



Regulatory Affairs Specialist

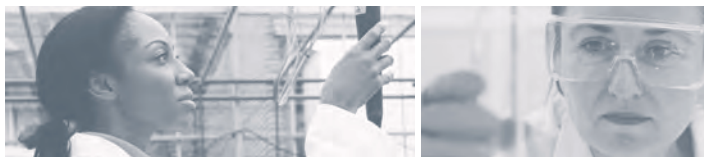
Bio-economy Skills Profile Summary

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.

Learn more about the role of Regulatory Affairs Specialist by downloading the full skills profile for free at www.biotalent.ca/profiles.



Regulatory Affairs Specialist



BioTalent Canada's Bio-economy Skills Profiles

Biotechnology's fusion of science and business creates unique requirements for jobs in the sector. Candidates often need skills suited both to the lab and the boardroom. As a result, occupational descriptions from other sources or sectors don't always fit the bio-economy exactly. That's why, in partnership with industry stakeholders, BioTalent Canada has developed skills profiles specific to the bio-economy—a project that will continue with the ongoing addition of other functions over time.

Each profile includes a definition of the occupation, a list of competencies and associated tasks, a summary situational analysis, language benchmarks, and essential skills.

Who can use these profiles?

Easy to use and interpret, our *Bio-economy Skills Profiles* were created to meet the needs of a wide range of audiences. Here's how you might use them if you're an:

Employer: Develop job descriptions, performance evaluation criteria, professional development programs, succession plans, team building initiatives and recruitment plans.

Job seeker: Identify your professional development needs, tailor your resume for a specific position, prepare for interviews and interpret job descriptions.

Educator: Build industry-oriented curricula to help produce job-ready graduates.

Student: Grow your understanding of employers' expectations and choose the right educational programs to equip yourself with the skills for success.

Validated by industry

BioTalent Canada created its *Bio-economy Skills Profiles* in consultation with industry to accurately capture the needs of biotechnology companies and produce truly practical, relevant resources. These profiles summarize the high-level skills required for each occupational profile and itemize in detail the common tasks associated with each function. Because the profiles are comprehensive, not every skill may be required for a single position: instead, the profiles present the full sets of skills that could be expected of a person in a given role within companies at various stages of development.

Information you can trust

BioTalent Canada is the country's source for reliable, objective and accurate information on skills development and human resources in the bio-economy. Our aim as Canada's biotechnology sector council is to deliver the human resources tools, information and skills development resources industry needs to ensure an adequate supply of job-ready people.

Understanding the bio-economy

Canada's bio-economy is engaged in the research, development, commercialization and manufacturing of biotechnology products. The bio-economy is constantly expanding as new technologies and techniques are applied to an ever-broader range of industries and sectors including:

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

Get started today

Even before you download the full Regulatory Affairs Specialist Skills Profile, get a sense of the information it contains and how you might use it in your work. Attached here is a quick-reference checklist that summarizes the core skills required for the position and the common tasks associated.



**Go to www.biotalent.ca/profiles
and download the complete skills profile.**

The function of a Regulatory Affairs Specialist demands specialized technical and scientific knowledge that may originate from experience in various scientific fields.

A Regulatory Affairs Specialist must be able to:

A. Contribute to regulatory agency initiatives

- 1. Carry out regulatory intelligence activities
- 2. Provide input to draft policies and guidelines
- 3. Coordinate company input
- 4. Participate in industry association meetings
- 5. Participate in regulatory agency pilot projects
- 6. Lobby to influence on behalf of your organization or industry

B. Apply regulations

- 1. Interpret regulations
- 2. Perform impact assessment
- 3. Create internal position papers/action plans
- 4. Create or modify plans/procedures for implementation of regulations, as required
- 5. Communicate plan and procedure related to regulation in question to stakeholders
- 6. Provide periodic regulatory training
- 7. Implement procedure

C. Manage regulatory processes to maintain compliance with current regulations

- 1. Develop regulatory processes
- 2. Maintain regulatory processes
- 3. Comply with company policies, procedures and processes
- 4. Review regulated or controlled documents
- 5. Maintain registration databases, as required
- 6. Manage information contained within the regulatory Information Management Systems
- 7. Share learning with colleagues

D. Develop regulatory strategies

- 1. Develop clear product or project scope
- 2. Identify applicable regulatory requirements for the product or project
- 3. Identify opportunities and restrictions
- 4. Identify options
- 5. Develop plan, critical path and timelines, as required
- 6. Author regulatory strategy documents, as required
- 7. Consult with regulatory agencies, if required
- 8. Present strategy for management approval
- 9. Revise, complete and obtain approval for strategy

E. Implement regulatory strategies

- 1. Continually monitor regulatory requirements/environment
- 2. Initiate strategy

- 3. Evaluate project progress periodically
- 4. Seek and provide input into project activities
- 5. Adjust regulatory project strategy
- 6. Communicate status of regulatory project
- 7. Update strategy in response to regulatory agency feedback on project, to the point of project completion

F. Prepare submissions

- 1. Identify submission content
- 2. Identify and consult with contributors/authors of various sections
- 3. Author summaries, if required
- 4. Review and approve summaries
- 5. Review and approve/prepare associated source documents, as required
- 6. Approve source documents for inclusion in the submission
- 7. Sign-off on dossier
- 8. Develop label
- 9. Complete administrative documents
- 10. Populate and publish submission
- 11. Submit dossiers
- 12. Respond to regulatory agency questions
- 13. Negotiate the label
- 14. Obtain regulatory authorization

G. Communicate with regulatory authorities

- 1. Determine rationale for agency communication
- 2. Plan agency communication
- 3. Prepare briefing documents
- 4. Facilitate agency meetings
- 5. Document regulatory agency communications
- 6. Communicate meeting outcomes to relevant stakeholders
- 7. Co-ordinate actions resulting from regulatory agency communications
- 8. Respond to submission deficiencies, as required
- 9. Respond to regulatory agency inquiries
- 10. Ensure that response was satisfactory to regulatory agency

H. Assist in internal and external regulatory inspections

- 1. Support internal audits, as required
- 2. Support non-clinical sites during regulatory agency inspection, as required
- 3. Support clinical trial sites during regulatory agency inspections, as required
- 4. Assist in preparation for third-party facility inspections
- 5. Assist with third-party facility inspections, as required
- 6. Assist in responses to citations
- 7. Submit responses to citations, as necessary

I. Manage product registrations

- 1. Ensure compliance with post-approval requirements
- 2. Manage post-approval changes
- 3. Communicate approval of changes
- 4. Review marketing material
- 5. Approve marketing material
- 6. Compile and submit adverse event reports and/or safety information
- 7. Manage or support external communication regarding product quality, if required
- 8. Manage or support product recalls, as required

J. Provide regulatory support to development of the product

- 1. Provide support for compassionate use of studies
- 2. Provide support for phase I-IV studies, as required
- 3. Provide support for investigator-led studies
- 4. Provide support for health policy studies, as required
- 5. Provide support for efficacy studies, as required
- 6. Provide support for infectious diseases surveillance
- 7. Provide support for dispensarization and prevention
- 8. Review published literature of product used in third-party studies, as required

K. Demonstrate personal competencies

- 1. Demonstrate attention to detail
- 2. Manage multiple projects
- 3. Demonstrate computer skills
- 4. Evaluate scientific information
- 5. Continually update scientific and regulatory knowledge
- 6. Demonstrate strategic planning skills to identify opportunities for product development
- 7. Actively engage in business strategies
- 8. Manage sensitive information
- 9. Demonstrate balanced judgment
- 10. Demonstrate interpersonal skills
- 11. Demonstrate teamwork
- 12. Share learnings with colleagues
- 13. Demonstrate problem solving skills
- 14. Demonstrate effective negotiation skills
- 15. Communicate with diverse audiences
- 16. Write and edit technical documents
- 17. Demonstrate presentation skills
- 18. Build strategic relationships
- 19. Develop and broaden networks
- 20. Demonstrate an above-average ability to communicate in the language of the regulatory environment