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Our client is a European R&D driven company within the Top 5 in Pharmaceuticals / Biotechnology / Biopharmaceuticals / Biosimilars.

We are looking for our client for a

Global Lead Regulatory Affairs (m/f/d).

The primary purpose of the position is to lead and supervise assigned regulatory liaisons (GPRDs, GPRMs or GMRMs) charged with the development and implementation of regulatory strategy and support of assigned development projects, marketed products and/or major line extensions within the assigned Business Franchise Global Therapeutic Area through development, registration and approval including post approval commitments and life cycle management.

Main responsibilities:

Regulatory Strategy

- Has GPRD responsibility for one or more projects.
- Ensure high quality and globally aligned regulatory strategies to achieve optimal development objectives and life cycle management plans.
- Contribute senior level operational and strategic regulatory input into BD&L and oversee Due Diligence evaluations of assigned BD&L projects.
- Partnering with regions to align on regulatory strategy in order to fulfill business objectives.

HA Interactions, Submissions and Approvals

- Ensure high quality and professional interactions with HAs globally including participation in key formal and informal HA contacts as required.
- Ensure appropriate TA input and consistency of HA interactions and registration activities within and across TAs in line with global strategy

Prescribing Information

- Ensure high quality, consistent labels across therapeutic areas and ensure timely implementation of CDS changes

Regional Excellence and Compliance

- Ensure compliance with global regulatory requirements and adherence to internal policies and processes and coordinate compliance activities at a global level.
- Oversee and provide support as needed for non-project related regional excellence activities.

Managerial

- Supervise and lead GPRDs, GPRMs or GMRMs assigned to the Global Therapeutic Area Team including performance management, in collaboration with the global line functions, and the DRA Global Franchise Head and the Global Program Head (if applicable).
- Ensure high quality global regulatory strategies within the Global Therapeutic Area Team.

Profile:

- Science based BS or MS with requisite experience and demonstrated capability. Advanced degree (MD, Ph. D, PharmD) preferred.
- Minimum 8–10 years development experience in pharmaceutical industry and minimum 5 years relevant regulatory experience which includes the following:
  GPRD or equivalent experience on multiple/complex projects.
  Involvement in MAA and NDA submission(s) and approval(s) with proven success.
- Extensive experience in leading HA negotiations in multiple regions.
- Experience with Due Diligence evaluations to support licensing activities.
- Innovation in regulatory strategy.
- Team management experience with cross functional responsibilities.

Do you feel attracted by this position? We kindly ask you to apply in full confidentiality in English, with resumee and list of key competences.

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Your application will be treated with strict confidentiality.