— we help people achieve healthy skin

HEALTHCARE AND ORGANIZATIONAL COMPLIANCE MANAGER

Are you passionate about fostering a culture of compliance in an organization that is committed to helping patients while ensuring our license to operate?

Are you a process focused individual who is system savvy and able to utilize your judgement and decision making to be a strategic partner within a business?

LEO Canada

LEO Canada has an amazing culture with approximately 100 employees who either work in or support the Dermatology and Thrombosis business units. All LEO Canada people are dedicated to helping patients live healthier lives while ensuring LEO is a sustainable business. Head Office for LEO Canada is located in Thornhill, Ontario; however, many employees are field based and work in various Provinces across the wide Canadian geography.

Position Overview

Reporting to the Scientific Affairs function, the mandate of this role is to, in partnership with Senior Leadership team, create a culture of compliance when it comes to health care interactions and adherence to LEO non-GXP standard operating procedures, guidelines and external legislations in the same areas.

This role positively contributes to LEO's non-GxP organizational compliance to enable efficient and effective business practices and ensure the business has an accurate account of spend on HCP activities in Canada. This role promotes ethical management and business behaviour, is both strategic and administrative in nature, and focuses on the following:

1. Fostering a culture of compliance.
2. Implementation and tracking of global and country specific non-GxP policies and procedures.
3. Ownership of the LEO Canada HCP interactions process and system.
4. Being the internal subject matter expert when it comes to non-GxP compliance policies and external legislation and trends. Staying abreast of regulatory changes in the non-GxP space. Resolving compliance issues in partnership with the business.
5. Auditing internal activities, documentation and training to ensure compliance with various internal SOPS and external legislations.
6. Identifying internal insights and trends and making recommendations to improve compliance and efficiency.

LEO®

This person will continuously partner with and support the business when it comes to health care compliance in a risk evaluated and fact-based manner. This position also works in collaboration with colleagues in the Region Europe+ structure as well as Global Compliance to ensure overall corporate and regional compliance policies and systems are adapted and implemented in Canada; also sits as a member of the Global Compliance team to help establish best practices on a global scale.

Our Ideal Candidate

- ✓ Bachelors degree a science or business administration related field and has solid hands on experience in a heavily regulated role/industry and in a role(s) that involves project management and process administration.
- ✓ Ability to operate in “the grey zone” while ensuring organizational compliance. Understanding of risk and helping organization make decisions that ensure our license to operate.
- ✓ Strong problem solving skills that are pragmatic and reflect a strong understanding of the business and the ability to differentiate between significant and less significant risks.
- ✓ Detail-oriented with strong writing skills in compliance with Good Documentation Practices (GDP).
- ✓ Must be system savvy with the ability to manipulate data and draw insights to make recommendations.
- ✓ Experience with conducting and responding to audits.
- ✓ Track record of reliance, accountability, and value-added business partnering.
- ✓ Must have courage to challenge the status quo and raise issues coming from non-compliant behaviour in a diplomatic and collaborative manner.
- ✓ Has strong knowledge of compliance and privacy legislation and relationships with /familiarity with Canadian regulatory authorities such as Innovative Medicines Canada, Biotech Canada, Advertising Standards Canada, Health Canada and PAAB.
- ✓ Ability to analyze complex situations to determine root cause.
- ✓ Strong courage and ability to elevate non-compliant behaviour and issues and make recommendations to resolve issues and gaps.
- ✓ Solid judgement and decision making skills.
- ✓ Excellent communication skills with an ability to persuade and influence others.
- ✓ Ability to plan and organize work, to streamline processes and track progress.

Responsibilities:

1. **Fostering a culture of compliance.**
    - Ensure effective implementation of a values-based ethics and compliance program within the business to prevent, detect and correct violations of company policy.

- Partner with the business to develop and implement tools which empower business units to make ethical and compliant decisions.
- Ensure appropriate visibility and mitigation of significant compliance-related issues.
- Promote transparency and comfort within the business modelling and ensuring others to speak up about compliance related matters.
- Ensure that monitoring and auditing systems are capable of detecting significant instances or patterns of illegal, unethical or non-compliant conduct by employees.
- Collaborate with Compliance colleagues in FCB Cluster and Global to share best practices and learn how to improve compliance in LEO CA.
- Write, assign and maintain non-GxP-related Deviations, CAPAs, Change Controls, perform investigations, perform trending.

2. Implementation and tracking of global and country specific non-GxP policies and procedures.

- Implementation of LEO global non-GxP compliance policies and procedures in the LEO CA organization.
- In partnership with the CA business, develop LEO CA policies and procedures to adhere to local legislations and align with global policies.
- Development, review, revision and implementation of SOPs for non-GXP processes as required.
- Together with RA/QA Director maintain and develop the non-GXP portion of the QMS system and manual.
- Contribute to the development of the communication and training strategy of non-GxP compliance; lead the implementation of compliance training and communication as required within the business units/functions.
- Educating employees on compliance and privacy policies and programs; including but not limited to training sessions for new employees / ongoing refreshers.
- Conduct internal employee training on LEO's Quality Management System, Group Guidelines and Group Policies (non-GxP).
- Act as Owner (SuperUser) of the MyDoc system for LEO Canada.
- Manage the applicability grid for all employees including local SOPs and Work Instructions, QMS documents, global strategic documents
- Work with Key Business User (KBU) in Region to manage applicability in the system and ensure timely rollouts of documents.
- Elevate system issues to KBU and work in partnership to resolve them as applicable.
- Train LEO Canada administrative personnel on the monitoring of SOP reading for their assigned departments.

3. Ownership of the LEO Canada HCP interactions process and system.

- Owner of the Health Care Professional (HCP) interactions system and process in partnership with responsible LEO personnel.
- Develop and maintain the SOP related to HCP interactions and ensuring timely training of other responsible parties ensuring local compliance.
- Manage incoming HCP interaction requests through global LEO HCP portal and ensure final compliance approval.
- Report trend deviations to the process to Senior Management and make recommen-

dations for improvement where needed to increase compliance.
- Work with internal systems support to deal with system issues; enhance system as much as possible given IT infrastructure.
- Ensure compliance to federal and provincial regulations with respect to HCP spend tracking and reporting; work internally to ensure system and processes enable extraction of this information for reporting purposes and return on investment analysis.
- Ensure HCP payments are in alignment with Fair Market Value; conduct regular external reviews to ensure competitiveness of grid.
- Support other departments with development of SOP's required to ensure compliance e.g. Grants, Donations, Sponsorships, HCP Vetting.

4. **Being the internal subject matter expert when it comes to non-GxP compliance policies and external legislation and trends.**
    - Staying abreast of regulatory changes in the non-GxP space. Resolving compliance issues in partnership with the business.
    - Be the internal subject matter expert with respect to non-GxP compliance; elevate external environment trends and laws to Senior Management and make recommendation to improve LEO Canada's compliance policies as required.
    - In partnership with HR and Senior Management, ensure that reported concerns related to non-GXP compliance are promptly and thoroughly investigated, with suitable corrective or remediation action and discipline when appropriate.
    - Acts as the subject matter expert with respect to privacy for LEO Canada.

5. **Auditing internal activities, documentation and training to ensure compliance with various internal SOPS and external legislations.**
    - Act as internal lead for any internal (Corporate) or External audits with respect to non-GxP elements.
    - Perform self-inspections (per established schedule), as well as regular process checks, on all departments other than QA, Regulatory, MIPV.
    - Prepare response documents to audit observations for non-GXP items.
    - Co-lead (non-GXP) Audit Readiness Committee in partnership with Director RAQA (GXP).

6. **Identifying internal insights and trends and making recommendations to improve compliance and efficiency.**

General

- Provide Canadian Leadership Team with regular updates on organizational compliance (deviations, audit readiness, audit tracking, non-compliance with processes, insights and trends) and make recommendations to improve gaps that may exist.
- Provides work direction and coaching/mentoring to administrative support to ensure timely completion of compliance objectives and responsibilities.
- Provides feedback to Director of RA/QA/Compliance on the performance of the administrative support.
- Ensure compliance with appropriate SOP's, policies and guidelines applicable to the Compliance Manager role.

- Complete mandatory training in assigned timelines upon hire as well as when new or revised policies, SOP's, guidances are issued.
- Participate in personal development and training sessions as required for the position.
- Work in a safe manner that does not endanger yourself or co-workers. Report any health or safety concerns (internal and external) in compliance with LEO policy and standard procedures.
- Strive to consistently uphold LEO Pharma's core values.
- Execute other duties as may be required by Executive team members and other members of LEO Pharma's Management team as training and experience allow.

Interview Process:

At LEO, finding the right person to join our organization is very important to us. As such, we conduct a very through interview process which allows both us and each candidate to assess fit with the company and the job. Below is an overview of the various steps that we take along our journey:

STEP	Details
Behavioural Assessments	Each candidate is asked to complete various behavioural assessments (Predictive Index and Insights) in order to provide LEO with a platform to engage in further discussions about your match with the job. Results are shared with each candidate during the process.
Interview with Human Resources	VP HR, Director Training & Development, External Compliance Consultant
Interview with the hiring manager/panel	President and CEO, VP Scientific Affairs, Business Unit Director Thrombosis, National Sales Manager
Reference and/or financial background checks	References are conducted for all hires and depending upon the position, a financial background check may also be required (roles in finance and for those with budget management responsibilities).

Application Process:

Interested applicants are asked to do the following within the job posting timelines:

1. Prepare a cover letter and resume and send them to the attention of Kimberly Stoddart at kisca@leo-pharma.com.
2. Internal applicants should follow step 1 and submit an Internal Application Form and have it signed by their immediate manager.