DESIGN PROCESS SPECIALIST

→ SWEDEN OR HOME-BASED IN EUROPE

→ Contact: kristina@elemed.eu

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Do you have experience with the design and development process of a medical device? Do you love working closely with quality processes and implementing them? Do you want to be a change champion and have influence in a global corporation? Read on...

→ THE COMPANY

This company has been enhancing performance in healthcare across the world for over 150 years so have a huge amount of history behind it including being the first company to mass-produce dressings for wound care. Even though they have developed and manufactured many revolutionary devices, the innovation doesn't stop and is done in-house! They are always looking for new ways to improve not just in what they produce but also how they do business so have recently undergone a huge business transformation.

The value of work-life balance is strongly recognised here so, even though the headquarters are based in Sweden, this opportunity is open to be based from home anywhere in Europe. If you are looking for a large, established company that still feels like family, this is the place for you!

THE OPPORTUNITY

The set-up of this position is quite unique to this business – it is an opportunity to be the change champion within the design and development part of the business and be responsible for ensuring quality compliance across all R&D activities in the four business areas. You will be responsible for identifying problems, devising and implementing solutions by influencing key stakeholders/teams and ensuring that all development activities across the business are harmonious and consistent. It's not often that you have the opportunity to transform and influence quality in such a large, established organisation...

If you enjoy working as a team in a solution-oriented way, have a passion for quality and experience in design and development, this is just the position for you!

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→ THE ROLE

As Design Process Specialist you will (not an exhaustive list):

- Author, review and maintain the quality system documentation (policies, procedures, working instructions) for the related QA/design processes
- Identify, interpret and evaluate new and existing regulatory and quality requirements to guide, advise and train the relevant teams to ensure compliance
- Anticipate compliance risks relating to the research and development processes and find solutions to mitigate the risks throughout the product lifecycle
- Implement the risk mitigation plan and train the stakeholders
- Support audit and inspection readiness and activities related to the relevant processes
- Influence key stakeholders to make and implement changes to the relevant R&D processes
- Deliver continuous training and support for the design QA processes to relevant teams and stakeholders
- Establish the governance and the collaboration area (how to, with who etc.) between the process owner, BAs and other stakeholders to assure that the processes are fit for purpose today and future product portfolios

→ YOUR QUALIFICATIONS

- 4+ years of design quality assurance experience in the medical device industry
- Good undestanding of design control/change control from concept to realisation of a product
- Willingness to travel bi-monthly to Sweden
- Eligbility to live and work in Europe

→ GET IN TOUCH

Interested to explore this further? Please send your CV to **kristina@elemed.eu** to arrange a confidential career discussion.

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