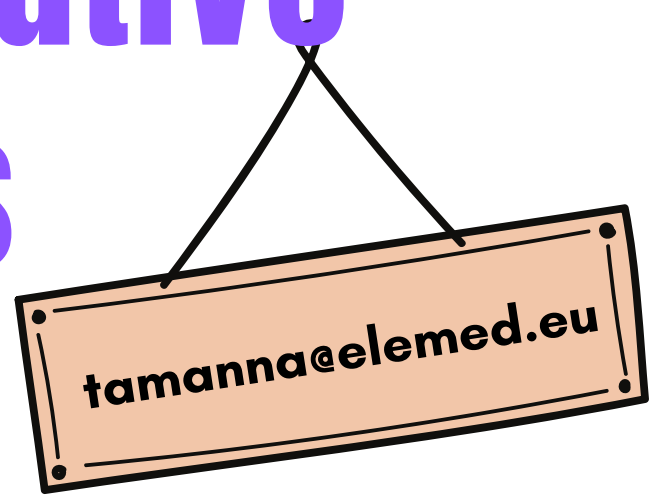
Regulatory Affairs Manager- Innovative Sterile Products

Solothurn Area, Switzerland



The Company

With over 30 years of experience, this company is producing innovative and world recognised products. Thus allowing you to be part of an organisation that really appreciates the global platform.

As a result of their investment in new product development projects, they are looking for experienced regulatory professionals to join their growing team. You will be registering devices in the EU and the US, working on the MDR, as well as supporting new product development products from a regulatory perspective. You will be one of the key managers focussing on the sterile product range; thus allowing you to develop as SME in this innovative device area.

The Company

This company also appreciates a strong employee development programme. As an employee, you will be enrolled in the flexible working scheme; which will allow you to gain the flexibility to have up to two days working from home. You will also be put on a strong career progression path, which will give you the opportunity to develop your career into people management in the future.

If working with cutting-edge technology, in an international environment, at the company's headquarters is what you are looking for, look no further!

The Role

As Regulatory Affairs Manager you will (this list is not exhaustive):

- Be one of the key regulatory managers developing strategy for the sterile product portfolio
- Prepare regulatory documents and register medical devices in Europe and US
- Create regulatory strategies for New Product Introduction
- Work closely with the QA team to develop QMS from a regulatory perspective
- Support various quality activities such as audits, creating quality documents, participating in training and more
- Be part of regulatory strategy meetings with senior management

The Requirements

As Regulatory Affairs Manager you should have:

- 5+ years of Regulatory Affairs experience with medical devices
- Specific experience within sterile products would be required for this role, thus an understanding of ISO 11135, 1137, 11607 etc
- Previous experience within biocompatibility would be an advantage for this role
- Experience liaising and communicating with notified bodies
- Minimum of a Bachelor degree
- Experience of communicating with internal stakeholders, inclusive of marketing departments
- Fluent English and German

Interested in further CONVERSATION?

Please send your application directly to

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