Regulatory Compliance Manager

Remote in Netherlands

The Company

Our client is a global leader in healthcare with locations across the world and around 8,000 employees. The devices (manufactured and sold globally) are groundbreaking and life changing. Thanks to a full pipeline of R&D and new products, this company is really leading the way and innovating within their space.

At this company you'll enjoy a flat hierarchy (no top down management here!), open communication style, as well as a supportive approach to home working. Work-life balance is key to employee happiness and so is their very unique culture - where everyone is a true expert in their own area and "partner". The result: less time wasted on non essential meetings, an opportunity to bring new ideas to the table and the chance to get more done!

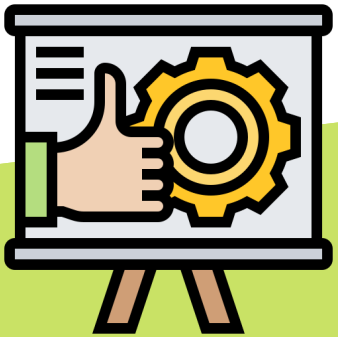
The Role

Due to a strategic move in the location of the Authorised Representative, this company has created a new position of Regulatory Compliance Representative. This is a highly independent role, as you'll be the main point of contact for the Authorised Representative, which means you'll have direct access to Competent Authorities, and make decisions relating to product holds, CAPA and other topical issues. As well as your core responsibilities as Regulatory Compliance Representative, you will also support the Regulatory Department with EU wide activities and have the opportunity to work cross functionally across the business.

This role offers a great oversight of the whole registration process in Europe, as well as the chance to oversee the whole company's product portfolio!

Activities associated with this role

- Be the main point of contact for the Authorised Representative towards the legal manufacturer regarding EU matters, and represent the company in the relationship with Competent Authorities
- Ensure Regulatory Compliance to the new MDR, as the named Person Responsible for Regulatory Compliance (PRRC). NOTE: You'll be provided with an "indemnification letter", removing you from any personal liability in this role



- Drive strong, business practices and processes within your area of the business.
- Use independent judgement and be the decision maker relating to product holds, QMS change requests, and CAPA issues, and raise awareness to the company's divisional or regional leadership team when necessary
- Develop, co-ordinate and ensure completion of local registration activities in the EMEA region
- Keep up to date with, and ensure compliance to relevant laws and policies for your region
- Collaborate with diverse functional teams to implement relevant regional requirements into the quality system and maintain continued compliance
- Support internal and external inspections
- Foster strong working relationships with various regulatory bodies and EU Competent Authorities
- Support the EMEA Regulatory Leader on European wide activities

Why this company?

- Be the face of the company for Regulatory Affairs in Europe for Competent Authorities
- Interact with all the teams and products across the business in a cross functional role
- An opportunity to shape the position around you
- Work remotely from anywhere in the Netherlands

The ideal candidate for this role will have:

- A deep understanding of the implications of the MDR
- Strong working experience in a regulatory/quality role in the medical device industry
- Fluent English and Dutch language skills
- The ability to build strong working relationships, both with internal and external partners
- A good network and experience working with Competent Authorities or regulatory bodies such IGJ, KvK, VWS

Interested in further conversation?

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

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