



**SENSILE
MEDICAL**
A Gerresheimer Company

Join Our Team!

Sensile Medical AG
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Your application: please use exclusively
this e-mail address.

Regulatory Affairs Manager 50% (f/m)

Enthusiasm, creativity, know-how and experience – your competences.

Tasks

- Accompanying development projects from the feasibility phase to the timely approval of products in international markets
- Preparation of regulatory strategies for the approval of products in different markets
- Collaboration with the disciplines R&D, Product Management, Medical Affairs, Industrialization and Quality
- Preparation and maintenance of regulatory documents such as intended use, classification, list of applicable regulations and standards, essential/
- general safety and performance requirements
- Collaboration with regulatory partners at customers and suppliers, authorities and conformity assessment bodies
- Registration of products worldwide; recertifications
- Assessment, documentation and communication of changes to authorities and conformity assessment bodies
- Representation of regulatory requirements in the company (MDD, upcoming MDR, US and global requirements)
- Supporting further development of regulatory processes in the quality management system

Expectations

- Successfully completed scientific or engineering studies (or comparable education)
- Profound experience and knowledge in Regulatory Affairs for medical devices (drug-delivery devices, active and connected medical devices would be an advantage)
- Experience in the registration of products in the US and EU (further markets desirable)
- Pleasure in goal-oriented writing and reviewing of documents
- Systematic, quality-oriented and well-documented working method
- Team player with strong analytical skills who is proactive and solution-oriented
- Dedication and good communication skills
- Fluency in German and English

Sensile Medical AG

Solothurnerstrasse 235 | CH-4600 Olten | Switzerland
www.sensile-medical.com

Who we are

Sensile Medical is a dynamic and growing company who has specialized in the development of medical devices for liquid drug-delivery based on the Sense-Core pump technology. We work daily to improve the quality of life of patients worldwide. The daily use of injection devices must be intuitive and easy to use. Very important – at home!

Perspectives

We offer a challenging, international environment and the opportunity to actively contribute to the company and different teams with knowledge and engagement, and to develop personally. We also offer a modern workplace in a historic building, advanced and flexible working conditions as well as salaries according to performance and well-developed social benefits.