REGULATORY AFFAIRS MANAGER

Posted on 22 december, 2022

Company Name Getinge

Location Stockholm

Job Description

At Getinge we have the passion to perform

Join our diverse teams of passionate people and a career that allows you to develop both personally and professionally. At Getinge, our passion is to secure that every person and community have access to the best possible care, offering hospitals and life science institutions products and solutions that aim to improve clinical results and optimize workflows. Every day we collaborate to make a true difference for our customers – and to save more lives.

Are you looking for an inspiring career? You just found it.

Are you interested in becoming part of an international and market leading medical technology company whose products make a huge difference for patients, healthcare professionals and societies all around the world? Apply to be a member of the Regulatory Affairs and Product Compliance team at Getinge (Maquet Critical Care). As one of the first companies in Sweden to achieve a MDR certificate for our Class IIb products, we strive to be at the front of regulatory compliance and quality process development.

The Position
This position offers you a great opportunity to work cross-functional, locally, and globally, with a wide variety of stakeholders inside the organization. It is an excellent chance to take part in improving world class med-tech products in a challenging regulatory environment within a global and fast-paced manufacturing organization.

As a Regulatory Affairs Manager you will be a member of the Regulatory affairs and Product compliance team taking ownership for the regulatory aspects of the product area of Anesthesia, Ventilation and Perfusion, towards internal and external stakeholders. The regulatory team strive for excellence in the regulatory process by taking a leading role in international standardization and development of Getinge global processes.

You will have the opportunity to collaborate in an open climate, with a diversified teams thru the whole product life cycle, from idea to release the product to market and through post market surveillance. This role leading cooperation between different sites within Getinge on a global level.

The main responsibilities and tasks for a Regulatory Affairs Manager at Getinge are:

- Establish and maintain documentation for CE-marking according to MDR, i.e. Technical Documentation and Declaration of Conformity
- Submit and support regulatory applications for China and US, for market clearance/approval
- Support the R&D throughout the product development process
  g. issue Quality Management Plans, participate in Risk Management and perform document review
- Support Post market surveillance activities including risk analysis, field actions, Periodic Safety Update Reports and communicating with authorities.
- Take the lead or participate in cross-functional and global projects such as development of global Getinge procedures.
- Within your area of expertise support the organization and e.g. participate in standardization and continuously improve our processes

We strive for all our employees to be able to achieve a good work-life harmony. We have introduced a flexible approach to our workplaces, and therefore you will have the opportunity to work remotely in this position a certain part of the week.

The position is located at our site in Solna but will require daily communication with stakeholders world-wide.

Is this you?

For this position, you have experience within QA/RA and/or R&D from the medical device industry. Experience from regulations and standards, such as QSR, MDD/MDR, ISO13485 and IEC60601, is expected. You have a Master's degree or corresponding education, in a relevant field together with fluent proficiency in English (our corporate language), and preferably Swedish.

We also believe that you, in addition, have worked in or with several areas of electrical medical devices, such as development, production, product management, customer support and complaints.

In this recruitment we are looking for someone that have the personal skills that promotes and develops a cross country and cross site cooperation. Your personal attributes will be of great importance! As a person you are accurate, action-orientated, driven, communicative and independent with a great amount of integrity.

You have a coherent, challenging and process-oriented attitude and an excellent ability to communicate and collaborate with both internal and external stakeholders. An ability to work in a changing environment is also a key factor for this position.

About us

Getinge is on an excitingtransformation journey constantly looking for new ways to innovate together with our customersto meet the healthcare challenges of the future. We are committed to diversity, equity and inclusion and to sustainability with a goal to beCO_2 neutral by 2025.We believe in giving our employees the flexibility they need and make every effort to foster a learning culture that supportstheirpersonal development andcreativity.Our passionatepeople hold our brand promise 'Passion for Life' close to heart.

Ifyoushareourpassionandbelievethatsavinglivesisthegreatestjobinthe world,thenwelook forwardtoreceivingyourapplication and resume. We hope you will join us on our journey to become the world's most respected and trusted medtech company.

To apply

This recruitment is managed by our recruitment partner, Moveup Consulting AB. Please send your application (CV and cover letter) as soon as possible, to daniel.kremer@moveup.se

For questions regarding Getinge or this open position, contact recruitment consultant Daniel Kremer at 0733-87 27 24.

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

With a firm belief that every person and community should have access to the best possible care, Getinge provides
hospitals and life science institutions with products and solutions that aim to improve clinical results and optimize workflows.

The offering includes products and solutions for intensive care, cardiovascular procedures, operating rooms, sterile
reprocessing and life science. Getinge employs over 10,000 people worldwide and the products are sold in more than 135
countries

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