PARIS, FRANCE

REGULATORY AFFAIRS

TEAM MANAGER

CDI

Calling all senior QA/RA professionals! Are you someone who:

- Loves having a variety of activities in your daily work?
- Has a problem-solving approach to regulatory challenges and an “esprit d’equipe”?
- Ready to step up and manage/develop a small team?

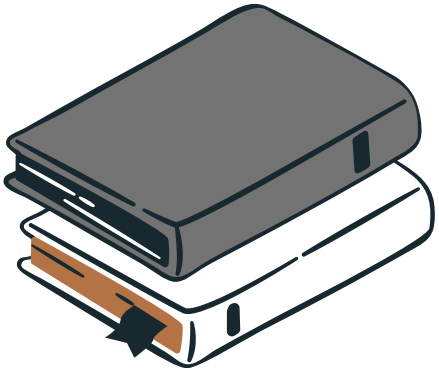
Then we have a really unique opportunity for you!

THE COMPANY

Join a boutique consultancy company at the heart of the medical device and pharmaceutical industry, known for its innovative and personal approach. The key pillars of the company: expertise, dynamism and reactivity. The employees at this company work with pharmaceutical and medical device manufacturers on a range of different topics: from Regulatory strategy, Compliance, QMS implementation and management, MDR/IVDR as well as delivering and developing training.

THE ROLE

This is a great opportunity for either a senior regulatory affairs specialist, searching for their first opportunity in management, or an established manager interested in leading a small, nimble team. If you love collaborative environments and working closely on projects and products whilst developing and supporting others, this role is for you!



This is <u>not</u> a freelance position; so you’ll enjoy all the normal benefits and security of being permanently employed, with a lot more variety than working for just one manufacturer!

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THE RESPONSIBILITIES

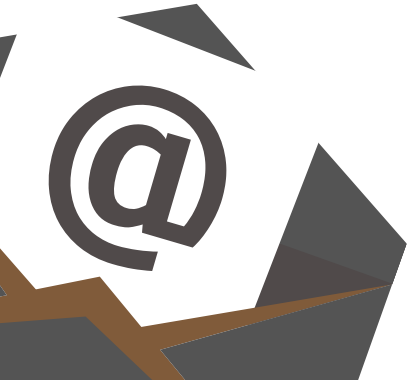
In this role you will cover the A-Z of regulatory/quality activities, across a range of different medical devices.

- Creating regulatory strategies for US and EU markets, authoring submissions for those key markets and maintaining contact with the US FDA and/or Notified bodies as required
- Supporting “hands on” regulatory projects for customers on activities spanning the full lifecycle of a medical device: CE marking, New product introductions, regulatory strategy, PMS, and more
- QMS implementation and improvements according to ISO 13485
- Carrying out and supporting audits: Internal, supplier, 3rd party etc.
- Guiding new product development project teams from a regulatory perspective, providing input on design controls
- Supporting with MDR/IVDR strategy and implementation
- Supporting the company’s growth through networking and business development activities

THE REQUIREMENTS

- 5+ years experience in regulatory affairs, quality OR clinical
- Experience with medical devices or IVD
- Fluent English and French

INTERESTED TO EXPLORE THIS FURTHER?



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