JOB DESCRIPTION

Position

Job Title: Global Regulatory Affairs, Regulatory CMC Intern

Division / Function: Global Regulatory Affairs (GRA), CMC Regulatory Strategy, Biological products
Manager (Name, Job Title): Senior Director/ Senior Manager or Manager, CMC Regulatory Strategy

Location: Paris Saclay (les Ulis) until approx. May 2025, Paris Balard from June 2025

A shuttle service is available in the morning and in the evening between Massy-Palaiseau RER/TGV train station and Les Ulis site.

Summary / purpose of the position

The position offers a full time 6-month internship in Global Regulatory Affairs, CMC Regulatory strategy, Biological products and reports to the Senior Director, Senior Manager or Manager in GRA CMC Regulatory Strategy.

- To support global regulatory Chemistry and Manufacturing Control (CMC) strategy development and CMC dossiers preparation on a portfolio of R&D products (large molecules) pertaining to EU/US regions
- Take part of strategic and operational tasks/discussions for development stage programs.
- Take part in developing and promoting harmonized tools across all projects throughout the CMC group and the global regulatory affairs community.

Main responsibilities / job expectations

- a full time 6-month internship
- Resume and cover letter (Lettre de motivation) are expected to apply for the position

- Regulatory coordination
- Participate to the CMC regulatory strategy liaising with cross functional teams
- Check current regulations to ensure strategy is developed in alignment
- Participate to build, review and maintain CMC regulatory documentation for ongoing clinical programs (IMPD/IND)
- Participate in the authoring and reviewing phase of briefing documents for consultation with Regulatory Agencies
- Support the definition and follow-up of the roadmaps build to guide the preparation of global dossier taking into account geographical specificities identified for submission to ensure dossier is in line with local regulatory requirements
- Support preparation of the strategy for response to question and participate in response authoring, review, submission and follow up
- Attend relevant project and non -project related team meetings
- Potentially present the CMC regulatory output at CMC pharmaceutical development forums

- Compliance
- Operates according to Regulatory and Ipsen SOPs
- Review and update trackers

- Regulatory Intelligence
- Contributes to Regulatory intelligence, by tracking and analysing the evolution of regulations relating to CMC topics;

- Informs the relevant departments and answers their questions as needed.

- GRQ and GRQ Trainee Academy active team member
- Attend/Present at GRQ knowledge sharing meetings
- Attend Ipsen internal events (Presentations, external speakers, forums, webinars, celebrations …)
- Ensures adequate reporting of his/her activities and participates to various meetings depending on project assignments
- Be an active member of the GRQ Trainee Academy (specific program designed to provide a framework for the GRQ interns and apprentices only): attending proposed trainings, prepare webcast, share experience, build network, site visits (if possible), get exposure to senior management. Provide feedback and participate in Trainee Academy further development and visibility.

- EHS Missions
- Respect the regulations and EHS procedures in force.
- Participate in the EHS performance of the site by reporting risks, malfunctions or improvements.
- Participate in mandatory EHS training.

Knowledge, abilities & experience

Education / Certifications:

- Degree (min Master 2 level) in scientific discipline (Pharmacy, Chemistry, Quality, Biological sciences or Engineering)

Experience:

- Preferred previous experience in Pharmacy, Regulatory and/or Quality, or in biotechnology (analytics, manufacturing process)

Languages:

- Professional English if not mother tongue

Key Competencies Required

- Written and communication skills
- Ability to speak-up and act as a team player
- Ability to demonstrate problem-solving skills and intellectual curiosity
- Strong scientific skills and interest for CMC area.
- Strong knowledge of Microsoft Office, especially Excel tool

Ipsen Way of Being

(The below apply for all employees and described how to act according to our way of being)

	We are: - Inclusive and diverse - Engaged with communities - Ethical and compliant - Dedicated to caring responsibly for our people and the environment - **Committed to a proactive approach to patient centricity**
	We are: - Insights-driven - Responsible for leveraging our collective intelligence - Dedicated to testing, experimenting and piloting - Externally focused - **Committed to becoming data- and science-driven**
	We are: - Agile and decisive - Innovative - Entrepreneurial - Determined to be a partner of choice for all our stakeholders - **Committed to proactive collaboration**
	We are: - Open to feedback - Ready to speak up - Listeners - Respectful - **Committed to taking responsibility for our words and actions**

	We are: - Focused and performance-driven - Consistent in promoting single-point accountability - Passionate about celebrating success - Prepared to unleash our full potential - **Committed to excellence in execution**

Other Useful Information

- Key Internal stakeholders: NA
- Key External contacts: NA
- Financial budget: NA
- Number of direct reports: NA

The statements contained herein reflect general details as necessary to describe the principles functions for this job, the level of knowledge and skill typically required, and the scope of responsibility, but should not be considered an all-inclusive listing of work requirements. Individuals may perform other duties as assigned, including work in other functional areas to cover absences or relief, to equalize peak work periods or otherwise balance workload.

This description is not intended to be constructed as an exhaustive list of duties, responsibilities, or requirements for the position. This position may change or assume additional duties at any time. The employee may be requested to perform different or additional duties as assigned. All Employees are expected to adhere to all company policies and act as a role model for company values.

Prepared by: Yves Bobinnec	Signature: Yves Bobinnec	Date: 9 January 2025
Employee:	Signature:	Date: