WE ARE LOOKING
FOR YOU!

GLOBAL VP QUALITY & REGULATORY AFFAIRS

Zug, Switzerland

Get in touch with
Elena at elena@elemed.eu

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THE COMPANY

If you are a QA/RA professional with an interest in innovation and groundbreaking development, we have an incredible role for you.

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THE COMPANY

This is a chance to join an extremely well funded, early commercialisation stage company with over 1000 patents - a huge innovation portfolio. Right now they are developing and bringing to market not one, but FOUR Class III active and (non active) implantable medical devices that are about to totally change the status quo.

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THE COMPANY

With a strong KOL network in Europe and North America the company is looking for a hands-on Global VP for Regulatory Affairs and Quality Management. The goal: to lead and drive the regulatory and quality management team and strategy for this business globally.

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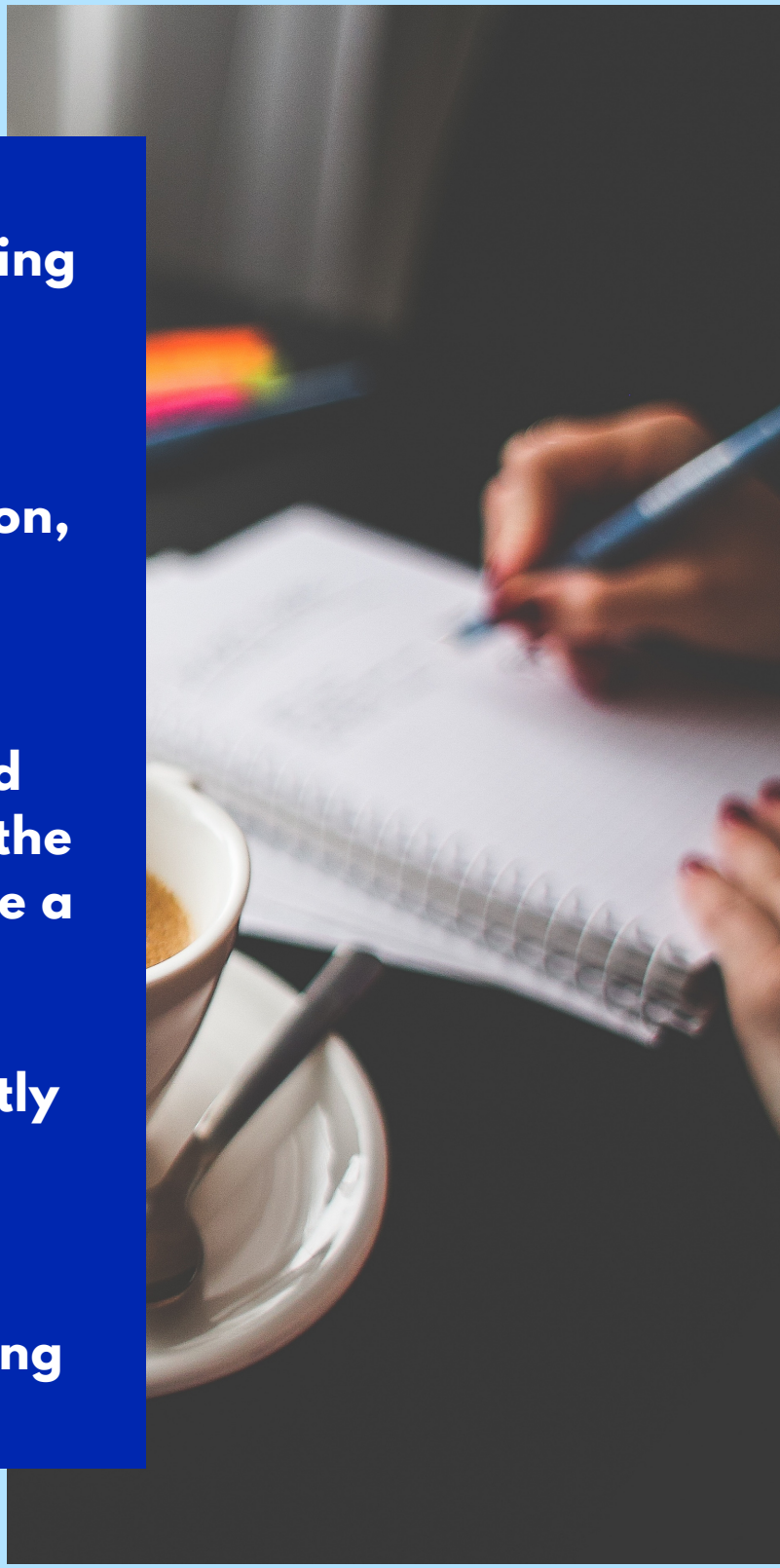
THE COMPANY



If you are looking for a corporate role navigating company politics, this position is not for you. This role is all about being close to innovation, products, and being responsible and accountable for all elements of Quality and Regulatory Affairs for the company. You will have a seat at the table of the company's leadership team, and report directly to the CEO; inventor, surgeon, and serial entrepreneur. Are you passionate about making a difference?

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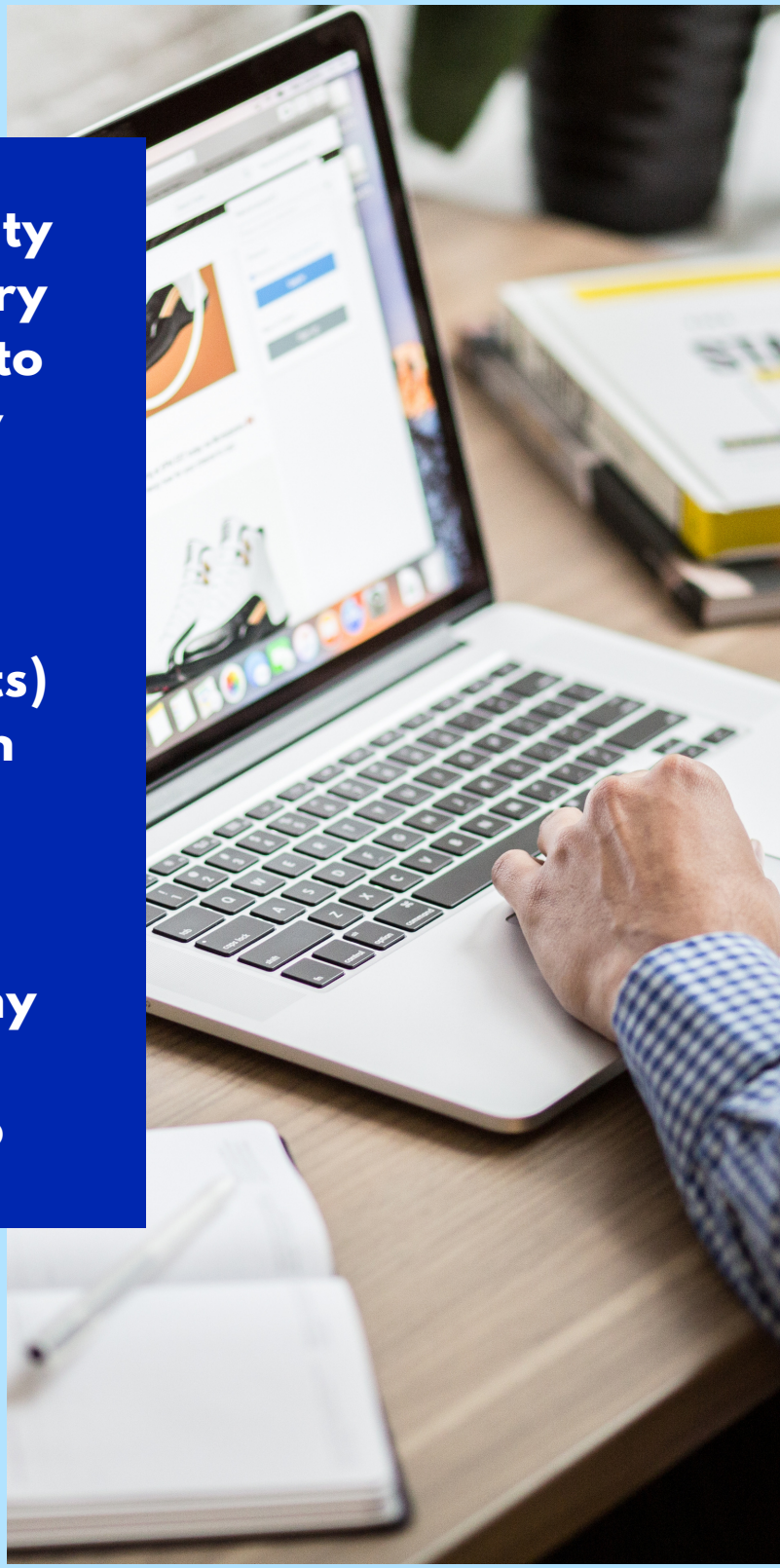
THE ROLE

As Vice President Quality Management Regulatory Affairs your mission is to

- **Head up Regulatory and Quality for the company at group level (Team of 4 reports + consultants)**
- **Represent QM/RA in the executive leadership team**
- **Manage, grow and upscale this company into a global multinational group**



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THE ROLE

Regulatory Affairs

- Lead all Regulatory Affairs activities from the company's HQ in Switzerland
- Represent the company and take the lead on world wide communication with regulators globally, including: Notified Bodies, and Competent Authorities including FDA, Canada, Australia and Switzerland
- Provide QA/RA strategic support to new product development teams
- Develop the regulatory strategy and pathway for market approval and new product introduction worldwide
- Oversee and coordinate the execution of operational regulatory activities such as local country (re) registrations
- Manage regulatory change implementation
- Be responsible for regulatory management of economic operators
- Carry out regulatory intelligence activities and keep abreast of any regulatory changes that may impact the company

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THE ROLE

Quality

- **Head up Quality Management for the HQ and all legal manufacturer sites**
- **Be accountable and responsible for overseeing the development, implementation and maintenance of the company's corporate Quality management system**
- **Act as management representative for the corporate organization**
- **Ensure QA/RA compliance worldwide through handling of activities such as Post Market Surveillance and vigilance, complaint handling, non conformity management and internal/external audits**
- **Establish corporate quality initiatives and oversee execution**
- **Contribute to corporate development initiative**

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THE ROLE

WHY ELEMED LOVES THIS ROLE?

- Game changing company
- 4 NEW products to bring to market
- Huge innovation and investment in R&D
- Young, dynamic and fast growing company
- More stable than a startup, very well funded
- Part of the management team
- You have white sheets of paper to implement your QA/RA idea and vision.

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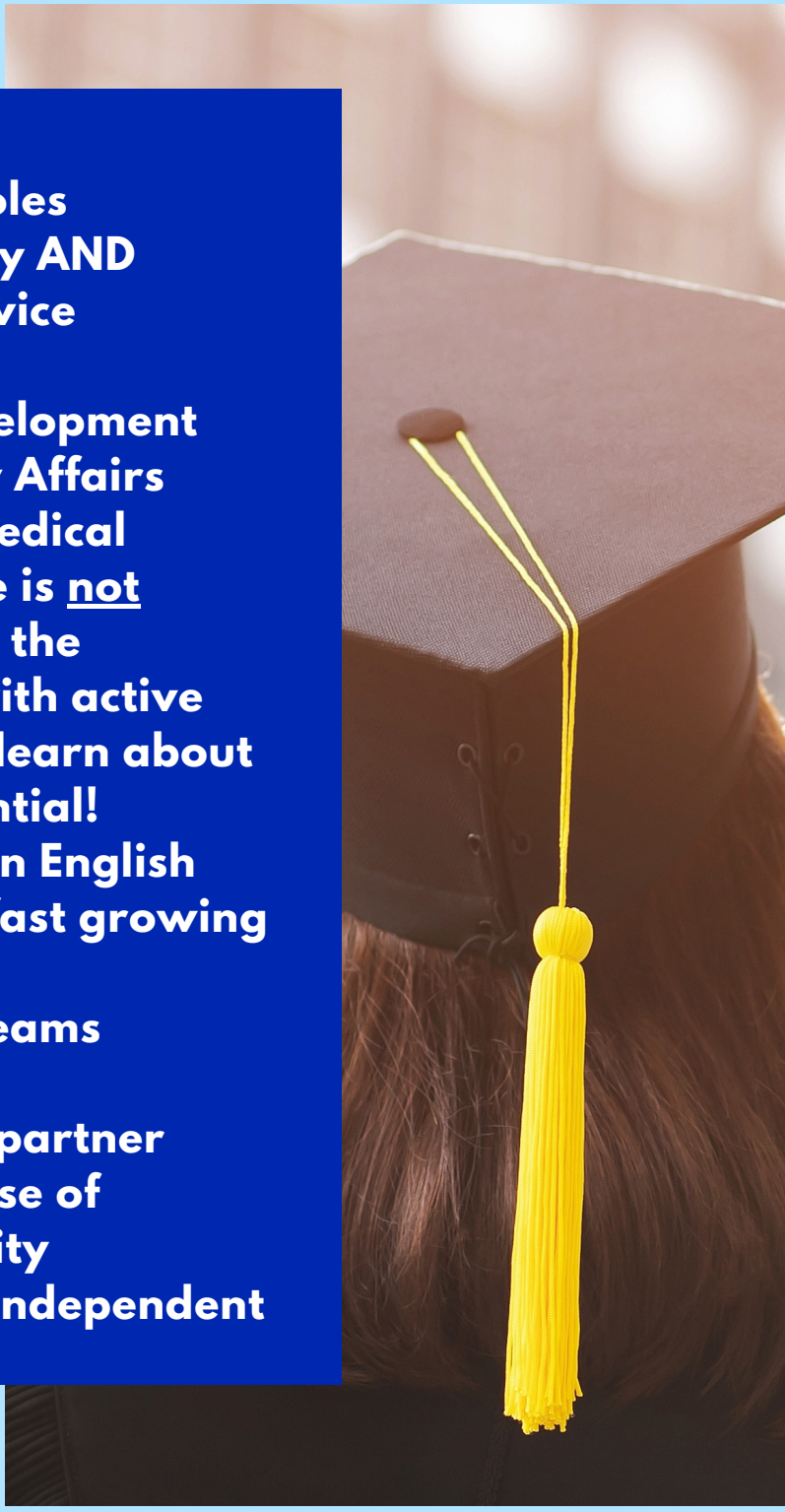
REQUIREMENTS

Do you have:

- **8+ years experience in roles covering BOTH regulatory AND quality in the medical device industry**
- **Strong New product development experience in Regulatory Affairs with Active (electrical) medical devices. AIMD experience is not required, but if you have the necessary background with active devices, a willingness to learn about AIMD and class III is essential!**
- **Fluent written and spoken English**
- **Experienced working in fast growing dynamic companies**
- **Experienced managing teams remotely**
- **Strong leadership skills, partner approach to QM/RA, sense of urgency and accountability**
- **Adaptable, reliable and independent**



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Interested to explore this further?

Please send your CV to elena@elemed.eu to arrange a confidential career discussion.

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For more vacancies,
visit elemed.eu/vacancies