DIRECTOR REGULATORY AFFAIRS, QUALITY & CLINICAL

Lyon, France

DO YOU HAVE THE FOLLOWING EXPERIENCE?

Essential requirements:

- 10+ years of experience from the perspective of a legal manufacturer:
  a) Regulatory affairs with class IIb medical devices

OR

  b) Regulatory & clinical experience with minimum class IIb devices
- Leadership experience of managing a team
- Fluent English and French

Desirable (but not a requirement)

- Quality
- Knowledge of implants
- Auditing experience / lead auditor certification

GET IN TOUCH WITH ELENA AT ELENA@ELMED.EU

elemed

THE COMPANY

Tired of working for the same big, slow-moving corporation where the key decisions are made outside of Europe? Are you looking for a role that will allow you significantly more autonomy in taking QA/RA/CL decisions, where you will sit at the table of the company's leadership team?

Located near the beautiful cultural city of Lyon sits Elemed's newest client; a small medical device manufacturer of 50 people. Small in terms of people, but not small in terms of presence. This is **not** an opportunity in a mono-product, mono-franco environment. This company has a product portfolio of around 15 devices, and designs, develops, manufactures and sells their products for the global market: EMEA, N.AMERICA, LATAM & APAC.

In this role you'll be at the heart of the company's operations as a legal manufacturer, overseeing a broad range of activities covering Regulatory, Quality and Clinical globally, as well as leading a young and dynamic team.

GET IN TOUCH WITH ELENA AT ELENA@ELMED.EU

elemed

THE ROLE

In this role as Director Regulatory, Quality and Clinical; your responsibilities will centre on the following goals:

Leadership: Manage the QA/RA/CL team, organising their work and priorities, supporting them to achieve their objectives and ensuring the continuous skills development of the group.

CL/RA: Oversee regulatory and clinical compliance of the products manufactured by the company, defining clinical and regulatory strategy and ensuring clinical studies are executed in compliance with regulatory requirements.

Quality: Be the PRRC and the quality management representative. You'll be responsible for ensuring the quality system is compliant and implemented correctly, as well as making sure that products and suppliers comply with qualified and approved standards/processes.

Want to learn more? Read on for a detailed breakdown of the role's responsibilities.

GET IN TOUCH WITH ELENA AT ELENA@ELMED.EU

elemed

LEADERSHIP

- Define your team's goals and objectives, and ensure they are achieved by driving, supporting, mentoring and motivating them. Define and implement key KPIs and ways to measure your team's performance
- Manage the team, allocated resources and budget in order to ensure the leadership's vision and objectives are achieved
- Review and approve the team's solutions and proposals, as well as be responsible for managing the calendar and pipeline of projects; providing progress reports and alerting the leadership team in case of problems or delays
- Maintaining an open channel of communication by sharing any changes or advancements ongoing within the company with your team
- Unlock talent and potential by ensuring each team member is performing at their best ability, providing them with support and guidance to help them advance in the development of their skills and competencies

GET IN TOUCH WITH ELENA AT ELENA@ELMED.EU

elemed

REGULATORY

REGULATORY AFFAIRS

- In this role, you'll also assume responsibility as PRRC; named person responsible for regulatory compliance
- You'll oversee regulatory monitoring and ensure compliance with regulatory requirements specific to Medical Devices (21CFR/820, 93/42/EEC) including the continual work on the transition to the new MDR (2017/745)
- Drafting and updating of technical files, CE marking, product risk classifications, conducting risk management, reviewing labelling and signing Declaration of Conformity documents in accordance with MDD/MDR
- Providing regulatory support to the R&D process
- Overseeing international registrations through connections with local partners, subsidiaries and distributors and ensure compliance with local country regulations
- Leading the relationship with competent authorities as the main point of contact, as well as holding the responsibility as Official Correspondent for activities relating to post market surveillance, vigilance and recalls
- Carrying out Regulatory Intelligence: make sure you are updated on the changing regulatory requirements around the world; in particular in markets of interest

GET IN TOUCH WITH ELENA AT ELENA@ELMED.EU

elemed

QUALITY ASSURANCE

- Be the company's quality representative in accordance with ISO 13485
- Driving the quality agenda and building an internal culture of quality through training of new and existing employees
- Advise the leadership team on company quality policy: supporting with the definition of key objectives and the relevant strategies on how to achieve them
- Overall management of the QMS, ensuring it is implemented correctly, and ensuring compliance with the standards and regulations applicable to Medical Devices such as ISO 13485, and 21 CFR/820, MDD 93/42/EEC, as well as the new medical device regulation 2017/745
- Monitor and look for opportunities to continually improve the Quality Management System
- Oversee the management of operational quality activities: Non-conformities, CAPA, change controls
- Audit: Conducting internal and supplier audits, as well as technical file audits. Being responsible for third-party audit follow-up
- Management of the validation engineer: oversee all activities relating to biocompatibility, cleaning, validation and sterilization

GET IN TOUCH WITH ELENA AT ELENA@ELMED.EU

elemed

CLINICAL

- Lead and define the clinical strategy for the company in relation to clinical evidence and approve clinical evaluation reports
- Oversee the carrying out of clinical studies through all phases: from setup to close-out
- Sign the declaration linked to annex XV, chapter II, section 4.1 of the MDR 2017/745

DESIRED EXPERIENCE

Essential requirements:

- 10+ years of experience from the perspective of a legal manufacturer:
  a) Regulatory affairs with class IIb medical devices

OR

  b) Regulatory & clinical experience with minimum class IIb devices
- Leadership experience of managing a team
- Fluent English and French

Desirable (but not a requirement)

- Quality
- Knowledge of implants
- Auditing experience / lead auditor certification

GET IN TOUCH WITH ELENA AT ELENA@ELMED.EU

elemed

Interested to explore this further?

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

GET IN TOUCH WITH ELENA AT ELENA@ELMED.EU

elemed