Vacancy: (Sr) (Medical Devices) Regulatory Affairs Manager

In this role, you have the opportunity to provide unique regulatory and quality support of medical devices and combination products by participating in the definition of the regulatory strategy during the product creation process and by contributing to the clients overall regulatory strategy plan at different stages of product development. You will be working in a team of professionals; together with other colleagues you will strengthen the medical device team within Starodub.

Start date: ASAP

Duration: 1 year with a possibility for extension

Salary: negotiable

If interested, please, contact our Starodub BV office via info@starodub.nl

JOB DESCRIPTION
(Sr) Regulatory Affairs Manager Medical Devices

- Interacts with clients and provides clients with regular updates.
- Participates in interdisciplinary project teams and interacts with all team-members to ensure high quality and efficiency.
- Defines the content and strategy for development of Technical Documentation and prepares and submits Technical Documentation dossiers worldwide.
- Ensures Technical Documentation complies with applicable regulations, standards and guidance documents.
- Defines the strategy for interaction with Health Authorities worldwide with respect to planned or submitted Technical Documentation.
- Maintains working knowledge of current governmental and worldwide requirements for initial submission, renewals and post-approval changes.
- Assures milestones and deliverables are achieved.
- Authors/Reviews policies/SOPs/WIs and other specific documents generated within the company.
- Coaches and trains new and/or junior employees or employees specializing in another regulatory field, e.g., pharmaceuticals.

General (Medical Device) Responsibilities:

- Identifies and promotes best practices within the company.
- Contributes to compliance to the company KPIs.
- Deploys lean six sigma principles.
- Implements pathways to ensure continuous improvement of the quality and efficiency of deliverables.

- Continually gains knowledge of current government regulations and worldwide requirements for initial registration, re-registration and post-approval changes and ensures dissemination of this knowledge within the company.
- Provides effective supervision (if applicable) by reviewing documents as necessary to ensure the quality, accuracy and timeliness.
- Possesses strong ability to work in teams and to initiate any necessary meetings and/or actions to resolve issues.
- Assures continuous efficient reporting to Line/Client Management.
- Has proactive approach to the Quality Management System.

Position Qualifications:

- Education Requirement: preferably at least BSc Degree in life sciences, analytical chemistry, organic chemistry, chemical engineering, or a related discipline.
- Extensive and relevant expertise in regulatory affairs and project/product development in medical devices, in vitro diagnostics or combination products.
  On average 3 – 5 years

Required Experience and Skills:

- Experience with writing of Technical Documentation
- Experience with respect to consultation with Health Authorities and answering questions from Health Authorities/Notified Bodies.
- Knowledgeable of ISO 13485 and QSR requirements
- Excellent working knowledge of medical device regulations (21CFR), FDA law and CE marking
- Experience in supporting international registrations
- Ability and experience to manage projects to achieve high productivity, prioritize and manage effective meetings.
- Strong oral and written communication skills in English.
- Innovative, flexible and collaborative, good team player.
- Effective problem solving and decision-making skills.