

Aston Life Sciences is the proud leading company in Consulting, Recruitment and Executive Search for Life Sciences industry in Switzerland. Part of Vulcain Engineering Group (+ 1'700 employees worldwide) through its Life Sciences branch Consultys, we are based in Switzerland and serve Eastern and Western Europe as well as North America. Life Sciences is our passion and we are committed to successfully support our clients in their quest to improve patient's health all around the world.

To be directly hired by one of the Medical Devices leaders in Switzerland, located in Solothurn area (Switzerland), we are looking for a:

## **Regulatory Affairs Manager (German speaker)**

***Solothurn area***

**Your role:** Within the Quality Management & Regulatory Affairs (RA) division, you will act as RA Manager. Your main mission will be to manage Medical Devices approvals worldwide with a focus on the US, China and the EU.

### **Your tasks:**

- Implement approvals for Medical Devices worldwide with a focus on the US, China and the EU
- Create and maintain documents' registration
- Supervise projects development relating to regulatory affairs
- Assess regulatory amendments
- Negotiate contracts with customers regarding RA aspects
- Assure the correspondence with authorities for inquiries and reports from authorities
- Assist customer and authority audits according to ISO 13485 and 21 CFR 820
- Manage general QM tasks such as training, creation of Q documents, etc.

### **Your profile:**

- Completed university degree, preferably in natural sciences or engineering (ETH / FH)
- At least 5 years of professional experience in regulatory affairs, preferably in the life science industry
- Experience with registration authorities in the USA (experience in China is an advantage)
- Experience with interactive medical products is an advantage
- Good organizational skills and a high degree of personal responsibility
- Customer-oriented and communicative personality
- Confident German language skills
- Very good knowledge of English (level C2 or mother tongue)

**Start date:** 1 March 2021

**Place of work:** Solothurn area