GROUND ZERO PHARMACEUTICALS

SENIOR REGULATORY AFFAIR SUBMISSION MANAGER

Job Title: Senior Regulatory Affairs 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 10, 2018

SUMMARY

The Regulatory Affairs Submission Manager is responsible for regulatory operations depending on client regulatory strategies. They are responsible for the planning, publishing (in eCTD format), review and delivery of regulatory submissions (e.g., INDs, NDA/BLAs, and other LifeCycle Management submissions) to global Health Authorities (with concentration on the FDA) within required timeframes.

PRIMARY RESPONSIBILITIES

1. Primarily responsible for the planning and publishing of regulatory submissions, monitoring the submission deadlines and ensuring timely submission of high quality compliant and valid submissions to global health authorities within required timeframes.
2. Liaise with the Project Manager of a designated program to ensure that submission requirements and timelines are understood.

ADDITIONAL RESPONSIBILITIES

1. Coordinate and participate in the preparation of different types of regulatory submissions (e.g. dossiers, variations, scientific advice submissions, INDs) to competent authorities worldwide for approved and developmental products.
2. Operate electronic submission tools (eCTD manager, validation tools) and electronic Data Management Systems (eDMS) as may be used by the company.
3. Provide regulatory feedback for project teams
4. Participate in contacting competent authorities for specific projects/products and interact with internal teams and departments and client teams as necessary.
5. Perform high level formatting in both word and PDF files according to guidelines.
6. Create Bookmarks and hyperlinks and assure file Optimization on final documents.
7. Perform technical quality control (electronic functionality, adherence to internal and external document standards) and validation of documents and submissions.
8. Interpret regulatory guidelines to ensure that requirements are met and stay current with new electronic submission regulations and regulatory documentation practices.
9. Serve as the Subject Matter Expert regarding eCTD processes and procedures.
10. Review R&D documents to ensure compliance with submission guidelines.
11. Contribute to new and updated process, policy and procedures.
12. Perform general regulatory and maintenance tasks.
13. Execute other tasks as requested by management.

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KNOWLEDGE AND SKILL REQUIREMENTS

1. Direct experience in electronically publishing regulatory documents, especially for FDA (i.e., eCTD INDs, NDA/BLAs, CSRs, and special designation requests, e.g., Orphan Drug Designation requests).
2. Knowledge of the drug development process, product development milestones and regulatory affairs in the pharmaceutical / biologics/medical device industries.
3. Familiarity with global regulatory document and submission requirements for pharmaceuticals, biologics, combination products and medical devices.
4. Understanding of FDA and EU regulations, and ICH guidelines.
5. High-quality professional written and verbal communication and interpersonal skills. Ability to communicate and interact with a diversified team.
6. Proficiency in publishing eCTD submissions.
7. A demonstrated ability to work with minimal supervision is necessary.
8. A Bachelor's Degree and 5 years' experience with electronic CTD Submissions or 7 years of eCTD Submission experience.
9. Willingness to work a flexible schedule and may require some travel, particularly within Europe and the Australia/New Zealand region.
10. Computer Skills: To perform this job successfully, an individual should have 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 in fluent English. Ability to respond to common inquiries or complaints from customers, regulatory agencies, or members of the business community.
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