Quality & Regulatory Affairs Manager

Slough, United Kingdom

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The company

This multinational company is a leader in orthopaedic and spinal medical devices striving to improve patients' lives and deliver innovative and quality-driven solutions. With over 1000 employees worldwide, you can be sure that you will not get lost in a sea of employees and have the opportunity to get to know many amazing colleagues that believe in a collaborative working environment.

You will have their support and encouragement to continually grow and develop yourself professionally whilst everyone pulls together in the same direction to work towards one over-arching, shared goal. This company is committed to maintaining a strong pipeline of products in development on one side whilst continually pushing through new product introductions on the other side.

If you want to be part of a dynamic business that has stability on the shoulder of the giants in one of their key markets (UK), then read on!

The opportunity

This is a brand new position that will support the development of the business in the UK, a key market for them. You will be responsible for managing crucial Quality and Regulatory Affairs activities for the site whilst acting as the bridging partner between manufacturing, distribution, and sales both locally and internationally across the business. If you enjoy translating requirements into ways that different mindsets will understand, this is for you.

As well as maintaining a positive relationship between the teams internally, you will also be the point of contact for external entities such as MHRA when needed giving you the chance to oversee many different parts of the organisation. From internal audits, to CAPA implementation, to regulatory documentation management, you will be the “go-to” representative for Quality and Regulatory Affairs on the UK site.

In this role you will:

- Develop and implement Quality processes/procedures and ensure that QMS is compliant to all relevant standards and requirements such as MDR, ISO 13485, and any other relevant legislation
- Define, monitor, and report on relevant Quality KPIs and how the QMS is performing
- Prepare, execute and close internal and external audits as the person of contact for notified bodies
- Coordinate with Regulatory Affairs to prepare and maintain regulatory documentation
- Develop and upkeep the relationship with the MHRA for product registrations and post-market activities
- Review process changes, deviations, non-conformities, CAPA implementation, and distribution processes
- Evaluate and qualify suppliers according to the QS procedures
- Support internal training

Requirements

- Minimum of 4 years of experience in Quality Management for the medical device industry
- Fluency in reading, writing, and speaking in English
- Regulatory Affairs experience is a bonus for this position

Get in touch

If you are interested in this exciting role, please send your application directly to **kristina@elemed.eu**

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