GROUND ZERO PHARMACEUTICALS

PROJECT MANAGER, REGULATORY AFFAIRS

Job Title: Regulatory Affairs Project Manager

Division/Department: Technical

Part Time or Full Time / Hourly or Salary:
Full Time / Salary

Reports to:
Sr. Vice President, Finance and Operations

Rate (USD): Negotiated

Last Revision Date: August 23, 2018

SUMMARY

The Project Manager, Regulatory Affairs will be responsible for the project management of regulatory submissions and operations activities as related to the Company's client development programs as applicable to the US and worldwide health agencies. This may include support for both products in early and late stage development and marketed products. The individual must have project management and regulatory experience, strong organizational ability and multi-tasking skills in order to successfully achieve the organizational and functional goals. This person must also be detail-oriented and able to provide hands-on individual contribution to meet RA team's objectives.

PRIMARY RESPONSIBILITIES

1. Provide day-to-day project management, acting as primary contact and liaison for Client Projects and the Technical Team.
2. Coordinate activities and resolve problems for Regulatory and project team.
3. Foster effective and productive communications among various functional groups including Nonclinical, CMC, Clinical and Regulatory Leads, Regulatory Operations, Medical Writing, Biostatistics, and representatives from other technical areas as appropriate.
4. Generate, maintain and monitor Regulatory Affairs tracker for all regulatory global submission milestones/schedules.
5. Develop, maintain and track detailed timelines and deliverables for cross-functional regulatory submission activities and submissions and assures planning and coordination of activities in a matrixed team environment.
6. Provide support for the US and worldwide submissions by coordinating with various functional team members such as Nonclinical, Clinical, CMC, Regulatory, Medical Writing, Management, and others as appropriate to obtain necessary documents required for timely submissions.
7. Assure that regulatory submissions are prepared in high quality manner according to defined Corporate or Regulatory timelines, and for working with Regulatory and Technical Leads to assure that submissions are prepared in line with ICH requirements, other local or regional regulatory requirements, as applicable, and company policies and procedures.
8. Detect and mitigate risks to project timelines.
9. Other duties may be assigned.

ADDITIONAL RESPONSIBILITIES

1. Comply with U. S. FDA and international regulations, other regulatory requirements, Company policies, operating procedures, processes, and task assignments.
2. Maintain positive and cooperative communications and collaboration with all levels of personnel, customers, contractors, and vendors.
3. Maintain up-to-date knowledge on regulatory requirements, especially FDA and EU requirements.
4. Provide input in terms of resource allocation across functional areas, submission operation, identification and mitigation of risks that have impact on resources, deliverables and timings in accordance to client and corporate timelines.
5. Provide guidance to RegOps/Submission teams and assist with paper and electronic submissions as needed.

KNOWLEDGE AND SKILL REQUIREMENTS

1. Ability to excel in a fast-paced and dynamic work environment.
2. Excellent verbal and written communication skills; • Excellent prioritizing, organizational, and interpersonal skills.
3. Excellent documentation skills including detail-oriented, record maintenance/ tracking and understanding of document traceability.
4. A detail-oriented individual, with a “can do” attitude, and the ability to work in a team environment, as well as individually (with minimal supervision).
5. Knowledge of product development milestones and regulatory affairs in the pharmaceutical / biologics / biotechnology / medical device industries.
6. Experience with global regulatory document requirements for pharmaceuticals, biologics, combination products, and medical devices.
7. Requires high-quality professional written and verbal communication and interpersonal skills. Ability to communicate and interact with a diversified team.
8. A Bachelor’s Degree and 3 years of regulatory Project Management experience in the pharmaceutical / biologic industry or 6 years of regulatory project management experience in the pharmaceutical / biologic industry, or similar equivalent experience.
9. Requires willingness to work a flexible schedule and may require some travel, particularly within Europe and Australia/New Zealand regions.
10. Computer Skills: To perform this job successfully, an individual should have proficient knowledge of Microsoft Office, Adobe Acrobat, eCTD Submission Software, and an ability to learn new software quickly.
11. Language Ability: Ability to read, analyze, and interpret common scientific and technical documents and journals. Ability to respond to common inquiries or complaints from clients, regulatory agencies, or members of the business community. Ability to write speeches and articles for publication that conform to prescribed style and format.
12. Reasoning Ability: Ability to solve practical problems and deal with a variety of concrete variables in situations where only limited standardization exists. Ability to interpret a variety of instructions furnished in written, oral, diagram, or schedule form.

WORKING CONDITIONS

1. Working conditions are normal for an office environment. May require occasional weekend and evening work and occasional overnight travel. The noise level in the work environment is usually low to moderate.
2. Physical Demands: The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. While performing the duties of this job, the employee is regularly required to sit; use hands; reach with hands and arms and talk or hear. The employee is occasionally required to stand and walk.

Send resumes to : ttempleton@groundzerous.com