qmedics UNIQUE MEDICAL SOLUTIONS

We encourage and support new ideas and are always seeking to improve the quality of patients' lifes.

Qmedics AG is a privately held, independent Swiss medical technology company founded in 2008. We develop and manufacture stents, stent systems and balloon dilatation catheters. Our portfolio offers standard and customized products, solutions, and technologies. With our passion for life, we focus on innovation and enhancement the concept of endovascular implants.

Are you the highly motivated and service-minded candidate as our new

Risk & Quality Compliance Specialist

The Risk & Quality Compliance Specialist will come with experience and expertise in regulatory affairs and will lead the risk process for the entire Qmedics device portfolio. In this role, the Risk & Quality Compliance Specialist will contribute to implementing cross-functional procedures.

Your Responsibilities

- Lead Risk Management efforts and processes, as well as process improvements for the entire Qmedics portfolio.
- Ensure the comprehensive implementation and maintenance of the Risk Management procedure in accordance with ISO 14971, ISO 13485, and the Medical Device Regulation MDR.
- Develop and maintain Risk Management Files for an EU class IIa, IIb and III device family that includes risk management plans, hazard analyses and (clinical) risk assessments.
- Signal detection and benefit/risk evaluation, including initiating appropriate measures e.g., prepare safety review presentations, update the risk documentation and resulting action plans, initiate IFU changes etc.
- Implement documentation necessary for Vigilance, such as Risk Management plans, and support the timely issuance of inter-departmental reports, e.g., clinical evaluation reports.
- Keep abreast of changes to regulations and standards as they impact on risk management.
- Support the review and improvement of the QMS to ensure it is in line with the MDR.
- Provide inputs to post-market / vigilance processes.
- Participate in audit session: planning and documentary preparation, assistance during audit, support to action plan definition and implementation.

Your Qualifications

- Bachelor's Degree in Biomedical or Life Sciences is required, Master's Degree is preferred.
- Proven experience in medical device risk management. Practical experience with ISO 14971 is required, working knowledge of ISO 13485 is desired and additional training on risk management is a plus.
- Hands-on experience with state-of-the-art risk management tools and techniques is a must.
- Ability to apply regulatory requirements to day-to-day risk and compliance activities.
- Capacity to be an expert in the field of responsibility, to define and implement specific actions, with the ability to quickly understand process flow /sequences in other fields.
- Strong writing and editing skills as well as attention to details is essential.
- Ability to collaborate effectively with others to obtain necessary information (across organizational and functional structures) as well as work independently on tasks.
- Commitment to finish tasks and projects on time and share responsibility as a team member.
- Capacity to understand, oversee and supervise complex activities/topics, as well as to propose and implement improvements.
- Project management, time management and problem-solving skills.
- Excellent knowledge of Microsoft Office package.
- Proactive attitude and ability to communicate effectively in a multi-cultural environment.
- Excellent command of spoken and written English; German is a plus.

With us you will find a challenging position in a motivated expert team. Qmedics AG is a growing innovative company with the ambition to make a substantial contribution to a world where everyone enjoys life without limitations.

We look forward to receiving your application at HR@qmedics.ch to the attention of our HR Manager Mrs. Monica Baumann. Please note, that we do not work with recruitment agencies to fill this vacancy.
Only direct applications will be considered.