JOB DESCRIPTION

Position Title: Global Regulatory Affairs Apprentice

Department: Global Regulatory Affairs (GRA), Transformation and Strategic Projects - Europe

Location: Les Ulis – Paris Saclay

Reports to: VP GRA Europe & Transformation

Primary Purposes of Position:

- To support Global Regulatory and Quality organisation: main management activities by helping the VP GRA Europe & Transformation on his day-to-day activities.
- Develop new strategies to expand and communicate about the department key achievements: interact with Local and Global collaborators, collect, structure and summarize this information to present it to the Leadership Team.
- Collect, screen and analyse information about the European affiliates. Develop a EU Regulatory/Quality Community, facilitate communication between Locals and Global to improve Ipsen's business activities.
- Work with Intercontinental/Therapeutic Areas Managers on regulatory activities: regulatory submissions, data management, data entry…

The position is hosted in Global Regulatory Affairs (European Region) and reports to the Global Regulatory Affairs and R&D Quality VP.

Main Duties to be performed:

- **Region and regulatory coordination**

Supports the coordination of the EU Regulatory Affairs activities with relevant functions and the assembly of regulatory news (EMA), strategic information and department's last news to be presented during the EU follow-up forums.
Ipsen's European Affiliates are fundamental links for Ipsen's business expansion. The apprentice will ensure adequate coordination of regulatory activities through reliable liaison with LRAs. He also maintains a continuous flow of information with LRAs depending on the progress of projects.
The apprentice will contribute to constructive leadership decisions with the VP and European Region Manager. He will also contribute to the development of an efficient tracker for the Region Coordination, and of promotional material (videos, infographics…).

- **Regulatory Activities**

Works on the content of regulatory submission dossiers in collaboration with GRA Director on EU/Intercontinental marketing authorization renewals and variations: including packaging and labelling review, cover letters and present proposed righting, dossier submission and follow-up.
Depending on the needs, may be solicited to help on the definition of the regulatory strategy (e.g. Regulatory Strategy Documents) for specific projects.

- **Transversal and communication activities**

Helps on the development of GRQ community. Update the org chart of our organisation. Major role on organizing our annual seminar. Develop corporate news to communicate about GRQ activities. Might be asked to collaborate with digital and biometry R&D teams if interested by digital health and innovative tools (AI, RWD…).

Education:

- **Competencies**

Degree in scientific discipline (Pharmacy, Chemistry, Biological sciences)
Knowledge on regulatory procedures and major interest on the global environment and strategies of an expanding Lifesciences company.

- **Skills**

Intermediate English if not mother tongue
Excellent written and communication skills.

Comments:

Duration: 12 months apprenticeship – weekly schedule can be flexible and discussed during interview