DIRECTOR/VICE PRESIDENT QUALITY *South of Zurich*

Scope:
(Quality Management systems and quality operations)

Industry:
Medical Devices

Are you passionate about quality, and believe that there's elegance in simplicity?

Do you like finding solutions to problems?

Are you a seasoned quality professional thinking about a new challenge?

www.elemed.eu

elemed

elena@elemed.eu

The Company

In this role, you will work for an innovative and bold startup with a revolutionary medical device. This startup is well backed financially; meaning that this is a great chance to benefit from all the excitement of joining a clinical stage startup, with minimal risk.

That means; a highly dynamic environment, fast moving decisions, a seat at the table to help drive the direction of the company and the chance to really leave your mark in an extremely fulfilling role.

With big ambitions to enter the US market, this company is looking for their new Director/VP Quality to join the leadership team. In this role you'll report to the CEO and be responsible for all areas of quality (quality systems and quality operations).

Looking for a big, corporate role in a large organization? This role isn't for you. Here you'll lead the strategy, AND roll up your sleeves to get things done!

The Role

This is a great role for someone who likes solving problems, with 3 major areas to work on

1. Simplifying the QMS & processes
2. Become a trusted partner to production
3. Driving a “solution oriented” culture change

You will oversee both quality operations and quality management system activities within the organisation, and work closely with operations to improve production process, documentation, infrastructure and systems, to bring them to a “state of the art”.

www.elemed.eu

elemed

elena@elemed.eu

The Role

In this role as Director/VP Quality you will:

- Positively impact the company's culture, through leadership and an outwardly facing solution oriented approach
- Review the existing documentation systems and processes with a view to upgrade them to "state of the art" by using a best in class approach
- Develop and implement the strategy for simplifying the existing QMS so that it is easy to use and workable for all major partners
- Lead FDA inspection preparations across the company site and support the company's PMA process from a quality perspective
- Partner with Production with a view to build up lean and workable QA processes
- Provide strategic direction and support on the topic of Quality management and Quality Operations to the CEO and other members of the senior management team
- Act as senior management representative in accordance with ISO 13485 and also as the Person Responsible for Regulatory Compliance under MDR
- Continuously monitor, develop and improve the quality policy and QMS, to ensure it is compliance with changing regulations
- Leadership & follow up of CAPAS, customer interactions, audits and management reviews

Are you motivated by having the chance to make improvements?
Do you see challenges as problems or opportunities?
Are you a pragmatic leader with strong influencing skills?

The Requirements

- Minimum 12+ years experience in a quality role in the medical device industry
- Class III implantable experience
- Experienced working in small company structures / or strong willingness to work for a startup
- Comfortable in leadership roles with high visibility
- First hand experience with Quality Management systems ISO 13485, 21CFR/820 **AND** quality operations
- Fluent English
- Confidence and ability to make independent decisions based on sound principles
- Ability to influence through communication

INTERESTED IN THIS ROLE?

elena@elemed.eu

Please send your CV to elena@elemed.eu for a confidential career discussion.

www.elemed.eu elemed elena@elemed.eu