QA PRODUCT DEVELOPMENT ENGINEER SOFTWARE/ELECTRONICS

Posted on 8 juli, 2022

Company Name Mölnlycke

Location Göteborg

Job Description

Are you passionate about making life better for patients worldwide? If the answer is yes, you think just like us. We are a world-leading medical solutions company, designing and supplying medical solutions to enhance performance in healthcare – from the hospital to the home.

We're looking for QA Product Development Engineer to help improve outcomes for healthcare professionals and their patients.

QA Product Development Engineer Software/Electronics

As a QA Product Development Engineer you are a key member in New Product Development projects as well as life cycle management activities to give guidance and support in how to navigate within the application of product related QMS processes to assure compliance and safe products are developed and released. As QA Product Development Engineer you also support process owners for product development and life cycle management in the implementation, maintenance and continuous improvement of the quality management system (QMS).

You will work in a global environment and in true cross functional collaborations to be able to develop safe and compliant products to enhance the performance in healthcare and improve the patient quality of life.

Key accountabilities

- Ensuring that Design Control, Change Control and Risk Management processes are followed during product development projects and product changes, especially for the devices including electronics, software or software as standalone devices
- Review and approve or reject relevant product related technical documentation for completeness and compliance according to QMS requirements and applicable regulation
- Participate in the development and improvements of QMS processes related to the development and life cycle management of products Including electronics, software or

software as standalone devices
- Support in root cause analysis of quality issues for design control or change control or related and as well as giving input to effective corrections, corrective actions and preventive actions
- Function as a source or reference point for QMS requirements related to product development and product changes and coach applicable Mölnlycke organisational roles and positions in QMS requirements
- Participate in external, corporate, local or any internal audit activities to support audit programs
- Provide feedback on the applicability and adherence to QMS processes during execution of product development projects and product changes within the areas of Design Control, Change Control, Risk Management, Post-Market surveillance and related sub-processes
- As QA representative judge whether relevant documentation for completeness and compliance can be QA approved or not during product development projects or product changes
- As QA representative in procedures and work instructions, judge if the document fulfils external regulatory requirements and is aligned with associated QMS documentation
- Escalate to next level of management if quality issues occur within design control or change control related documentation or records with no actions identified

Qualifications & Experience

- Academic background in engineering, life sciences, medical biology, chemistry or other relevant area
- Minimum 2-3 years' experience from medical device industry or equivalent
- Working experience within Product Development/Life Cycle Management preferably within the areas of Quality Assurance or Product Development
- Knowledge of regulations for Medical Device Software and Medical Electrical Equipment such as IEC 60601, IEC 62304 and other relevant e.g. IEC 82304
- Knowledge in applicable quality system regulation i.e. ISO 13485, MDD/MDR, FDA 21 CFR part 820 and ISO 9000
- Experience from work in an international organization or environment
- Analytical Skills
- Fluent in English, and preferably Swedish

To apply

We are looking forward to receiving your application 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.

Applications must be sent by e-mail to: tom.bergqvist@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 solutions company. We design and supply solutions to enhance performance at every point of care – from the hospital to the home proving it every day.

We specialise in:

- *Wound management: including dressings with Safetac® such as Mepitel® and Mepilex®*
- *Preventing pressure ulcers: with Mepilex® Border used prophylactically and devices to help turn and re-position patients*
- *Surgical solutions: including Mölnlycke trays, HiBi® antiseptics and Biogel® surgical gloves*

Mölnlycke was founded in 1849. Nowadays our solutions are available in around 100 countries; we're the number one global provider of advanced wound care and single-use surgical products; and we're Europe's largest provider of customised trays. Our headquarters are in Gothenburg, Sweden and we have about 7,800 employees around the world.

www.molnlycke.com

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