



**National Occupational Standard for**  
Regulatory Affairs Manager in Bio-Health



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## 2 A COMPETENCY FRAMEWORK FOR INDIVIDUALS WORKING IN THE BIO-ECONOMY

### 2.1 What is a National Occupational Standard?

In Canada, National Occupational Standards are industry-developed and validated documents that identify and group tasks/competencies associated with a particular occupation. They also describe the knowledge and skills that a worker must demonstrate to be considered competent.

The former Alliance of Sector Councils (TASC) outlined 11 guiding principles for creating National Occupational Standards (NOS). NOS for the Canadian bio-economy meet all 11 principles and are developed to meet the current and future human capital management needs of the Canadian bio-economy.

### 2.2 How are we defining a competency?

We define a competency as *a set of related behaviors that describe successful performance in a designated area. It is a behavioural expression of how people integrate knowledge, skills, attributes, and attitudes to produce a value-adding result in a defined situation.*

The competency statement includes a description that integrates skills, knowledge, and actions into a sequence of activities that deliver a value-added product or service.

**Performance Indicators** is the term we use for the behaviours grouped under each competency that describe the level of mastery the incumbent role must demonstrate when executing a task.

For this project, we have organized the competencies into four categories.

**Core Competencies** are those competencies that describe the "essence of the role" — that is, they are the one to three most critical competencies that may be applicable across multiple roles in a function or job family. All levels of personnel in this function would typically share them. These competencies may also act as qualifiers that differentiate the function from other functions.

**Technical Competencies** are those competencies related to specific roles or professions that enable an individual to work, function, and succeed in that role. They address the various responsibilities that job incumbents encounter in a role. For example, a surgeon's technical competencies would encompass multiple surgical tools, techniques, and conditions that could be part of the position.

Similarly, technical competencies for a lawyer would contain various legal situations that they encounter in the context of a particular field of practice.


**Regulatory Competencies** are those competencies that describe compliance with prescribed practices and mandated obligations under applicable laws, regulations, and industry standards. They ensure that critical work processes are implemented and integrated into all work activities. They are of absolute importance where economic behaviours can impact human conditions.

**Personal/professional Competencies** are those competencies that enable an individual to be successful working with others and fulfilling their responsibilities in a work context. Personal and professional competencies are not necessarily role specific.

### 2.3 Levels of complexity of work

It is important to recognize how the complexity of work varies along an organizational continuum. At one end of this continuum is low-complexity, clearly-defined, task-driven work. At the other end of the continuum is work that is higher in complexity, not as well-defined, and requires higher-level thinking and decision-making skills and a greater degree of autonomy. Results are recognised over a longer period of time and are more difficult to assess.

Figure 1: Demonstrates how the level of complexity changes with the role responsibilities

Complexity Level	Examples of Work at Different Complexity Levels	Typical Roles/Titles
Most Complex	Construct and pursue worldwide strategic plans in large corporations.	CEOs of the largest trans-global corporations
	Construct and pursue worldwide strategic plans.	C-suite executives at multi-national organizations
	Lead the accumulated impact of multiple business units.	C-suite executive at large, multi-location organizations
	Optimize the function of a single business unit or corporate support staff.	General manager; plant manager
	Manage multiple, interdependent projects; balance resources among departments.	Engineering manager
	Plan and carry out sequential projects while considering contingencies and alternatives.	Maintenance manager
	Accumulate information to diagnose and anticipate problems; proactive; notice trends.	Maintenance technician
Least Complex	Follow predefined procedures; seek help when encountering an obstacle. The ability to anticipate problems is not expected.	Maintenance labourer

We define the complexity levels within the profiles at four levels:

**Foundational** — performance focus is on the execution of procedures and tasks involving own job role.

**Operational** — performance focus includes some discretion in the planning and executing of work. The work typically includes assessing the quality of the work outcomes and taking corrective action to ensure quality.

**Specialist** — performance focus is on translating goals and standards to team members and ensuring that work done under the person's responsibility area complies with all corporate standards.

**Strategic** — performance focus is on leading work and the accumulated impact of work in an independent business unit or across a whole organization. The impact of work at this level is often not visible until the medium to longer term.

The following example illustrates the different complexity levels within a profile.

<p><b>Competency Name: Research Ethics</b></p> <p><b>Competency Definition:</b> Exercises integrity and professionalism to ensure all research is performed responsibly in keeping with the ethical principles of beneficence and nonmaleficence.</p> <p>Competence at this level is demonstrated when the <b>Research Manager:</b></p>			
<b>Performance Indicators</b>			
Foundational	Operational	Specialized	Strategic
Diligently follows research procedures and protocols mandated by legitimate authorities and professional organizations.	Regularly monitors own actions and decisions to ensure they align with professional and organizational values.	Holds self and staff accountable to the organization's values, ensuring compliance with the policies and procedures related to scientific ethics and rules of conduct.	Fosters an organizational culture of integrity and ethical business practices by unwavering personal example.

## 2.4 Overview methodology for the development of national occupational standards

National occupational standards were developed using a multi-step process.

Step	Description	Result/Output
1	Identify critical roles in the bio-economy through primary and secondary research.	List of 50 key roles
2	Create draft profiles with critical competencies for the roles, performance, and knowledge indicators.	Draft profiles
3	Review the draft profiles with industry subject matter experts to refine the competencies, performance, and knowledge indicators.	Reviewed profile with design inputs from industry experts
4	Further validation and review by industry via online focus group.	Validated profiles by industry experts
5	Broader validation of the draft profiles via national online surveys.	Occupational Standards validated on a national level by experts from the different sectors
6	Addition of the Essential Skills and Canadian Language Benchmark (ES/CLB) ratings.	Nationally validated NOS profiles with ES/CLB profile for each NOS

### 3 REGULATORY AFFAIRS MANAGER - BIO-HEALTH COMPETENCY FRAMEWORK

#### 3.1 Competency diagram for Regulatory Affairs Manager - Bio-health

Competencies		Complexity Level				Complexity Level Legend
		1	2	3	4	
<b>Core Competency</b>						1. Foundational
1	Ethics/Integrity					
2	Quality Orientation					2. Operational
<b>Technical Competencies</b>						
3	Regulatory Systems and Documentation					3. Specialist/Manager
4	Regulatory Support for Product Development in Bio-health					
5	Post-market Product Registration and Compliance					4. Expert/Executive
6	Developing a Regulatory Strategy for the Organization					
7	Liaising with Regulatory Professionals					
8	Risk Management					
9	Professional Writing for Regulatory Affairs					
10	Digital Skills for Regulatory Affairs					
<b>Industry Regulatory Competencies</b>						
	Included in Technical Competencies above					

Competencies		Complexity Level			
		1	2	3	4
<b>Personal and Professional Competencies</b>					
11	Collaboration for Regulatory Affairs				
12	Continuous Learning				
13	Effective Interpersonal Communication for Regulatory Affairs				
14	Judgement/Strategic Thinking in Regulatory Affairs				
15	Planning and Organizing Work				
16	Professionalism/Emotional Intelligence				

### 3.2 Definition of occupation

The Regulatory Affairs Manager in Bio-health collaborates strategically throughout the organization's product life cycle in order to ensure that new and existing products such as drugs, cosmetics, medical devices, and nutritional products comply with applicable rules, regulations, and industry standards. They are involved in risk assessment and management to ensure products meet research standards and quality, efficacy, and safety requirements. They provide advice on the regulatory boundaries in the commercialization process. Regulatory Affairs Managers in Bio-health are responsible for the process of obtaining and maintaining government approval for the products. They represent the organization's interests and objectives while interacting and negotiating with regulatory agencies. The Regulatory Affairs Manager may also provide input and feedback on proposed government regulations directly and/or through their association.

The duties and responsibilities of the Regulatory Affairs Manager in Bio-health have expanded in recent years as a result of acquisitions and restructuring, worldwide globalization of markets, and constantly evolving legal, technical, and scientific requirements. They work within a dynamic work environment where communication with employees at all levels and within different departments is extremely important. The Regulatory Affairs Manager in Bio-health not only ensures regulatory compliance but works to foster a positive regulatory culture within the organization.

The role works in the following subsectors:

Applicable To	Bio-Health	Agri-Bio	Bio-Industrial	Bio-Energy

The level of complexity of the role is:

Span of Complexity Levels	Foundational	Operational	Specialist/ Management	Expert/Executive

### 3.3 Level of education, training, or designations requirements

Typical Education Required	Secondary	College	Bachelor	Master	PhD
Typical Starting Experience	0–5 yrs.	5–10 yrs.	10–15 yrs.	15–20 yrs.	20+ yrs.

- Minimum bachelor’s degree in a relevant science (such as food science, biology, biochemistry, pharmacy, medicinal chemistry, biomedical science, and biomedical engineering)
- Relevant postgraduate qualification in Regulatory Affairs or a research-based MSc or PhD is an asset
- Academic research, practical research, or laboratory work experience is an asset
- Experience in a generalist role in regulatory affairs within the biotechnology or biopharmaceutical industry, at a health authority, or other relevant experience

- Experience working in cross-functional teams
- Experience with institutional review boards (IRBs) and ethical committees (ECs) is an asset

### 3.4 Core competencies list for Regulatory Affairs Manager - Bio-Health

#### 3.4.1 Ethics/Integrity

Consistently holds self and staff accountable to a high standard of ethical conduct in all regulatory actions and decisions, including the integrity of data generated and transmitted, to foster a positive culture of ethical regulatory compliance within the organization.

Competency in this role is demonstrated when the individual:

- Models integrity and respect in all business actions and decisions.
- Ensures own actions and decisions follow the letter and spirit of regulatory professionals' code of conduct.
- Holds self and staff accountable to the organization's values and code of conduct.
- Ensures processes are in place to protect the safety and security of all regulatory data as per GDPR (General Data Protection Regulation) standards.

#### **Knowledge required for competency at this level:**

- Working knowledge of the organization's code of conduct
- Working knowledge of the code of conduct for regulatory professionals
- Working knowledge of the implications of the GDPR for Canadian businesses

#### 3.4.2 Quality Orientation

Assures quality through the implementation and monitoring of repeatable and/or auditable processes in order to confirm that all regulatory activities are appropriately conducted and that regulatory data is generated and managed according to approved standards and best practices.

Competency in this role is demonstrated when the individual:

- Implements a quality control plan and standard operating procedures (SOPs) following best practices for all regulatory processes and activities.
- Ensures regulatory work throughout the organization complies with quality standards through site visits and active monitoring of reported violations of regulatory protocol.
- Ensures that appropriate and timely corrective action is taken when made aware of noncompliant quality practices within regulatory activities.
- Assures that any deviance or proposed changes to regulatory procedures comply with required quality assurance standards.
- Contributes to the development of internal auditing processes and procedures.

**Knowledge required for competency at this level:**

- Working knowledge of quality management systems (QMSs) and best practices
- Working knowledge of internal and external auditing practices and appropriate terminology for verbal and/or written communication with auditors or auditing bodies
- Working knowledge of statistical tools commonly used in quality assurance such as flowcharts, check sheets, Pareto diagrams, cause and effect diagrams, histograms, scatter diagrams, and control charts
- Working knowledge of relevant quality standards (ISO, ICH, Health Canada, FDA, etc.)

## 3.5 Technical competencies list for Regulatory Affairs Manager - Bio-Health

### 3.5.1 Regulatory Systems and Documentation

Develops and manages regulatory systems in order to govern compliance with current biotechnology product regulations and to communicate corrective action taken, as required.

Competency in this role is demonstrated when the individual:

- Ensures the timely preparation and submission of dossiers and regulatory transactions.
- Assesses the impact of biotechnology product regulations on the organization's operations.

- Provides guidelines to accurately interpret regulatory agency requirements for the organization.
- Monitors the organization's research and development (R&D) and/or manufacturing activities to ensure regulatory compliance, as applicable.
- Participates in regulatory inspections and audits to ensure the organization's regulatory compliance.
- Compiles reports such as **MDL renewal, Safety,,** etc. in compliance with applicable regulatory requirements.

**Knowledge required for competency at this level:**

- Thorough knowledge of all regulatory requirements relative to the organization's operations from sources such as the Canadian Biotechnology Strategy (CBS), the EMEA, and provincial and other regulations, as required
- Thorough knowledge of all relevant best practices (GxP) and industry standards
- Knowledge of appropriate response format for deficiencies noted by regulatory bodies

### 3.5.2 Regulatory Support for Product Development in Bio-Health

Builds and exercises knowledge of the **research and development**, preclinical and clinical steps, and related regulations in healthcare in order to facilitate product development to commercialization and beyond.

Competency in this role is demonstrated when the individual:

- Provides strategic input and technical guidance to product development teams on national and global regulatory requirements.
- Provides support for preclinical studies, clinical trials, manufacturing, packaging, and product claims/labeling as required in order to ensure product development is conducted within regulatory guidelines.
- Provides guidance to the clinical research process to identify and mitigate potential product and clinical safety risks in order to ensure successful regulatory submissions.
- Recommends and monitors the implementation of regulatory-compliant solutions.
- Assesses the efficacy of proposed regulatory pathways, including expedited pathways and clinical development plans for proposals and submissions.
- Collaborates with marketing and legal to guide appropriate product positioning that remains in compliance with the terms of market authorization.

- Provides knowledge and critical analysis of pre-approval inspections, good clinical practice (GCP) inspections, and clinical investigator relationships.
- Ensures internal regulatory policies and procedures are in place to guide studies, trials, processes, and regulatory proposals/submissions.
- Leads key interactions with regulatory authorities prior to market clearance/licensing and throughout the product's life cycle.

**Knowledge required for competency at this level:**

- Thorough knowledge of the applicable product development process
- Thorough knowledge of all relevant best practices (GxP) and industry standards
- Comprehensive knowledge of regulatory submissions and amendments relevant to the organization's products

### 3.5.3 Post-market Product Registration and Compliance

Manages post-market product registrations, complaint handling, recall reporting, labeling, and submissions in order to ensure ongoing compliance with current government and industry regulations.

Competency in this role is demonstrated when the individual:

- Collaborates with domestic and international teams to ensure execution and adherence to reporting timelines and requirements for the complaint handling and recall reporting processes.
- Consults with contributors of the various source documents to confirm the accuracy and completeness of post-approval/post-market product dossiers.
- Ensures all required source documents are compiled and reviewed before submission of post-market product dossiers.
- Negotiates product summaries and labels with the regulatory agencies, responding to questions and submission deficiencies, as required.
- Develops processes to ensure required reports, supplemental submissions and other post-marketing commitments are met in order to maintain product registrations.
- Determines the level of change and consequent submission requirements for significant post-approval/post-market product events.

**Knowledge required for competency at this level:**

- Comprehensive knowledge of regulatory requirements for post-approval change management
- Comprehensive knowledge of regulatory notifications and amendments
- Comprehensive knowledge of current post-market regulatory requirements

**3.5.4 Developing a Regulatory Strategy for the Organization**

Develops and implements strategies to create a strong regulatory framework in order to support the organization's mission.

Competency in this role is demonstrated when the individual:

- Conducts environmental scans of stakeholder concerns and scientific, regulatory, and other factors in order to contribute to the development of the organization's regulatory strategy.
- Conducts a thorough analysis of options available to recommend a strategy to address specific regulatory issues.
- Creates an organizational plan for strategic regulatory projects based on an analysis of national and international business opportunities and regulatory restrictions and future regulatory changes.
- Oversees the implementation of strategic regulatory projects.
- Updates organizational strategies in response to agency feedback on regulatory projects.
- Analyzes the impact of changing regulations on the organization's pre- and post-approval strategies and approaches to recommend a new course of action.
- Manages training programs to ensure internal stakeholders are kept up to date on regulatory requirements.

**Knowledge required for competency at this level:**

- Sufficient scientific knowledge to understand regulatory issues and facilitate scientific discussions
- Thorough knowledge of all regulatory requirements relative to the organization's operations from sources such as the CBS, the EMEA, the military, the province, and other regulations, as required
- Working knowledge of the strategic planning process, including SWOT and gap analysis

### 3.5.5 Liaising with Regulatory Professionals

Liaises with regulatory bodies and other related professionals and agency authorities to help shape regulatory decisions to the organization's benefit in compliance with regulatory requirements.

Competency in this role is demonstrated when the individual:

- Determines the rationale and strategy for regulatory inquiries and responses to global, federal, and provincial authorities.
- Serves as an internal consultant and advocate on regulatory issues and concerns as they arise throughout the organization.
- Carries out regulatory intelligence activities to identify potential changes and trends that may affect the organization.
- Engages actively with internal and external stakeholders, including associations, to influence regulatory decisions that impact the organization's product approval and market access and distribution.
- Provides technical support to lobbying efforts to influence changes to regulations and guidance on behalf of the organization or industry.

#### **Knowledge required for competency at this level:**

- Knowledge of the organization's business and processes
- Understanding of effective communication principles
- Working understanding of the regulatory culture and mindset

### 3.5.6 Risk Management

Applies knowledge and understanding of the organization's research, development, manufacturing, and marketing processes in order to identify potential regulatory risks inherent to these processes and to contribute to the development of risk mitigation plans that minimize the organization's exposure and insurance requirements.

Competency in this role is demonstrated when the individual:

- Ensures relevant regulatory protocols are identified for all the organization's relevant processes.
- Ensures all staff are trained to exercise due diligence in the execution of organizational responsibilities.
- Analyzes the organization's processes and resource capacity to identify potential regulatory risks and exposures.
- Proactively develops SOPs and risk mitigation plans that will safeguard against potential risks and limit regulatory exposures.
- Evaluates product risks and adverse events identified during any phase of the product life cycle.
- Develops recommendations to mitigate regulatory risks identified in product evaluation, inspections, and incident reports, etc.

**Knowledge required for competency at this level:**

- Comprehensive knowledge of the organization's processes and procedures
- Thorough knowledge of all regulatory requirements relative to the organization's operations
- Knowledge of the proper use of risk management tools

### 3.5.7 Professional Writing for Regulatory Affairs

Compiles and maintains regulatory records, scientific reports, and other technical documents in order to ensure that all required written documentation is available to regulatory bodies and the organization to demonstrate compliance with all regulatory requirements.

Competency in this role is demonstrated when the individual:

- Develops synopses of papers, documents, and/or reports for dissemination.
- Reviews regulatory submissions, documents, and reports for content flow, technical accuracy, and completeness.
- Provides a written interpretation of complex technical information for the understanding of a non-technical audience.
- Prepares reports on new product registrations, regulatory compliance, citations, and remedial action.

**Knowledge required for competency at this level:**

- Fluency in English or French language and grammar, as applicable
- Comprehensive knowledge of technical and scientific document structure
- Awareness of language in documentation that may impact staffing, political, and financial resources
- Comprehensive knowledge of regulatory guidance documents

**3.5.8 Digital Skills for Regulatory Affairs**

Makes effective use of computer software and the Internet to maintain data, develop and disseminate documents and presentations, and file documents electronically as per applicable regulatory guidance.

Competency in this role is demonstrated when the individual:

- Develops strategies to utilize web databases in order to gather information in the most effective way and identify data gaps.
- Uses Microsoft Excel or an equivalent spreadsheet to organize and analyze data for inclusion in reports and filings.
- Successfully navigates existing and emerging technologies and electronic tools required for the conduct of regulatory affairs such as regulatory submission platforms, ERPs, QMSs, and CRMs.

**Knowledge required for competency at this level:**

- Comprehensive knowledge and skill in the application of the Microsoft Office Suite and analytics
- Comprehensive knowledge and skill in the use of the Internet for targeted research and electronic filing
- Comprehensive knowledge of software applications used within the organization (e.g., ERP, QMS, and CRM) and their compliance requirements

**3.6 Industry Regulatory competencies list for Regulatory Affairs Manager - Bio-health**

Included in Technical Competencies above.

## 3.7 Personal and professional competencies list for Regulatory Affairs Manager - Bio-health

### 3.7.1 Collaboration for Regulatory Affairs

Works effectively with others in order to foster trust and cooperation in the achievement of common goals and to promote a culture of regulatory compliance.

Competency in this role is demonstrated when the individual:

- Identifies the background, interests, and needs of key stakeholders in order to achieve mutually beneficial outcomes.
- Creates an environment of trust and mutual respect with relevant colleagues and stakeholders, regardless of relative level of authority, by consulting them in key decisions and taking their views, expectations, and priorities into account.
- Seeks to understand difficult situations and issues from the others' perspectives, providing support where necessary to move things forward.
- Continuously coordinates with internal and external stakeholder to effectively achieve goals and responsibilities.

**Knowledge required for competency at this level:**

- Working knowledge of effective collaboration models and techniques
- Working knowledge of change management processes and techniques
- Knowledge of project management tools and techniques

### 3.7.2 Continuous Learning

Continuously undertakes introspection to understand current knowledge and skills in a changing environment, recognizes personal knowledge gaps, undertakes independent action to actively seek targeted opportunities to acquire new knowledge, and reflects on how new knowledge can be integrated and applied.

Competency in this role is demonstrated when the individual:

- Makes a positive contribution to discussions and round tables on current legislative and regulatory issues and policies.
- Dialogues with regulatory experts and industry leaders to stay abreast of current and future developments in regulatory issues and policies.
- Analyzes information from a wide variety of sources to leverage the knowledge to the organization's benefit.
- Leverages insights into prior internal and external regulatory issues and deviations to help the organization address issues and barriers with minimal impact on the organization.
- Uses feedback and self-reflection to identify and pursue learning gaps and development opportunities.

**Knowledge required for competency at this level:**

- Working knowledge of latest adult learning principles as related to learning processes and techniques
- Working knowledge of training resources that can be utilized for personal and professional development
- Working understanding of personal learning style

### 3.7.3 Effective Interpersonal Communication for Regulatory Affairs

Communicates in ways that create a clear understanding of regulatory obligations internally and the organization's position externally in order to facilitate internal compliance and to positively influence the reputation and interests of the organization with government and non-government organizations.

Competency in this role is demonstrated when the individual:

- Delivers multi-mode communications that convey a clear understanding, appropriate to the target audience and context, e.g., communicating technical regulatory requirements to a non-technical audience.
- Disseminates regulatory and policy papers appropriately in order to increase understanding and optimize receptivity.
- Uses persuasive language to ethically advocate for the organization's position.
- Resolves conflict with a resistant audience in a manner that maintains a positive working relationship.
- Communicates with discretion and integrity to effectively balance regulatory/policy requirements and organizational needs.
- Translates complex information so that it becomes understandable and actionable by others.

**Knowledge required for competency at this level:**

- Understanding of a variety of individual and group communication models and strategies
- Understanding of conflict management approaches and techniques
- Knowledge of change management resources to affect staff culture

**3.7.4 Judgement/Strategic Thinking in Regulatory Affairs**

Analyzes information and situations rigorously while considering the future implications for the organization, and exercises sound judgement to recommend courses of action that strategically benefit the organization.

Competency in this role is demonstrated when the individual:

- Recommends a course of action based on an analysis of preliminary and incomplete information when action must be taken immediately.
- Provides an accurate interpretation of current and new regulations and legislation as well as their impact on organizational policies and processes.
- Accurately analyzes regulatory deviations to identify the root cause(s) of the problem.
- Evaluates solutions to regulatory and legislative conditions in order to determine a course of action that will create the greatest strategic benefit for the organization.

**Knowledge required for competency at this level:**

- Understanding of problem-solving frameworks and techniques
- Understanding of root cause analysis tools such as the Ishikawa diagram or the 5 Whys method
- Understanding of systems thinking approaches
- Understanding of the organization and its relationship to the larger economic and political environment

### 3.7.5 Planning and Organizing Work

Plans, organizes, and prioritizes work in an efficient manner in order to maximize the use of time and resources and successfully manage the multiple, varied, and time-sensitive responsibilities of the role.

Competency in this role is demonstrated when the individual:

- Juggles multiple, competing priorities and associated stressors with minimal loss of productivity.
- Uses discretion to manage work assignments from multiple sources with careful consideration of priorities, resources, deadlines, and the schedules of all involved.
- Uses formal time management tools and work management platforms to maximize efficiency and effectiveness.
- Uses delegation as appropriate to manage the workload.

**Knowledge required for competency at this level:**

- Advanced knowledge of planning and time management strategies such as mind mapping

### 3.7.6 Professionalism/Emotional Intelligence

Applies emotional and professional sensitivity to become aware of own emotions and those of others they interact with in such a way that they can manage personal and professional decorum and maintain productive relationships.

Competency in this role is demonstrated when the individual:

- Consistently models ethical conduct such as discretion, personal integrity, and respect for diversity in order to foster cooperation and collaboration in the achievement of organizational objectives (self awareness).
- Exercises initiative to proactively address emerging organizational, regulatory, and technological concerns (self management/regulation).
- Implements positive, personal stress management techniques to effectively deal with stress (self management/regulation).
- Works cooperatively with multiple stakeholders, demonstrating tact, diplomacy, and a willingness to consider alternative approaches or ideas that achieve results within ethical guidelines (relationship management).

- Navigates effectively through personal and political agendas to avoid or overcome barriers to the organization's progress (social awareness).

**Knowledge required for competency at this level:**

- Working understanding of the principles of emotional intelligence (see the work of authors like Daniel Goleman and Travis Bradberry)
- Working understanding of motivational theories

### 3.8 Essential Skills for Regulatory Affairs Manager – Bio-health

Essential Skills (ES) are foundational skills required for all types of work. They are not technical skills, but the core skills people need to acquire knowledge and complete workplace tasks and daily activities.

Understanding the ES requirements for a role can allow individuals to compare their skills to those required, assist training/learning providers in developing appropriate supports to ensure ES levels are developed during training, and provide employers with an additional tool for determining who/how to place in particular roles.

Human Resources and Skills Development Canada has defined Essential Skills as follows:

- Reading
- Document Use
- Numeracy, which is further divided into:
  - Money math; Scheduling, budgeting, and accounting math; Measurement and calculation math; Data analysis math.
  - Several different factors related to estimations, including the presence of a set procedure, the number of items being estimated, the consequences of errors in estimation, the amount of information missing, and the accuracy required.
- Writing
- Oral Communication
- Thinking Skills, which are further divided into:
  - Problem Solving

- Decision Making
- Critical Thinking
- Job Task Planning and Organizing
- Finding Information
- Significant Use of Memory
- Digital Skills
- Working with Others
- Continuous Learning

Most of the ES have levels based on complexity, and a role can be analyzed to determine the appropriate levels of ES. The exceptions are noted below:

- "Working with Others" does not have a complexity rating: it simply describes the ways in which the role would be required to interact with other people, either internally within the organization or externally (i.e., with clients, customers, or the public).
- "Continuous Learning" does not have a complexity rating: it describes the types of learning expected in the context of the role (e.g., on the job, being mentored by others, formal training as part of the job, etc.).

*NOTE: as of January 2020, ESDC was undertaking a comprehensive review of ES with the intent of adding additional skills, refining existing ones (particularly digital skills) and better aligning ES with similar approaches used in other countries. However the detail was not finalized in time to be used, therefore the profiles developed for this project follow existing standards as of December 2019.*

### 3.9 Canadian Language Benchmark for Regulatory Affairs Manager – Bio-health

Canadian Language Benchmarks (CLB) are a 12-point scale for task-based language proficiency descriptors which were originally developed as a guide for measuring the teaching and assessment of English as a Second Language (ESL) learners in Canada. Since they

were originally developed, the Canadian Centre for Language Benchmarks (CCLB) has continued to refine CLB, and it now includes scales for both English and French language proficiency.<sup>1</sup>

The CLB has been validated against both the Common European Framework for Language (CEFL) and the American Council for the Teaching of Foreign Languages (ACTFL) benchmarks and is considered accurate for high-stakes evaluation<sup>2</sup>.

The ES levels for Oral Communication were developed with reference to the Canadian Language Benchmarks<sup>3</sup>. Comparative work to determine the alignment between the CLB and other Essential Skills has been ongoing, with recent work providing additional alignment with the ES for Oral Communication in both spoken and listening domains, Reading, Writing, and Document Use.<sup>4</sup>

CCLB has developed a set of crossover tables that align CLB ratings with ES ratings for reading, writing oral communication and document use.

### Regulatory Affairs Manager (Bio-Health) ES/CLB Profile

Essential Skills	Equivalent CLB Level	ES Level				
		1	2	3	4	5
Reading	Reading: 11–12	1	2	3	4	5
Document Use	Reading: 11–12 Writing: 9–10	1	2	3	4	5
Writing	Writing: 9–10	1	2	3	4	5
Oral Expression	Speaking: 11–12 Listening: 11–12	1	2	3	4	

<sup>1</sup> Centre for Canadian Language Benchmarks. Theoretical Framework for The Canadian Language Benchmarks And *Niveaux De Compétence Linguistique Canadiens*. CCLB. Ottawa 2015. p8

<sup>2</sup> Centre for Canadian Language Benchmarks. Canadian Language Benchmarks: English as a Second Language for Adults, CCLB. Ottawa 2012 p.11

<sup>3</sup> Essential Skills Research Group. Readers Guide to the Essential Skills. ESDC. Ottawa ND. p57

<sup>4</sup> Canadian Centre for Language Benchmarks. Relating Canadian Language Benchmarks to Essential Skills: A Comparative Framework. 2015, p3

Essential Skills	Equivalent CLB Level	ES Level				
		1	2	3	4	5
Numeracy	n/a	1	2	3	4	5
Thinking Skills – Problem Solving	n/a	1	2	3	4	
Thinking Skills – Decision Making	n/a	1	2	3	4	
Thinking Skills – Job/Task Planning and Organizing	n/a	1	2	3+	4	
Thinking Skills – Significant Use of Memory	n/a	Types 1,2,3				
Thinking Skills – Finding Information	n/a	1	2	3	4	
Digital Skills	n/a	1	2	3	4	5
Working with Others	n/a	See Below				
Continuous Learning	n/a	See Below				

### Explanation of the Essential Skills and the Canadian Language Benchmark for Regulatory Affairs Manager (Bio-health)

#### Reading: ES 5 CLB: 11–12

Regulatory Affairs Managers read and interpret a wide array of complex scientific, technical, legal, and regulatory documentation in the course of their duties. They must synthesize information from various sources and use this information to inform the creation of regulatory reports and filings on behalf of their organization.

#### Document Use: ES 4 CLB: Reading: 11–12, Writing: 9–10

Regulatory Affairs Managers access and interpret information from a variety of electronic and paper-based sources. Information may be textual, graphical, tabular, and/or numerical in nature. They must be able to interpret legislation and regulations in order to

understand the potential impacts to their organization's regulated activities, and will also use this information to inform the creation of regulatory reports and filings on behalf of their organization.

**Writing: ES 4 CLB: 9–10**

In addition to routine internal and external correspondence (emails, memos, etc.). Regulatory Affairs Managers write formal reports and submissions to regulatory bodies (Health Canada, Agriculture Canada, Environment and Climate Change Canada, etc.) on behalf of their organization. They also take part in developing internal documents, reports, and briefings for management to use in making strategic and tactical decisions for the business.

**Oral Expression: ES 4 CLB: Speaking: 11–12, Listening: 11–12**

Regulatory Affairs Managers communicate orally with internal and external stakeholders on matters of importance with respect to regulatory compliance. They translate legal and regulatory language for non-technical audiences in order to ensure understanding and compliance. Oral communication may be directive (e.g., explaining a procedure to ensure regulatory compliance) or informative. They may be involved in, or asked to facilitate, group discussions related to regulatory matters with other regulatory affairs personnel and management and technical staff on matters related to changing regulations and their impact on the organization's commercialization efforts.

**Numeracy: ES 2 (Money Math: 2, Scheduling, Budgeting and Accounting: n/a, Measurements: n/a, Data Analysis: 2)**

Regulatory Affairs Managers support the organization's marketing and commercialization strategies and require an intermediate level of skill with regards to budgets and accounting in order to understand the business implications of regulatory activities and contribute meaningfully to discussions on regulatory processes. This can include multi-variate cost/benefit/risk analysis, using standardized formulae to support decisions. They must access data and use basic data analysis protocols in order to include relevant information in corporate regulatory filings.

**Thinking Skills:**

Thinking skills are subdivided into five domains:

- Thinking Skills — Problem Solving
- Thinking Skills — Decision Making
- Thinking Skills — Job/Task Planning and Organizing
- Thinking Skills — Finding Information
- Thinking Skills — Significant Use of Memory

- **Thinking Skills — Problem Solving: ES 3**

Regulatory Affairs Managers solve problems and determine best solutions related to regulatory compliance, taking into account a range of factors. The necessary information for problem solving is known and there are generally historical precedents that may be used to inform future action.

- **Thinking Skills — Decision Making: ES 3**

Regulatory Affairs Managers make decisions on courses of action for regulatory compliance that can have significant impact on the future financial well-being of the organization. Decisions are made in a climate of uncertainty, and often the results of these decisions are not immediately apparent and can only be reversed with difficulty in the future.

- **Thinking Skills — Job/Task Planning and Organizing: ES 3**

Regulatory Affairs Managers plan their own work and have discretion over how they will perform their tasks, within a framework of acceptable practice that is determined by their profession and by the organization in which they work. As professionals they are expected to be able to use judgement to set and manage their own priorities and task sequencing, although these may be overridden by more senior management. They work in a fluid environment and are expected to react dynamically to disruptions while remaining on schedule. They may be part of a team and will need to coordinate their work with others.

- **Thinking Skills — Finding Information: ES 3**

Regulatory Affairs Managers use a variety of data sources including regulatory databases (domestic and international), recent regulatory decisions, scientific reports, research data, and company records in order to design effective regulatory compliance strategies. Some information is in known locations, but they may be required to expand their information search to non-standard sources in order to uncover all of the information they need to accomplish their task and achieve the desired results.

- **Thinking Skills — Significant Use of Memory: Types 1, 2, 3**

Regulatory Affairs Managers must memorize, retain, and use information through one or all of the following methods:

- Purposeful memorization of procedures, codes, parts numbers, memorization through repetition (Type 1)
- Remembering information for brief periods, e.g., minutes or hours (Type 2)
- Unique events in which learning occurs from exposure (Type 3)

**Digital Skills: ES 3**

Regulatory Affairs Managers utilize standard office productivity software tools (Word processing, spreadsheets, presentations, etc.), electronic communication tools (email, text, instant messaging, video conferencing, etc.), and a variety of data retrieval and analysis tools and technologies in the performance of their duties.

**Working with Others: Work Contexts 2, 3 & 4**

The following work contexts and functions are relevant to the Regulatory Affairs Manager role:

- Works independently (Work Context 2)
- Works jointly with a partner or helper (Work Context 3)
- Works as a member of a team (Work Context 4)

**They may also be involved in supervisory or leadership activities, as follows: Functions 1–5**

- Participate in formal discussions about work processes or product improvement (S/L Function 1)
- Have opportunities to make suggestions on improving work processes (S/L Function 2)
- Monitor the work performance of others (S/L Function 3)
- Inform other workers or demonstrate to them how tasks are to be performed (S/L Function 4)

- Orient new employees (S/L Function 5)

**Continuous Learning: Type of Learning 1, 2, 3 How Learning Occurs: 1, 2, 3, 4, 5, 6**

**Type of learning may include:**

- Training in job-related health and safety (Type 1)
- Obtaining and updating credentials (Type 2)
- Learning about new equipment, procedures, products, and services (Type 3)

**The learning may occur:**

- As part of regular work activity (Context 1)
- From coworkers (Context 2)
- Through training offered in the workplace (Context 3)
- Through other forms of self-study (Context 4):
  - At work
  - On worker's own time
  - Using materials available through work
  - Using materials obtained through a professional association or union
  - Using materials obtained through worker's own initiative
- Through offsite training (Context 5):
  - During working hours at no cost to the workers
  - Partially subsidized
- With costs paid by the worker (Context 6)

## 4 REFERENCES

### Gathering the data

The development of the National Occupational Standards started with a review of existing information for the role. This review process included: referencing books, job postings, websites, articles, and BioTalent Canada's existing skills profiles to create the first draft. After several iterations via written feedback, focus groups and a national survey with subject matter experts, the National Standards were developed. The following are sources consulted during the creation of the **Regulatory Affairs Manager – Bio-Health** profile:

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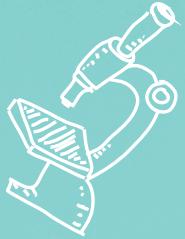
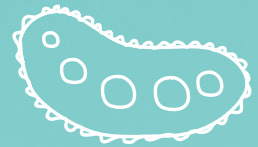
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During the research period, several job posting boards were reviewed for this profile

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