



Regulatory Affairs -Technical Assistant

Main Purpose

To provide a high level of technical and administrative support to the Regulatory Affairs group of LEO Pharma Inc. The scope of this position will include Regulatory Affairs Activities and Support for the QA/QC function. This role reports to the Manager, Regulatory Affairs.

Link to Strategy

In this role the incumbent will supply a high level of support in two capacities: 1) technical duties by assisting in preparation of submissions to Health Canada in accordance with TPD/BGTD guidelines, setting up and maintaining electronic and paper filing systems, and assisting in the quality control/assurance area to maintain compliance of the company's products and 2) administrative duties to enable the team to focus on their projects at hand. The activities will contribute to the delivery of high quality, timely business targets relating particularly to the Regulatory Affairs and the QA/QC area, thus enhancing the service by LEO to our internal and external customers.

Key Accountabilities

Technical support:

- Prepare regulatory documents (submission templates and administrative forms, applications) for review by the Manager, Regulatory Affairs Scientist and QA Manager
- Regulatory Compliance of physician sample storage (ie temperature monitoring) and maintain Regional Manager's physician sample audits
- Set up and maintain electronic (ie. eDoc and eCTD) systems, departmental databases and regulatory information management systems
- Assist QA Department with product returns and complaints.
- Prepare annual DIN notifications and annual Establishment License renewals
- Assist with annual filing of the registration summaries with DK
- Prepare CTA / CTA-A submissions and assist in preparation of NC submissions
- Assist in preparation of NDS and SNDS files and clarifax responses
- Monitor Regulatory environment vs. specific targets (regulatory intelligence)

Administrative support:

- Answer calls as backup for all departmental members; open and circulate mail, deal with couriers and mailings, faxing
- Prepare correspondence, reports, PowerPoint presentations, graphs and charts, and various documents as needed
- Co-ordinate/organize meetings (internal & external) eg. with Health Canada including travel, hotel, catering and audiovisual; assist with travel and hotel arrangements for the department and guests
- Assist with the preparation of the departmental monthly report and maintain project tracking logs
- Function as the department's documentarian with accountability for departmental hardcopy and electronic filing and archiving
- Coordinate the donation of slightly damaged or short dated stock to Health Partners, logging and recording quantities, lot and expiry dates for recall purposes
- Maintain and circulate industry and regulatory subscriptions
- Order office supplies for the department

- Miscellaneous requests and projects as required

Knowledge, Skills and Experience

- College/ university degree in scientific discipline
- Minimum of 2 years pharmaceutical industry experience that includes regulatory and quality technical roles; knowledge of medical terminology is required.
- Exceptional written and verbal communication skills
- Ability to work well independently and as part of a team
- Great attention to detail
- Willingness and ability to work in compliance with SOPs and guidelines and understanding the importance of the same
- Excellent time management skills to deal with time-sensitive projects and multi-tasking capability
- Superior computer skills with Lotus Notes, Microsoft Word, Excel, and PowerPoint in a Windows environment, with ability to adapt the a changing electronic environment (to meet eCTD requirements)

Key competencies required to be successful in this role

Organizational knowledge

- Must develop a solid understanding of local processes, systems and documentation requirements
- Knowledge of Canadian regulatory environment and requirements
- Understanding of GMP principles
- Knowledge of local and corporate (clinical/Regulatory/QC) SOPs
- Exhibits good judgment when making decisions

Interpersonal

- Ability to build good rapport and effective working relationships with a variety of people at all levels internally and externally
- Is open, approachable and dependable; supports and helps others
- Deals well with ambiguity
- Understands underlying issues, problems or reasons for other's feelings, behaviors or concerns
- Respected both internally and externally as a team player

Communication

- Exceptional verbal and written communication skills
- Effective listener and communicates clearly and effectively in appropriate style
- Uses good judgment in handling situations and knows when to refer situations to the next level.

Leadership

- Confident of self and abilities and an effective team player
- Works to ensure personal and organizational reputation is positive
- Volunteers for new assignments and opportunities, must be pro-active and able to perform duties without assistance
- Constantly delivers on individual objectives which contribute to achieving team objectives
- Ability to act with a high level of integrity and confidentiality
- Uses knowledge to solve problems but also knows where and when to redirect inquiries
- Ability to work within environment where priorities are often changing and meeting deadlines is critical to success

Performance Management

- Establishes efficient work procedures to meet objectives
- Learns from experiences, actively pursues learning and self development
- Ability to modify behavior in light of feedback
- Has a strong understanding of the position within the overall structure
- Knows what is important vs. urgent
- Monitors progress and performance against expectations

Risk Taking and Innovative Thinking

- Critically evaluates scientific data and analyzes the meaning of the results
- Using the best judgment, recommends the most appropriate way to present data
- Ensures that decisions are timely and based on logical assumptions and factual information
- Ability to understand the implications of decisions and recommends strategies and tactics to deal with negative outcomes

For more information or to apply, please go to www.leo-pharma.ca and click on "human resources" then "careers".

If you are interested in applying for the position, please submit your resume and cover letter to our HR department at **fax number 905-886-6622**, or via e-mail to jennifer.tong@leo-pharma.com.

Please note that only candidates selected for interview will be contacted.