Position Title: Global Regulatory Affairs, Intercontinental Region Apprentice
Department: Global Regulatory Affairs, Intercontinental Region
Location: Les Ulis
Reports to: GRA Intercontinental

Objectives:

The position offers a 12 months apprenticeship in Global Regulatory Affairs (Intercontinental Region & Oncology Therapeutic Area) and reports to the Head of Intercontinental

Starting date: Sept/Oct 2020

To support global regulatory plans for the registration of new indications on a cancer product internationally (Intercontinental & Europe regions) and to contribute to regulatory lifecycle activities.

Role and Responsibilities:

- **Regulatory coordination**
  - 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 (New registrations, New indications, Renewals, Variations)
  - Ensures quality authoring of core-administrative parts of submission packages
  - Works on the content of regulatory submission dossiers
  - Ensures adequate planning and timelines management/adjustment depending on the deliverable
  - Participates to the preparation of regulatory agencies consultations
  - Participates to the coordination of the responses of questions from authorities
  - Ensures adequate coordination of regulatory activities through reliable liaison with affiliates Maintains a continuous flow of information with affiliates 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

- **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/GRQ 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**
  - Degree in scientific discipline (Pharmacy, Chemistry, Biological sciences).
  - Knowledge of regulatory procedures in at least one region is preferred.

- **Skills**
  - Advanced English level
  - Excellent written and communication skills.

Duration:

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