DUTCH SPEAKING

# Regulatory Compliance Manager

Netherlands / Home based in Europe

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.

## THE COMPANY

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!

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## 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.

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!

# IN THIS ROLE YOU WILL

- 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 the legal entity is correctly registered as the new Authorised Representative, and stays compliant with all requirements for Authorised Representatives
- 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

# DO YOU HAVE:

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

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Please contact **hello@elemed.eu** for a confidential career discussion.