HEAD OF QUALITY ASSURANCE & REGULATORY AFFAIRS

Posted on 4 augusti, 2020

Company Name Handicare AB

Location Stockholm

Job Description

We are a team of some 300 employees and are passionate about what we do. Our commitment is tied to our awareness that our efforts make a difference in the lives of individuals. We are also driven by the ongoing need to continuously improve, enhance and develop our solutions.

Our global Quality Team is spread between UK and Sweden, and for our Quality department in Sweden, specialized in transfer products, we are recruiting a **Head of Quality Assurance and Regulatory Affairs** to further expand our Quality Team.

Reporting to the Quality & Regulatory Director DHG, the role will give you the opportunity to grow in a truly international company. This new role is about bringing direction, purpose and clarity to the Regulatory Affairs & Quality Systems function. You will be responsible for ensuring product compliance and maintain and improve the existing Quality Management System.

The role is based at the Handicare office in Kista, Sweden.

The key responsibilities of the role are to:

- Lead the Quality & Regulatory team of 3 in Kista
- Lead and participate in internal and external audits
- Lead and manage the Supplier Quality assurance, with suppliers mainly in Europe and Asia
- Be accountable for the Quality Management system and the Environmental System in both Sweden and the Netherlands and ensure that requirements from the ISO 13485, 9001, 14001 and FDA standards are met
- Be accountable for the management review and follow-up actions decided by management team
- Support the organization in their reviews to identify improvement opportunities
- Stay updated on the development of relevant standards and regulations concerning our product areas
- Be the company's contact person for certifying bodies for medical devices
- Be accountable for the structure, plan and implementation of processes, writing routines and creation of forms for relevant areas to cover QMS and EMS
- Perform internal Quality related training

Your background:

You have a MSc or at least 5 years' experience from working in a similar role within MedTech or similarly controlled environment. Experience from regulatory reporting in EU and US (FDA). You are good at Project Management and can independently drive change projects.

A good knowledge of the Medical Device Regulation, MDR, is required and you have experience from managing a team.

Your English is fluent. Swedish, and any other European or Asian language is an asset. The role will require travelling, mainly to our office in the Netherlands and to our Suppliers.

To apply

We are looking forward to receiving your application (in English) as soon as possible! Selection and interviews are ongoing, so hurry up, the position may be assigned earlier. For more information about Handicare, the role and to apply, please contact Tom Bergqvist, Moveup Consulting AB, +46(0)733 87 27 22 or tom.bergqvist@moveup.se

Please send your application (CV and Cover letter) to Tom Bergqvist at; tom.bergqvist@moveup.se

For more information about Handicare, please visit www.handicare.se

We are looking forward to hearing from you!

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

Handicare AB, *a company in the Direct Healthcare Group (DHG), offers solutions and support to increase the independence of disabled or elderly people, and to enable them to live an active life — on their terms — and to facilitate for their care providers and family.*

Direct Healthcare Group seeks to be the market leader in the prevention and treatment of voidable harms caused by reduced mobility across acute and post acute settings operating in all key EU markets and rest of the world through distributors.