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 willing to actively support the development and further growth of our company?

Regulatory Affairs Manager

Your Responsibilities

- Implement the new MDR in the regulatory processes with MDD considering for class II – III medical devices.
- Prepare international submissions.
- Develop and write clear arguments and explanations for new product certifications and license renewals.
- Monitor and set timelines for certification and/or license variations and renewal approvals.
- Collect, collate, and evaluate scientific data that has been researched by colleagues.
- Provide input to project teams during the development of regulatory plans & filing strategy to ensure acceptable labelling in markets assigned.
- Provide regulatory intelligence information to the organization.
- Monitor the regulatory competitor landscape and keep the organization abreast of potential threats and opportunities jeopardizing global development goals.
- Stay abreast of current and new legislation related to medical devices.

Your Qualifications

- Master's degree in scientific discipline such as biology, chemistry, engineering or equivalent
- Five to ten years of experience in general regulatory affairs, with at least four years of international regulatory experience.
- Profound experience with international medical device (class II & III) regulatory approvals and submissions.
- In depth knowledge on the new MDR and on all international regulations.
- Familiar with the medical device and combination device European regulations (93/42/CE and 2001/83/CE).
- Strong understanding of international regulatory landscape & required approaches and strategies.
- Agility to handle and deliver on a multitude of projects, programs, and priorities paired with high sense for execution and teamwork.
- Collaborative, empathic and solution-oriented individual.
- Excellent command of spoken and written English and German, any other language is an asset.

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.