



Vice President, Regulatory Affairs

QLT Inc. is a biotechnology company dedicated to the development and commercialization of innovative therapies for the eye. We are focused on our commercial product Visudyne® for the treatment of wet-AMD, developing drugs to be delivered in our proprietary punctal plug delivery system, as well as developing our synthetic retinoid program for the treatment of certain inherited retinal diseases. For more information, visit our website at www.qltinc.com.

DESCRIPTION

Responsible for the development of Regulatory strategies, policies, guidelines, programs, procedures, investigative approaches, and monitoring mechanisms for all QLT Inc. products. Leads and manages the Regulatory Affairs department.

1. Develops mechanisms to ensure that development programs for pharmaceutical and medical device products comply with regulatory requirements with respect to chemistry, manufacturing and controls (for drugs), preclinical investigations and clinical trials.
2. Develops mechanisms to ensure compliance with post-marketing regulations with respect to promotion, advertising, and pharmacovigilance. Advises and collaborates with Quality Assurance, Quality Control, and Development departments to monitor Company activities that are subject to GxP regulations, with the participation of members of the Regulatory Affairs department.
3. Develops registration strategies for all products, in collaboration with strategic co-development partners.
4. Participates in interactions between the Company and Health Regulatory Authorities. The coordination of inspections from Health Authorities for manufacturing practices and pre-inspection audits by Company or consultant personnel is the responsibility of the Quality Assurance Department with participation of members of the Regulatory Affairs department.
5. Controls and oversees the preparation and submission of:
 - investigational applications (INDs), registration applications (NDSs, NDAs, MAAs, PMAs), and other submissions (e.g. requests for orphan drug status, export permits, special regulatory status (Subpart E), etc.);
 - annual and other periodic reports required for investigational and approved products; and
 - initial and revised physician- or patient-information product labeling (Package Inserts, Product Monographs, Patient Package Inserts, etc.) for products in jurisdictions where the Company has the lead Regulatory responsibility. The Regulatory Affairs department approves vial, box, carton, and other packaging-types of labelling that are prepared by other departments.
6. Conducts ongoing research, and maintains and disseminates up-to-date information on regulatory matters including legislation, regulations, policies, procedures and precedents in drug and device development and post-approval obligations.
7. Oversees the maintenance of electronic or paper copies of all relevant Board of Health laws, regulations, guidelines, and policies relevant to the Company's products, development activities, and post-marketing responsibilities.
8. Disseminates relevant regulations, guidelines and policies to other departments within the Company to ensure that all development programs and post-approval activities are based on current regulatory requirements.
9. Participates in and supports compliance with 21 CFR Part 11.
10. Manages the Regulatory Affairs department budget, encompassing financial and human resources.
11. Attracts and retains highly qualified personnel by providing a rewarding and stimulating professional environment. Evaluates performance, assesses training needs, and ensures the ongoing development of Regulatory Affairs employees.

REQUIREMENTS

- B.Sc. or graduate degree in an applicable scientific area.
- Significant Regulatory Affairs senior management experience in the pharmaceutical industry, preferably including Ophthalmology. Experience must include pharmaceuticals. Device experience is strongly preferred. Biologics would be an asset.
- Experience must include: the development of effective regulatory strategies, INDs through to NDAs; assessment of corporate risks related to regulatory and development activities; building a regulatory function; and the management, mentoring and development of employees.
- Excellent working knowledge of regulatory requirements for FDA registration and sound, broad knowledge of regulatory guidelines for other major health authorities.
- Must be comfortable driving innovative strategies with various agencies.
- Broad knowledge of quality assurance requirements.
- Excellent verbal, written and oral presentation skills. A proven ability to negotiate and achieve consensus.
- Highly developed leadership and management skills.

Apply online at www.qltinc.com - Ref # PS-1112