ZUG AREA, HOME OFFICE OPTIONS AVAILABLE

Associate Director, Regulatory Affairs

REGION: GLOBAL

TAMANNA@ELEMED.EU

The company

Is it time for a new leadership role where you will have an impact on a global scale?

This role has short reporting lines where you will have a chance to make a real impact and difference on international projects, with the chance to develop and manage a team of seasoned regulatory experts in the future.

This company prides itself on maintaining true quality culture at its heart, with vast investment into the RA/QA department to ensure continued growth and development of its high-risk and combination products. This role is perfect for an experienced team leader or a project manager looking to work in a close-knit team and be part of developing and maintaining a true QA culture.

The company produces exciting high-risk products within medical devices but also has a portfolio of combination products - thus allowing you to develop your product portfolio span.

The role

Are you comfortable challenging the status quo? Having your voice heard in the regulatory, quality, and clinical departments globally? Then this is the role for you...

In this role, you will lead global RA projects, and be the face within IECs and IRBs for clinical and regulatory matters. The role is a great combination of having strategic and leadership input to having a hands-on role in driving the registration process globally, inclusive of the emerging markets and the US.

This role is all about providing direction across different regions where there is regulatory complexity, setting strategic priorities based on business needs, getting the best out of your team, and building the future. Do you have a creative, problem-solving mindset across both regulatory and clinical?

Your responsibilities

This is a position with a high level of visibility within the company and reports to the Global VP of Regulatory Affairs. As an associate director of regulatory affairs, you will be an active member of the global regulatory affairs leadership team:

- Create the clinical and regulatory road map for this company's novel medical devices and combination products
- Conduct pre-submission meetings with the FDA and Notified Bodies as the main point of contact for clinical and regulatory matters
- Support the R&D and Quality team as the senior advisor for regulatory and clinical matters
- Collaborate internally and with external consultants throughout the course of the project
- Managing regulatory projects from a clinical perspective
- Play a key role within the MDR transition projects
- Have a hands-on role in preparing regulatory submissions with a primary focus on the EU, but globally too

Expectations

We are looking for a strong regulatory leader with a proven track record 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!

- Degree in Life Sciences or Engineering
- Min. 10+ years of working experience in medical devices, combination products within regulatory affairs
- Strong clinical understanding with regard to risk mitigation and the requirements following on from clinical studies
- Previous team management experience would be a bonus, but having at least project management experience is required
- Fluent English
- Regional/International Regulatory experience

Get in touch

INTERESTED IN FURTHER CONVERSATION?

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

TAMANNA@ELEMED.EU

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