REGULATORY AFFAIRS SPECIALIST - SOFTWARE/WOUNDCARE

Posted on 21 december, 2021

Company Name Mölnlycke

Location Gothenburg

Job Description

Are you looking for a great career and want to make your mark? Please keep on reading but don't just take our word for it.

We've interviewed colleagues around the world about their jobs, the Mölnlycke unique culture and Mölnlycke people and it is simply A great company to work for!

Could you help improve healthcare outcomes around the world? If the answer is yes, you think just like us and should apply for this exciting opportunity that we have below.

We are now looking for a **Regulatory Affairs Specialist** - **Software/Woundcare** to play a critical role in our global Regulatory Affairs team and with an opportunity to join Mölnlycke's digital journey.

The ideal candidate for this position must be able to integrate business objectives and product development with regulatory requirements. The Regulatory Affairs Specialist will define and manage all regulatory aspects of projects and medical device submissions to Health Authorities worldwide.

Key Accountabilities

As a Regulatory Affairs Specialist – Software/Woundcare your role will include:

- Being the Regulatory Affairs responsible in projects developing new products including software stand-alone medical devices, line extensions and upgrades according to product launch plan
- Being the Regulatory Affairs consultant and coordinator collaborating with other functions such as Research & Development to build and mentor best practice
- Reviewing and approving documents necessary for achieving CE-mark and product approval
- Compiling and submitting regulatory applications worldwide to achieve market access
- Monitoring new regulatory regulations as well as changes to existing regulations to secure compliance with regulations for medical devices on a global arena
- Reviewing and approving labelling as well as claims and marketing messages
- Together with Global Regulatory Affairs secure synergies and optimal resource utilization to support the global company strategy

Qualifications

You should have a university degree, or equivalent, in Chemistry, Biology, Engineering or corresponding experience. You must have experience from Medical Device Companies and experience working with regulations and requirements for medical devices, from Regulatory Affairs or related areas. In addition, experience of working with software medical devices or electronic medical devices.

In order to succeed in this position you must be a really good communicator and possess strong team working skills. Experience from working in an international environment using English on a daily basis, both orally and written is a prerequisite.

You are a good planner and organizer and you do have the ability to establish fruitful relationships and maintain networks as you will be the link between Research & Development and Marketing projects.

The position will report to the manager for Strategic Regulatory Affairs within Global Regulatory Affairs and will be located at HQ in Gothenburg.

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

If you have questions regarding Mölnlycke or this open position, please contact Tom at +46 (0)733 87 27 22. We are screening applications continuously. Please send your CV and Cover letter no later than 16 January.

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

Mölnlycke is a world-leading medical solutions company. We design and supply solutions to enhance performance at every point of care – from the hospital to the home proven it every day.

We specialize in:

- Wound management: including dressings with Safetac® such as Mepitel® and Mepilex®
- Preventing pressure ulcers: with Mepilex® Border used prophylactically and devices to help turn and re-position patients
- Surgical solutions: including Mölnlycke trays, HiBi® antiseptics and Biogel® surgical gloves

Mölnlycke was founded in 1849. Nowadays our solutions are available in around 100 countries; we're the number one global provider of advanced wound care and single-use surgical products; and we're Europe's largest provider of customised trays. Our headquarters are in Gothenburg, Sweden and we have about 7,800 employees around the world.

www.molnlycke.com

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