Director/Associate director, Regulatory Affairs

Position Summary

This position is responsible for directing the operational and strategic activities of the Global Regulatory Affairs organization for Palisade Bio. The incumbent will be responsible for ensuring that Palisade Bio's Regulatory Affairs Function is robust, integrated to the company's businesses, focused on enabling new product introductions, and will support the governance processes for regulatory affairs in alignment with regulatory requirements.

The incumbent must have a comprehensive understanding of FDA/EU/ICH requirements, principles, concepts, industry practices, and standards. In this hands-on role, s/he manages, reviews and edits the preparation of regulatory documents. Duties include preparing, reviewing, and editing of clinical trial applications (CTAs), investigational new drug applications (INDs), and key documents associated with these applications as appropriate and in compliance with national and international regulations and laws (e.g., Annual updates, Investigator's Brochure, labeling). S/he will be a key member of the product development teams and will work in close partnership with the department heads to refine and execute the multi-year strategic roadmap. We are seeking a strong team player with global regulatory affairs and gastrointestinal drug development experience, strong communication skills, and the ability to contribute to a collaborative interdisciplinary environment. This position will report directly to the Chief Medical Officer. Minimal travel is required.

Role and Responsibilities

- Represent Regulatory Affairs in project teams to develop and implement global clinical development regulatory strategies to maximize successful and expedient product registrations in worldwide jurisdictions. Provide expert guidance to project teams on regulatory mechanisms to optimize product development.
- Conduct and manage the preparation, review and submission process for global regulatory documents (e.g., orphan drug designations, INDs, Annual Reports, protocol/CMC amendments, clinical trial applications, NDAs, etc.) ensuring regulatory submissions are complete, organized, of high quality, and compliant with applicable regional regulations.
- Build and maintain relationships with outside service providers to prepare and submit dossiers globally.
- Maintain knowledge of existing and new regulations and guidance pertaining to clinical development, quality, CMC, etc. and advise company on requirements for compliance.
- Maintain effective working relationships with multiple international regulatory agencies, as well as represent company at agency meetings.
- Monitor regulatory trends and provide risk assessments and recommendations to senior management for various regulatory scenarios.
- Provide advice, training, and guidance to the team regarding relevant regulatory requirements/review processes for FDA/EMA and other regulatory agencies.
- Participate as an active member during regulatory agency inspections.

- Periodically perform review/audits of internal systems to ensure ongoing compliance with SOPs and regulations. Participate in multidisciplinary team audits.
- Assist in generation and maintenance of company SOPs.
- Actively manage departmental resources and budget to meet strategic goals.
- Responsible for managing regulatory archives and databases
- Supervise regulatory affairs personnel, as directed.

Qualifications and Education Requirements

- Bachelor's degree in a Life Sciences discipline. Advanced degree highly desirable.
- Six or more years of Regulatory Affairs experience in the pharmaceutical or biotech industries required.
- Knowledge of regulatory submissions, marketing applications and overall drug development from non-clinical and CMC through phase 1 to phase 4 clinical development.
- Knowledgeable in ICH/cGMP/GLP/GCP, and regulatory guidelines as applied to the entire development lifecycle of biotech and pharmaceutical companies.
- Gastrointestinal experience is highly desired.
- Demonstrated experience with successful INDs, NDAs, Breakthrough and Fast-Track designation requests and submissions as well as agency meetings.

Preferred Skills

- Capable of implementing a regulatory project plan based on input from internal and external experts, agency feedback and own experience.
- Reliable to execute responsibilities with minimal direction.
- Ability to develop excellent relationships internally, with vendors and with regulatory agencies.
- Ability to organize and manage the regulatory function to meet corporate goals and objectives.
- Broad knowledge of the US regulations and drug development process.

Personal Characteristics and Cultural Fit

- Ability to thrive and flourish in a fast paced entrepreneurial early-stage company environment that requires “hands-on” implementation, optimal use of limited resources and an ability to work closely with others in a small team setting.
- Must be a highly motivated self-starter, show initiative/ independence, and be driven to make an important business contribution.
- Excellent collaboration, influencing and facilitation skills across functions and employee levels
- Evidence of solution-oriented thinking skills
- Treats others with respect and consideration.
- Creative, strategic, flexible and able to think “out of the box.”
- Ability to work under pressure and time constraints and easily adapt to ever-changing conditions

- Persistent in the face of resistance and adaptable to rapid change
- Open minded and place high value on other's experience and perspectives in the field of drug development, regulatory affairs and compliance
- Demonstrated ability to participate in cross-functional teams and to achieve results through cooperation with other departments.
- Excellent interpersonal, presentation, written and verbal communication skills.
- Strong time management and organizational skills coupled with a sense of urgency and strong work ethic.