



CLINICAL REGULATORY MANAGER

Barcelona, Spain

Do you like to be at the forefront of innovation? Do you wish you could escape the politics of large corporations? Do you want to positively change patients' lives? If yes, we have just the opportunity for you...

This growing company is meeting a huge unmet need in vascular diseases with their new and unique device. With a strong background in research and engineering they are aiming to positively impact society with the most advanced technology available. It is a young, dynamic and fast growing business, giving you the opportunity to grow and develop alongside it; building something together.

Reporting into the CEO, you will have the opportunity to directly impact the direction and future of the business alongside your responsibilities for all Clinical and Regulatory activities. This is an opportunity to join in the early phases of product development and set out the clinical and regulatory pathway for the high-risk device in global markets.

As Clinical Regulatory Manager you will...

- Create the clinical and regulatory road map for the device
- Define the clinical strategy, clinical & pre-clinical needs, and write out the clinical protocols
- Conduct pre-submission meetings with the FDA and Notified Bodies as the main point of contact for clinical and regulatory matters
- Support the R&D team as the senior advisor for regulatory and clinical matters
- Write Standard Operating Procedures, indications for use and technical documentation
- Register the device in Europe and the US
- Collaborate internally and with external consultants throughout the course of the project

As Clinical Regulatory Manager you should have...

- 5+ years of experience in the medical device industry
- Experience with vascular devices; aortic device experience is beneficial
- Previous experience defining clinical strategy and protocols
- Registered a medical device in Europe OR the US
- Fluent English (spoken AND written)
- Willingness to travel up to 10%

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We'd love to hear from you!

Please send your CV to kristina@elemed.eu
for a confidential career discussion.

Only applicants who meet the requirements above will be considered for the role. Unless otherwise stated we are not able to consider applicants without EU work authorization.

Elemed is an executive search firm, specialized in finding and representing exceptional talent in medtech. To find out more about our Candidate Services click
here:<https://www.elemed.eu/candidates/>

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