Head of Regulatory Affairs

Solothurn / Bern , Switzerland

1 DAY HOME OFFICE POSSIBLE,
100% POSITION
5 DAYS/WEEK.

When you work for a company, in the global headquarters, you are at the heart of all decisions. You have the chance to cross key leaders in the company corridors and have face to face meetings with your partners. If you are interested to work for a groundbreaking company where you can directly take ownership of regulatory vision and strategy, whilst at the same time building successful relationships with other company leaders - this might be the opportunity you are looking for!

This is a great chance to join a leading Swiss Medtech company, with offices near Bern and Solothurn. This company has a very strong R&D group, which means the opportunity to work on bringing new innovation to market globally.

Elemed has been asked to search for a head of regulatory affairs, this person will lead a group of 10 regulatory managers.

Some of your core responsibilities as head of regulatory affairs will include: (non exhaustive)

- Establish yourself as the voice of regulatory within the company
- Set, lead and implement the regulatory vision for the department
- Building the internal awareness and perception of regulatory affairs within the company, forging strong partnerships with stakeholders and supporting business success
- Plan the strategic goals, milestones and objectives for the regulatory team and ensure their implementation
- Develop innovative regulatory strategies to give patients access to new and innovative devices in global markets
- Provide strategic regulatory support, to R&D teams and other company leaders on new product development projects
- Co-ordinate the implementation of global regulatory approvals, and build up company presence in strategic markets such as the US and China
- Working together with your team, you'll assist the development of technical documentation and ensure it is submitted to the company's Notified Body and relevant authorities, and then continuously maintained
- Support contract negotiations with clients, in particular with regard for regulatory aspects
- Lead the communication and negotiation with competent authorities and Notified Bodies, regarding potential questions and enquiries
- Mentor, train, monitor and develop your team and your own skills as needed
- Supporting the Vice President in resource planning and budgeting
- Be the responsible person who takes action in the event of non compliance with regulations - such as prohibiting batch release, but also taking a proactive and pragmatic approaches to find solutions
- Leading other key projects and initiatives as determined by the VP

This is the chance to establish yourself as a regulatory leader who can navigate the grey, and build strong partnerships within a growing company. The company is very employee centric, with a strong focus on work-life balance, flexibility and teamwork. Up to 1 day home office can be offered with this role. As this is a leadership role, this will be a full time position (5 days/week).

We are looking for proven regulatory leaders with medical device experience who want the chance to have ownership over the strategy and direction of the team.

Please apply if you have

- 8+ years experience in the **medical device industry** in a **regulatory affairs role**
- Previous experience leading a team of a **minimum** of 5 people
- Hands on regulatory experience; CE marking & 510(k) submission, Strong knowledge of ISO 13485, MDD 93/42 And MDR (medical device regulation).
- Strong English and good spoken German

We'd love to hear from you!

Send your CV to
elena@elemed.eu