Position Title: Global Regulatory Oncology/Rare diseases Apprentice
Department: Global Regulatory Affairs, Rare diseases/Oncology team
Location: Les Ulis
Reports to: Regulatory Affairs Director

Objectives:

The position offers a 12 months apprenticeship in Global Regulatory Affairs (Oncology or Rare diseases therapeutic area) and reports to the Global Regulatory Affairs Director.

Starting date: Sept/Oct 2020

- To support global regulatory development and registration plans supporting Commercialization, both pertaining to Europe/US/Canada.
- Take part of strategic and operational tasks/discussions for either early or late stage programs.

Role and Responsibilities:

· **Regulatory coordination**

- Contributes to the drafting and implementation of the regulatory strategy (e.g. Regulatory Strategy Documents) for specific projects, in particular ensures that the needs for his/her region are adequately reflected.
- Supports the coordination of the preparation with relevant functions and the assembly of regulatory documentation to be submitted according to the strategy validated.
- Contributes to critical and constructive review of regulatory dossiers (MAA/NDA, New indication, CTA, special designation, pediatric development, etc.)
- Ensures quality authoring of core-administrative parts of submission packages.
- Works on the content of regulatory submission dossiers in collaboration with GRA Director, and approves change control.
- Ensures adequate planning and timelines management/adjustment depending on the deliverable.
- Attends/Drives cross functional meetings with Project team depending on deliverables
- Supports Europe marketing authorization procedures (centralized, decentralized, and/or MRPs) with support from GRA Director and Local Regulatory Affairs (LRAs) when applicable.
- Supports NDA/sNDA/Health Canada submissions when applicable.
- Participates to the preparation of regulatory agencies consultations (e.g. EMA or national scientific Advice, protocol assistance, FDA meetings, Health Canada meetings).
- Participates to the coordination of the responses of questions from authorities.
- Ensures adequate coordination of regulatory activities through reliable liaison with LRAs.
- Maintains a continuous flow of information with LRAs depending on the progress of projects.
- Ensures that the manufacturer is informed of the registered dossier to allow manufacturing in compliance with the terms of the marketing authorization.
- Strong collaboration with CMC Regulatory and Intercontinental Regulatory teams
- Interaction with Regulatory Neuro/Endocrine therapeutic area and knowledge sharing

- Participates to maintaining good relationships with working partner when applicable (CROs, vendors, development partners …)

· **Compliance**
  - Operates according to Regulatory and Ipsen SOPs.

· **Reporting**
  - Ensures adequate reporting of his/her activities and participates to various meetings.
  - Ensures that registration status is adequately reported in VREG (regulatory tracking tool) through data entry.

· **Regulatory Intelligence**
  - Contributes to Regulatory intelligence, by tracking and analyzing the evolution of regulations relating to his/her areas;
  - Informs the relevant departments and answers their questions.

· **GRA/GRSQ active team member**
  - Attend/Present at GRA knowledge sharing meetings.
  - Attend/Lead monthly GRA Rare diseases/Oncology team meetings.
  - Represent GRA at Ipsen internal events (eg. Poster presentation, R&D forum …).
  - Attend Ipsen internal events (Presentations, external speakers, forums, webinars, celebrations …).

Education:

· **Competencies**
  - Completed or soon to be completed Degree (min Master 2 level) in scientific discipline (Pharmacy, Chemistry, Biological sciences).
  - Knowledge of regulatory procedures in at least one region is preferred.

· **Skills**
  - Advanced English if not mother tongue.
  - Excellent written and communication skills.
  - Strong scientific skills and interest for Rare diseases or Oncology area.

Duration:

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

Contact:

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