Regulatory / Quality Manager

CALLING ALL REGULATORY PROFESSIONALS!
ARE YOU LOOKING FOR A ROLE THAT OFFERS YOU MORE INDEPENDENCE, AND OWNERSHIP OVER YOUR CAREER DEVELOPMENT?
REPORTING DIRECTLY TO THE COMPANY'S GENERAL MANAGEMENT AND VP REGULATORY, THIS ROLE AS MANAGER REGULATORY AND QUALITY WILL DEFINITELY GIVE YOU THE CHANCE TO HAVE YOUR VOICE HEARD!

THE COMPANY:

You will be based in the heart of the company's EMEA headquarters. With offices overlooking the beautiful city of Lausanne, and offering spectacular views of the nearby Alps, you can truly enjoy a great working environment, and lots of face to face contact with your partners.
This company is unique. A well known leader in its field, with medical device AND (famous!) consumer brands, the environment is fast paced, collaborative and dynamic.

THE ROLE:

As regulatory and Quality manager, you will be responsible for all areas of Regulatory (approx. 70%) and Quality (approx. 30%) and have 1 direct report.

This is an exciting role for a regulatory affairs professional looking for career development in an environment where learning is encouraged:

- **You'll have responsibility over a wide ranging portfolio of products: active medical devices, non active disposables, as well as the chance to dip into the company's FMCG product portfolio, and learn about this new regulatory environment (REACH, RoHs, WEEE)**
- **Your coverage will reach all the major world markets; and you will offer expertise to regional teams (APAC/US/LATAM etc)**
- **You will also enjoy a broad role; Regulatory pre-market project work, post market activities, and management of the QMS which will give you a well rounded experience, that is very difficult to find in big corporations**
- **You will play a critical role in the transition to the Medical Device Regulation, and support the implementation of the new GDPR regulation**

>>> Swipe up

RESPONSIBILITIES (NOT EXHAUSTIVE):

- Manage a challenging portfolio of medical devices and consumer products; active, disposables, consumer care, non medical
- Participate in worldwide registrations in major markets: EU, U.S, further afield
- Closely collaborate with partners in Quality, Technical, Marketing & R&D on new product development projects and international product launches
- Maintain existing registrations, and be responsible for the full lifecycle management of your devices, including vigilance reporting and post market surveillance, with direct exposure to authorities
- Regulatory intelligence – Following the changing regulatory landscape and provide guidance and recommendations to the site management and international teams
- Manage the company's EMEA QMS to ensure compliance with local regulations, client and corporate expectations
- Represent the company during agency inspections, notified body audits, and third party audits
- Lead regulatory compliance projects
- Team up with the clinical group and support the set up of clinical study sites in Europe

Are you able to navigate the grey?

We are looking for regulatory professionals who are commercially oriented and don't just see things in black and white.

If you already have:

- **4 years experience in a Regulatory position, interfacing with Quality**
- **Active (electromedical) medical device experience**
- **Fluent English**

We'd love to hear from you! Please send your CV to elena@elemed.eu to arrange a confidential career discussion.