« Regulatory Affairs (Associate) Director » (M/F)

Promethera Biosciences is a global innovator in liver cell-based medicines whose mission is to help patients overcome acute and chronic liver diseases. Our lead clinical program, derived from our patented cell technology platform HepaStem, is designed to benefit from its immune-modulatory and anti-fibrotic properties. We are a team of international experts operating out of R&D and GMP facilities in Mont-Saint-Guibert, Belgium, and Durham, NC, USA.

If you are sharing our vision of becoming the world leader in regenerative medicine in the liver space by developing innovative advanced therapies for acquired liver diseases and if you are looking for new challenges amongst a dynamic and international team, consider a collaboration with our fast-growing company. Promethera Biosciences is currently hiring an Regulatory Affairs (Associate) Director.

MAIN RESPONSIBILITIES

By integrating a dynamic matrix of Promethera Biosciences' organization, the selected candidate will serve the regulatory part of the score and interface with internal stakeholders to best achieve Promethera Biosciences' objectives.

The ideal candidate will initiate, carry on and achieve the tasks with a "can-do-pull-the-sleeves-up" attitude. (S)he is expected to "jump-on-the-ball" and keep it rolling.

- Within the regulatory department:
  - Report directly to the VP Regulatory Affairs (RA).
  - Become a dynamic member of the RA department of Promethera Biosciences and closely collaborate with other departments.
  - Provide Global Regulatory strategy on the overall development planning, and implementation for multiple complex programs of (investigational) medicinal products.
  - Keep abreast and implement policies to ensure ongoing compliance of regulatory requirements (i.e. international legislation, guidelines) and provide guidance to the company's departments (i.e. R&D, medical/clinical and production teams) accordingly taking into account the product specificities.
  - Participate in identification of risk areas and develop alternative courses of action including anticipation of regulators responses through scenario planning and development of contingency plans and communicating those to any stakeholder within and apart of the regulatory department.
  - Provide direct supervision of individuals including mentoring, performance management and staffing decisions.
  - May participate in management of budgets.
- Across the whole Company :
  - Initiate and maintain appropriate communication within the RA function and represent RA with all internal functions and external stakeholders.

- Participate in the meetings/negotiations with regulatory bodies the product development/registration program in line with the regulations applying for Advanced Therapy Medicinal Products (ATMP), Orphan Drugs and Paediatric Medicinal Products.
    - Preparing, Coordinating, Attending and Following-up interactions with Regulatory Stakeholders part of the ICH region (such as Scientific Advices, pre-IND meetings, pre-MAA/BLA/NDS).
    - Preparing, Coordinating, and Following-up submissions to Regulatory Stakeholders part of the ICH region (such as clinical trial applications CTAs (Writing and/or reviewing of clinical trial-related documents., Writing and submitting an IND according to the common technical document (CTD) system, follow-up.).
    - May act as primary contact with regulatory authorities including the planning and leadership of meetings.
  - Participate in potential and established third party efforts (i.e. Due diligence activities, joint ventures, etc).
- Represent Promethera Biosciences externally at appropriate industry associations.

QUALIFICATIONS

- Sound basis of Scientific (Training/Communications) knowledge in multiple areas,
- Expert knowledge of regulations, and experience with interpretation and application,
- Excellent English written and verbal communication, presentation, and facilitation skills,
- Strong negotiation skills and significant experience in interacting with regulatory authorities,
- Risk identification and problem-solving skills,
- Excellent organizational skills,
- Demonstration of flexibility, professionalism and good interpersonal skills (within the RA field and across all the departments of the Company),
- Demonstrated ability to lead, mentor, and develop others for future growth and development (within the RA field and across all the departments of the Company),
- Established relationships with regulatory authorities.

EDUCATION/EXPERIENCE

- Advanced degree or country equivalent in related scientific discipline (Pharm D, Ph D).
- At least 8-10 years of experience in Regulatory Affairs.
- At least three-year experience managing people.
- Proven track record as a Team player who can work independently and who is hands on.
- Proven track record as a resilient initiator and achiever.
- Experience in ATMPs with a preference to Stem Cells/cell cultures would be an advantage.

You may apply for this position by sending your CV and application letter to HR@promethera.com

For information, resumes and application letters received will be retained as long as the employment's offer is valid and will be destroyed as soon as the position is filled. We will contact you in case we wish to keep your CV after the recruitment period.