REGULATORY AFFAIRS MANAGER

Posted on 22 november, 2024

Company Name XVIVO

Location Göteborg

Job Description

Why work at XVIVO?

Working at XVIVO is more than a job – it is an opportunity to change the world for transplant patients waiting for a new organ. This position offers an opportunity for the right candidate to be part of the challenging and exciting journey shaping the company's future and taking the business to new heights.

XVIVO is in a rapid growth phase, including both geographical expansion and the development and launch of new products and supporting processes. We are now looking for a Regulatory Affairs Manager to join our team. This is an opportunity to play a crucial role at a global medical technology company dedicated to extending the life of organs – so transplant teams around the world can save more lives.

Responsibilities:

- Handle vigilance/MDR reporting for markets where XVIVO has a presence, such as Europe, US, Canada, Australia, and Brazil.
- Act as the Regulatory Affairs lead in projects developing new products, including line extensions and upgrades according to the product launch plan.
- Execute Project Regulatory Planning, including fulfilling requests for documentation, information, and data for registration purposes across all regions. Key markets include Europe, US, Australia, and Canada.
- Monitor new regulatory regulations and changes to existing regulations to ensure compliance with global medical device regulations.
- Maintain product registrations by ensuring compliance with applicable regulatory requirements, including re-registrations/certifications and change notifications.

Requirements:

- University degree in a relevant field such as Science, Engineering, or Medicine.

- Professional experience in Regulatory Affairs, with demonstrated knowledge/experience in the following areas:
    - Deep understanding of Quality Management Systems and quality standards.
    - Broad understanding of medical device regulations and quality system standards associated with the product development and approval process for the EU and USA.
    - Proven track record of handling product registrations and/or submissions with authorities/agencies/partners, and maintenance of regulatory filings within set time frames.
- Comfortable speaking and writing English at a professional level.

Additionally, we are looking for someone who has:

- A strong sense of ownership and accountability.
- Ability to plan and prioritize multiple work activities.
- A collaborative and flexible attitude.
- A passion for continuous improvement and innovation.

Why XVIVO?

Join our mission to help clinicians provide each patient with optimal time to receive a new organ. XVIVO has a long-term commitment to our customers, employees, and partners. We are in it for the long run. Our core values focus on Customer Value, Entrepreneurship, Competence & Cooperation, Innovation, and Sustainability. Our motto is "People have priority."

Joining XVIVO, you will be part of a company that has a clear strategy for growth in a global market. You will be working in an international environment in a professional and highly competent team, supported by world-leading partners. XVIVO is headquartered in Gothenburg, with a centrally located office. We offer the advantages of being a smaller company with high individual impact, combined with the stability of being supported and owned by the W&H Group.

This role will give you the opportunity to truly develop, grow, and broaden your skills.

Application:

This recruitment is managed by our recruitment partner, Moveup Consulting AB. To apply, please send your CV to Fredrick Asare at fredrick.asare@moveup.se

If you have questions regarding Xvivo or this open position, please contact Fredrick Asare at +46 733

440 900 or fredrick.asare@moveup.se By submitting your application, you also consent to us storing your personal data,

including CV & cover letter and that we have the right to share this information with

third parties (our client). You can revoke the consent whenever you want.

Om företag

XVIVO is a medical technology company listed on the Nasdaq Stockholm exchange, with headquarters in Gothenburg, Sweden, a production site in Lund, Sweden, offices in USA, Italy, and the Netherlands. The company is firmly rooted in medical science with its core business in organ transplantation. XVIVO is the first in the world to offer both machines and consumables for all major solid organs. We are committed to bringing innovative technology for storage, evaluation, and treatment of organs to transplant centers around the world, enabling the safe use of more donated organs and ultimately giving more patients the chance of a life-saving transplant.

Company culture

The culture of XVIVO is the culture of a small company with high growth ambitions based on the foundation of a common belief that patient safety, our vision – "Nobody should die waiting for a new organ", is key for our success. We strongly believe in the fact that nothing is impossible and thrive to get the job done. We, no matter which position or work description, are always focused on helping our customers.

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