Regulatory-Affairs Specialist

Reports to: Director or Manager

Pharmabio Développement
Comité sectoriel de main-d'œuvre des industries des produits pharmaceutiques et biotechnologiques

Main Duties

may vary from one company to another

- **Participates in the development and implementation of the regulatory strategy:** compiles information and data pertaining to regulatory and project requirements; assesses needs; identifies the project's critical factors; presents decision-makers with options; applies strategies.
- **Assembles a regulatory file/dossier:** coordinates acquisition of all applicable data; assessed data; drafts and submits the regulatory file.
- **Monitors product files in the developmental phase:** updates data; reconciles requests from authorities based on scientific and ethical constraints; makes amendments/changes and submits them to authorities.
- **Conducts regulatory monitoring of approved products:** assists and supports in-house teams; maintains files current; ensures regulatory compliance; evaluates the effects of an amendment/change; takes appropriate regulatory actions.
- **Provides counselling to internal and external clients with regulatory issues:** ensures regulatory monitoring; formulates a regulatory opinion; supports employees and the management team; represents the company; conveys information about regulatory matters and their application.

Evolution of the Profession

- The duties and responsibilities of Regulatory-Affairs Specialists have expanded as a result of company acquisitions and restructuring, worldwide globalization of markets, and ever-evolving regulations.
- The office of regulatory affairs is considered one of a company's strategic pillars. The operations in support of the strategic aspects include file preparation, information management, file maintenance, and interaction with different departments. The guiding principle is to strike a balance between regulatory concerns, technology, marketing objectives, time to market, and costs.
- The office of regulatory affairs is an extremely dynamic work environment where communication with employees at all levels within the organization is of paramount importance.

Best Practices

- Upgrade knowledge in order to remain effective in the profession.
- Attend conferences as well as continuing-education and development activities.
- Regulatory-Affairs Specialists are required to undergo training on all direct and indirect aspects of drug development: good clinical practices, good laboratory practices, good manufacturing practices, regulations (Canada, United States, Europe, etc.), and management. Introductory courses in other areas — such as law, marketing, statistics, pharmacology, toxicology, communications and interpersonal relationships — are also recommended, as are a second language and software proficiency.

Main responsibilities[1]

Participation in the Development and Implementation of Regulatory Strategy

- Correctly compiles applicable guidelines for the project.
- Realistically defines the project profile.
- Consults external authorities in order to confirm the strategy.
- Accurately identifies short- and long-term needs.
- Ensures the high quality of written materials.
- Scrupulously analyzes risks.
- Formulates an organized contingency plan based on the project's critical factors and a risk-mitigation plan.
- Specifies the different project phases and the corresponding deadlines.
- Provides suitable support to stakeholders in implementing the strategy.
- Respects timelines.

Preparation, Submission, and Follow-up of a Regulatory File

- Properly documents all file data.
- Diligently verifies that collected data comply with the regulations in effect.
- Accurately analyzes and verifies file contents.
- Conducts proper assessments in order to anticipate questions and critical issues.
- Updates preclinical, clinical (efficacy and safety), and CMC (chemical-manufacturing control) data.
- Clearly responds to questions from regulatory authorities.
- Justifies position (legal, ethical, or scientific) when there are differences of opinion in connection with a request from regulatory authorities.
- Regularly monitors commitments/obligations in response to regulatory requirements or requests.
- Submits documentation to concerned authorities within prescribed timelines.

Regulatory Monitoring of an Approved Product

- Revises and approves the information in the product monograph, label, and finished-product documentation.
- Actively involved in reviewing promotional materials for compliance.
- Maintains drug identification number (DIN) and other licences.
- Properly prepares and submits annual notification of changes.
- Collects data and diligently analyzes the effects of a change.
- Properly notifies authorities about changes and their implementation.
- Properly manages post-approval commitment plans.

[1] As per the company's mode of operations.

Qualifications

Regulatory-Affairs Specialists have:

- A university degree in science (bachelor's, *D.É.S.S. [Diplôme d'Études Supérieures Spécialisées]),* master's, doctorate) biology, chemistry, biochemistry, toxicology, pharmacy, pharmacology, or a related discipline.
- Two to five years of relevant experience in research, laboratory testing, manufacturing procedures, or clinical trials.

Employers are looking for candidates who possess, among other skills, the following:

- Autonomy and leadership.
- Ability to communicate effectively, negotiate, and persuade.
- Ability to work on multiple projects at the same time.
- Ability to keep tight deadlines and work under pressure.
- Flexibility and ability to adapt to change.
- Sound judgment in applying regulatory requirements.
- Diplomacy and ease in establishing and maintaining interpersonal relationships.
- Strategic thinking as well as analytical and synthesis skills.
- Fluency in French and English (written and spoken).
- Scientific rigour, attention to detail, meticulousness.
- Organizational skills and structured work habits.

Career-Path Options

With experience, depending on interests and training, Regulatory-Affairs Specialists can aspire to, among other positions, the following:

- Project Leader.
- Director.
- Consultant.
- Regulatory-Agency Inspector.
- Trainer or Educator.

Competencies	Behavioral Indicators
Leadership Ability to influence achievement of strategic objectives.	• Evaluates the facts in order to make the best decisions. • Is able to negotiate and persuade. • Ensures proactive management of the company's response and commitment in dealings with authorities. • Makes realistic and appropriate decisions within a regulatory context.
Communication and Interpersonal Skills Ability to build relationships of trust and demonstrate professional ethics.	• Communicates clearly and effectively within all levels of the organization and with external resources. • Acts as liaison between authorities as well as outside partners and clients in order to provide adequate regulatory direction to in-house resources. • Develops effective working relationships. • Takes patient safety into account in all required regulatory actions. • Drafts reports within prescribed time lines in accordance with regulations.
Problem Solving Ability to implement solutions in response to regulatory changes.	• Adopts an innovative and rigorous approach to problem solving within a regulatory context. • Assesses the urgency of situations. • Proposes relevant solutions to achieve objectives.
Advisory Role Ability to support employees from different company departments and outside resources.	• Offers a strategic opinion compliant with the requirements of authorities. • Offers sound advice and assists managers in strategy development. • Performs monitoring activities and provides appropriate support to concerned resources. • Ensures that representatives of regulatory agencies are apprised of innovative drugs and new technologies. • Makes a positive contribution during representations.

Please refer to the *Regulatory-Affairs Specialist's Analyse de profession** and *Profil de compétences** for all additional information.
The Competency Profile was made through funding by *the Commission des partenaires du marché du travail.*
* This document has not been translated yet.

Commission des partenaires du marché du travail
Québec