REGULATORY AFFAIRS SPECIALIST

Posted on 11 april, 2023

Company Name Mölnlycke

Location Göteborg

Job Description

Grow your career in an international environment

If you're ready to have an impact in a career that makes a difference, Mölnlycke could be your next step. You'll be helping to equip medical professionals around the world with solutions to improve outcomes for patients. And you'll be developing yourself in a global environment with an inspirational culture, with lots of opportunities. All the while building a successful career, with real purpose.

Looking for an inspirational environment to take your next step?

Mölnlycke is now looking for a **Regulatory Affairs Specialist** to play a critical role in our global Regulatory Affairs team.

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 your role will include:

- Being the Regulatory Affairs responsible in projects developing new products, line extensions and upgrades according to product launch plan
- Being the Regulatory Affairs consultant and coordinator supporting other functions such as Research & Development to build and mentor best practice
- Reviewing and approving documents necessary for achieving CE-mark and product approval
- Supporting 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 in order 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 for at least five years and at least three years of experience working with regulations and requirements for medical devices, from Regulatory Affairs or related areas.

In order to succeed in this role, you must be a really good communicator and possess strong team working skills. Experience from working in an international environment using English daily, 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 Regulatory Affairs Director Wound Care within Global Regulatory Affairs and will be located at HQ in Gothenburg.

Your work-life balance

- The placement of this position is our headquarter in Gothenburg
- Hybrid working – Mölnlycke has a policy giving you the opportunity to work 2 days/week from home

Our approach to diversity and inclusion

We strive to have a diverse mix of people from different cultures, ages, geographies, and genders, to reflect the world in which we operate and to facilitate innovative thinking across the business.

To apply

We are looking forward to receiving your application (in English) as soon as possible. For more information about Mölnlycke, the role and to apply, please contact Tom Bergqvist, Moveup Consulting AB, 0733 – 87 27 22 or Fredrick Asare at 0733 - 44 09 00.

Applications must be sent by e-mail to: fredrick.asare@moveup.se

By submitting your application, you also give your consent to storing your personal information, including CV & Cover letter, and that we own the right to share this information with third parties (our

client). You can withdraw the consent at any time.

Om företag

***Mölnlycke** is a world-leading medical products and solutions company that equips healthcare professionals to achieve the best patient, clinical and economic outcomes. Our business is organised in the four business areas Wound Care, Operating Room Solutions, Gloves and Antiseptics, where customer centricity, sustainability and digitalisation are at the heart of everything we do. Mölnlycke employs around 8,400 people. The company headquarters are in Gothenburg, Sweden and we operate in more than 100 countries worldwide. Since 2007, the company has been part of Investor AB, an engaged owner of highquality, global companies which was founded by the Wallenberg family in 1916. For more information, please visit www.molnlycke.com and www.molnlycke.com/careers*

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