Regulatory Affairs Manager

CLASS III IMPLANTABLE MEDICAL DEVICES

Cologne Area, Germany
(Home Office Possible)

Are you excited by challenges?
Do you hate the political red tape of huge corporations?
Do you thrive in a fast-paced, dynamic environment?

If your answer is YES then we have just the opportunity for you!

Come and join this start-up, located just outside of Cologne, as they begin their very exciting journey. With 4 high-risk cardiovascular implants, the CEO is looking for a strong regulatory professional to be responsible for all activities related to regulatory affairs. We are looking for a regulatory superstar to successfully obtain CE mark under the new MDR for these 4 products. This is a great opportunity to be very hands-on and, as you will be reporting directly to the CEO, impact the direction and future of the business.

Regulatory Affairs Manager

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As Regulatory Affairs Manager you will:

Drive the regulatory strategy within the business

- Write and review all technical documentation
- Create and maintain CE submission under the new MDR and support with testing activities related to the relevant standards
- Interface and build relationships with European Authorities and Notified Bodies
- Support the creation and continuous improvement of regulatory related processes
- Collaborate with external partners on innovation, R&D and manufacturing
- Report directly to the CEO

Do you have...

- 5+ years Regulatory Affairs experience in a medical device context?
- Experience successfully obtaining CE certification for a new product?
- A hands-on attitude and enjoy challenge?
- Fluent English?

If your answer is yes to the above, we would love to hear from you! Please send your CV to kristina@elemed.eu to arrange a confidential career discussion!