Regulatory Affairs Manager

Solothurn Area, Switzerland

tamanna@elemed.eu

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 lead managers developing the US project strategy for innovative high-risk products, inclusive of software devices.

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:

- Collaborate with the US team on all FDA related matters for existing and new product development projects from a regulatory aspect
- Prepare regulatory documents and register medical devices in Europe and US
- Create regulatory strategies for New Product Introduction
- Communicate, liaise and drive relationships with authorities such as Notified Bodies and Competent Authorities
- Evaluate change requests
- Support various quality activities such as audits, creating quality documents, participating in training and more
- Play a critical role within internal and external stakeholder management; often playing a decision-making role
- 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
- Experience liaising and communicating with notified bodies, with key attention to the FDA
- Minimum of a Bachelor degree
- Experience in communicating with internal stakeholders, inclusive of marketing departments
- Fluent English and German

Interested in this role?

If you are interested in this exciting role, please send your application directly to

tamanna@elemed.eu