RA MANAGER

Posted on 28 februari, 2020

Company Name RA Manager

Location Göteborg

Job Description

Breas Medical was founded in 1991 in Mölnlycke, Sweden, as an entrepreneurial company that quickly developed to become one of the global leaders in home mechanical ventilation and sleep treatment. We successfully market the Vivo and iSleep product ranges, the Nippy and Clearway brands, and the Z1 CPAP range, redefining CPAP use in terms of size, weight, and portability. Today we are a global company selling in more than 40 countries through our network of subsidiaries (Sweden, UK, Spain, Germany, USA) and highly specialized distributors. Our 150 employees are the backbone of the company. We all share the same passion for patients and customers which shows in how we approach customer service, product development, manufacturing, sales, marketing, quality and service.

If you want to make a difference to home care patients, welcome to join us as our new ***Regulatory Affairs Manager.***

RA Manager

We are now recruiting a Regulatory Affairs Manager (RA-Manager) to our office in Mölnlycke/Göteborg. As our RA-Manager you promote the awareness of regulatory, customer and statutory requirements throughout the organization. The main focus is on regulatory compliance and product registration worldwide.

You will be responsible for monitoring regulatory requirements and changes to such and initiate actions to implement and maintain compliance to applicable regulations.

Essential tasks would be to;

- Mentor, coach & train the organization on activities within Regulatory Affairs
- Plan and do new and changed product registration submissions in EU, US and rest of the world.
- Inform excutive management on changes to regulations and standards that has impact on Breas product range.
- Being the Regulatory representative in new design projects and design changes to define regulatory requirements and assess compliance.
- Review and approve labeling

- Identify and report any quality or compliance concerns and take immediate corrective action as required
- Maintain up-to-date knowledge and understanding of current regulatory requirements within area of responsibility

Your qualifications

- Working knowledge of Nonconformance, CAPA, Complaint Handling and Post Market Surveillance systems
- Demonstrated knowledge of regulatory issues, and experience interfacing with local & international regulatory bodies, such as FDA, European competent authorities & notified bodies, Health Canada, SFDA, KFDA, MHLW
- Demonstrated project management skills; ability to prioritize, plan, evaluate & execute deliverables for established tactical goals
- Ability to influence and make recommendations at multiple levels of the company
- Excellent verbal and written communication and presentation skills with the ability to speak and write clearly and convincingly in English and Swedish.
- Regulatory Affairs Certification (RAPS) would be considered an advantage

To be successful in this position you have demonstrated experience prioritizing conflicting demands from multiple business entities in an extremely fast paced environment. You have strong problem solving- and negotiation skills and the ability to drive change, stimulating others to change and manage implementation effectively.

Application

Applications are handled continuously. Please send your CV and Cover Letter to linda.andersson@moveup.se

If you have any questions please feel free to contact Tom Bergqvist at + 46 (0)733 – 87 27 22.

Om företag

Breas Medical was founded in 1991 in Mölnlycke, Sweden, as an entrepreneurial company that quickly developed to become one of the global leaders in home mechanical ventilation and sleep treatment. We successfully market the Vivo and iSleep product ranges, the Nippy and Clearway brands, and the Z1 CPAP range, redefining CPAP use in terms of size, weight, and portability. Today we are a global company selling in more than 40 countries through our network of subsidiaries (Sweden, UK, Spain, Germany, USA) and highly specialized distributors. Our 150 employees are the backbone of the company. We all share the same passion for patients and customers which shows in how we approach

customer service, product development, manufacturing, sales, marketing, quality and service.

Consultant Name Tom Bergqvist

Consultant Number +46 (0)733 87 27 22

Consultant Email tom.bergqvist@moveup.se

Cosultant Linkdin
https://www.linkedin.com/in/tombergqvist?lipi=urnlipaged_flagship3_profile_view_base_contact_detailsZbj2BKDiScWsZiTL2Z6QCw