CLINICAL EVIDENCE MANAGER

Posted on 22 mars, 2021

Company Name XVIVO

Location Göteborg

Job Description

XVIVO is a growing international medical technology company focused on developing optimized solutions for organ, tissue and cell preservation and perfusion in connection with transplantation. We are now expanding our Clinical Affairs team at the Gothenburg head office with a **Clinical Evidence Manager**.

The culture of XVIVO is the culture of a small company with ambition to grow, based on the foundation of a common belief that patient safety is key for our success. Our vision is that nobody should have to die waiting for an organ. We strongly believe in the fact that nothing is impossible and thrive to get the job done. We are, no matter which position or work description, always focused to help our customers. 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 a great team and join us on our exciting growth journey!

As a **Clinical Evidence Manager** at XVIVO you will write clinical evaluation plans and reports in compliance to applicable regulations, standards and guidance documents, such as MDR, ISO13485, ISO14791, MEDDEV 2.7.1, and MDCG. This translates to high quality in all deliverables and documentation with attention to detail, consistency, and integrity of data. Thorough knowledge of assigned products and cross-functional collaboration with R&D, Regulatory Affairs, Clinical Affairs and Sales & Marketing are the keys to success in this role.

Responsibilities in detail:

- Provide technical and strategic planning and writing expertise throughout the product development and life cycle process.
- Evaluate and summarize clinical evidence including data from sources such as clinical investigations, literature, post-market surveillance, risk management, and post market clinical evaluations.
- Deliver clinical evaluation plans (including clinical development plans) and reports, PMCF plans and reports, as well as SSCPs.
- Ensure alignment of risk information in IFUs, risk management files, clinical investigation plans and clinical evaluation documentation.

- Provide input to new product development and product claims.
- Contribute to regulatory submissions and quality management system audits.

Qualifications

- Master's or PhD degree in relevant field
- Related work experience in medical device industry
- Understanding of EU regulatory requirements (MDD, MDR, MEDDEV, MDCG)
- Ability to review and summarize scientific publications and product documentation, medical writing

Although not mandatory we hope that you also have:

- Experience of scientific research methodologies and information management (clinical investigation design, biostatistics, PubMed)
- Experience from working in clinical trials (ISO14155)
- Experience with citation management software such as EndNote
- Understanding of regulatory requirements outside EU (e.g. US, Canada, Australia)

As a person you have a can-do attitude, and you have a personal drive. You take initiative and you have a strong focus to achieve goals and targets. You enjoy working in cross-functional teams and you have the ability to communicate effectively.

Application and contact
This recruitment is handled by our recruitment partner, Moveup Consulting AB. To apply, please send your CV and a cover letter to karin.tomin@moveup.se

If you have questions regarding XVIVO or this open position, please contact Karin Tomin at +46 (0)733 44 09 00

We are screening applications continuously. Please send your CV and Cover letter no later than 23 April.

We look forward to your application!

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

Founded in 1998, **XVIVO** is the only medical technology company dedicated to extending the life of all major organs – so transplant teams around the world can save more lives. Our solutions allow leading clinicians and researchers to push the boundaries of transplantation medicine. XVIVO is headquartered in Gothenburg, Sweden, and has offices and research sites on two continents. The company is listed on Nasdaq.

Watch XVIVO's brand movie using the link below:

https://vimeo.com/534303422