BASEL, SWITZERLAND- HOME OFFICE OPTIONS

Head of Regulatory Affairs & Quality Assurance

TAMANNA@ELEMED.EU

A fantastic new and exclusive role has come into elemed, with the opportunity to develop your career into joining an executive board of an international company. You will work alongside the CEO and C-suite to develop key strategies for the RA department, providing a great opportunity for someone looking to leave a legacy within a growing business.

The company

Be the Head of RA/QA at the company's headquarters, based in a great location within the Basel area with very easy access to the train station. You will report directly to the CEO providing for a fantastic opportunity to have short decision pathways and no red tape. As you learn and develop your skills, you will be provided the perfect platform to develop strategy for the department according to your own ideas and expertise; thus allowing you to leave a legacy within a company at an exciting point of their growth.

The company is developing novel devices on a global scale, including the US. A great opportunity for you to provide leadership on international and developing markets.

There are strong opportunities in the future to mentor and manage a team of regulatory affairs and quality assurance professionals.

Responsibilities

As the Head of Regulatory Affairs and Quality Assurance, your responsibilities will include but not be limited to:

Management- You will manage a team of 2 people from the start, with the future prospect of hiring and developing more experts.

MDR Project- You will be in charge of the MDR project, and play a critical role in the future roadmap of the company's novel devices.

Technical Documentation- You will be the process owner for all regulatory documentation activities, inclusive of CE marking and product development. You will manage and drive forward strategy for the product to be developed globally, inclusive of new market areas. Great opportunity to still have a part in the hands-on day-to-day activities.

Owner of QMS- You will be in charge of all strategy and processes linked to the QMS. There is already a strong QMS in place.

Qualifications

The ideal candidate for this role will have:

- A strong regulatory background, with 6+ years of experience within regulatory affairs for medical devices
- Ideal experience would be product knowledge within the area of active medical devices, with knowledge of 60601 and 62304
- Good working knowledge of QMS and audits
- Previous management or mentoring experience would be required for this role, where you are an excellent delegator of tasks and able to strategise for future tasks
- Excellent knowledge of the international registration process
- Expertise within MDR, MDSAP
- Excellent communication skills in English

We are looking for a strong regulatory leader with a proven track record of managing culturally diverse teams. If you are excited by the prospect of working in a growing company that favours innovation and inclusion, this is the role for you!

Get in touch

INTERESTED IN FURTHER CONVERSATION?

IF YOU ARE INTERESTED IN THIS EXCITING ROLE, PLEASE SEND YOUR APPLICATION DIRECTLY TO:

TAMANNA@ELEMED.EU

Please note: Elemed has sole rights and a mandate to recruit for this role. Be vigilant of 3rd parties advertising or promoting this role as any 3rd party applications will not be accepted and will be withdrawn.

Elemed is an executive search firm, specialised in finding and representing exceptional talent in Medtech.