Vacancy: (Sr) (CMC) Regulatory Affairs Manager

Start date: ASAP

Duration: 1 year with a possibility for extension

Salary: negotiable

If interested, please, contact Valentyna Starodub: valentyna.starodub@starodub.nl

JOB DESCRIPTION
(CMC) Regulatory Affairs Manager

- Interacts with clients and provides clients with regular updates.
- Participates in interdisciplinary project teams.
- Interacts with all team-members to ensure high quality and efficiency.
- Defines the registration strategy for submissions worldwide.
- Prepares and submits registration dossiers worldwide.
- Ensures submissions comply with applicable regulations and guidance documents.
- Defines the strategy for interaction with Health Authorities worldwide with respect to planned or submitted registration dossiers.
- Responds to agency questions.
- Maintains working knowledge of current governmental and worldwide requirements for initial registration, re-registration 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., medical devices.
- Has responsibility for a team and the performance of the team.

General (CMC) 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.
- Ensures compliance to GMP regulations.

- 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. On average 3 – 5 years

Required Experience and Skills:

- International registration experience (e.g., CP, DCP, MRP, NDA/JNDA) in CMC submissions, including post-approval, chemical/pharmaceutical research and/or manufacturing including processing, analytical testing and/or medical devices.
- Experience with writing of CMC documents
- Experience with respect to consultation with Health Authorities and answering questions from Heath Authorities.
- Demonstrated knowledge of international regulations.
- Demonstrated knowledge or regulatory data bases.
- Ability and experience to manage projects to achieve high productivity, prioritize and manage effective meetings.
- Strong oral and written communication skills in English.
- Working knowledge of WORD, EXCEL, POWERPOINT. Knowledge of Documentum and Trackwise is advantageous.
- Innovative, flexible and collaborative, good team player.
- Effective problem solving and decision making skills.