QMS Manager

iSTAR Medical SA, founded in 2011 and headquartered in Wavre, Belgium, is a clinical-stage, medical technology company focused on the development of novel ophthalmic implants for patients with glaucoma. Glaucoma is the second leading cause of adult blindness globally

Reporting to the Senior Director, the QMS Manager has the responsibility and authority for ensuring that efficient quality management processes are implemented, maintained and improved to comply to international quality standards and appropriate regulations. The QMS Manager is also responsible for the Supplier Management, Audit, Feedback, Management Review, Customer complaints, CAPA, Change Control and FSCCA.

The QMS Manager has the following responsibilities:

- Ensure that efficient processes related to QMS are in place, in use and comply to ISO 13485 and European MDR and, as appropriate to 21 CFR 803, 806 and 820, Canadian Food, Drugs, and Medical Devices Regulations (CMDR).
- Constantly assess the QMS relevance and efficiency against the Company strategy, organization, Quality Policy, Quality Objectives and value creation
- Assist QA management representative in reporting on the effectiveness of the QMS and need for improvement (Management reviews)
- Assist QA Management representative in ensuring promotion and awareness of applicable regulatory requirements and quality management system requirements
- Ensure normative and regulatory changes related to quality systems are identified in a proactive manner and establish action plans to proactively build continued compliance
- Ensure the compliance of the reporting and post-market surveillance obligations in accordance with applicable standards and regulation
- Lead and support supplier selection, qualification and evaluation
- Lead and support internal and suppliers audit process
- Ensure the compliance and Support Vigilance
- Manage Electronic Management System
- Establish budget contributing to the development of annual proposals for funding of the Quality function

As the successful candidate, you have the following profile:

- You own a BSc degree in engineering (or equivalent)

- You have at 5 to 10 years of demonstrated experience in QMS management as Supervisor and/or Manager in Medical Device or consulting firms.
- You already have excellent knowledge of ISO 13485 and EU Medical Device Directive and EU Medical Device Regulation.
- You have sound knowledge of risks management (ISO14971)
- You have experienced validation of special processes (cleaning, sterilisation…) and work environment (clean rooms)
- You have managed quality audit (internal & external)
- You have supported elaboration of Technical Files

- You are recognized for your Leadership and Project Management capabilities.
- You can communicate effectively; set priorities and you have strong time management skills.
- You are pragmatic, organized and detail oriented.
- You are Fluent in English, written and spoken. Knowledge of another language is beneficial.
- You are a team player with positive constructive attitude to solve problems
- You are Eager to learn, stress resistant and ready to work independently in a start-up environment (Hands on);
- You are available to travel 5% of your time

What do we offer?

We offer an Belgium based full-time permanent position along with an attractive remuneration package.
Headed by a solid management team, you will be part of a highly skilled (engineers, scientists) capable and dynamic team of innovative leaders with proven tracks records in the pharmaceutical and medical device industries.
We have an agile start-up company culture focused on values of entrepreneurship, engagement, integrity, passion and excellence.

Excited about the role?

To apply, please send your CV to careers@istarmed.com with Reference **QMS_2021**