SUPPLIER QUALITY ENGINEER

Sweden or home-based in Europe

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contact

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Are you an expert in SaMD or embedded software (IEC 62304)? Do you want to define and shape your own role? Are you tired of working in slow moving corporations where you can't make an impact? 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 woundcare. 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 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

Due to a recent transformation in the business, this new position in Quality was created and we are looking for you! If you're ready for a step into fresh shoes where you can mould and shape them to fit you, this is the position for you. This is an opportunity to work on high-priority software projects and expand this area for the company as well as manage broad responsibilities relating to suppliers. You will be actively supporting suppliers with design transfer, risk management, process validation and process improvements amongst other things.

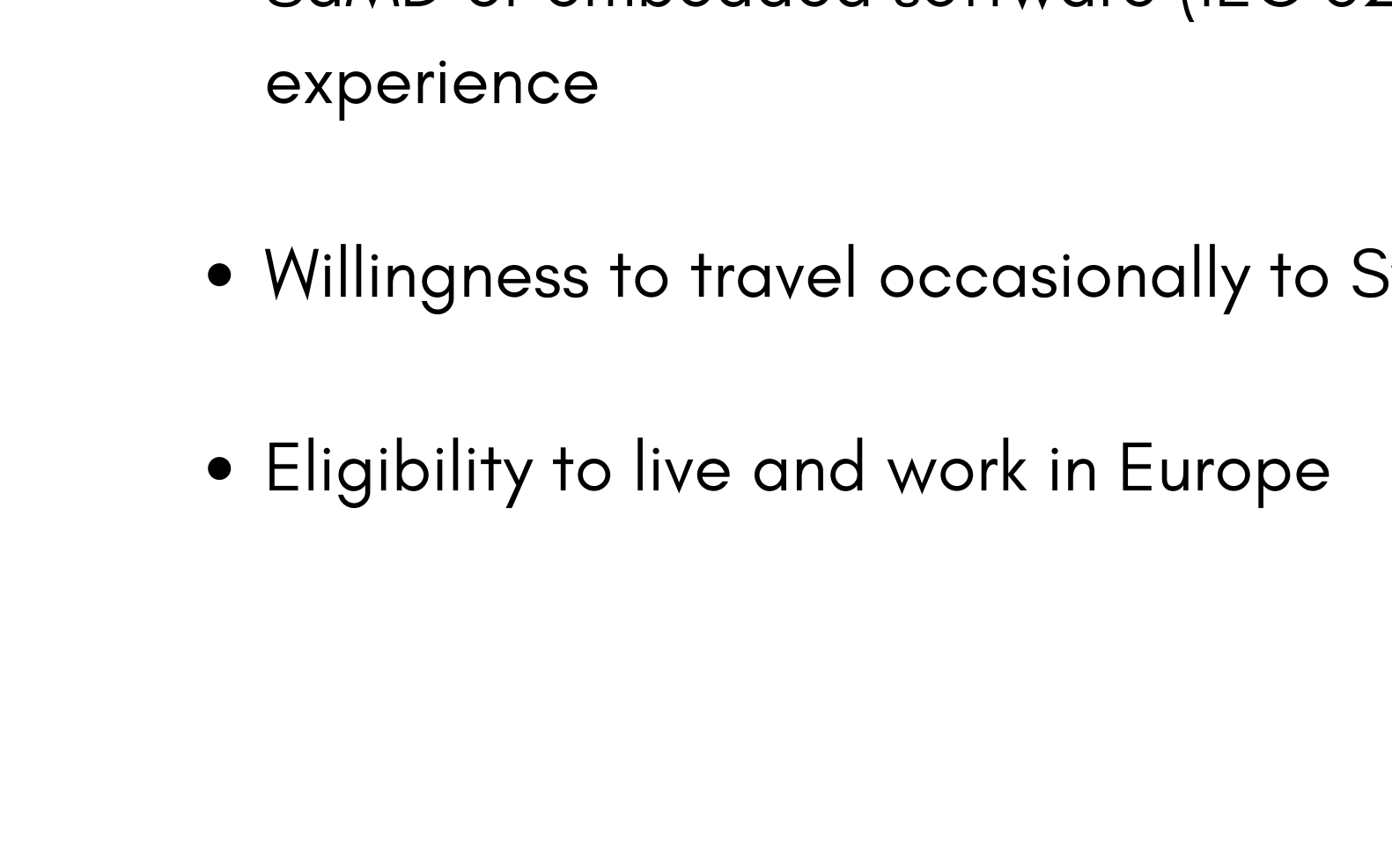
RESPONSIBILITIES

As Supplier Quality Engineer you will (not an exhaustive list):

- Evaluate, approve and monitor suppliers according to the relevant company requirements
- Ensure effective agreements are in place with suppliers compliant with the relevant requirements and that the suppliers consistently distribute products in compliance with the relevant requirements
- Manage supplier audits, CAPAs, root cause analysis, non-conformities, deviations for suppliers
- Execute and lead activities such a process validation, PFMEA, risk management, control plans
- Lead, follow up and action complaints, CAPA and audit findings related to suppliers
- Oversee the design transfer from supplier
- Drive software projects as the SME within the business

QUALIFICATIONS

- 3+ years of quality assurance experience in the medical device industry with a focus on CAPA management, root cause analysis and non-conformities
- SaMD or embedded software (IEC 62304) experience
- Willingness to travel occasionally to Sweden
- Eligibility to live and work in Europe



INTERESTED?

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

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