Director – Regulatory Affairs (m/f)

Date posted: September 14, 2020
Location: New York, USA

About Hookipa:

HOOKIPA Pharma Inc. (NASDAQ: HOOK) is a clinical stage biopharmaceutical company developing a new class of immunotherapeutics, targeting infectious diseases and cancers based on its proprietary arenavirus platform that is designed to reprogram the body's immune system.

Position Summary:

We are looking for a highly motivated Director, Regulatory Affairs to join our team. He/she will be responsible for providing strategic and operational direction for the planning, management, support and execution of regulatory activities. In collaboration with the management team and other cross-functional team members this individual would independently formulate regulatory strategies and lead the preparation of regulatory submissions. This position may be assigned as the regulatory affairs lead for clinical development projects. He/she would be the point of contact for all other cross-functional team members and will be required to lead team(s) in orchestrating health authority interactions.

Ideally, you will have a scientific, oncolytic virus/gene therapy, manufacturing or clinical development background. You will demonstrate a strong understanding of oncology and hematology therapeutic areas and filing of regulatory submissions associated with those areas. Good listening skills, capability to bring cross-functional teams together in a cohesive way, ability to work in a fast-paced environment, leadership and professionalism are all essential behaviors for this role.

Main Responsibilities:

- Develop and implement US regulatory strategies for projects in different stages of development (Phase I through Registration).
- Work cross-functionally with pre-clinical, clinical, manufacturing departments and CROs on Regulatory Affairs related issues.
- Serve as a primary liaison to US FDA, EMA, and other key market health authorities for assigned projects.
- Define appropriate regulatory strategies, coordinate the execution of regulatory submissions including, but not limited to clinical trial applications, Investigational Drug (IND/IMPD) applications, marketing applications etc.
- Develop strategies and drafts and/or review responses and other documents intended for submission to FDA and other global health authorities, including but not limited to information requests, risk mitigation strategies, CAPA'S, meeting requests, briefing packages, fast track applications, priority medicines, orphan drug applications, breakthrough therapy designation applications etc.
- Integrate global regulatory understanding and responsibilities in developing strategy and development of regulatory submission documents.
- Manage the completion of documents and other assigned tasks within established timelines and with high quality.
- Maintain awareness of developing views/guidance within FDA and EMA on general and specific topics related to the therapeutic area and other development projects as appropriate.

Qualifications & Skills:

- An advanced degree, MD, PhD, PharmD, or JD
- Preferably 7 years or more of regulatory work experience
- RAC and BLA experience would be a plus
- Viral vector and gene therapy experience preferred
- Experience with quality systems (e.g. GMP; GLP) is an advantage
- Full functional knowledge of regulatory requirements pertaining to the development and registration of biological viral drugs/gene therapy
- Experience with clinical and registration filings
- Experience communicating with the health agencies and organizing scientific advisory meetings
- Proven ability to manage complex projects
- Previous experience in managing and leading submission teams
- Independent, efficient, and proactive workstyle
- Must be detailed oriented and be able to communicate to Sr. Management
- Well organized, succinct, hands-on mentality, and solution-oriented
- Motivated, flexible, team player with the ability to work under time pressure
- Eager to learn and develop in fast- paced, multiple project company

What we offer:

- Strong team with dedicated and passionate scientists
- Excellent working atmosphere
- Opportunities for personal development
- Working in a multinational and multicultural environment

We offer a comprehensive package with competitive salary, paid holidays and sick leave, along with a full range of medical, dental/vision insurance and 401(K) plan. In addition, we offer a performance-related bonus payment and participation in our stock option compensation program.

Starting date: As soon as possible

Contact:
If you (m/f) are interested in this challenging position, please send your CV including a cover letter (summarizing your qualification and experiences) as well as your credentials to: **talent@hookipapharma.com**

For more information on HOOKIPA please visit **www.hookipapharma.com**