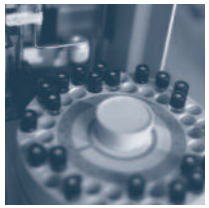

Scientific/Medical Writer

Bio-economy Skills Profile

BioTalent™ Canada

Building skills for Canada's bio-economy

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.

BioTalent™ Canada

Building skills for Canada's bio-economy

Canada This project is funded by the Government of Canada's Foreign Credential Recognition Program

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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 scientific/medical Writer.

Occupational Definition

A scientific/medical writer understands and synthesizes large amounts of technical and scientific information and composes an accurate narrative that appeals to a broad audience. The writer creates a wide range of medical and scientific documents that meet defined communication objectives. The scientific/medical writer has a strong knowledge and understanding of science, particularly biology, pharmacology, chemistry and biotechnology. In addition to composing scientific documents, reports, presentations and other comprehensive materials, the writer may also perform background research and fact checking and use statistical analyses.

The writer works closely with content experts, communication agencies and industry to develop materials that are accurate and easy to understand. The professional scientific/medical writer plays a critical role in developing effective communications for the Canadian biotechnology industry, serving companies of different sizes in areas such as:

- Agriculture
- Aquaculture
- Bioenergy
- Bioproducts
- Biosciences
- Genomics
- Human and Animal Health
- 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

Scientific/medical writers work closely with subject matter experts across the bio-economy to develop research documentation and communications materials that are accurate, easy to understand and respond to the needs of the targeted audience. They research, interpret, write, and edit scientific and medical information for audiences that may include regulatory authorities, the medical and/or scientific communities, investors, academia and the general public. They develop a wide range of written documents including regulatory submission reports and forms, research articles, press releases, fact sheets and other materials in newspapers, medical journals and on websites. A strong background in science (particularly in areas such as biology, pharmacology, chemistry and biotechnology) and a good understanding of medical terminology, coupled with excellent verbal and written communication skills are essential for success in this field.

Scientific/medical writers enjoy a wide range of employment opportunities in many types of organizations across the bio-economy and peripheral industries. Some specialize in scientific writing and/or editing for medical professionals. Others work in medical marketing, advertising, or public relations, or in journalism, writing for a lay audience and/or medical professionals. Some scientific/medical writers are freelancers and work in one or more areas often specializing in specific subject matter.

The pharmaceutical industry in particular employs a large number of scientific/medical writers to draft documents for regulatory agencies and to produce promotional and marketing material for doctors and for the end users of their products (patients). Employment opportunities in industries peripheral to the bio-economy exist for example at hospitals, medical education companies, medical advertising and communications agencies, and associations related to patient advocacy/information and disease research/awareness. A number of advertising and communications agencies specialize in providing marketing and public relations support to the medical and pharmaceutical industries in Canada. These agencies use the knowledge and expertise of scientific/medical writers to produce written documents and promotional materials to support their clients marketing objectives.

Scientific/medical writers often enter the profession from another related field. These can include (but are not limited to): copywriting and design, education, medicine, pharmacy, publishing and journalism, dentistry, medical research, nursing, public relations and veterinary medicine. Most scientific/medical writers have considerable formal education in subjects such as mathematics, biology, chemistry and biochemistry and it is not uncommon for scientific/medical writers to hold graduate-level degrees. A study carried out in 2008 of scientific/medical writers in Canada found that 22% had an undergraduate degree, 20% had a Masters degree and 17% had a doctorate or medical degree. The study also showed that industry, government and communications/ marketing sectors tend to employ freelance writers to a greater degree than as full-time employees. Based on a review of job postings and secondary research, a scientific/medical writer position generally requires a bachelor's degree (preferably in a scientific field) as a minimum level of education, as well as at least three years of technical writing experience.

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		

Scientific/medical writers above all need strong writing and critical thinking skills in order to explain often complex concepts in clear text and images that are appropriate for the targeted audience. They also a need well developed capacity to find information that complements or completes the material/data that they have at the start of a project.

Language Benchmarks

The majority of communications tasks associated with the required competencies and activities of a competent scientific/medical writer were found to be between Canadian Language Benchmark levels 8 – 12. This finding is based on a limited sampling of representatives in industry. The actual language benchmark requirements for this occupation within an organization will be subject to the organization's requirements, and the definition of the occupational role within the organization.

Competency Profile

A Scientific/Medical Writer must be able to:

A. Plan for document development

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Prepare a Document Development plan for a product	1.1. Identify documents/work/activities to be completed.	
	1.2. Outline timeline and schedule.	
	1.3. Define roles and responsibilities.	
	1.4. Estimate level of work.	
	1.5. Determine the quality and level of resources needed to do the work.	
	1.6. Identify outsourced resources (if necessary).	
	1.7. Develop key performance indicators.	
	1.8. Submit Document plan to Management for review and approval.	
	1.9. Address concerns/issues.	
2. Follow established materials/aids	2.1. Develop guidelines and policies to support the plans i.e. Standard Operating Procedures (SOPs), Terms of Reference (TORs), etc.	
	2.2. Develop and document processes and procedures (SOPs) to support the plans.	
	2.3. Design and develop the templates, forms and document formats.	
	2.4. Submit the document package to Management for review and approval.	
	2.5. Address concerns/issues.	
	2.6. Obtain approval for the supporting materials/aids.	

A Scientific/Medical Writer must be able to:

B. Conduct supporting background research

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Establish the methodology for the research	1.1. Identify the area of interest.	
	1.2. Define the scope and breadth of the area of interest.	
	1.3. Define the objectives of the investigation of the area of interest.	
	1.4. Develop the research plan.	
	1.5. Identify data and information sources to be consulted in executing the research plan.	
2. Apply the research methodology	2.1. Conduct literature search(es) (e.g., books, journals, conference papers, indexes, abstracts, other reference materials, electronic databases, the internet, government publications, published research and peer-review journals and published articles relevant to the area of interest).	
	2.2. Find and review market, therapy area, product and competitor information.	
	2.3. Investigate other research organizations in terms of research activities, position in the research cycle.	
	2.4. Review study documents.	
	2.5. Review statistical analysis plans and case report forms, as required.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	2.6. Proactively review and understand company molecules and protocols (where applicable) that are associated with specific writing projects.	
	2.7. Review medical documents generated by other organizations.	
	2.8. Network with peers/colleagues.	
3. Consolidate gathered information	3.1. Compile the information from the various sources.	
	3.2. Organize the information to facilitate review and analysis.	
	3.3. Categorize sourced information (relevant, somewhat relevant, not relevant).	
	3.4. Determine that sufficient information has been gathered.	
	3.5. Continue research until sufficient information has been gathered and compiled.	
4. Analyze the gathered data/information	4.1. Complete an analysis of gathered data/information.	
	4.2. Determine current state of knowledge, including controversies and consensus.	
	4.3. Identify knowledge and research gaps.	
	4.4. Summarize and document findings.	
	4.5. Communicate findings with team.	
	4.6.Create master Reference list.	
	4.7.Store notes/materials in the document management system.	

A Scientific/Medical Writer must be able to:

C. Develop clinical study/trial documents

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Create documents, (e.g., clinical trial documents, health care, technical, medical, scientific, public education, communications)	1.1. Organize key themes and messages for the document.	
	1.2. Analyze supporting data, charts and tables.	
	1.3. Evaluate research findings from internal and external sources.	
	1.4. Format the document in accordance with regulatory requirement, templates, etc.	
	1.5. Write the content of the document.	
	1.6. Circulate to the documents for review, input and feedback.	
	1.7. Edit the draft document in light of feedback.	
	1.8. Submit the draft document to management for approval.	
	1.9. Address any issues/concerns.	
	1.10. Finalize the document and obtain approval.	

A Scientific/Medical Writer must be able to:

D. Manage document development process

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Inspect and evaluate the quality of the documents	1.1. Confirm correct grammar, punctuation, spelling, formatting used throughout the development of a document.	
	1.2. Validate compliance of documents with regulatory requirements (e.g. *International Conference on Harmonisation (*ICH) guidelines) and company document standards.	
	1.3. Ensure developed documents meet company document standards.	
	1.4. Verify application of consistent style guidelines.	
	1.5. Review layout including tabular and graphical displays of data to ensure they are accurate and effectively present and communicate study results.	
	1.6. Confirm documents are scientifically accurate.	
	1.7. Review the work of other writers (in-house and/or contract) for accuracy, quality, focus, and adherence to format and stylistic requirements.	
	1.8. Verify accurate/precise implementation of client/author amendments and comments.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	1.9. Check proofs and printer's proofs (i.e., text, layout, colour, specifications) and sign-off for print/production.	
2. Manage contributions to the documents	2.1. Participate regularly on task force teams and cross-functional working groups including different suppliers, agencies, industry, content experts, and other stakeholders.	
	2.2. Work with team to plan and implement document development plan.	
	2.3. Communicate priorities to team members.	
	2.4. Track and monitor writing project issues and status of corrective actions	
	2.5. Keep the team(s) updated on project status and issues related to writing the documents.	
	2.6. Assist the team(s) in resolving issues related to document preparation.	
3. Apply document/information management protocols	3.1. Work effectively with a document management system.	
	3.2. Organize and classify multiple pieces of information.	
	3.3. Store data safely and securely.	
	3.4. Retrieve data/information.	
	3.5. Dispose of data/information in accordance with company policies and procedures.	

A Scientific/Medical Writer must be able to:

E. Manage stakeholder relationships

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Establish relationships with appropriate multi-disciplinary team members in various internal and external functions (e.g., Marketing, Medical, Statistics, Clinical, Graphic design, Agency, Translation, consumer/patient advocacy groups, other stakeholders)	1.1.Identify individuals and organizations in the field of interest.	Professional writing colleagues, organizations, associations, companies, and other experts relevant to the subject area
	1.2. Develop contact with the identified individuals and organizations.	
2. Maintain relationships with appropriate multi-disciplinary team members in various internal and external functions (e.g., Marketing, Medical, Statistics, Clinical, Graphic design, Agency, Translation, consumer/patient advocacy groups, other stakeholders)	2.1. Listen.	
	2.2. Communicate well, clearly, and in a timely manner.	
	2.3. Ensure awareness of differences, treat everyone equitably and accommodate special needs.	
	2.4. Recognize and acknowledge the skills and abilities of others.	
	2.5. Adapt effectively to different individual styles.	
3. Develop and maintain relationships with identified thought leaders	3.1. Contact identified thought leaders.	
	3.2. Establish credentials and the parameters of the relationship and project.	
	3.3. Ensure thought leaders understand their role and responsibilities with respect to the project.	
	3.4. Communicate clearly concerning project and its status, as appropriate.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.5. Inform project team of contact with thought leaders and their project participation and any concerns.	
	3.6. Recognize, acknowledge and respect their contribution to the project.	
	3.7. Adapt to personal style and requirements.	

A Scientific/Medical Writer must be able to:

F. Apply generally accepted management practices

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Apply generally accepted management techniques	1.1. Create opportunities for information sharing across the team e.g. meetings, brainstorming.	
	1.2. Comply with corporate policies and guidelines.	
	1.3. Keep team informed of progress and performance.	
	1.4. Provide coaching, mentoring and training as required.	
2. Apply project management leading practices	2.1. Develop and work to a documented project plan.	
	2.2. Understand management expectations and set milestones accordingly.	
	2.3. Determine the level and nature of resources needed to support the project plan.	
	2.4. Monitor project hours/budget and inform client of any discrepancies.	
	2.5. Monitor progress to plan and achievement of project milestones.	
	2.6. Revise timelines, as required.	
	2.7. Identify and communicate emerging risks, issues and concerns.	
	2.8. Report on performance to the project plan and recommended actions to address variances to plan.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
3. Identify and protect intellectual property	3.1. Understand and follow corporate policies, guidelines and procedures pertaining to intellectual property.	
	3.2. Ensure that all necessary steps are being taken regarding intellectual property.	
4. Protect and respect sensitive/confidential information	4.1. Respect confidentiality of records that meet the definition of sensitive information under the *Personal Information Protection and Electronic Documents Act* (PIPEDA).	
	4.2. Communicate confidential information appropriately to those who have a functional 'need to know'.	
	4.3. Store and secure confidential information in observance of applicable laws and company policies/procedures.	
5. Use information management systems/computers to manage documents	5.1. Use computers and applications to collect, analyze and interpret and present complex data e.g. Microsoft Office and proprietary enterprise solutions.	
	5.2. Use document management systems and related technology for document tracking and information management.	
6. Manage work activities	6.1. Use materials and resources in a cost effective manner.	
	6.2. Oversee temporary personnel.	
	6.3. Apply continuous quality improvement techniques to ensure the quality and efficiency of writing services.	
	6.4. Follow established policies and procedures.	
7. Establish effective working relationships	7.1. Work effectively with team members and others.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	7.2. Share current knowledge with new colleagues.	
	7.3. Recognize the skills and abilities of others.	
	7.4. Show respect.	
	7.5. Accept and appreciate different ways of doing things.	
8. Encourage team building	8.1. Contribute to team planning efforts.	
	8.2. Work towards measurable objectives.	
	8.3. Promote accountability.	

A Scientific/Medical Writer must be able to:

G. Apply professional practices

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Comply with established internal policies, procedures and protocols and external regulations and legislation	1.1. Review corporate policies, procedures, guidelines and directives and know and understand applicable rules, regulations and legislation.	
	1.2. Work within regulatory framework and corporate policies, procedures, guidelines and directives.	
	1.3. Identify situations/instances of non-compliance and assess impact on writing project(s) and deliverables.	
	1.4. Provide input to determine appropriate corrective and/or mitigating action(s).	
2. Demonstrate writing skills	2.1. Apply scientific and technical writing skills.	
	2.2. Use grammar, syntax and spelling skills.	
	2.3. Apply scientific and technical editing skills and consistent style.	
	2.4. Ensure scientific accuracy.	
	2.5. Apply proof-reading skills, as required.	
	2.6. Apply professional association writing guidelines (e.g. American Medical Association (AMA) guidelines).	
3. Demonstrate medical/scientific/regulatory knowledge and understanding	3.1. Apply knowledge of the scientific research process and regulations/guidelines, as required.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.2. Exploit knowledge of global regulatory requirements where appropriate (Food and Drug Act (FDA), International Conference on Harmonization (ICH) etc.).	
	3.3. Apply experience with medical, scientific and statistical concepts to document creation.	
	3.4. Demonstrate understanding of the business of science and medicine (e.g. marketing, regulatory, research).	
4. Demonstrate professional integrity	4.1. Report results and progress accurately and honestly.	
	4.2. Respect confidentiality (e.g., data, records, intellectual property, client information).	
	4.3. Take responsibility for actions and decisions.	
	4.4. Maintain high standards in practice.	
	4.5. Apply relevant nationally and internationally accepted guidelines and practices.	American Medical Writers Association (AMWA), American Medical Association (AMA)
	4.6. Demonstrate openness, transparency and fairness.	
	4.7. Show respect for team members, peers and other individuals.	
	4.8. Act with regard to corporate ethics and values.	

A Scientific/Medical Writer must be able to:

H. Demonstrate personal competencies

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Apply critical thinking/problem-solving skills	1.1. Identify the problem.	
	1.2. Analyze, identify and assess the cause(s) of the problem.	
	1.3. Apply knowledge, training and creativity to determine the appropriate course of action.	
	1.4. Implement the selected course of action.	
2. Set priorities	2.1. Keep goals and objectives in mind.	
	2.2. Maintain awareness of time-sensitive issues and critical deadlines.	
	2.3. Multi-task where possible and practical	
3. Organize work	3.1. Set goals, objectives and priorities according to available resources.	
	3.2. Manage time effectively.	
	3.3. Establish processes to enhance effectiveness.	
	3.4. Determine the information/data needed.	
	3.5. Recognize where templates and standard forms would facilitate data and information management.	
	3.6. Develop and maintain hard copy and electronic templates/forms to facilitate standard and consistent collection of information and data.	
4. Manage multiple tasks	4.1. Recognize competing priorities.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	4.2. Divide time appropriately.	
	4.3. Prioritize tasks.	
	4.4. Identify and manage resources to assist in completing tasks.	
	4.5. Monitor progress.	
	4.6. Reset priorities in accordance with changing timelines and requirements.	
	4.7. Delegate, when required.	
5. Communicate well and clearly	5.1. Deliver and adapt message for appropriate audiences.	
	5.2. Demonstrate above average communication skills (written and oral).	
	5.3. Demonstrate an ability to clearly articulate complex issues orally and in writing.	
	5.4. Explain point of view clearly and concisely, as appropriate.	
	5.5. Prepare and deliver presentations.	
	5.6. Prepare briefing notes for general presentations.	
	5.7. Translate, simplify, and explain terms when communicating to parties who understand clinical trial/scientific terminology, but also those who may not.	
	5.8. Understand subtleties of communication (e.g. body language, cultural differences, individual communication styles).	
	5.9. Use appropriate terminology.	
6. Demonstrate ability to work in a team	6.1. Encourage and accept diverse opinions.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	6.2. Recognize the skills and abilities of others.	
	6.3. Collaborate and consult with team members.	
	6.4. Motivate team members.	
	6.5. Identify when to follow and when to lead.	
	6.6. Participate actively.	
	6.7. Support team decisions.	
	6.8. Mentor/coach junior team members.	
7. Demonstrate interpersonal skills	7.1. Show respect.	
	7.2. Recognize group dynamics.	
	7.3. Listen.	
	7.4. Share personal opinion or understanding.	
	7.5. Use variable approaches to respond to individual styles.	
	7.6. Communicate well and clearly.	
	7.7. Show empathy and sensitivity.	
8. Embrace continuous learning and development	8.1. Allocate time for continuous learning.	
	8.2. Build on 'lessons learned' from past writing engagements/projects (e.g. seek feedback).	
	8.3. Identify opportunities for continuous learning.	
	8.4. Keep abreast of relevant science and technology.	
	8.5. Nurture the ability and enthusiasm to learn new skills and techniques.	

Strong Board of Directors

The Board of Directors is composed of experts in the field of HR, CEOs, CFOs and CSOs 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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