

## **Quality Assurance Manager (f/m)**

QA • Selzach/Kiel • Start: asap • Position permanent

## Your Talent – our passion as a Top-Employer in MedTec!



33.000+ employees



5.638 patents owned globally



\$ 11.3 Billion turnover



Various perspectives and possibilities for personal development



Flexible working hour arrangements



Unique and engaged colleagues

## Our offer

The principal activities of Quality Assurance Manager - Risk and Security, Software and Electronics are:

- Management of Risk Management Specialists, providing training, mentorship, supervision, and development
- Resource planning and assignment of RMS resources to support R&D Projects at all T&E sites
- Supervision of all Risk Management activities and documentation, providing leadership and training, responsibility for all content
- Fulfilling the DQA role in design reviews and on design teams for software and electronics products to ensure compliance to quality system requirements (internal procedures, MDD/MDR, IEC 60601, ISO 13485, QSR, etc.) and complete documentation
- Participation in Quality System Audits, design file (DHF/TechFile) audits, Risk Management system audits, and Design Reviews.
- Acting as QA approver for Design documents to ensure compliance, completeness, and accuracy.
- Cooperation with subject matter experts for Stryker T&E on policies, standards, and activities related to Design Development Control, Design Change Control, Design Verification and Validation, and Human Factors Engineering / Usability.

## Your profile

You are a perfect candidate for the position if you have:

- University Degree in Medical Device Technology, Mechanics, or similar.
- 3+ years of work experience with a strong understanding of functional areas, or an equivalent combination of education & work experience in the medical industry.
- Knowledge of IEC 60601 family, ISO 13485, ISO 14971, and QSR requirements.
- Multiple years of experience in software/electronics development and/or in the field of quality assurance and risk management of safety related products, preferable medical devices.
- Ability to interact ad provide feedback to R&D and operations for quality improvement, corrective actions, and quality cost reductions.

We are looking forward to your online application via our career page, reference number 24307BR.

Please notice that the title of this advertisement can differ from the position title.



Katarzyna Gniazdek +48 12 881 0537 www.stryker.de katarzyna.gniazdek@stryker.com











