

## To support our Regulatory Affairs Team for OTC Medical Devices, we are looking for a qualified and ambitious Senior Regulatory Affairs Manager (m/f/d)

### Your work at bitop will mainly focus on:

- the preparation of international approval documents for our substance based medical devices (OTC, Class I to IIs) and the corresponding European and international registration process
- the review and approval of product documents
- the maintenance of bitop's regulatory compliance
- you are the contact person for our notified body and internal/external customers on regulatory topics
- you are the PRRC (§15 MDR) for regulatory aspects (technical documentation, post-market surveillance, reporting obligations)
- This position entrusts you with leading responsibilities in interdisciplinary projects as well as the technical guidance of two junior colleagues.

### Your qualifications:

- University or college degree in the field of natural sciences, pharmacy, medicine, biochemistry, biology or others
- Min. of 2 year's professional experience in regulatory affairs for OTC medical devices (class I-II) and with the health authorities at national and international level
- Profound knowledge of EU medical device legislation (including 93/42 / EEC; MDR) and DIN EN ISO 13485 and other international regulations
- Ability to assess regulatory risks/benefits and applicable guidance
- Business-fluent written and spoken English and good German skills
- Ability to work independently in a structured, pragmatic way
- Confident demeanor and excellent communication skills

### We offer you:

- remote working (home office; up to 90%), flexible working hours and an attractive salary

- international customers and varied tasks
- a committed and inspired team, that cherishes the collegial, highly motivated atmosphere within bitop
- flat hierarchies with short communication channels
- a culture that encourages initiative, independent thinking, and creativity and rewards enthusiasm
- bitop yoga classes (online), company events
- company pension scheme
- company canteen with subsidized lunch, free drinks, fresh fruit, and coffee bar
- pet-friendly, modern working environment in an attractive setting

**contact:**

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