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 company founded in 2008.
Since 2016 we are focusing on the development and manufacturing of our own product portfolio of stent delivery systems alongside their balloon dilation catheter. The broader view to innovate and improve the concept of endovascular implants - particularly stent and balloon technology - is based on our OEM activity during the first years.

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

Regulatory Affairs Manager (m/w)

Your Responsibilities

- Implement the new MDR in the regulatory processes with MDD taking into account 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
- 5 – 10 years' experience in general regulatory affairs, with at least 4 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

Are you our new results oriented Regulatory Affairs Manager looking for challenge in a dynamic environment?

Become part of our highly motivated and qualified team and make a substantial contribution to a world where everyone enjoys life without limitations.
We look forward to receiving your application at **HR@qmedics.ch**
Do not hesitate to call our HR Manager Mrs. Sabine Anna Gnädinger at +41 44 515 82 29