Head of US CMC Regulatory Affairs

Date posted: November 07, 2018

Location: New York, NY, USA

Position Summary:
The Regulatory Affairs Manager/ Senior Manager is a creative, resourceful, integrative thinker for a highly-visible role that is responsible for key regulatory activities supporting the development and commercialization of Hookipa's products, with a focus on developing and implementing regulatory strategies as well as coordinating and responding, as necessary, to requests for information regarding Genetically Modified Organisms (GMO) from Regulatory Authorities. Responsibilities will include: development and implementation of strategy for the earliest possible product approval, preparation and review of CTD Module 3, QOS, and other documents for FDA/EMA submission, assistance with preparation for FDA meetings, regulatory review and approval of cGMP documentation, and general regulatory compliance activities.

Roles and Responsibilities (include but are not limited to):

- Drive adherence to US and EU regulatory CMC and GMO requirements and guidelines for development of Hookipa products
    - Represent CMC and GMO concerns on interdisciplinary project teams; partner within Regulatory, Quality, Research, Manufacturing, Nonclinical, and Clinical teams
    - Participate in regulatory intelligence activities with particular regard to GMO; monitor regulatory guidelines and trends
    - Ensuring CMC and GMO issues impacting global regulatory strategy for proposed regulatory filings are considered
- Provide leadership on regulatory interactions on CMC and GMO related topics
    - Author and/or review CMC and GMO documentation for Health Authority and other submissions and documentation
    - Manage regulatory submissions that involve CMC components including CBEs/PASs/ CTAs/INDs/NDAs and agency meeting packages
    - Contribute to the preparation of meetings with regulatory agencies
    - Accountable for management of global and regional CMC and GMO submissions and responses to Health Authority CMC questions
    - Drive follow-up action plans resulting from agency feedback
    - Participate in negotiations with regulatory agencies to resolve CMC and GMO issues
    - Assist during regulatory agency inspections
- Actively participate in RA infrastructure and capability building

- Lead knowledge of current industry-related topics, in particular GMO testing events and requirements
- Proactively participate in design of global regulatory strategies for the development of therapeutic oncology and infectious disease products
- Provide company representation at regulatory and industry organizations involved in setting standards for GMO therapies
- Available to travel (approximately 1 week per 2-4 months)

Qualifications:

- BS in life science related field required, MS/PhD preferred.
- Minimum 6 years of experience in the pharmaceutical/biotechnology/life science industry. 4+ years regulatory affairs experience including regulatory CMC and/or GMO strategy for development and/or commercial pharmaceutical products required.
- Experience with immuno-oncology products, ATMPs, cell and gene therapy, and vaccines are a plus.
- Experience of working in a global, matrix environment (multidisciplinary international team). Must have good understanding of the line functions and their role in the research and development (i.e. Pre-clinical Research, Manufacturing process, Regulatory, Clinical Development, and Quality Assurance.)
- Strong interpersonal skills and ability to collaborate effectively with various technical area experts within the company and with alliance partners.
- Excellent written and oral English, communication skills, and attention to detail.
- Demonstrated strong organizational skills including ability to prioritize tasks and adhere to agreed timelines.
- Understanding of electronic submissions.
- Knowledge and understanding of US, EU, Canada, and ICH guidelines. Understanding of international GMO requirements is a plus.
- Highly computer literate (MS Office suite; WebEx and secure file sharing…).

What we offer:

- Strong team with dedicated and passionate scientists
- State of the art infrastructure
- An excellent working atmosphere
- Opportunities for personal development
- Working in a multinational and multicultural environment

Salary is dependent on experience and qualifications.
Starting date: As soon as possible

Contact:
If you are interested in this challenging position, please send your CV including a cover letter summarizing your qualification and experiences to: **Victor.Paulus@hookipapharma.com**

For more information on Hookipa please visit **www.HookipaPharma.com**