



# Regulatory Affairs Specialist

Bio-economy Skills Profile



Building skills for Canada's bio-economy

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## About BioTalent Canada

### Helping Canada's Bio-economy thrive globally

Canada is a world leader in biotechnology—the application of living organisms to industrial, agricultural, medical and other processes and products. To maintain and build on this leadership, the sector needs highly trained, job-ready people.

By acting as a national hub and central resource for employers, job-seekers, students, educators and government agencies, BioTalent Canada helps make this happen.

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Building skills for Canada's bio-economy

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## About the BioTalent Canada bio-economy skills profiles

Biotechnology's fusion of science and business creates unique requirements for occupations in the sector. Executives and managers must have technical expertise; technical staff often need entrepreneurial skill sets. Occupational descriptions from other sources don't always fit the bio-economy context. That's why, in partnership with industry stakeholders, BioTalent Canada has developed skills profiles specific to the bio-economy including this description of the role of Regulatory Affairs Specialist.

## Occupational Definition

**Regulatory Affairs Specialists** perform a proactive role in directing and overseeing the development of new products and maintenance and care of existing marketplace products in the biotechnology industry, and use their specific scientific and regulatory knowledge to provide strategic input to the development process. They represent the company's interests and objectives while interacting and negotiating with regulatory agencies, and work to ensure product and company regulatory compliance in the pre- and post-approval stages. They seek to anticipate, reduce and manage risks associated with regulations related to product development; to influence and provide feedback to the development of new regulations, policies and guidelines; to be cognizant of reimbursement issues in product development; to ensure the quality and safety of the product; to advise on how products are sold and promoted; and to ensure quality standards of research are met. Regulatory Affairs Specialists work for Canadian bio-economy companies of different sizes (e.g., small, medium, large) and in various bio-economy areas, such as:

- Agriculture
- Aquaculture
- Bioenergy
- Bioinformatics
- Bioproducts
- Biosciences
- Environment
- Food Processing
- Forestry
- Genomics
- Human Health
- Industrial
- Life Sciences
- Medical Devices
- Natural Resources
- Nanotechnology
- Nutraceuticals
- Pharmaceuticals

### ***Components of the skills profile***

Every BioTalent Canada skills profile presents the areas of competence, tasks and sub-tasks associated with a specific occupation.

**Area of competence (AC):** This describes a major function or responsibility associated with the profession, trade or position.

**Task:** This is a specific, observable unit of work with definite start and end points. Tasks can be broken down into two or more steps and are generally performed in a limited period of time. Tasks and ACs are identified in behavioural terms, beginning with a verb that describes the applied behaviour.

**Subtask:** This is a distinct, observable activity that comprises the steps involved in a task.

**Important Action/Performance Standard:** This provides a criterion for assessing competence and may be used as a performance indicator.

### ***Focus on competencies***

The BioTalent Canada skills profiles are built around *areas of competence* because competencies are flexible, inclusive and linked directly to performance: they are the traits or qualities a professional must have to succeed in a given role within a given organization, and can be used for recruiting, professional development, curriculum planning and many other purposes.

### ***How to use the profiles***

The complete contents of this or any BioTalent Canada skills profile are unlikely to be used for any one position. Because they are comprehensive, they include every area of competence, task and subtask that *could* be required for a specific occupation. In reality, the definition of a given job will encompass a narrower subset of the profile. Hiring organizations must choose the elements of the profiles that are relevant to their businesses—and tailor those elements as necessary to more precisely describe their particular job requirements.

The profiles can be put to many uses:

- **Employers** can use them to develop job descriptions, performance evaluations, professional development, succession planning, team building, target skills needed, and recruitment plans.
- **Job seekers** can use them to tailor their resumes, prepare for interviews, see job descriptions and identify additional professional development needs.
- **Educators** can build industry-oriented curricula from the profiles to produce job-ready graduates.
- **Students** can enhance their understanding of employers' expectations and choose the right educational programs to equip themselves with the skills for success.

### **Scenario**

The following illustrates how an employer might use the BioTalent Canada skills profiles to identify professional development priorities for his or her team.

#### *Step 1*

The employer would review the ACs for each occupation and identify which apply to the related positions within his or her company, omitting those that are not relevant.

#### *Step 2*

Under the selected ACs, the employer then notes which of the associated tasks, subtasks and important actions are relevant to that specific position within his or her business.

#### *Step 3*

Now with a complete, tailored profile, the employer can assess employee performance. Needs areas are easily identified and defined—to a significant depth of detail.

#### *Step 4*

Based on the needs analysis, the employer can either develop or seek out professional development programs that address employee needs areas.

## **Situational Analysis**

The functions of a Regulatory Affairs Specialist is one that demands specialized technical and scientific knowledge, although this background knowledge may originate from experience in various scientific fields. Regulatory Affairs Specialists play a key role in a variety of disciplines and, as a result, job incumbents may perform multiple regulatory functions. Regulatory Affairs Specialists must communicate effectively and in an informed manner with a variety of people. They must assist in providing guidance and coaching to specialists, staff and peers regarding fulfilment of responsibilities in adhering to regulatory Standard Operating Procedures (SOPs), operational SOPs and internal departmental procedures. They must communicate in the same language as their product and process development colleagues, and interact and negotiate with regulatory agencies.

Regulatory Affairs Specialists work with, develop and oversee the completion of a variety of documents to ensure regulatory compliance. Regulatory Affairs Specialists establish and maintain regulatory information systems both electronically and in hard copy. They work to ensure that documents are accurately presented, scientifically sound, and encompass all relevant material necessary for a complete submission and represent the best interests of the company.

As part of the product development process, Regulatory Affairs Specialists take an active, early role. They take part in scientific analysis, manage project timelines, prepare clinical and regulatory development plans, and provide clinical/regulatory strategic consulting services. They participate in business/product development efforts and provide significant guidance on regulatory requirements to the development team. They must apply and observe Good Laboratory Practices (GLP) and Quality System Regulations (QSR) while organizing and planning their work. They must also understand and promote safety and efficacy and ensure adherence to applicable SOPs and internal department procedures. They apply and oversee adherence to national and international regulations, and to the regulatory processes of industrialized markets as well as emerging markets. Regulatory Affairs Specialists maintain databases, and may manage the complaint handling system. They complete work in a timely manner and must work well under the pressure to meet deadlines. They adapt procedures, processes and techniques to complete assignments in line with the company's activities and goals, and may be required to develop and innovate processes that are 'value added'.

Regulatory Affairs Specialists must identify and manage risk. They may assess risk through functional analysis, fault-tree analysis, failure modes and effects analysis, hazard analysis and critical control point analysis (for example, Six Sigma methods). They identify regulatory options and seek to reduce risks of gaps present in data submitted at registration and to reduce time to market. They apply a problem-solving approach and work to reduce loss and control liability. They must understand the risks and legal consequences associated with product failures, and may advise on recalls, crisis management insurance and legal actions. They may also conduct post-marketing risk management.

Regulatory Affairs Specialists must be diligent, detail-oriented individuals who are able to work well independently. Attention to detail is particularly important when preparing applications. They should be technically and analytically adept, and should promote integrity in their work. They must be able to communicate and negotiate effectively, and be proficient at preparing and working with various documents.

Entry into the occupation of Regulatory Affairs Specialist is almost universally based on a post-secondary degree, preferably in a relevant scientific field such as biology, chemistry, biochemistry, engineering, agriculture, health, medicine, nursing, pharmacy, food and nutrition. Some Regulatory Affairs Specialists who are performing supervisory functions also commented that a business degree can be a helpful background for the occupation. A review of current industry job postings revealed that a Masters or PhD in a related scientific field or the completion of a certificate in Regulatory Affairs from a recognized post-secondary institution are highly desirable educational backgrounds. They could not overemphasize the importance of on-the-job training experience in the biotechnology industry.

Regulatory Affairs Specialists entering the biotechnology industry may achieve an edge over the competition through the acquisition of foundational or specialized industry knowledge, certification through a recognized professional association, or useful skills such as familiarity with or competence in e-filing techniques for applications. Project management experience and experience in processing documents for submission or good manufacturing procedures compliance is generally considered an asset.

Regulatory Affairs Specialists must be willing to spend time learning on-the-job and be prepared to evolve with the continuous changes and developments inherent to the regulatory field in the biotechnology industry. They should be adaptable to changing work environments, projects and priorities. It is desirable that Regulatory Affairs Specialists have specialization in a functional scientific area or service, and they must seek to remain current with emerging scientific and industry trends, regulations and requirements.

Biotechnology industry-specific knowledge is an important factor in the training, recruitment, employment and retention of individuals working as Regulatory Affairs Specialists in the Canadian biotechnology industry.

The ever-evolving nature of the regulatory industry translates into increased workloads for Regulatory Affairs Specialists as there are increasing rules and regulations to comply with. Rising prices are making it much less possible for smaller companies to develop a drug from start to finish. A need for Regulatory Affairs Specialists to be increasingly flexible and knowledgeable about related science and fields as companies partner and expand or alter the focus of their research and developments. Another significant industry trend is global harmonization. Regulatory Affairs Specialists must thus stay abreast of company or organizational movements towards increased standardization and harmonization. They must monitor the transition toward electronic processes and media. There is an increased demand of open transparency toward the public. It seems that, confronted with increasing financial challenges for operating and developing, Regulatory Affairs Specialists may also be needing to defend their role in the research and development process.

## Essential Skills

The most important Essential Skill(s) for this Profile:				
	Reading Text	✓	Thinking Skills – Problem Solving	Working With Others
✓	Document Use		Thinking Skills – Decision Making	Computer Use
✓	Writing		Thinking Skills – Critical Thinking	Continuous Learning
	Numeracy		Thinking Skills – Job Task Planning & Organizing	
	Oral Communication		Thinking Skills – Significant Use of Memory	
			Thinking Skills – Finding Information	

Regulatory Affairs Specialists set their own learning goals and take advantage of a variety of internal and external continuing education opportunities. To stay abreast of new products, trends and regulatory developments they read industry publications and professional journals, review industry discussion boards and attend annual conferences. They may fill out company training records to confirm that they have read new standards. Depending on their company’s regulatory activities they may be required to take and update courses such as auditing courses or recall and complaint handling courses. Regulatory Affairs Specialists who have regulatory affairs certification may update their learning on a periodic basis.

To succeed in their work, Regulatory Affairs Specialists must be co-operative, diligent, helpful individuals who have the ability to negotiate and enforce regulations. They should approach work with a motivated, analytical attitude and also maintain a positive outlook when addressing the difficulties inherent to the job.

In the future, increasingly stringent and numerous regulations will require Regulatory Affairs Specialists to be more diligent and informed when registering products and carrying out audits and validations. The trend toward fully electronic submissions will require Regulatory Affairs Specialists to be increasingly computer literate. The trend toward global harmonization of regulations will mean that companies and organizations will look to harmonize and standardize their processes and products. This will require Regulatory Affairs Specialists to actively seek out and take advantage of continuous learning opportunities.

## Language Benchmarks

Regulatory Affairs Specialists must be able to perform the full range of tasks and will need an upward language benchmark level of 12. The majority of the criteria used in the Canadian Language Benchmarks were found to be between the levels of 8 – 12.

## Competency Profile

A Regulatory Affairs Specialist must be able to:

### **A. Contribute to regulatory agency initiatives**

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Carry out regulatory intelligence activities	1.1 Identify websites of interest	For example: <ul style="list-style-type: none"> <li>• Food and Drug Administration</li> <li>• Health Canada</li> <li>• European Union</li> <li>• Industry associations</li> <li>• Non-governmental organizations (NGOs)</li> <li>• International Standards Organization (ISO)</li> <li>• Government</li> <li>• Agency</li> </ul>
	1.2 Subscribe to industry blogs or website communications	
	1.3 Review and assimilate information from relevant literature	For example: <ul style="list-style-type: none"> <li>• Global websites</li> <li>• Publications</li> <li>• Email lists</li> <li>• Pink sheets</li> <li>• Blogs</li> <li>• Industry-based newsletters</li> <li>• Comprehensive summaries of current news</li> </ul>
	1.4 Process, archive and retrieve information	For example, put on company's website or intranet

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	1.5 Alert or communicate relevant information to appropriate audiences	
	1.6 Attend industry and professional association meetings	
	1.7 Monitor codes of practice, standards, guidelines, legislation and their development	
2. Provide input to draft policies and guidances	2.1 Identify and interpret draft policies and guidances relevant to the company	Follow company policies and procedures Comply with laws and ethics
	2.2 Communicate initiatives to company	
	2.3 Research and review draft policies or guidances	Follow company policies and procedures Comply with laws and ethics
	2.4 Identify issues in draft policies or guidances	Follow company policies and procedures Comply with laws and ethics
	2.5 Provide feedback to regulatory agencies	Follow company policies and procedures
3. Coordinate company input	3.1 Develop plan and timeline	Follow company policies and procedures
	3.2 Identify contributors to review	Follow company policies and procedures
	3.3 Facilitate discussion and/or review of draft policy or guidance	Follow company policies and procedures
	3.4 Compile issues and comments	Follow company policies and procedures
	3.5 Co-ordinate review of compilation	Follow company policies and procedures
	3.6 Coordinate international regulatory policy initiatives	Follow company policies and procedures
	3.7 Submit compilation to regulatory agency or via industry association	Follow regulatory agency requirements
	3.8 Communicate outcome to internal stakeholders	Follow company policies and procedures
	3.9 Guide, coach and mentor contributors to reviews	

<b>TASKS</b>	<b>SUBTASKS</b>	<b>IMPORTANT ACTIONS / PERFORMANCE STANDARDS</b>
4. Participate in industry association meetings	4.1 Monitor industry communications for relevant meetings	Follow company policies and procedures
	4.2 Express interest in attending and contributing to consultations	Follow regulatory agency requirements
	4.3 Attend and contribute to meeting or consultation	Follow company policies and procedures
	4.4 Proactively identify and propose regulatory initiatives to the industry association and/or government	
	4.5 Share company's issues and comments	Follow company policies and procedures
	4.6 Communicate outcome of meeting to internal stakeholders and act on outcomes, as appropriate	Follow company policies and procedures
5. Participate in regulatory agency pilot projects, as required	5.1 Monitor regulatory agency and industry websites	
	5.2 Identify projects relevant to the company	
	5.3 Express interest in participation to regulatory agency	Follow company policies and procedures
	5.4 Participate in project and feedback to regulatory agency	
	5.5 Communicate outcome to internal stakeholders and act on outcomes, as appropriate	Follow company policies and procedures
6. Lobby to influence on behalf of your organization or industry	6.1 Register as lobbyist, as necessary	
	6.2 Define target organizations and individuals	For example: <ul style="list-style-type: none"> <li>• Government and administrators</li> <li>• Members of Parliament</li> </ul>

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
		<ul style="list-style-type: none"> <li>• Ministers</li> <li>• Deputy ministers</li> <li>• Civil servants</li> <li>• Chiefs of Staff</li> <li>• Regulators</li> </ul>
	6.3 Prepare strategy for meetings, letters, etc.	
	6.4 Execute the strategy	

*A Regulatory Affairs Specialist must be able to:*

**B. Apply regulations**

<b>TASKS</b>	<b>SUBTASKS</b>	<b>IMPORTANT ACTIONS / PERFORMANCE STANDARDS</b>
1. Interpret regulations	1.1 Assimilate and interpret information from relevant regulations and standards	Follow regulatory agency requirements
	1.2 Interpret existing regulations in context to the current situation	
	1.3 Consult with experts when interpreting regulations and guidelines	Ask wider than own experience, as appropriate. For example, consult: <ul style="list-style-type: none"> <li>• Legal experts</li> <li>• Regulatory consultants</li> <li>• Colleagues</li> <li>• Industry associations</li> </ul>
	1.4 Cross-reference new regulations with existing regulations	
	1.5 Determine critical studies and compliance needs, when required	Follow company policies and procedures
	1.6 Summarize key elements or requirements	Follow company policies and procedures
	1.7 Provide regulatory direction	
2. Perform impact assessment	2.1 Analyze what processes may be involved	Follow regulatory procedures
	2.2 Identify where new and existing requirements apply	Follow regulatory procedures
	2.3 Identify new and existing studies/processes or documents for each requirement	Follow regulatory procedures
	2.4 Complete summary document and flow chart, if needed	Follow regulatory procedures
	2.5 Identify risks for non-compliance	Follow regulatory procedures

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	2.6 Identify business opportunities in new regulations	
3. Create internal position papers/action plans	3.1 Identify issue for action	
	3.2 Explain key regulatory requirements and refer to the act or legislation, as required, and reinterpret against current policies and guidelines	Follow regulatory procedures
	3.3 Compile executive summary of requirements, procedure changes, impacts and non-compliance risks	Follow company policies and procedures
	3.4 Outline regulatory decisions or directions for compliance	Follow company policies and procedures
	3.5 Identify internal stakeholders impacted and communicate news and impact to organization in understandable terminology	For example, communicate the regulation and the impact  Follow company policies and procedures
4. Create or modify plans/procedures for implementation of regulations, as required	4.1 Develop or modify standard templates	In the document: <ul style="list-style-type: none"> <li>• Cross-reference to position paper</li> <li>• List regulatory requirements</li> <li>• Develop steps for compliance</li> <li>• Identify standards required</li> </ul> When modifying the document: <ul style="list-style-type: none"> <li>• Cross-reference with position paper</li> <li>• Identify procedure changes for each item on the procedure document</li> <li>• Submit modified procedures for review</li> <li>• Review and edit any approval changes, if applicable</li> </ul>

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
		Follow company policies and procedures
	4.2 Cross-reference to position paper	Follow company policies and procedures
	4.3 Perform gap analysis	
	4.4 List regulatory requirements	Follow company policies and procedures
	4.5 Develop steps for compliance	Follow company policies and procedures
	4.6 Identify internal standards required	Follow company policies and procedures
	4.7 Obtain required approvals	Obtain approvals from management and relevant stakeholders, following company policies and procedures
	4.8 Implement document control procedures	For example: <ul style="list-style-type: none"> <li>• Routing</li> <li>• Filing</li> <li>• Archiving</li> </ul> Follow company policies and procedures
	4.9 Identify alternative paths to compliance, or produce arguments for why requirements do not apply	
5. Communicate plan and procedure related to regulation in question to stakeholders	5.1 Identify list of stakeholders impacted, as required	Communicate the plan and procedure to be followed as a result of the new regulation
	5.2 Develop presentation/summary in understandable terminology	Follow company policies and procedures
	5.3 Send request for meeting to stakeholders explaining what the issue is and why it is important	Follow company policies and procedures
	5.4 Organize communication or meeting with relevant hand-out material	Follow company policies and procedures

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	5.5 Communicate or make presentation to stakeholders	Follow company policies and procedures
	5.6 Seek feedback and check for understanding	Follow company policies and procedures
	5.7 Seek buy-in with stakeholders	Follow company policies and procedures
	5.8 Proceed to arrange training	Follow company policies and procedures
6. Provide periodic regulatory training	6.1 Identify list of groups or individuals to be trained	
	6.2 Provide clear direction on needs for trainees and job incumbents	
	6.3 Seek management approval on the training list	Follow company policies and procedures
	6.4 Arrange timing and mechanism for training	
	6.5 Develop documents needed for training	Follow company policies and procedures
	6.6 Implement a training program or carry out additional training, as necessary	Follow company policies and procedures
	6.7 Seek feedback and check for understanding	Follow company policies and procedures
	6.8 Document participation in the training event	Follow company policies and procedures
	6.9 Follow up audit of procedural changes	Follow company policies and procedures
	6.10 Assess need for adjustments	Follow company policies and procedures
	6.11 Repeat training, as necessary	Follow company policies and procedures
	6.12 Determine and create a specialist database for critical reviews and priority reviews	
7. Implement procedure	7.1 Establish implementation date	
	7.2 Ensure implementation	

A Regulatory Affairs Specialist must be able to:

**C. Manage regulatory processes to maintain compliance with current regulations**

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Develop regulatory processes	1.1 Define the objectives of the required regulatory process	Follow company policies and procedures
	1.2 Determine applicable guidelines	For example, review: <ul style="list-style-type: none"> <li>Regulatory agency requirements</li> <li>Company policy</li> </ul> Follow company policies and procedures
	1.3 Determine contributors/participants	Follow company policies and procedures
	1.4 Conduct working meetings	Follow company policies and procedures
	1.5 Draft the process in compliance with company policies and procedures	Maintain awareness of and observe current company policies, procedures and processes
	1.6 Circulate for review/approval	Follow company policies and procedures
	1.7 Conduct and document training	Follow company policies and procedures
	1.8 Implement the process	Follow company policies and procedures
2. Maintain regulatory processes	2.1 Perform periodic reviews	Follow company policies and procedures
	2.2 Identify updates required	Follow company policies and procedures
	2.3 Seek buy-in for the process, as required for update	
	2.4 Update the process	Follow company policies and procedures
	2.5 Circulate for review/approval	Follow company policies and procedures
	2.6 Conduct and document training or give notification of update	Follow company policies and procedures
	2.7 Implement updated process	Follow company policies and procedures
3. Comply with company policies, procedures and processes	3.1 Maintain awareness of current policies, procedures and processes	Follow company policies and procedures

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.2 Ensure training (formal or self) is completed and documented in a timely manner	Follow company policies and procedures
	3.3 Ensure the policies, procedures and processes are followed	Follow company policies and procedures
	3.4 Monitor timelines and strive for efficiency	
4. Review regulated or controlled documents	4.1 Establish requirements for review	
	4.2 Review regulated or controlled documents on a periodic basis, as per requirements (internal or external)	Follow company policies and procedures Follow regulatory agency requirements
	4.3 Consult with regulatory peers, if necessary, and compile comments	Follow company policies and procedures Follow regulatory agency requirements
	4.4 Provide comments to author	Follow company policies and procedures Follow regulatory agency requirements
5. Maintain registration databases, as required	5.1 Update the registration database, as required	Follow company policies and procedures
	5.2 Ensure verification of updates	Follow company policies and procedures
	5.3 Notify relevant stakeholders of updates	Follow company policies and procedures
6. Manage information contained within the regulatory Information Management Systems	6.1 Ensure access is controlled to the system	For example, to: <ul style="list-style-type: none"> <li>• Registration database</li> <li>• Quality database</li> <li>• List of questions database</li> </ul> Follow company policies and procedures
	6.2 Maintain the information management system and update, as necessary	For example, validate updates and notify stakeholders of updates

<b>TASKS</b>	<b>SUBTASKS</b>	<b>IMPORTANT ACTIONS / PERFORMANCE STANDARDS</b>
	6.3 Develop and maintain training materials	Follow company policies and procedures Follow regulatory guidelines, for example, International Conference on Harmonization (ICH)
	6.4 Train the users and document the training, as required	Follow company policies and procedures Follow regulatory guidelines, for example, International Conference on Harmonization (ICH)
	6.5 Provide assistance to users in terms of system and process	Follow company policies and procedures Follow regulatory guidelines, for example, International Conference on Harmonization (ICH)
	6.6 Perform periodic audits to ensure adherence to processes	Follow company policies and procedures Follow regulatory guidelines, for example, International Conference on Harmonization (ICH)
7. Share learnings with colleagues	7.1 Conduct 'lessons learned' meetings, as required	Follow company policies and procedures
	7.2 Draft 'lessons learned' summaries	Follow company policies and procedures
	7.3 Circulate for review/approval	Follow company policies and procedures
	7.4 Communicate 'lessons learned' to interested parties	Follow company policies and procedures
	7.5 Implement 'lessons learned'	Follow company policies and procedures

A Regulatory Affairs Specialist must be able to:

**D. Develop regulatory strategies**

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Develop clear product or project scope	1.1 Identify company requirements	For example, with regards to: <ul style="list-style-type: none"> <li>• Marketing authorization</li> <li>• Clinical trial applications</li> <li>• Medical affairs initiatives</li> <li>• Corporate affairs/provincial initiatives</li> <li>• Commercial activities (Sales and Marketing)</li> <li>• Pharmacovigilance</li> <li>• Manufacturing</li> </ul>
	1.2 Confirm product types	For example, Therapeutic Product Profile (TPP)  Follow company policies and procedures
	1.3 Confirm intended use or indication	Follow company policies and procedures
	1.4 Confirm intended patient population, end-user or targeted industry/segment	Follow company policies and procedures
	1.5 Confirm targeted mechanism of action, operating principle, as applicable	Follow company policies and procedures
	1.6 Confirm intended markets	For example, determine: <ul style="list-style-type: none"> <li>• Regions</li> <li>• Countries</li> </ul> Follow company policies and procedures
	1.7 Confirm targeted launch timelines	Follow company policies and procedures
	1.8 Confirm proposed development plan	Follow company policies and procedures
	1.9 Identify applicable agencies	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
2. Identify applicable regulatory requirements for the product or project	2.1 Review and assimilate information relevant to the project	Follow company policies and procedures  For example, from: <ul style="list-style-type: none"> <li>• Agency</li> <li>• Government</li> <li>• ISO</li> <li>• NGOs</li> <li>• Industry Association</li> </ul> Resources such as: <ul style="list-style-type: none"> <li>• Websites</li> <li>• Email lists</li> <li>• Newsletters</li> <li>• Publications</li> </ul>
	2.2 Advise on critical studies and compliance needs	Follow company policies and procedures
	2.3 Summarize key elements or requirements	Follow company policies and procedures
	2.4 Analyze what processes may be involved	Follow regulatory procedures
	2.5 Identify required studies, processes or documents	Follow regulatory procedures
	2.6 Review previous similar submissions and correspondences	For example, requests for additional information
	2.7 Compile a 'document inventory list' of required documents, data and reports based on requirements and previous submissions for each region or agency	
	2.8 Consult with internal and external experts to assist in building strategy	
	2.9 Determine best format for the intended audience	

<b>TASKS</b>	<b>SUBTASKS</b>	<b>IMPORTANT ACTIONS / PERFORMANCE STANDARDS</b>
3. Identify opportunities and restrictions	3.1 Observe regulations, policies and guidelines	
	3.2 Perform gap analysis, as required	
	3.3 Compare scope against regulatory requirements and note or document discrepancies, deficiencies and redundancies with regard to planned actions	For example: <ul style="list-style-type: none"> <li>• Patent issues</li> <li>• First-to-market approval</li> <li>• Data protection</li> <li>• Creating best label</li> </ul>
4. Identify options	4.1 Compare identified opportunities and restrictions against regulatory requirement(s)	For example, alternate strategy
	4.2 Brainstorm on options with weighted probabilities of feasibility and approvals	
	4.3 Generate risk-benefit analysis and management plan	
5. Develop plan, critical path and timelines, as required	5.1 Identify project timeline and costs	
	5.2 Map out required documents, key steps and information versus timeline	For example, use Gantt chart, create deliverable list, conduct gap analysis
	5.3 Coordinate reviews	
	5.4 Identify contributors	For example, assign area subject matter experts or owners for required documents, key steps and information to act as contributors and reviewers
	5.5 Ensure alignment of plan with internal stakeholders	
	5.6 Obtain input from product team	
	5.7 Obtain input from subject matter experts	For example, route strategy through subject matter experts and revise and obtain support as required or as possible

<b>TASKS</b>	<b>SUBTASKS</b>	<b>IMPORTANT ACTIONS / PERFORMANCE STANDARDS</b>
6. Author regulatory strategy documents, as required	6.1 Formalize regulatory strategy	For example, Gantt chart, executive summary
	6.2 Route documents for review and edit through regulatory team and other stakeholders	Follow company policies and procedures
	6.3 Revise plan and obtain support as required or as possible	For example, support from regulatory manager for final strategy documents
7. Consult with regulatory agencies, if required	7.1 Determine appropriate method of consultation	For example, communicate with regulatory agency via: <ul style="list-style-type: none"> <li>• Telephone</li> <li>• E-mail</li> <li>• Meeting</li> <li>• Management/director</li> </ul> Follow regulatory procedures
	7.2 Document all communication	
	7.3 Carry out pre-submission consultation with regulatory agencies	
	7.4 Incorporate feedback and any required or feasible recommendations into a strategy document	
8. Present strategy for management approval, as required		Follow company policies and procedures
9. Revise, complete and obtain approval for strategy	9.1 Obtain senior management/director approval	Follow company policies and procedures

A Regulatory Affairs Specialist must be able to:

**E. Implement regulatory strategies**

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Continually monitor regulatory requirements/environment	1.1 When changes are required: <ul style="list-style-type: none"> <li>• Review and assimilate information relevant to the project</li> <li>• Advise on critical studies and new compliance needs</li> <li>• Summarize key elements of new requirements</li> <li>• Analyze what processes may be involved</li> <li>• Identify required studies, processes or documents</li> </ul>	
2. Initiate strategy	2.1 Establish start date	
	2.2 Inform stakeholders that strategy has been initiated	
3. Evaluate project progress periodically	3.1 Assess and document impacts of changes, deviations from other functional strategies and plans on regulatory strategy during periodic, routine stakeholder and cross-functional product team meetings	Ensure representation of regulatory on company product team, if applicable  Follow company policies and procedures
4. Seek and provide input into project activities	4.1 Evaluate and, if necessary, integrate planned changes or deviations from other functional strategies and plans that impact the regulatory strategy	Follow company policies and procedures
	4.2 Negotiate actions associated with planned changes or deviations to mitigate,	

<b>TASKS</b>	<b>SUBTASKS</b>	<b>IMPORTANT ACTIONS / PERFORMANCE STANDARDS</b>
	minimize or eliminate impacts on the regulatory strategy	
	4.3 Document outcomes of negotiations	Follow company policies and procedures
5. Adjust regulatory project strategy	5.1 Adjust regulatory strategy based on documented outcomes, as required	
6. Communicate status of regulatory project	6.1 Communicate to all internal and external stakeholders, as applicable	<p>Follow company policies and procedures regarding confidentiality</p> <p>For example, communicate status to:</p> <ul style="list-style-type: none"> <li>• Business Director(s)/ Leader(s)</li> <li>• Business or Product Manager(s)</li> <li>• Corporate Regulatory Affairs (if not the manufacturer or parent organization)</li> <li>• General Manager (for the significant product launchers or initiatives)</li> <li>• Research and Development Team</li> <li>• Contract Manufacturing Organizations (CMO)</li> <li>• Contract Research Organizations (CRO)</li> <li>• Industry partners</li> </ul>
7. Update strategy in response to regulatory agency feedback on the project, as required, to the point of project completion	7.1 Review regulatory agency feedback and assess impact on the strategy and what needs to be changed in the strategy	
	7.2 Update and conduct internal review of the revised strategy	
	7.3 Circulate strategy for internal approval	
	7.4 Implement project with updated strategy	

A Regulatory Affairs Specialist must be able to:

**F. Prepare submissions\***

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Identify submission content	1.1 Determine submission type required	For example: <ul style="list-style-type: none"> <li>• Clinical trials</li> <li>• Marketing authorization</li> </ul>
	1.2 Review relevant guidelines	Follow applicable regulatory requirements and guidelines  For example, <ul style="list-style-type: none"> <li>• International Conference on Harmonization (ICH) Common Technical Document (CTD)</li> <li>• Health Canada Food and Drug Regulations</li> <li>• Organization for Economic Co-operation and Development (OECD)</li> </ul>
	1.3 Evaluate data	For example: <ul style="list-style-type: none"> <li>• Clinical data</li> <li>• Manufacturing data</li> </ul>
	1.4 Develop core data sheets for labelling	
	1.5 Perform gap analyses	Review previous submissions for guidance
	1.6 Utilize standard company templates	
	1.7 Review previous submissions, as required	

\* Regulatory Affairs Specialists carry out Areas of Competence A through E (A - Contribute to regulatory agency initiatives, B - Apply regulations, C - Manage regulatory processes, D - Develop regulatory strategies, and E - Implement regulatory strategies) to arrive at the point of Preparing Submissions.

<b>TASKS</b>	<b>SUBTASKS</b>	<b>IMPORTANT ACTIONS / PERFORMANCE STANDARDS</b>
	1.8 Create a list of associated documents and develop table of contents	Follow company policies and procedures Follow accepted company practice
	1.9 Identify contributors/authors of various sections, as required	Follow company policies and procedures
	1.10 Collect data required for the dossier	For example: <ul style="list-style-type: none"> <li>• Clinical trial reports</li> <li>• Research reports</li> <li>• Clinical Trial Application (CTA)</li> <li>• Investigational New Drug (IND)</li> </ul>
	1.11 Establish timelines for the components for the submission	
2. Identify and consult with contributors/authors of various sections	2.1 Conduct submission meetings with contributors	Follow company policies and procedures
	2.2 Track progress of associated document completion	
	2.3 Manage timelines for associated document completion	Follow regulatory agency requirements
	2.4 Confirm document requirements and availability	Measure performance by timelines of progress versus plan
3. Author summaries, if required	3.1 Review relevant source documents	Follow company templates and standards
	3.2 Write summaries based on associated source documents	Follow national and international regulatory agency requirements and guidelines  For example: <ul style="list-style-type: none"> <li>• International Conference on Harmonization (ICH)</li> <li>• Common Technical Document (CTD)</li> <li>• Health Products and Food Branch (HPFB)</li> <li>• Food and Drug Administration (FDA)</li> <li>• European Medicines Agency (EMA)</li> </ul>

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.3 Coordinate review by subject matter experts, contributors and management	Follow company policies and procedures
	3.4 Cross-reference to source documents	
4. Review and approve summaries	4.1 Compare summary to source documents for consistency and accuracy	Follow regulatory agency requirements
	4.2 Read and understand required guidelines and determine compliance	
	4.3 Edit summaries	Edit for, for example: <ul style="list-style-type: none"> <li>• Language</li> <li>• Formatting</li> <li>• Objectivity</li> <li>• Completeness</li> <li>• Bias (fair/balance)</li> <li>• Scientific validity</li> </ul> Follow company policies and procedures
	4.4 Peer review summaries with external experts, if desired	
5. Review and approve/prepare associated source documents, as required	5.1 Review source documents for accuracy and completeness	Review reports and protocols, for example: <ul style="list-style-type: none"> <li>• Clinical study protocols</li> <li>• Clinical study reports</li> <li>• Chemistry manufacturing documents</li> <li>• Toxicological study protocols</li> <li>• Informed Consent Forms</li> <li>• Investigator’s Brochures</li> </ul>
	5.2 Ensure document compliance	Follow, for example: <ul style="list-style-type: none"> <li>• International Conference on Harmonization (ICH)</li> <li>• National regulatory agencies’ GxPs:               <ul style="list-style-type: none"> <li>▪ Good Manufacturing Practices (GMP)</li> </ul> </li> </ul>

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
		<ul style="list-style-type: none"> <li>▪ Good Clinical Practices (GCP)</li> <li>▪ Good Laboratory Practices (GLP)</li> <li>• International Organization for Standardization (ISO)</li> </ul>
	5.3 Review conclusions to ensure fit with label	Review for, for example: <ul style="list-style-type: none"> <li>• Language</li> <li>• Accuracy</li> <li>• Appropriateness</li> </ul>
6. Approve source documents for inclusion in the submission	6.1 Ensure availability of the source documents	Follow company policies and procedures Follow established timelines Follow regulatory agency requirements
7. Sign-off on dossier	7.1 Obtain sign-off/approval on dossier from stakeholders	Stakeholders such as: <ul style="list-style-type: none"> <li>• Functional leaders</li> <li>• Senior regulatory manager</li> </ul>
8. Develop Label	8.1 Identify target indication and patient population	Develop the product monograph, United States Product Information (USPI) or European Summary of Product Characteristics (SmPC)
	8.2 Consult with relevant stakeholders	Stakeholders such as: <ul style="list-style-type: none"> <li>• Marketing</li> <li>• Medical</li> <li>• Clinical scientists</li> <li>• Provincial formulary</li> </ul>
	8.3 Based on core data sheet, input the relevant information into label format	
	8.4 Circulate internally for review and comment	
	8.5 Revise per feedback obtained	
	8.6 Finalize the label	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
9. Complete administrative documents	9.1 Obtain required information to complete documents	For example, review: <ul style="list-style-type: none"> <li>• Patent information</li> <li>• Application numbers</li> <li>• Previous submissions</li> </ul> Follow company policies and procedures
	9.2 Circulate for review	Follow company policies and procedures
	9.3 Obtain required signatures	Follow company policies and procedures
	9.4 Copy and archive, as required	Follow regulatory agency requirements
10. Populate and publish submission	10.1 Compile regulatory dossiers in appropriate format	For example, select: <ul style="list-style-type: none"> <li>• Paper</li> <li>• Electronic submission</li> <li>• Hybrid</li> </ul> Follow company publishing standards Follow regulatory agency requirements
	10.2 Cross reference or hyperlink	
	10.3 Validate	
	10.4 Check source documents for compliance with formatting standards, if required	Follow company publishing standards
	10.5 Remediate non-compliant and legacy documents, if required	Follow company publishing standards
	10.6 Prepare dossiers in appropriate, compliant format	For example, place into binders Follow company publishing standards
	10.7 Check to ensure completeness and consistency	Follow company publishing standards
	10.8 Periodically update submission content	Follow company publishing standards

<b>TASKS</b>	<b>SUBTASKS</b>	<b>IMPORTANT ACTIONS / PERFORMANCE STANDARDS</b>
11. Submit dossiers	11.1 Dispatch dossier through appropriate electronic or physical means	For example, transmit electronic dossiers through secure gateways  Follow company policies and procedures Follow regulatory agency requirements
	11.2 Notify regulatory agency of impending application and receive application reference number, as required	
	11.3 Ensure receipt of dossier by regulatory agency	Follow company policies and procedures Follow regulatory agency requirements
12. Respond to regulatory agency questions	12.1 Respond to regulators, as appropriate	For example, respond to screening deficiencies, clarifaxes  Follow company policies and procedures Follow regulatory agency requirements
	12.2 Resubmit, if necessary	
13. Negotiate the label		
14. Obtain regulatory authorization		For example: <ul style="list-style-type: none"> <li>• Notice of Compliance (NOC)</li> <li>• No Objection Letter (NOL)</li> <li>• Approval letter</li> <li>• Marketing authorization (EU)</li> </ul>

A Regulatory Affairs Specialist must be able to:

**G. Communicate with regulatory authorities**

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Determine rationale for agency communication	1.1 Define the objective or message	Follow company policies and procedures
	1.2 Determine pros and cons to contact agency	Follow company policies and procedures
	1.3 Determine 'go'/'no go' to proceed with communication	Follow company policies and procedures  For example, seek approval for 'go'/'no go' decisions at a higher managerial level, as required
	1.4 Initiate contact with agency, as required	
2. Plan agency communication	2.1 State the objective for communication	Follow company policies and procedures
	2.2 Define the contributors and/or participants	Follow company policies and procedures
	2.3 Consult the contributors and/or participants to determine the scope	Follow company policies and procedures
	2.4 Propose meeting/communication time and setting	Follow company policies and procedures
	2.5 Contact agency, communicate objective and arrange meeting time and setting	Follow company policies and procedures
3. Prepare briefing documents	3.1 Define contributors	Follow company policies and procedures
	3.2 Articulate requirements and message to be developed	Follow company policies and procedures
	3.3 Receive briefing document	
	3.4 Co-ordinate review/approval	Follow company policies and procedures

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.5 Compile and submit to regulatory agency	Follow company policies and procedures  Note: depending upon the country and agency, the briefing document may be required at the same time of requesting the meeting
4. Facilitate agency meetings	4.1 Arrange rehearsal meeting	Be sure to, for example: <ul style="list-style-type: none"> <li>• Define participants and roles</li> <li>• Ensure extra copies of briefing documents are available</li> <li>• Ensure back-up slides are available</li> </ul> Follow company policies and procedures Follow regulatory agency requirements
	4.2 Coordinate review and approval of presentation	
	4.3 Attend/facilitate meeting	Follow company policies and procedures Follow regulatory agency requirements
5. Document regulatory agency communications	5.1 Draft meeting minutes	Follow company policies and procedures Follow regulatory agency requirements
	5.2 Circulate draft minutes for internal review/approval	Follow company policies and procedures Follow regulatory agency requirements
	5.3 Finalize and approve meeting minutes	Follow company policies and procedures Follow regulatory agency requirements
	5.4 Submit to regulatory agency, if required	Follow company policies and procedures Follow regulatory agency requirements
	5.5 Archive regulatory agency communications, as required	Follow company policies and procedures Follow regulatory agency requirements
6. Communicate meeting outcomes to relevant stakeholders	6.1 Define stakeholders	Follow company policies and procedures Follow regulatory agency requirements

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	6.2 Circulate approved meeting minutes/ results	For example, communicate via: <ul style="list-style-type: none"> <li>• E-mail</li> <li>• Hardcopy</li> </ul> Follow company policies and procedures Follow regulatory agency requirements
	6.3 Archive record of circulation, as required	Follow company policies and procedures Follow agency regulations and guidances
7. Co-ordinate actions resulting from regulatory agency communications	7.1 Define contributors and timelines	Follow company policies and procedures
	7.2 Complete/track actions and results*	
8. Respond to submission deficiencies, as required	8.1 Notify stakeholders and upper management of deficiencies	For example: <ul style="list-style-type: none"> <li>• Clarifax questions</li> <li>• Notice of Deficiency (NODs)</li> <li>• Notice of Non-Compliance (NONs)</li> <li>• Deficiencies</li> <li>• Section 31 in Australia</li> </ul>
	8.2 Initiate and facilitate meeting to establish roles, responsibilities and timelines for assembling information for the response	
	8.3 Compile and review response	
	8.4 Submit response	
9. Respond to regulatory agency inquiries	9.1 Inform stakeholders of regulatory agency questions	

\* Remember that it may take years to complete studies such as stability or clinical studies.

<b>TASKS</b>	<b>SUBTASKS</b>	<b>IMPORTANT ACTIONS / PERFORMANCE STANDARDS</b>
	9.2 Inform upper management of the questions and of regulatory interpretation	
	9.3 Call meeting with relevant subject matter experts to discuss the proposed response/company's position	
	9.4 Assign authorship to Subject Matter Experts	
	9.5 Establish timeline for response	
	9.6 Collate responses, if applicable	
	9.7 Circulate response for review and approval	Follow company policies and procedures
	9.8 Compile response for submission	Follow company policies and procedures
	9.9 Submit the response	Follow company policies and procedures
	9.10 Archive response submission	Follow company policies and procedures
	9.11 Notify relevant stakeholders of response being submitted	Follow company policies and procedures
	9.12 Archive notification	Follow company policies and procedures
10. Ensure that response was satisfactory to regulatory agency		

A Regulatory Affairs Specialist must be able to:

**H. Assist in internal and external regulatory inspections \***

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Support internal audits, as required	1.1 Identify regulatory standard(s) required	Follow company policies and procedures
	1.2 Interpret regulatory standard(s), as requested	Follow company policies and procedures
	1.3 Provide responses to auditors' questions and follow up on identified deficiencies	
2. Support non-clinical sites during regulatory agency inspection, as required	2.1 Provide training on regulatory inspections to site staff, if required	
	2.1 Support the review study(ies) included in submissions	Follow company policies and procedures
	2.2 Ensure all study deviations are closed, corrective actions completed and documented	Follow company policies and procedures
	2.3 Ensure site has a copy of submission	Follow company policies and procedures
	2.4 Provide company regulatory representative to site, if required	Follow company policies and procedures
	2.5 Provide regulatory interpretation for company submission questions, if required	Follow company policies and procedures
	2.6 Assist in site response to citations, if requested	Follow company policies and procedures

\* In some Biotechnology companies, assistance with regulatory inspections may be performed by Quality Assurance Department personnel.

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	2.7 Report outcomes to relevant stakeholders	Follow company policies and procedures
	2.8 Provide responses to auditors' questions and follow up on identified deficiencies	
3. Support clinical trial sites during regulatory agency inspections, as required	3.1 Provide training on regulatory inspections to site staff, if required	Follow company policies and procedures
	3.2 Ensure all study documents are complete and ready for review	For example, that protocol deviations and queries are resolved and documented  Work with, for example, clinical development staff  Follow company policies and procedures
	3.3 Support clinical development staff in preparing site for inspection	Follow company policies and procedures
	3.4 Ensure site has copy of final study report, if required	Follow company policies and procedures
	3.5 Provide company representative to site, if required	Follow company policies and procedures
	3.6 Assist in site response to citations, if required	Follow company policies and procedures
	3.7 Report outcome to relevant stakeholders	Follow company policies and procedures
4. Assist in preparation for third-party facility inspections	4.1 Provide regulatory input at team meetings	Follow company policies and procedures
	4.2 Provide training in regulatory inspection procedures, if required	Follow company policies and procedures
	4.3 Critique proposed presentations for inspection, if required	Follow company policies and procedures

<b>TASKS</b>	<b>SUBTASKS</b>	<b>IMPORTANT ACTIONS / PERFORMANCE STANDARDS</b>
	4.4 Provide final submission and associated documents to internal team	Follow company policies and procedures
	4.5 Review documents submitted to internal team for accuracy and completeness	Follow company policies and procedures
5. Assist with third-party facility inspections, as required	5.1 Accompany inspection team	For example, participate in World Health Organization (WHO) site visits as regulatory product specialist  Follow company policies and procedures
	5.2 Present regulatory overview at the opening meeting, if required	Follow company policies and procedures
	5.3 Transcribe inspection dialogue, if requested	Follow company policies and procedures
	5.4 Assist in document control during inspection, if required	Follow company policies and procedures
	5.5 Provide regulatory interpretation, if required	Follow company policies and procedures
	5.6 Participate in daily internal wrap-up meetings	Follow company policies and procedures
6. Assist in responses to citations	6.1 Facilitate meeting to discuss citations received	Follow company policies and procedures
	6.2 Coordinate development of responses to citations	Follow company policies and procedures
	6.3 Circulate responses to relevant stakeholders for review	Follow company policies and procedures
	6.4 Finalize responses	Follow company policies and procedures
	6.5 Circulate final draft to relevant stakeholders for approval	Follow company policies and procedures

<b>TASKS</b>	<b>SUBTASKS</b>	<b>IMPORTANT ACTIONS / PERFORMANCE STANDARDS</b>
7. Submit responses to citations, as necessary	7.1 Submit to appropriate regulatory agency, as directed	Follow company policies and procedures
	7.2 Provide clarifications, as requested	Follow company policies and procedures
	7.3 Report outcomes to relevant stakeholders	Follow company policies and procedures

A Regulatory Affairs Specialist must be able to:

**I. Manage product registrations**

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Ensure compliance with post-approval requirements	1.1 Ensure knowledge of regulatory requirements for marketed products	For example, review: <ul style="list-style-type: none"> <li>• Annual reports</li> <li>• Post-marketing commitments</li> <li>• Annual product reports (Canada)</li> </ul> Follow company policies and procedures Follow regulatory agency requirements
	1.2 Document and track post-approval commitments	Follow company policies and procedures Follow regulatory agency requirements
	1.3 Schedule and execute post-approval submissions that are required, as per regulations	Follow company policies and procedures Follow regulatory agency requirements
	1.4 Participate in the change control process	Follow company policies and procedures Follow regulatory agency requirements
	1.5 Demonstrate post-registration product stewardship, as required	For example, regarding environmental impact
2. Manage post-approval changes	2.1 Assess proposed post-approval changes and obtain feedback from the relevant functional areas as part of the assessment	Follow regulatory guidelines, for example: <ul style="list-style-type: none"> <li>• Health Canada</li> <li>• US Food and Drug Administration (FDA)</li> </ul> Follow company policies and procedures
	2.2 Provide regulatory assessment to the change control team	Follow regulatory guidelines, for example: <ul style="list-style-type: none"> <li>• Health Canada</li> <li>• US Food and Drug Administration (FDA)</li> </ul> Follow company policies and procedures
	2.3 If a submission is required, plan and execute the submission strategy	Follow company policies and procedures

<b>TASKS</b>	<b>SUBTASKS</b>	<b>IMPORTANT ACTIONS / PERFORMANCE STANDARDS</b>
	2.4 Draft/review/approve the submission	Follow company policies and procedures
	2.5 Submit to the regulatory agency	Follow company policies and procedures
	2.6 Respond to deficiencies and obtain approval from the regulatory agency	Follow company policies and procedures Follow regulatory agency requirements
3. Communicate approval of changes	3.1 Communicate approval to relevant stakeholders	Follow company policies and procedures for, for example: <ul style="list-style-type: none"> <li>• Circulating approval</li> <li>• Filing and notifying approval</li> <li>• Updating registration databases</li> <li>• Notifying stakeholders</li> <li>• Maintaining regulatory information</li> </ul> For example, communicate approval via: <ul style="list-style-type: none"> <li>• Telephone</li> <li>• Contact report</li> <li>• E-mail</li> </ul>
	3.2 Archive approval and notification of approval	Follow company policies and procedures
	3.3 Update registration database, if required	Follow company policies and procedures
	3.4 Notify the relevant stakeholders that the change is approved and the database has been revised, if required	Follow company policies and procedures
4. Review marketing material	4.1 Review and assimilate requirements from relevant resources on advertising and promotional material	Follow industry association standards Resources such as: <ul style="list-style-type: none"> <li>• Websites</li> <li>• Email lists</li> <li>• Newsletters</li> <li>• Publications</li> <li>• Pharmaceutical Advertising Advisory Board</li> </ul>

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
		(PAAB) <ul style="list-style-type: none"> <li>• Rx&amp;D</li> <li>• Federal Trade Commission (FTC)</li> <li>• Division of Drug Marketing, Advertising, and Communications (DDMAC)</li> </ul>
	4.2 Review, provide comments and inform marketing group of requirements for regulatory submission and compliance on proposed marketing material (approved label)	Follow industry association standards, for example: <ul style="list-style-type: none"> <li>• Pharmaceutical Advertising Advisory Board (PAAB)</li> <li>• USPI</li> <li>• Product monograph</li> <li>• Summary of Product Characteristics (SmPC)</li> <li>• Rx&amp;D</li> <li>• Food and Drug Administration (FDA)</li> <li>• Division of Drug Marketing, Advertising, and Communications (DDMAC)</li> </ul> <p>Inform sales/marketing of restrictions on use of material. For example, inform of restrictions such as 'Physicians only', 'Provide with P.I. (Product Information)', etc.</p> <p>Also, ensure material has 'fair balance' (efficacy and adverse events) and is on label and inform marketing group of requirements for regulatory submission and compliance regulations</p>
5. Approve marketing material	5.1 Ensure regulatory affairs approval is documented and file copy is retained	Follow industry association standards Follow agency regulations and guidances, for example: <ul style="list-style-type: none"> <li>• Pharmaceutical Advertising Advisory Board (PAAB)</li> </ul>

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
		<ul style="list-style-type: none"> <li>• Rx&amp;D</li> <li>• Food and Drug Administration (FDA)</li> <li>• Division of Drug Marketing, Advertising, and Communications (DDMAC)</li> </ul>
	5.2 Obtain and archive copies of final approved marketing materials to confirm compliance, as required	Follow industry association standards Follow agency regulations and guidances, for example: <ul style="list-style-type: none"> <li>• Pharmaceutical Advertising Advisory Board (PAAB)</li> <li>• Rx&amp;D</li> <li>• Food and Drug Administration (FDA)</li> <li>• Division of Drug Marketing, Advertising, and Communications (DDMAC)</li> </ul>
	5.3 Respond to regulatory agency questions on marketing material, as required	Follow industry association standards Follow agency regulations and guidances, for example: <ul style="list-style-type: none"> <li>• Pharmaceutical Advertising Advisory Board (PAAB)</li> <li>• Rx&amp;D</li> <li>• Food and Drug Administration (FDA)</li> <li>• Division of Drug Marketing, Advertising, and Communications (DDMAC)</li> </ul>
6. Compile and submit adverse event reports and/or safety information	6.1 Determine reporting requirement for local/national regulatory agency	For example, assessing adverse events signal that would have impact to conduct of a clinical trial  Follow national regulations and requirements. For example: <ul style="list-style-type: none"> <li>• Food and Drug Administration (FDA)</li> <li>• Health Canada</li> <li>• European Medicines Agency (EMA)</li> </ul>

<b>TASKS</b>	<b>SUBTASKS</b>	<b>IMPORTANT ACTIONS / PERFORMANCE STANDARDS</b>
	6.2 Compile and submit reports to regulatory agency, as required	Follow national regulations and requirements. For example: <ul style="list-style-type: none"> <li>• Food and Drug Administration (FDA)</li> <li>• Health Canada</li> <li>• European Medicines Agency (EMA)</li> </ul>
7. Manage or support external communication regarding product quality, if required	7.1 Support review and submit product release protocols, if necessary	Follow regulatory agency requirements Follow company policies and procedures
	7.2 Interact with regulatory agencies regarding product quality standards, if necessary	Follow regulatory agency requirements Follow company policies and procedures Ensure compliance with international standards of product quality requirements, as applicable
	7.3 Negotiate wording with regulatory agencies of public statements regarding product quality issues, if necessary	Follow regulatory agency requirements Follow company policies and procedures
	7.4 Coordinate regulatory agency lot release inquiries, if necessary	Follow regulatory agency requirements Follow company policies and procedures
	7.5 Assist with/Coordinate any unexpected manufacturing or testing findings, if necessary	Follow regulatory agency requirements Follow company policies and procedures
	7.6 Coordinate information requests from health practitioners, if necessary	Follow company policies and procedures Follow regulatory agency requirements Follow association requirements
	7.7 Coordinate regulatory agency requests for reference standards and reagents, if necessary	Follow regulatory agency requirements Follow company policies and procedures
8. Manage or support product recalls, as required	8.1 Determine whether recall is required	
	8.2 Schedule recall strategy/meeting with all relevant stakeholders	Follow company policies and procedures

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	8.3 Chair recall strategy meeting, as required	Chair strategy to: <ul style="list-style-type: none"> <li>• Determine what the issue is</li> <li>• Confirm product</li> <li>• Confirm lot number(s)</li> <li>• Negotiate customer communications</li> <li>• Negotiate corrective or preventative actions</li> <li>• Negotiate recall initiation date</li> <li>• Determine impacted customers</li> </ul> Follow company policies and procedures for chairing recall meeting
	8.4 Support drafting, coordinating review and approval of initial recall notification to regulatory agency	
	8.5 Communicate initial recall notification and strategy to regulatory agency	Follow regulatory agency requirements Follow company policies and procedures
	8.6 Work with regulatory agency to recall the product	
	8.7 Communicate recall to public through the media	
	8.8 Implement company recall process	Follow company policies and procedures  Monitor customer responses for, for example: <ul style="list-style-type: none"> <li>• Confirmation of receipt of recall notification</li> <li>• Confirmation of stop-use</li> </ul> Ensure destruction or return of impacted product and lot(s)

<b>TASKS</b>	<b>SUBTASKS</b>	<b>IMPORTANT ACTIONS / PERFORMANCE STANDARDS</b>
	8.9 Evaluate effectiveness of the recall process and modify process, as required	
	8.10 Update regulatory agency on the status of the recall	Follow regulatory agency requirements Follow company policies and procedures
	8.11 Ensure all impacted product has been recalled following prescribed regulations and guidelines	For example, make decisions based on receipt of all impacted product taking into consideration: <ul style="list-style-type: none"> <li>• Time period</li> <li>• Customer response rates</li> </ul>
	8.12 Contribute to submission of proposed closure to relevant regulatory agencies	Follow regulatory agency requirements Follow company policies and procedures
	8.13 Negotiate closure date of recall with regulatory agencies	Follow regulatory agency requirements Follow company policies and procedures

A Regulatory Affairs Specialist must be able to:

**J. Provide regulatory support to development of the product**

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Provide support for compassionate use studies, as required	1.1 Contact regulatory agency to determine requirements for compassionate use studies	For example, compassionate use, through the Special Access Program (SAP) or for compassionate use of an un-approved product  Follow company policies and procedures Follow regulatory agency requirements
	1.2 Review protocol and associated documents for compliance with regulatory agency requirements and consistency with regulatory strategy	For example, review drug labels and information consent  Follow company policies and procedures Follow regulatory agency requirements
	1.3 Submit and obtain No Objection Letter (NOL) for Clinical Trial Application (CTA), as required	For example, obtain lot release for study drug, if required Follow company policies and procedures Follow regulatory agency requirements
2. Provide support for phase I-IV studies, as required	2.1 Review protocol for scientific/ethical/clinical/regulatory acceptability*	Follow regulatory agency requirements
	2.2 Review protocol to determine if regulatory agency and ethics board review and prior approval are required	
	2.3 Submit and obtain No Objection Letter (NOL) for Clinical Trial Application (CTA), as required	Follow regulatory agency requirements Follow company policies and procedures

\* Note: Regulatory is not accountable for the scientific validity.

<b>TASKS</b>	<b>SUBTASKS</b>	<b>IMPORTANT ACTIONS / PERFORMANCE STANDARDS</b>
3. Provide support for investigator-led studies, as required	3.1 Review protocol for scientific/ethical/clinical/regulatory acceptability and for consistency with regulatory and development strategy	For example, review/approve investigator's brochure
	3.2 Review protocol to determine if regulatory agency and ethics board review is required	
	3.3 Provide investigator with associated documentation required for regulatory and ethics board submission, as required	For example, documents may include quality information and x-reference letters  Follow regulatory agency requirements Follow company policies and procedures
	3.4 Contribute to review and edit of study reports or publications resulting from study	
4. Provide support for health policy studies, as required	4.1 Review protocol for scientific/ethical/clinical/regulatory acceptability	
	4.2 Review protocol to determine if agency review and prior approval are required	
	4.3 Submit protocol and associated documents for review to agency, if required	Follow company policies and procedures
5. Provide support for efficacy studies, as required	5.1 Support efficacy studies for various products	For example: <ul style="list-style-type: none"> <li>• Efficacy of insecticide for West Nile Virus</li> <li>• Efficacy of nutritionally-enhanced animal feed</li> <li>• Efficacy of novel or enriched food (such as Omega-3 food)</li> <li>• Animal toxicology studies</li> </ul>
6. Provide support for infectious diseases surveillance, as required		
7. Provide support for dispensarization and prevention, as required		

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
8. Review published literature of product used in third-party studies, as required	8.1 Check for use or misuse of company product	For example, identify if: <ul style="list-style-type: none"> <li>• Off-label</li> <li>• Wrong dose</li> <li>• Wrong method</li> </ul>
	8.2 Contribute to analysis of scientific integrity of study design	Follow company policies and procedures
	8.3 Communicate analysis to relevant stakeholders	Follow company policies and procedures

A Regulatory Affairs Specialist must be able to:

**K. Demonstrate personal competencies**

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Demonstrate attention to detail	1.1 Complete regulatory submissions with minimal to no deficiencies and inconsistencies reported from regulatory agency	For example, ensure proper hyperlinks, internal consistency of documentation, etc.  Follow regulatory agency requirements, for example, Health Canada, FDA, etc.
	1.2 Write regulatory documents with minimal revisions by peers	Follow company policies and procedures
	1.3 Pro-actively identify regulatory changes on assigned areas	Follow company policies and procedures
	1.4 Manage regulatory agencies review on schedule	Follow company policies and procedures
	1.5 Participate in or contribute to successful agency inspection audits	Follow company policies and procedures
	1.6 Seek feedback from product teams	Follow company policies and procedures
2. Manage multiple projects	2.1 Demonstrate effective project management and time management skills	Follow company policies and procedures Follow regulatory agency requirements  For example: <ul style="list-style-type: none"> <li>• Seek clarity from management on relative importance/impact/timing and prioritize projects relative to business direction and impact</li> <li>• Create action plan or critical path for each project</li> <li>• Identify milestone targets for tracking critical path</li> </ul>

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
		<ul style="list-style-type: none"> <li>• Communicate and negotiate actions with contributors</li> <li>• Follow-up with contributors relative to action plan timelines</li> <li>• Deliver projects on schedule</li> <li>• Develop contingency plans and adjustments</li> <li>• Communicate project status and monitor business priority changes</li> <li>• Celebrate successes or milestones</li> </ul>
	2.2 Provide clear plan for implementing critical point measures in multiple projects	
3. Demonstrate computer skills	3.1 Apply electronic submission and database management techniques, as required	Follow company policies and procedures Follow regulatory agency requirements
	3.2 Utilize document and company electronic systems	Follow company policies and procedures
	3.3 Seek training on new systems	Follow company policies and procedures
	3.4 Practice effective e-mail communication with teams	Follow company policies and procedures
	3.5 Utilize web search and agency sites to communicate regulatory changes for action	Follow company policies and procedures
4. Evaluate scientific information	4.1 Read material/scientific information critically	Employ and adhere to good scientific principles and standards
	4.2 Identify biases and weaknesses	For example, check for biases and weaknesses in: <ul style="list-style-type: none"> <li>• Interpretation</li> <li>• Data analysis</li> <li>• Execution</li> <li>• Study design</li> <li>• Conclusions</li> </ul>

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	4.3 Understand and apply basic statistics	
	4.4 Offer recommendations on how information could be improved	
	4.5 Evaluate and summarize scientific information	
	4.6 Assess validity of information	
	4.7 Apply conclusions and evaluation to the regulatory strategy for that project	
5. Continually update scientific and regulatory knowledge	5.1 Attend appropriate scientific, medical and regulatory conferences and seminars	Follow company policies and procedures
	5.2 Attend internal scientific and product seminars	
	5.3 Enroll in continuing education courses, such as online courses	Follow company policies and procedures
	5.4 Read applicable journals	Follow company policies and procedures
	5.5 Visit patient and customer websites to find out how products are being used, as required	Follow company policies and procedures
	5.6 Participate in industry or professional association committees	Follow company policies and procedures
	5.7 Consult with key opinion leaders or subject matter experts	Follow company policies and procedures
6. Demonstrate strategic planning skills to identify opportunities for product development	6.1 Consider the consequences or future implications of proposals, plans and actions	For example, plan Global Product Development Process  Follow company policies and procedures
	6.2 Recommend actions or options to mitigate or prevent negative consequences	
	6.3 Anticipate future trends and developments	
	6.4 Develop contingency plans	
	6.5 Recommend appropriate action	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
7. Actively engage in business strategies	7.1 Participate in business team meetings	Follow company policies and procedures
	7.2 Develop relationship with marketing product managers	
	7.3 Establish credibility as a regulatory expert	
	7.4 Read and understand business plans	
	7.5 Research competition's and own product in the market	For example, for competition's product with regards to: <ul style="list-style-type: none"> <li>• Pipeline</li> <li>• Regulation strategies</li> <li>• New indications</li> </ul>
	7.6 Provide regulatory input on the business plan to the marketing department	Measure success by feedback from the business unit
	8. Manage sensitive information	8.1 Recognize confidential and sensitive information in compliance with 'hold' orders per instruction by legal department
8.2 Confirm with legal advisors or management the status of information		
8.3 Maintain confidentiality of the information used		Observe national and international laws, as applicable. For example: <ul style="list-style-type: none"> <li>• Access to Information and Privacy Act</li> <li>• Freedom of Information Act (US)</li> </ul>
8.4 Communicate confidential information appropriately to those who have a functional 'need to know'		Follow company policy regarding Confidential Business Information (CBI) and applicable laws
8.5 Maintain trade secrets		Follow company policy and applicable laws
8.6 Store and secure confidential information		Follow company policy and applicable laws

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	8.7 Respond to access to information and privacy act requests	For example: <ul style="list-style-type: none"> <li>• Access to Information and Privacy Act</li> <li>• Freedom to Information Act (US)</li> <li>• observe national and international laws, as applicable</li> </ul>
9. Demonstrate balanced judgement	9.1 Think analytically	
10. Demonstrate interpersonal skills	10.1 Listen to understand diverse opinions	Adhere to company values Observe best practices Participate in company or third party training seminars
	10.2 Recognize group dynamics	Adhere to company values Observe best practices Participate in company or third party training seminars
	10.3 Share personal opinion or understanding	Adhere to company values Observe best practices Participate in company or third party training seminars
	10.4 Seek 360° feedback on working relationships	Adhere to company values Observe best practices Participate in company or third party training seminars
	10.5 Use variable approaches to respond to individual styles	Adhere to company values Observe best practices Participate in company or third party training seminars
	10.6 Demonstrate sensitivity	
11. Demonstrate teamwork	11.1 Identify when to follow and when to lead	Adhere to company values Observe best practices Participate in company or third party training seminars
	11.2 Participate actively	Adhere to company values Observe best practices Participate in company or third party training seminars

<b>TASKS</b>	<b>SUBTASKS</b>	<b>IMPORTANT ACTIONS / PERFORMANCE STANDARDS</b>
	11.3 Support team decisions	Adhere to company values Observe best practices Participate in company or third party training seminars
	11.4 Accept diverse opinions	Adhere to company values Observe best practices Participate in company or third party training seminars
12. Share learnings with colleagues	12.1 Conduct 'lessons learned' meetings, as required	
13. Demonstrate problem solving skills	13.1 Demonstrate ability to solve problems individually as well as collectively	
14. Demonstrate effective negotiation skills	14.1 Negotiate to obtain timely approvals with the best label possible	
	14.2 Listen actively	Adhere to company values Observe best practices Participate in company or third party training seminars
	14.3 Identify difference between transactional approach versus relational approach	Adhere to company values Observe best practices Participate in company or third party training seminars
	14.4 Identify shared or common principles	Adhere to company values Observe best practices Participate in company or third party training seminars
	14.5 Identify shared or common goals	Adhere to company values Observe best practices Participate in company or third party training seminars
	14.6 Resolve any conflicts, as necessary	
15. Communicate with diverse audiences	15.1 Research your audience	Adhere to company values Observe best practices Participate in company or third party training seminars

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	15.2 Respect cultural diversity	Adhere to company values Observe best practices Participate in company or third party training seminars
	15.3 Adapt message to audience	Adhere to company values Observe best practices Participate in company or third party training seminars
16. Write and edit technical documents	16.1 Utilize appropriate industry terminology	Follow regulatory agency requirements Follow company style guides
	16.2 Apply scientific, technical and regulatory knowledge	Follow regulatory agency requirements Follow company style guides
	16.3 Gather source documents	Follow company style guides
	16.4 Verify accuracy of data and information	Follow regulatory agency requirements Follow company style guides
	16.5 Ensure consistency throughout document	For example, ensure consistency of: <ul style="list-style-type: none"> <li>• Nomenclature</li> <li>• Data</li> <li>• Writing style</li> <li>• Grammar</li> <li>• General format</li> </ul> Follow regulatory agency requirements Follow company style guides
	16.6 Ensure appropriate application of statistics and mathematical skills, as required	Follow regulatory agency requirements Follow company style guides
	16.7 Demonstrate effective use of software or technology	
17. Demonstrate presentation skills	17.1 Research your audience	Adhere to company values Observe best practices Participate in company or third party training seminars

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	17.2 Use presentation software, as required	Adhere to company values Observe best practices Participate in company or third party training seminars
	17.3 Demonstrate sound knowledge of the topic	For example, anticipate questions Adhere to company values Observe best practices Participate in company or third party training seminars
18. Build strategic relationships	18.1 Network and manage working relationships with key stakeholders and influencers	Adhere to company values Observe best practices Participate in company or third party training seminars
	18.2 Apply relational and transactional approaches as appropriate to the situation	Adhere to company values Observe best practices Participate in company or third party training seminars
	18.3 Identify key expertise	Adhere to company values Observe best practices Participate in company or third party training seminars
	18.4 Identify internal and external mentors	Adhere to company values Observe best practices Participate in company or third party training seminars
	18.5 Identify potential barriers and build strategies to manage barriers	Adhere to company values Observe best practices Participate in company or third party training seminars
19. Develop and broaden networks	19.1 Identify and familiarize yourself with sectors or science that are new or important to you	Adhere to company values Observe best practices Participate in company or third party training seminars
	19.3 Continuously explore and build networks with new sectors of importance to your company	Adhere to company values Observe best practices Participate in company or third party training seminars

<b>TASKS</b>	<b>SUBTASKS</b>	<b>IMPORTANT ACTIONS / PERFORMANCE STANDARDS</b>
	19.4 Participate in agency, industry or professional association committees and attend meetings	Observe best practices Participate in company or third party training seminars
20. Demonstrate an above-average ability to communicate in the language of the regulatory environment	20.1 Use appropriate terminology	Note: English is the working language in the Canadian Biotechnology industry
	20.2 Understand nuances	
	20.3 Express complex concepts clearly	

## Strong Board of Directors

The Board of Directors is composed of experts in the field of HR: CEO's, CFO's and CSO's from across Canada with extensive financial and industry experience representing companies and organizations in Canada's bio-economy. BioTalent Canada is not a membership organization and therefore relies on the guidance provided by its dedicated volunteer Board of Directors.

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