DIRECTOR, REGULATORY AFFAIRS

Date posted: June 26, 2019
Location: Vienna, Austria

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 pre-clinical, clinical, CMC complex 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, 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 EMEA on general and specific topics related to the therapeutic area and other development projects as appropriate.

Qualifications:

- An advanced degree, preferably PhD, in Virology/Immunology
- Preferably 10 years or more of regulatory work experience
- RAC would be a plus
- Independent, efficient, and proactive workstyle
- Well organized, succinct, hands-on mentality, and solution-oriented
- Experience with quality systems (e.g. GMP; GLP) is an advantage
- Motivated, flexible, team player with the ability to work under time pressure
- Eager to learn and develop

Skills:

- Full functional knowledge of regulatory requirements pertaining to the development and registration of oncolytic 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 leading submission teams

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 are required by Austrian law to post a minimum salary. The minimum monthly gross salary for this position is EUR 5.143. Depending on experience and qualification, we are willing to overpay.
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 to: talent@hookipapharma.com

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