Canadian Custom Packaging

Job Posting

Job Title:	Regulatory Affairs and ISO Manager
Reports to:	General Manager
Type of position:	Full time Permanent

Position Description: This position is instrumental to the organization and provides complete Regulatory Affairs and ISO support to both internal departments, as well as directly to our customers. Main liaison with external partners such as auditors, inspectors, consultants, etc. on matters relating to Regulatory, ISO and QMS.

Key Responsibilities:

- Obtain and evaluate technical documentation relative to regulatory requirements.
  - On-going review of product compliance relative to the changing regulations
  - Implement appropriate strategies and changes necessary to meet evolving regulatory initiatives
- Plans and executes the preparation of regulatory submissions, amendments, and annual reports for all authorities and governing bodies
  - Including, providing assistance with annual product quality reviews (APQR) and adverse drug reporting (ADR) specifically in the area of literature search in support of annual summary reports.
- For markets outside Canada, (as required), works with regulatory contacts and consultants to facilitate preparation of their marketing application, post approval submission documents
- Monitors the progress of agency review of regulatory submissions and follows up with applicable parties
  - Coordinates, prepares, and submits response to Health Authority questions
  - Follows up with regulatory contact on their progress with the foreign agency
- Responsible to promote awareness of ISO standards and requirements throughout the organization
- Provides regulatory advice/support to internal departments such as R&D, QA, and product development
- Assist in the review of all technical documentation for product release; develop procedures and maintain files in compliance with Canadian GMP's
- Lead support to all Health Authority inspections such as Health Canada and FDA audits
- Lead support for all ISO audits
- Registering of products including DIN's, NHP's, Medical Devices, etc.
- Responsible for the renewal and maintenance of all licenses including DEL, MDE, NHP, etc.
- Reviews and prepares ingredient lists as requested
- Review and prepares SDS and MSDS's as requested
- Other duties as assigned

Skills & Qualifications:

Proficient in Microsoft office, including: outlook, word, excel, power point, TEAMS, etc.
Excellent organizational, time management, written and verbal communication skills
Demonstrated ability to work well under pressure, while managing conflicting priorities and tight deadlines
Ability to work professionally and collaboratively with all internal departments and external customers
Self-starter who is analytically minded, adept problem solver and able to work independently and efficiently
In-depth understanding of global regulatory requirements for cosmetics, DIN's, NHP's and Medical Devices

Education requirements:

University degree in Life Sciences (biology, chemistry, pharmacology), regulatory affairs program an asset
3+ years of direct regulatory experience in a manufacturing environment
Completion of ISO 9001:2000 Internal Auditor Training as asset

Qualified persons can send resumes to mbillings@cdncustompackaging.com