imara

SENIOR REGULATORY SPECIALIST

POSITION SUMMARY

We seek a Senior Regulatory Specialist who will be responsible for product submissions, periodic updates and registrations to regulatory agencies. This position will be responsible for organizing regulatory information and tracking and controlling regulatory submissions to regulatory authorities, IRBs/ECs and other regulatory entities to support clinical trials and product development activities. This position will partner closely with Clinical, Technical Operations, and Quality teams to ensure timely submission of regulatory documents for development programs.

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Assist in the day-to-day procedures used to support regulatory submission and publishing activities.
- Collaborate with other departments and contribute on planning global submissions.
- Support Project Teams to ensure deliverables are met.
- Provide regulatory support and guidance to various departments, projects, and teams.
- Participate in the preparation, quality check, and delivery of regulatory submissions in accordance with regulatory requirements and company standards.
- Coordinates with external regulatory operations staff to compile and publish regulatory submissions to ensure on-time delivery to regional markets.
- Assures completeness and quality of submissions.
- Analyzing all available information to bring potential issues to light as well as provide solutions.
- Ensures health authority correspondence and dispatched submissions are archived appropriately in a timely manner.
- Supports audits for documentation support as requested.
- Exercises judgment within defined procedures and practices to determine appropriate action.
- Assists with various projects as assigned.

JOB REQUIREMENTS

Education

- BA/BS degree in life sciences

Experience, Knowledge, Skills and Abilities

- 2-5 years of pharmaceutical product development
- Knowledgeable in ICH, FDA and EMA guidelines
- Experience successfully executing regulatory activities in the US, EU, and globally required
- Ability to work independently and thrive in a fast-paced environment
- Attention to detail
- Excellent people leadership skills

- Excellent communication skills and ability to influence across multiple functions
- Must be highly proficient in MS Office (emphasis on MS Word), Adobe Acrobat (version 5.0 or higher) and document publishing tool (ToolBox or similar).