

REGULATORY AFFAIRS MANAGER

Posted on 16 oktober, 2020

Company Name ABIGO Medical AB

Location Göteborg

Job Description

Do you want to be an important part of a globally strong, Swedish-owned company that always puts patients and customers in focus?

Are you challenged by finding effective solutions, moving forward and to be part of an entrepreneurial driven company?

Do you consider yourself as a structured, analytical, and responsible person?

Do you have at least five years of experience from Life Science and at least three years within medical device Regulatory Affairs work?

WELCOME TO ABIGO

At ABIGO Medical you can expect an exciting and developing environment with high ambitions to always be at the forefront. ABIGO Medical is a company of strong growth and entrepreneurial spirit. We work together, see opportunities, and focus on high quality in all our work. With us, you are challenged to grow and have great opportunities to work independently and be a central part of our innovative and progressive work.

We are now looking for a new colleague to join our Regulatory Affairs team, to contribute to our medical device segment related to advanced wound management products (Sorbact®). As a Regulatory Affairs Manager, you will work in close cooperation with colleagues within Regulatory Affairs, as well as cross-functionally throughout the company. In addition, in this role, you will focus, in close cooperation with ABIGO's main partner, on supporting regulatory compliance in the US and local markets worldwide (e.g. North and South America, Asia, Africa).

RESPONSIBILITIES

- Build and maintain positive, professional relationship with ABIGO's main partner
- Maintain regulatory compliance in current markets through the necessary regulatory actions

related to product changes (listings, registrations, change notifications, pre-approval submissions, including e.g. US 510(k))

- Enable geo-expansion through coordination and management of registration activities in new markets
- Secure continued growth in current markets through registration of additional products
- Enable continued sales through renewal applications/listings in current markets
- Act as RA representative in product change projects
- Create and maintain product related regulatory documentation
- Monitor regulatory requirements internationally
- Initiate and support actions to implement and maintain compliance to relevant jurisdictions
- Contribute to and lead process improvement

SKILLS AND QUALIFICATIONS

- Academic background within life science or other scientific education
- At least five years of experience within Life Science
- At least 3 years of experience within medical device Regulatory Affairs and work with US and local markets
- Effective communication skills in Swedish and English, both verbally and in writing
- Ability to build and maintain positive, professional relationships cross-functionally and cross-culturally, both internally and with ABIGO's partner
- Positive attitude toward challenges
- Taking initiatives
- Strong focus and drive to achieve goals and targets

WE OFFER

An exciting and varied position at a Swedish Pharmaceutical and Medical Device company. Our corporate culture is characterized by a family atmosphere with a strong entrepreneurial spirit and where cooperation and personal development are encouraged. You will be a member of an inspiring and affirmative team, where we help each other and work together towards set goals. We emphasize the importance of working professionally in an environment that is enjoyable and fulfilling.

This position is a permanent full-time employment based in Askim, Gothenburg.

Apply today

This recruitment is handled by our recruitment partner, Moveup Consulting AB. To apply, please send your CV and a cover letter to katarina.wanderydz@moveup.se no later than **12 November**.

If you have questions regarding ABIGO Medical AB or this open position, please contact Katarina at +46 (0)738 55 44 51 or Tom Bergqvist at +46 (0)733 87 27 22 or tom.bergqvist@moveup.se

We are looking forward to hearing from you!

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

ABIGO Medical AB develops, manufactures and markets products including the Sorbact® technology, which is a clinically established innovation for advanced wound care. ABIGO was founded in 1989 by the brothers Jan G and Leif Smith. The company has about 170 employees and distribution of products in some 60 countries through own sales organisations and partners. An active research and development program in selected areas opens up exciting opportunities for growth and has also led to a number of international patents and patent applications. Unique, patented products developed in house, with international potential in niche areas, are part of ABIGO's business philosophy. Early this year, Essity acquired 75% of ABIGO Medical, securing the potential to continue the journey of growth.

www.abigo.com

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