# REGULATORY AFFAIRS MANAGER

*Posted on 25 maj, 2022*

**Company Name** XVIVO

**Location** Göteborg

**Job Description**

**Do you want to be a part of the QA/ RA team that leads XVIVOs efforts to structure and implement the Group Regulatory Plan? Are you challenged by maintaining global regulatory compliance and registrations for the products we design, manufacture, and distribute to our customers on a global market? Then this role as a Regulatory Affairs Manager would be right for you. Welcome to be a part of our journey!**

As **Regulatory Affair Manager** at XVIVO you will be you will be responsible for planning and execution of product registrations world-wide and for maintenance of product compliance with applicable regulations and standards. You will also be responsible for determining regulatory pathways for new products and indications, involving discussions with authorities and internal stakeholders.

In this role, you will be responsible for maintaining and assessing the international market's regulatory framework and the regulatory activity planning for any new or changed products, market segments, or local regulations, in accordance with the Group Regulatory Plan.

You will support the organization with regulatory compliance guidance and reviews in the design and development, manufacture, and distribution of products and related services, and assure appropriate regulatory release of products to markets.

You will be part of a collaborative team in a global context and supporting the QA & RA team in the daily work, including audits. You will be reporting directly to the Global QA/ RA Director.

**YOUR RESPONSIBILITY INCLUDES BUT ARE NOT LIMITED TO:**

- Being the Regulatory Affairs responsible in projects developing new products including, line extensions and upgrades according to product launch plan
- Reviewing and approving labelling as well as claims and marketing messages
- Execution of the Project Regulatory Planning, including fulfilment of requests for documentation, information, and data for registration purposes across all regions. Key markets are Europe, USA, China, Australia and Canada.
- Monitoring new regulatory regulations as well as changes to existing regulations to secure

compliance with regulations for medical devices on a global arena
- Vigilance/ MDR reporting of markets where XVIVO has presence e.g. Europe, US, Canada, Australia, Brazil.
- Article creation and control in regulatory databases, for example EUDAMED and GUIDID
- Maintain product registrations by ensuring compliance with applicable regulatory requirements; re-registrations/certifications, change notifications

**KEY CAPABILITIES:**

Professional experience in Regulatory Affairs, with demonstrated knowledge/experience in the following areas:

- Quality Management Systems and quality standards
- Medical device regulations and quality system standards associated with the product development and approval process for EU and USA.
- Product registrations and/or submissions with authorities/agencies/partners, and maintenance of regulatory filings within set time frames

To be successful in your role you have a collaborative mindset. You have a good understanding of commercial aspects of innovation and working efficiently in cross-functional organizations.

**QUALIFICATIONS:**

- University degree in relevant field such as Science, Engineering, Medicine
- You are comfortable speaking and writing in English at a professional level

**APPLY TODAY**

This recruitment is handled by our recruitment partner**, Moveup Consulting AB**. To apply, please send your CV and a cover letter to Ann Rütt; ann.rutt@moveup.se
If you have questions regarding XVIVO or this open position, please contact Ann at +46 (0)733 44 09 00 or Tom Bergqvist at +46 (0)733 87 27 22.

*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.*

**XVIVO is an equal opportunity employer. We look forward to your application!**

**Om företag**

**THE COMPANY**

**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 and 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, evaluations, and treatment of organs to all transplant centres in 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 to help our customers.

**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.

**Consultant Name** Ann Rütt

**Consultant Number** 0733 440900

**Consultant Email** ann.rutt@moveup.se

**Cosultant Linkdin** https://www.linkedin.com/in/ann-r%C3%BCtt/