

HEAD OF REGULATORY AFFAIRS & QUALITY ASSURANCE

*Nice, France (home
office flexibility)*



MONIA@ELEMED.EU

THE COMPANY

Are you a real leader? Are you able to use quality and regulatory as an enabling tool, rather than a blocker? Are you able to build good business relationships?

As a Head of RAQA, you will be part of the COMEX and be at the very heart of the company's operations and decision-making. This is a very unique company where strong quality knowledge is essential, combined with an excellent cultural awareness and business-oriented attitude. Communication is key as this is a role interfacing with multiple stakeholders, where you will be the face of RAQA for the company.

This position will give you the chance to work with a large portfolio of products in different therapeutic areas from Class I to Class IIa. You will be based in the south of France near the Mediterranean with perfect weather all year round! You will also have flexibility in working from home, so this is the chance to have a great work-life balance.



RESPONSIBILITIES

- Set up, maintain, and improve the most suitable QMS to guarantee the efficiency and reliability of products
- Comply with international regulations and take charge of changes or new regulations maintain the efficiency of processes
- Draw up reports on performance (based on KPIs), you are responsible for keeping procedures and work instructions up to date
- Responsible for the further development of integral quality management and quality assurance (providing advice and stimulating improvement actions)
- Internal point of contact for quality assurance
- Support processes in compliance verification activities and in the management of non-conformities and other deviations



RESPONSIBILITIES

- Management representative (within the meaning of ISO 13485 and 21CFR820)
- Organizes the work and manages the staff within the quality department according to the needs and skills
- Reports to Management on the performance of the quality system
- Ensure proper contact with certification bodies and authorities
- In charge of setting priorities, assuring resources, leading and developing a team of RAQA
- Ensure operational compliance with local regulations
- Help guide the organization on the appropriate filing strategy, and coordinate across disciplines to ensure timely filings



YOUR QUALIFICATIONS

- Minimum of 10 years experience in Quality and Regulatory Affairs
- FDA Experience is a plus
- Fluent in English

INTERESTED TO EXPLORE THIS FURTHER?

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

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