

Regulatory Affairs Associate in Agri-bio, Bio-industrial, Bio-energy

National Occupational Standard Summary



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Definition of occupation | **Regulatory Affairs Associate in Agri-bio, Bio-industrial, Bio-energy**

The Regulatory Affairs Associate in Agri-bio, Bio-industrial, Bio-energy (ABB) works under the guidance of a manager or external expert to provide regulatory support to the development of new products and maintenance and care of existing marketplace products in the biotechnology industry. They execute the organization's interests and objectives while interacting with regulatory agencies and work to ensure product and organizational regulatory compliance in the pre- and post-approval stages. They seek to anticipate risks associated with regulations related to product development; contribute to the development of new regulations, policies, and guidelines; help ensure the quality and safety of the product; make recommendations on how products are sold and promoted; and help ensure products meet research standards and quality.

Under the guidance of a manager, Regulatory Affairs Associates in ABB work on the development and completion of a variety of documents to ensure regulatory compliance. They maintain regulatory information systems both electronically and in hard copy, as applicable. They help to ensure that documents are accurately presented, scientifically sound, and encompass all relevant material necessary for a complete submission while representing the best interests of the organization. They adhere to regulatory Standard Operating Procedures (SOPs), operational SOPs, and internal departmental procedures, and help to identify necessary revisions.

Level of education, training or designations requirements



- Bachelor's degree in a relevant science (such as biology, animal health or veterinary, biochemistry, biotechnology, biomedical science, or chemical engineering) is recommended
- Academic research, practical research, or laboratory work experience is an asset

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- Experience in a generalist role in regulatory affairs within the biotechnology industry, at a regulatory authority, or other relevant experience is an asset
- Experience working in cross-functional teams
- Experience with institutional review boards (IRB's) and ethical committees (EC's) is an asset

This role works in the following subsectors:

Applicable To	Bio-Health	Agri-Bio	Bio-Industrial	Bio-Energy
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The level of complexity of the role is:

Span of Complexity Levels	Foundational	Operational	Specialist/ Management	Expert/Executive
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REGULATORY AFFAIRS ASSOCIATE IN AGRI-BIOTECH, BIO-INDUSTRIAL, BIO-ENERGY COMPETENCY SUMMARY

Competencies	Complexity Level Required			
	1 Foundational	2 Operational	3 Specialist/ Manager	4 Expert/ Executive
Core				
Ethics/Integrity				
Quality Orientation				
Technical				
Regulatory Systems and Documentation				
Regulatory Support for Product Development in Agri-biotech, Bio-industrial and Bio-energy				
Post-market Product Registration and Compliance				
Developing a Regulatory Strategy for the Organization				
Liaising with Regulatory Professionals				
Risk Management				
Professional Writing for Regulatory Affairs				
Digital Skills for Regulatory Affairs				
Industry Regulatory Competencies				
Included in Technical Competencies above				
Personal and Professional Competencies				
Collaboration for Regulatory Affairs				

Competencies	Complexity Level Required			
	1 Foundational	2 Operational	3 Specialist/ Manager	4 Expert/ Executive
Personal and Professional				
Continuous Learning				
Effective Interpersonal Communication for Regulatory Affairs				
Judgement/Strategic Thinking in Regulatory Affairs				
Planning and Organizing Work				
Professionalism/Emotional Intelligence				

Core competencies

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, in order to foster a positive culture of ethical regulatory compliance within the organization.

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.

Technical competencies

Regulatory Systems and Documentation

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

Regulatory Support for Product Development in Agri-biotech, Bio-industrial and Bio-energy

Provides regulatory expertise for product development to ensure compliance with current biotechnology product regulations throughout the product development life cycle.

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.

Developing a Regulatory Strategy for the Organization

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

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.

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.

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.

Digital Skills for Regulatory Affairs

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

Industry regulatory competencies

Included in Technical Competencies above.

Personal and professional competencies

Collaboration for Regulatory Affairs

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

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

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 nongovernment organizations.

Judgement/Strategic Thinking in Regulatory Affairs

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

Planning and Organizing Work

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

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.

USE NATIONAL OCCUPATIONAL STANDARDS TO:

- ✓ Build a job description
- ✓ Plan professional development
- ✓ Map career progression and succession planning
- ✓ Benchmark compensation

View the full National Occupational Standards at biotalent.ca/NOS

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