplification, automation and improvement across the end to end quality processes within your remit (i.e complaint management) with a view to maximise human potential.
- Proactively monitor regional regulatory requirements and ensure key partners (Regulatory, Business, Regions) are aware of changing requirements and strategies across EMEA.

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Your responsibilities

- Strategically and proactively develop the relationship and engage in direct dialogue and negotiation with Competent Authorities across EMEA
- Lead and manage post market compliance across EMEA, and ensure reporting to Competent Authorities where required. Also, ensure compliance of the EMEA region to US and other global regulations.
- As a senior leader within the company, you will also be a member of the EMEA Quality leadership team and will support enterprise quality decision making
- Represent the company in industry groups and use advocacy to influence the development of industry positions on specific QA/ Post market topics within your remit across EMEA

(This isn't an exhaustive list, but should give you a good feeling of what the role entails!)

Are you someone who wants to progress in your career? This role has excellent long term career progression potential as you grow with the company.



Your qualifications

If you meet the following 5 criteria, we'd love to hear from you!

- 15+ years experience working in the medical devices/IVD industry in a multinational company
- Experience in a quality or regulatory role (post market or pre-market or quality operations or regional)
- Out of the box thinker, with a demonstrated track record of leading and driving improvement initiatives.
- Ability to influence through a matrix environment, fostering strong relationships with partners and promoting collaboration
- Demonstrated experience leading senior, experienced leaders

Interested in further CONVERSATION?

If you are interested in this exciting role, please send your application directly to elena@elemed.eu