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Senior Manager Regulatory Affairs

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Company: Gan & Lee Pharmaceuticals

Location: Bridgewater

Category: other-general

Summary

This position reports to the Functional Area Head, Global Regulatory Affairs. The incumbent responsible for supporting the development and implementation of regulatory strategies, work closely with the cross functional asset teams to prepare, review and submit regulatory filing documents, manage documentation systems and maintain interactions with regulatory agencies.

Education and Credentials

• Bachelor of Science Degree in a relevant area is required. Advanced science degree is preferred.

• RAC certification or other equivalent is preferred.

Experience

• Minimum Bachelor’s degree in a scientific or related discipline, 5+ years of pharmaceutical industrial experience, at least 3 years of regulatory CMC experience with US product development.

• Deep knowledge of US and EU regulations for biosimilars is preferred.

• Deep knowledge of regulations for drugs and biologics.

• Familiarity with GLP/GCP/GMP, clinical laboratory regulations, and licensing.

• Experience in various regulatory submissions and communication with regulatory agencies. Hosted communication with the agencies on clinical development plans, clinical design and other clinical aspects (including document package writing, meetings and discussions with the agency, etc.) is preferred.

• Led at least one drug IND application in US and get it approved. Experience in endocrine drugs such as insulin and GLP-1 is preferred.

• Experience in working in multi-culture/multi-countries environment is preferred.

Skills

• Demonstrated ability to manage multiple and diverse projects concurrently.

• Demonstrated ability to develop positive relationships and collaborations.

• Strong analytical skills; a strategic thinker, planner, and implementer.

• Ability to operate independently with minimal supervision.

• Strong proficiency in major Microsoft Office products (i.e., Word, Excel, PowerPoint, Project).

• Enthusiastic, genuine, ethical, fair, and loyal to the organization and its vision and goals.

Responsibilities

1. Actively contribute to the development of regulatory strategies for investigational products in Investigational New Drug (IND)/ Clinical Trial Applications (CTA), Biologics Licensing Application (BLAs)/ Marketing Authorization Application (MAA), through evaluating scientific merits of Chemistry, Manufacturing and Control (CMC) and nonclinical study data package;

2. Participate as Global Product Strategy Lead in cross-functional teams, including but not limited to, contract research organizations (CROs), functional working groups, global regulatory team, submission team, product development team, to ensure compliance with regulatory requirements;

3. Author Module 2 and 3 documents for regulatory filings such as INDs/ IMPDs/ CTAs/ MAAs/NDAs/ global registrations and eCTD submissions, ensuring that they meet current regulatory standards.

4. Drive the preparation and review of regulatory submissions, such as INDs, BLAs, MAAs, meeting packages to ICH member Health Agencies, and supplemental filings ensuring regulatory documents are written per guidelines and timelines.

5. Manage and track filing submission dates, questions from Regulatory Health Authorities, responses, and approval dates.

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