Regulatory Affairs Lead

iSTAR Medical SA, founded in 2011 and headquartered in Wavre, Belgium, is a pre-commercial stage, medical technology company focused on the development of MINIject, a novel minimally-invasive ophthalmic implant (MIGS) for patients with glaucoma.

Reports to: VP Regulatory & Clinical Affairs

Location: Wavre, Belgium

The Regulatory Affairs Lead is responsible of writing technical documentation to support clinical study applications, CE marking and FDA registration, under the supervision of accountable persons for Clinical & Regulatory, Manufacturing, and R&D. He/She ensures compliance of product Technical files with regulatory standards and provides support to ensure that regulatory requirements are integrated in the Product Development, Manufacturing and Clinical Processes. He/She is responsible for the execution of the Regulatory Affairs Intelligence process to foresee the impact of changing regulations on product marketing authorization and commercialization. He/She supports regulatory compliance of the Quality Management System under the supervision of the accountable person for Quality.

Responsibilities

The Regulatory Affairs Lead has responsibility and authority to, under the direction of accountablepersons for Clinical & Regulatory, R&D, Manufacturing, and Quality:

- Direct or perform coordination and preparation of product technical documentation (including Investigator Brochure, Product Risk Analysis, Biocompatibility Risk Assessment, CIP, ClinicalEvaluation Report, etc.). Ensure documentation packages are compliant and kept up-to-date.
- Assist global regulatory submissions such as original IDE, original PMA and 510(k)submissions and supplements, EU Design Dossiers and Technical Files.
- Provide regulatory affairs input for product development and manufacturing including productspecifications, establishment of product/process validation strategy, and clinical evaluation.
- Ensure labelling compliance for all regulatory submissions and commercialization
- Ensure normative and regulatory changes are identified in a proactive manner and coordinateactions plan with SMEs.
- Manage and/or execute product registration processes worldwide.
- Develop and deliver presentations to regulatory agencies and/or conferences. Assist

in developing and maintaining positive relationships with device reviewers through oral andwritten communications.

- Manage the preparation for Notified Body audits, act as main contact during audits, and shareaccountability for audit output together with the QA management representative.
- Act as iSTAR internal auditor as required.
- Identify the need for new regulatory procedures and SOPs and lead their development andimplementation. Assist other departments in the development of SOPs to ensure regulatorycompliance.
- Ensure the post-market surveillance and vigilance regulatory requirements are met.
- Other tasks, as assigned.

Profile

- Master's degree or Ph.D. degree in Sciences / Engineering
- Good understanding of product development process and design control
- Effective written and oral communication, excellent technical writing and editing skills
- Working knowledge of regulatory requirements for implantable devices. Previous experience supporting Regulatory Affairs for Medical Devices Class IIb is a plus
- Ability to work independently with minimal supervision
- Fluent in English, written and spoken. Knowledge of another language is beneficial.