DIRECTOR POST QUALITY (POST MARKET)



VAUD, SWITZERLAND

ele∿ed

Get in touch with Elena at elena@elemed.eu

THE COMPANY



Do you want to join a company where quality is top of the agenda?

Where moving the needle on quality is a strategic global initiative fully backed by the CEO? A company where quality is not just a generic department?

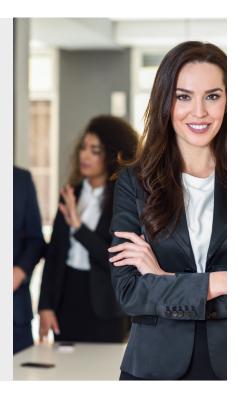
Then we have something **GREAT** for you, working for a world leader in the healthcare industry.

As part of this global strategic initiative of quality, a new role has been created as Director post quality (post market), reporting to the Vice President of Quality. 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 director of PMS is a strategic, senior-level role within the organisation, leading a team of 7 people who look after all post market quality activities for the company's most important business unit. As Director of Post Market Surveillance, you will be the face of the company towards interactions with competent authorities and you will also be the **DECISION MAKER** regarding field actions and recalls. So if you're looking for a role where you can use influencing, networking, leadership and negotiation skills, keep reading to find out more!



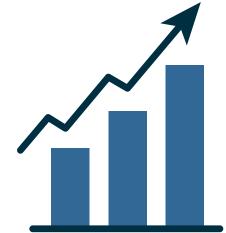
THE OPPORTUNITY

The scope of this role covers everything from A-Z related to post market quality and vigilance; overseeing compliance activities linked to risk assessments and outcomes, incident reporting/evaluations and notifications, field actions, and direct interaction with competent authorities. You'll also work closely with the VP of Quality, to take a proactive leadership role in addressing your business unit's compliance needs related to both products and processes. In this role you won't just be executing orders; you will have a seat at the table.



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.



KEY RESPONSIBILITIES

- You'll be responsible for leading and guiding the resolution of post market quality issues relating to the company's most important line of business and division
- Strategically and proactively develop the relationship with key external partners and stakeholders, including regulators
- Be proactive, responsible and accountable for the relationship with competent authorities; ensuring deliverables are met on time
- Keep your finger on the pulse: prepare, track, monitor and report on monthly metrics and other key data, as well as staying up to date with all new and changing requirements linked to medical devices
- Manage and oversee all activities linked to the Field Action Committee, ensuring the correct responsibilities, accountabilities and outcomes are assigned and achieved
- Manage a wide spectrum of quality activities; reporting on MDV/MDR, health hazard evaluations (HHE), field actions, and post market surveillance
- You'll support new business acquisitions by ensuring the integration, implementation and adoption of company processes and procedures
- Provide expertise and guidance when needed, to support the end-to-end complaints process, including regulatory reporting
- Be part of key strategic divisional projects and work with other leaders across the division to achieve those goals and objectives
- Support other quality-related activities as required: take part in internal and external audits, be the face of post market surveillance and quality at divisional meetings, identify and highlight high priority quality issues to the management team

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

THE REQUIREMENTS

If you meet the following **4 CRITERIA**, we'd love to hear from you!

- 8+ years experience working in the medical devices industry
- 2.In a quality or regulatory role covering specifically post market activities/vigilance/regulatory compliance
- 3. Strong experience interacting with competent authorities
- 4. Demonstrated experience mentoring, managing and developing talent



Interested to explore this further?

Please send your CV to Elena at <u>elena@elemed.eu</u> to arrange a confidential career discussion.

