Apellis

Position: Manager Regulatory Affairs – Medical Devices

Reports to: Vice President, Regulatory Affairs and Quality

Description: Provides regulatory support and expertise associated with US and global registration of device products (infusion pump portfolio), including in-depth analysis of the requirements and tracking of medical device submission deliverables and assure full regulatory compliance of all documentation for submissions. The Manager will support creation of global regulatory strategies and assists in execution including creation and maintenance of global registration dossiers. Coordinate and oversee preparation of regulatory documentation in a timely manner to meet corporate objectives for medical device submissions. Manager of Regulatory Affairs is a critical position responsible for direction, planning and execution of medical device product registration activities. The Manager will plan, drive, coordinate and execute the device strategy and work closely with external manufacturing partners to make sure regulatory issues are addressed properly and according to Apellis standards.

Under the direction of the VP RA & QA, the Manger will direct regulatory activities for developing and executing device strategies. Manage submissions and interactions with the FDA and other international regulatory agencies.

Job Responsibilities:

- Plans and organizes registration packages for device products. Prepares registration packages in line with local regulatory requirements and guidelines.
- Experienced in regulatory affairs medical device development and provide regulatory strategy around clearance/approval (e.g. 510(k), PMA, CE Mark etc.).
- Prepare FDA submissions for new products to ensure timely clearances and market release (e.g. 510(k)s, Notes to File, Pre-Submissions, IDEs, and Additional Information Responses etc.).
- Responsible for communicating program status, milestones, issues and challenges to Senior Management.
- Ensure delivery of program schedules and resolving conflicts by removing obstacles which may require negotiations with our partners.
- Provides regulatory strategies, advice, identifies registration needs and support medical device teams.
- Liaison with regulatory agencies pertaining to medical devices in preparation and submission of meeting packages.
- Effectively manage and prepare regulatory documents and submissions to ensure timely approvals of products and processes in accordance with business strategies and marketing plans.
- Maintains excellent working relationships with regulatory authorities.

- Develops product regulatory approval strategies in collaboration with senior department management. Independently oversee implementation of project plans for assigned products/product lines.
- Manages assigned Regulatory Affairs devices personnel. Hire, train and develop staff members. Provide timely and appropriate performance feedback.
- Provides regulatory guidance to product development teams. Advise teams and management on worldwide regulatory requirements.
- Ensures compliance with US (FDA), Canadian, Mexican and other regulatory submission requirements for medical device registrations.
- Manages timelines and priorities on all submissions.
- Ensures that submissions are processed in a timely fashion.
- Oversees preparation of regulatory assessments for proposed product design changes.
- Interacts with FDA or other regulatory agencies regarding regulatory strategies for assigned products/product lines.
- Prepare SOPs to ensure compliance with all applicable US and international regulatory requirements.
- Additional duties and responsibilities as required.

Experience and Background:

- Qualified candidates must have 6-8 years' in regulatory affairs, regulated industry. BS or above is required in Pharmacy, Biology, Chemistry, Pharmacology, Engineering, or related subject. Able to travel domestically and internationally.
- Worked in a team environment to oversee the process of preparing device-related information in combination product submissions to domestic and international regulatory bodies and manages the process from inception to approval.
- Provided oversight and regulatory advice throughout the device development life cycle, including guidance on facilitating design controls, risk management and post-market activities.
- Experienced in working with Class II/Class III medical devices, combination products (drug-device) and disposable medical devices.
- Provided regulatory review of Human Factor study/clinical protocols, investigator's brochures, labeling, and integrated summary documents for adequacy.
- Enjoyed working in a collaborative, energetic, team-oriented environment that is poised for exciting future growth.