LYON, FRANCE (HYBRID)

Senior RA/QA Manager

CLARISSE@ELEMED.EU

THE COMPANY

Come and join this leading MedTech company. With a brand known globally, innovative devices from Class I-III and a care for quality, they have been recognised as one of the top employers in the industry.

Due to continued growth and investment in product development they are looking for an experienced leader who enjoys implementing process, developing people and managing a team of regulatory and quality professionals working with Class III devices.

This is a strategic role, with a high visibility within the Management Committee and the RAQA Europe team.

This is the chance to have a leadership role in a division that has been overperforming in the last few years. They provide great future prospects!

THE RESPONSIBILITIES

As Senior RA/QA Manager you will:

- Lead a team of 7 RA/QA and be responsible for performance monitoring and team development
- Assist in the development of regulatory and quality strategy and update the strategy based on regulatory changes.
- Manage the quality system and ISO 9001, be responsible for audits and questions from the authorities
- Provide strategic advice to the business units to effectively address the complex situations they face and respond to their development opportunities
- Assess regulatory and quality intelligence to assist in the development of local, regional, and global regulatory strategies.

THE RESPONSIBILITIES

As Senior RA/QA Manager you will also:

- Determine requirements (local, national, international) and options for regulatory submission, approval pathways, and compliance activities
- Negotiate with regulatory authorities throughout the product lifecycle
- Evaluate the regulatory environment and contributes to providing internal advice throughout the product life cycle
- Represent the French RA/QA during international meetings with the company and professional union

REQUIREMENTS

- 8+ years of experience in regulatory and quality, medical devices experience is a plus but not essential. If you are not coming from the medical device industry, you must have previous experience within a highly regulated industry.
- Excellent experience within the technical documentation process, inclusive of submission
- Strong hands on Leadership experience (minimum 3 years)
- Fluent in French and English

INTERESTED IN FURTHER CONVERSATION?

IF YOU ARE INTERESTED IN THIS EXCITING ROLE, PLEASE SEND YOUR APPLICATION DIRECTLY TO CLARISSE@ELEMED.EU

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