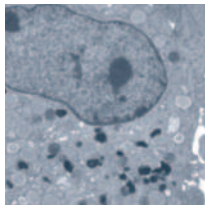

Pharmacologist

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.

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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 pharmacologist.

Occupational Definition

Pharmacologists are scientists who investigate how drugs and chemicals interact with biological systems. Their aim is to understand drugs and their actions to enable their effectiveness and safety. They carry out research to aid drug discovery and development. They determine how biological systems function with the aim of identifying how components of the subsystem can be targeted by drugs and/or chemicals for therapeutic gain. Their role includes improving the diagnosis, prevention and treatment of physiological and psychological diseases. Areas of specialization include clinical pharmacology (carrying out work involving the effects of medicines on people within clinical trial studies), neuropharmacology (studying the effect of chemicals on the nervous system), chemotherapy (the study of drugs that kill cancer cells, germs or viruses without harming healthy cells), cardiovascular pharmacology (the study of drugs that affect blood flow and heart function) and regulatory pharmacology. Related occupations include toxicology (studying the effects of poisonous substances, such as chemicals and air pollutants), biochemistry, physiology, genetics, immunology, and cell biology. Much of their role is laboratory-based, working as part of a scientific research team with a focus on the design, planning and conduct of controlled experiments to improve understanding of a compound's activity. A pharmacologist may participate in or lead research studies and/or clinical trials.

Private organizations, government agencies, hospitals, universities and research institutions all employ pharmacologists. A significant proportion of their time is spent in laboratories and conducting online research. Pharmacologists work for Canadian biotechnology companies of different sizes (i.e., small, medium, large) and in various biotechnology areas such as:

- Agriculture
- Bioinformatics
- Bioproducts
- Biosciences
- Food Processing
- Pharmaceuticals
- Genomics
- Human and Animal Health
- Industrial
- Life Sciences
- Medical Devices
- Nanotechnology
- Nutraceuticals

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

Pharmacologists are research scientists who investigate how drugs and other chemicals interact with biological systems. They study the complex interactions between chemicals and living things. Their goal is to understand chemicals and their actions so they can be used effectively and safely. They work as part of a scientific research team with a focus on the design, planning and conduct of controlled experiments to improve understanding of a compound's activity. A pharmacologist may participate in or lead research studies and/or clinical trials.

A pharmacologist's role includes improving the diagnosis, prevention and treatment of physiological and psychological diseases. They explore the properties of a given compound to determine its make-up and composition, and the interactions it has when given to living organisms. They develop and use animal models to identify and characterize new bio-active compounds, and to identify the effects of different doses of new compounds. Information from these models enables pharmacologists to formulate a 'safety window' or balance between efficacy and the potential for adverse side effects. Research teams use this information to determine and select dosages that can be used safely in clinical trials.

As research scientists, pharmacologists are also concerned with disseminating the results of their work to others. They share research results with colleagues, prepare and deliver presentations as national and international scientific conferences, write and publish scientific papers in per-reviewed medical and/or scientific journals. In private industry there is also often a lag period for any publications due to intellectual property issues.

Depending on the nature of the position, a pharmacologist may manage staff and have administrative responsibilities. These typically include recruiting team/staff members, managing their work assignments, monitoring performance and providing feedback and supporting individual career growth and development. As well, pharmacologists promote and ensure that standard protocols and practices are adopted and implemented in their team or organization, for example standard operating procedures for safety, compliance with Good Clinical and Good Laboratory practices. From time to time there may be a requirement to work with sub-contractors. Pharmacologists may be responsible for managing the working relationship with these parties, reviewing and reporting on performance and approving invoices for payment.

Pharmacologists typically hold an advanced degree such as a Pharm.D. or a PhD in a relevant scientific field. Bachelor's degrees, including courses in sciences and mathematics, are required to enter pharmacology programs. Graduate study includes theoretical courses and laboratory research. An individual usually completes education/training in medicine, pharmacy, molecular biology or biochemistry before specializing in pharmacology. Pharmacologists must have both doctorates and medical degrees to conduct clinical testing on humans. Employers look to pharmacologists to have several years' experience in the pharmaceutical/biotechnology industry. Some will also require knowledge of drug discovery programs, and advanced data analysis experience (including modeling

and population kinetics). Post-doctoral research experience is usually required before employment in academic departments or research institutions.

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		

A pharmacologist must be able to read and understand large volumes of literature and data to develop an understanding specific biological systems and how a particular drug or chemical interacts with those systems. As they most often work in multi-disciplinary project teams, they also require strong oral communication skills to build research strategies, discuss data and decide on its meaning. Given the complexity of biological systems they also need well developed critical thinking skills to combine information from potentially disparate sources in order to understand the mechanism(s) of action of drugs and other chemicals.

Language Benchmarks

The majority of communications tasks associated with the required competencies and activities of a competent pharmacologist were found to be between Canadian Language Benchmark levels 9 – 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 Pharmacologist must be able to:

A. Develop a research hypothesis

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Identify potential research areas appropriate to company goals and objectives	1.1. Review corporate strategic plan and company growth objectives.	
	1.2. Review research targets and objectives currently underway.	
	1.3. Assess gaps and opportunities.	
	1.4. Identify potential research areas.	
2. Review research trends and directions	2.1. Conduct literature search (both hard copy and web-based materials) and identify relevant literature in search results.	
	2.2. Review relevant search literature (both hard copy and web-based materials).	
	2.3. Review secondary data.	
	2.4. Network with peers/colleagues.	
	2.5. Research competitors in terms of research activities, position in the research cycle.	
	2.6. Conduct SWOT (strengths, weaknesses, opportunities, threats) analysis.	
3. Develop a research hypothesis	3.1. Compile and organize gathered data and information.	
	3.2. Analyze gathered data/information.	
	3.3. Document the research hypothesis.	
4. Assess hypothesis from a business perspective	4.1. Evaluate potential benefits of the hypothesis - to the company, to individuals, to the scientific community.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	4.2. Evaluate potential drawbacks or barriers related to the hypothesis - to the company, to individuals, to the scientific community.	
	4.3. Apply profit/loss considerations.	
	4.4. Assesses potential of hypothesis for further development (feasibility study).	
	4.5. Seek approval for the research hypothesis.	

A Pharmacologist must be able to:

B. Develop the research plan

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Develop a research plan for the initiative	1.1. State approved goals and objectives.	
	1.2. Outline timeline and milestones.	
	1.3. Define roles and responsibilities.	
	1.4. Develop the experimental design.	
	1.5. Identify experimental controls.	
	1.6. Specify the protocols and test equipment/apparatus that will be required to support the experiment(s).	
	1.7. Identify outsourced resources (if necessary).	
	1.8. Circulate the draft research plan for review.	
	1.9. Address review findings.	
	1.10. Obtain Director/Executive Team approval for the research plan.	
2. Develop a research business plan	2.1. Analyze research capacities.	
	2.2. Identify gaps in research capacity.	
	2.3. Identify personnel resources needed to implement the research plan.	
	2.4. Estimate requirements for materials, subcontractors, space, equipment, etc.	
	2.5. Determine in-house versus external research options.	
	2.6. Identify changes required in current organization/structure.	
	2.7. Identify and assess risks.	
	2.8. Mitigate assess risks.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	2.9. Develop funding estimate.	
	2.10. Prepare business case.	
	2.11. Seek approval for the research business plan.	
	2.12. Address objections/concerns.	
	2.13. Obtain Executive team approval for the plan.	
3. Develop key performance indicators	3.1. Solicit input on key performance measures.	
	3.2. Develop potential performance measures for both progress to plan and meeting milestones.	
	3.3. Determine availability and retrievability of data/information needed to measure performance.	
	3.4. Assess feasibility of potential performance measures in terms of data/information availability.	
	3.5. Identify supporting data and information requirements.	
	3.6. Obtain approval for key performance measures	
	3.7. Develop standard report template for reporting purposes.	
	3.8. Develop standard reporting schedule.	

A Pharmacologist must be able to:

C. Execute the research plan

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Secure funding for the research plan	1.1. Identify internal funding sources.	
	1.2. Obtain Executive team commitment re: internal funding.	
	1.3. Identify external sources of funding.	
	1.4. Identify eligibility requirements for external sources of funding.	
	1.5. Assess eligibility qualifications for external sources of funding.	
	1.6. Prepare submissions for external funding.	
	1.7. Obtain Director/Executive team approval for the funding submissions.	
	1.8. Submit approved submissions to appropriate funding sources.	
	1.9. Prepare contingency plans in event submissions denied or approvals delayed.	
2. Organize to support the research plan	2.1. Identify work/activities to be completed.	
	2.2. Estimate level of work.	
	2.3. Determine quality and level of resources needed to do the work and address any skills development requirements.	
	2.4. Arrange for third party resources as needed.	
	2.5. Staff vacant/open positions.	
3. Complete the research	3.1. Direct/oversee the conduct of experiments.	Complying with regulatory and legislative requirements

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.2. Ensure application of the scientific method.	
	3.3. Plan, coordinate and supervise the duties of technical staff.	
	3.4. Provide appropriate direction (quality, scope and depth) to technicians, assistants etc.	
	3.5. Gather and maintain accurate records of work undertaken.	
	3.6. Use computers, high technology measuring systems and other sophisticated equipment to collect experimental data.	
	3.7. Make and record detailed observations.	
	3.8. Follow established scientific protocols.	Complying with regulatory and legislative requirements
	3.9. Follow established laboratory safety practices.	Complying with regulatory and legislative requirements (e.g., Workplace Hazard Management Information Management System (WHMIS), Ontario Health and Safety Act (OHSA))
	3.10. Monitor emerging external research results (literature, journals, conferences, etc.).	
	3.11. Ensure the application of techniques appropriate to the field of study e.g. histology, biochemistry, pathology, pharmacology.	
	3.12. Comply with regulatory authorities to ensure compliance with local, national and international regulations.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
4. Evaluate performance to research and business plan	4.1. Monitor and evaluate progress and performance to established performance indicators.	
	4.2. Identify gaps.	
	4.3. Assess impact of gaps on research plan and objectives.	
	4.4. Manage expectations of Director/Executive Team.	
	4.5. Identify appropriate corrective actions	
	4.6. Communicate performance and results to the Research Manager/Director.	
	4.7. Obtain approval(s) for proposed corrective actions (if needed) or research plan updates.	
	4.8. Implement approved corrective actions.	
	4.9. Update plan(s) as per approvals.	
	4.10. Communicate updates to plan(s) and expected outcome of any planned corrective actions.	
5. Analyze data and interpret results	5.1. Use specialist computer software to analyze data and to produce diagrammatic representation of results.	
	5.2. Apply the experimental model.	
	5.3. Evaluate the experimental design and update, if required.	
	5.4. Confirm validity of experimental design.	
	5.5. Redesign and re-run experiment based on results of validation.	
	5.6. Confirm achievement of expected results.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	5.7. Revisit original research hypothesis based on actual experimental results.	
	5.8. Evaluate need for further experimentation based on original research results.	
6. Report findings	6.1. Prepare reports on research results for the Research Manager/Director.	
	6.2. Determine scope of dissemination of research findings in line with company guidelines, intellectual property designation and protection of sensitive and confidential information.	
	6.3. Share results and findings with colleagues and team members in group meetings.	
	6.4. Produce written reports for clients such as contract research organizations or funding organizations.	
	6.5. Submit reports to clients/funding bodies.	

A Pharmacologist must be able to:

D. Plan for the trial

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Develop a trial plan	1.1. State approved goals and objectives.	
	1.2. Develop the design for the trial.	
	1.3. Outline timeline and schedule.	
	1.4. Contribute and provide input to the development of the monitoring strategy/plan.	
	1.5. Define roles and responsibilities.	
	1.6. Identify work/activities to be completed.	
	1.7. Estimate level of work.	
	1.8. Determine quality and level of resources needed to do the work.	
	1.9. Identify outsourced resources (if necessary).	
	1.10. Develop key performance indicators.	
	1.11. Submit trial plan to the Trial Manager for review and approval.	
2. Develop trial protocol	2.1. Outline the overall direction of the clinical trial.	Complying with regulatory and legislative requirements
	2.2. Develop the design for the clinical trial.	
	2.3. Apply 'lessons learned' from past clinical trials.	
	2.4. Review and validates the trial design.	
	2.5. Review protocols used in past trials.	
	2.6. Develop and documents trial protocols (outlining the trial's purpose and methodology).	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	2.7. Present trial protocols to the Steering Committee.	
	2.8. Address issues/concerns.	
	2.9. Update trials design/protocols as necessary.	
	2.10. Obtain Steering Committee approval for the trial design and protocol.	
3. Develop trial documents	3.1. Develop guidelines and policies to support trial protocols (i.e., prepare standard operating procedures (SOPs), Terms of Reference (TORs), etc.).	
	3.2. Develop and document processes and standard operating procedures (SOPs) to support the trial protocol.	
	3.3. Design the information and data collection forms to be used in the trial e.g. Informed Consent Forms (ICFs), Case Record Forms (CRFs).	*Personal Information Protection and Electronic Documents Act (*PIPEDA)
	3.4. Submit the document package to the Trial Manager for review and approval.	
	3.5. Update guidelines, policies, processes and procedures based on review feedback.	
	3.6. Obtain approval for the trial documents.	
4. Confirm supply of test material	4.1. Review manufacturing plan with the Research Team.	
	4.2. Liaise with the supplier/vendor regarding proposed trial plans, timelines, supply requirements.	
	4.3. Assess state of manufacturing readiness.	
	4.4. Identify gaps, issues, concerns.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	4.5. Work with Research Team and supplier to address findings.	
	4.6. Communicate status of Investigational New Drug (IND) submission and approval.	
5. Develop test population	5.1. Define exclusion criteria.	
	5.2. Determine trial population demographics.	
	5.3. Document recruitment plans.	
	5.4. Feed the exclusion criteria, population demographics and recruitment plans into the Investigational New Drug (IND) submission folder.	
6. Co-ordinate the Investigational New Drug (IND) submission and approval	6.1. Confirm understanding of the Investigational New Drug (IND) submission requirements.	
	6.2. Coordinate compilation of necessary data/information from the research team.	
	6.3. Complete required documentation for the submission package.	
	6.4. Submit the submission package for review and approval..	
	6.5. Update the submission package based on review feedback, as needed.	
	6.6. Forward the Investigational New Drug (IND) submission package to the appropriate authorities (e.g.,Health Canada, the Ethics Committee, Food and Drug Act (FDA), etc.).	Comply with Health Canada, Ethics Committee, Food and Drug Act (FDA) regulations

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	6.7. Coordinate with the Ethics Committee and Health Canada to address questions, obtain and supply additional information/data to support the approval of the submission.	Comply with Health Canada, Ethics Committee, Food and Drug Act (FDA) regulations
	6.8. Communicate approval of the Investigational New Drug (IND) submission to the Trial Manager, the Research Team and other internal stakeholders.	
	6.9. Execute the approved recruitment plan.	

A Pharmacologist must be able to:

E. Monitor the trial

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Monitor trial progress	1.1. Verify that clinical trials are proceeding according to requirements: trial protocols and procedures, regulatory requirements and Good Clinical Practices (GCPs).	
	1.2. Report any issues/concerns that put patient health/safety at risk to the appropriate internal and external authorities.	
	1.3. Attend Investigator meetings as required.	
2. Collect trial data/information	2.1. Define and document data collection protocols.	
	2.2. Ensure trial site staff understand data collection protocols and measures to be taken in protecting confidential information.	*Personal Information Protection and Electronic Documents Act (*PIPEDA)
	2.3. Monitor incoming data packages from trial sites with regard to frequency, timeliness and conformance to confidential information requirement.	
	2.4. Identify gaps.	
	2.5. Advise trial site staff of findings/concerns.	
	2.6. Work with trial site staff to address gaps.	
	2.7. Store trial site documentation in accordance with company guidelines and policies regarding sensitive/confidential information.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
3. Verify integrity of trial site data/information	3.1. Oversee the review and verification of Case Record Form (CRF) data.	
	3.2. Question inaccuracies.	
	3.3. Sign off on trial data accuracy and completeness.	
	3.4. Discuss review results with clinical trial staff and Investigators.	
	3.5. Provide input to the development of corrective actions to address identified shortcomings in trial site documentation/data.	
	3.6. Review impact of inaccuracies on overall trial objectives and integrity.	
	3.7. Discuss findings/trends with the Trial Manager.	
4. Review trial data/information	4.1. Collate or direct the collation of data	
	4.2. Use specialist computer software to analyze data and to produce diagrammatic representation of results, e.g. trends, statistical charts.	
	4.3. Apply the mathematical model for the trial.	
	4.4. Evaluate the trial findings to date.	
	4.5. Confirm validity of trial results.	
	4.6. Identify potential outliers, unexpected results, expected results.	
	4.7. Investigate outliers and unexpected results.	
	4.8. Advise the Trial Manager of any unforeseen or unexpected results/findings.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
5. Evaluate performance to trial plan and protocol	5.1. Evaluate progress and performance to established performance indicators.	
	5.2. Identify gaps.	
	5.3. Assess impact of gaps on research plan and objectives.	
	5.4. Manage expectations of the Trial Manager and management team.	
	5.5. Identify appropriate corrective actions.	
	5.6. Communicate performance and results to the Trial Manager and management team.	
	5.7. Obtain approval(s) for proposed corrective actions (if needed) or research plan updates.	
	5.8. Implement approved corrective actions.	
	5.9. Update plan(s) as per approvals.	
	5.10. Communicate updates to plan(s) and expected outcome of any planned corrective actions.	
6. Report trial results	6.1. Prepare reports on trial results and progress for the Trial Manager.	
	6.2. Prepare reports on trial results for the Investigators.	
	6.3. Produce written reports for clients such as contract research organizations or funding organizations.	
	6.4. Submit prepared reports to the Trial Manager for review and approval.	
	6.5. Share results and findings with the Research Team.	

A Pharmacologist must be able to:

F. Advance the research agenda

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Assess research/trial outcomes	1.1. Evaluate research/trial outcomes objectively.	
	1.2. Conduct due diligence.	
	1.3. Evaluate potential for continued development/ commercialization.	
	1.4. Complete a feasibility review.	
	1.5. Seek internal and external input.	
	1.6. Prepare recommendations and report on moving research outcomes forward in the development process.	
2. Contribute to the registration dossier	2.1. Understand registration requirements (both local and international requirements).	
	2.2. Understand dossier content.	
	2.3. Prepare documents required for registration.	
	2.4. Complete administrative documents.	
	2.5. Submit dossier documents for approval.	
	2.6. Protect supporting research results, notes, work books, records and data in keeping with corporate guidelines and policies on sensitive/confidential information.	
3. Present results to the scientific community	3.1. Respect corporate guidelines re: intellectual property and sensitive business information.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.2. Share results and findings with colleagues and key opinion leaders (KOLs) in group meetings.	
	3.3. Write original papers outlining research and results.	
	3.4. Publish in reputable scientific journals.	
	3.5. Present findings at scientific/medical conferences.	

A Pharmacologist must be able to:

G. Provide expert/advisory services

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Serve as an in-house consultant	1.1. Maintain networks with other experts in the appropriate field.	
	1.2. Stay current with pertinent legislation and regulations.	
	1.3. Share 'lessons learned' (both positive and negative) from past pre-clinical studies and clinical/field trials.	
	1.4. Communicate leading practices with respect to trial design, data collection and analysis.	
	1.5. Update knowledge and understanding by reading scientific/medical journals and attending professional conferences.	
	1.6. Participate in industrial route realization, including empirical route evaluation, process development and technology transfer.	
	1.7. Collaborate with academia to apply the results of research and develop new techniques, products or practices and liaise with academic research scientists to explore alternate applications of research materials.	
2. Participate in peer reviews	2.1. Evaluate content of a proposed publication/funding application.	
	2.2. Provide a critique of a proposed publication/funding application.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	2.3. Make suggestions to improve quality/scientific basis of a proposed publication/funding application.	
	2.4. Identify overlooked ideas, theories or bodies of knowledge pertinent to the content of a proposed publication/funding application.	
	2.5. Highlight shortcomings of a proposed publication/funding application (e.g. incomplete conclusions, faulty logic, inappropriate experimental design).	
3. Maintain status as a 'recognized' authority	3.1. Publish in peer reviewed journals.	
	3.2. Act as keynote presenter at national conferences.	
	3.3. Author and publish books and reviews.	
	3.4. Maintain a strong publication record.	
	3.5. Pursue public recognition through association awards, press releases.	
4. Mentor and coach peers and the management team	4.1. Discuss opportunities for growth with peers/team members.	
	4.2. Share expert knowledge and experience.	
	4.3. Explore avenues available for peers/team member personal and professional growth.	
	4.4. Provide guidance and support.	
	4.5. Provide contacts and open networks.	
	4.6. Offer positive reinforcement and recognition.	
5. Assume the role as the 'scientific face' of the organization	5.1. Make presentations at scientific/medical conferences on behalf of the organization.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	5.2. Make media appearances as a spokesperson of the company on corporate research.	
	5.3. Act as point of contact on company web site.	
	5.4. Speak at meetings.	
	5.5. Communicate with regulatory bodies on behalf of the organization.	
	5.6. Provide advice and guidance on product use to clients/external users (e.g., other research organizations, academia).	

A Pharmacologist must be able to:

H. Demonstrate generally accepted management capabilities

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Apply generally accepted management principles and techniques	1.1. Align management and leadership style with the corporate culture and objectives.	
	1.2. Ensure that team uses accepted management principles and techniques.	
	1.3. Create opportunities for information sharing across the team (e.g. regular meetings, governance structure).	
	1.4. Comply with corporate policies and guidelines.	
	1.5. Make sure the procedures and structures are in place to achieve goals.	
	1.6. Establish the appropriate framework for evaluating performance and progress to plan.	
	1.7. Monitor and measure progress and performance.	
	1.8. Establish reporting schedule and distribution listing for regular reporting.	
	1.9. Keep team informed of progress and performance.	
	1.10. Provide coaching, mentoring and development opportunities to staff 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.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	2.3. Determine the level and nature of resources needed to support the project plan.	
	2.4. Administer project budget.	
	2.5. Monitor progress to plan and achievement of project milestones.	
	2.6 Revisit and revise timelines, as required.	
	2.7. Identify emerging risks, issues and concerns.	
	2.8 Mitigate identified risks, issues and concerns and monitor to ensure the resolution of issues.	
	2.9. Report on performance to the project plan and recommended actions to address variances to plan.	
3. Identify and protect intellectual property	3.1. Understand corporate policies, guidelines and procedures pertaining to intellectual property.	
	3.2. Determine whether developments are able to be protected.	
	3.3. Identify work considered to be intellectual property.	
	3.4. Take the necessary actions to protect intellectual property.	
4. Protect sensitive/confidential information	4.1. Identify those records which meet the definition of sensitive information under the Personal Information Protection and Electronic Documents Act (PIPEDA).	
	4.2. Assure maintenance of confidentiality of the information.	Personal Information Protection and Electronic Documents Act (PIPEDA)
	4.3. Identify personnel with access to sensitive information.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	4.4. Communicate confidential information appropriately to those who have a functional 'need to know'.	
	4.5. Store and secure confidential information in observance of applicable laws and company policies/procedures.	Personal Information Protection and Electronic Documents Act (PIPEDA)
5. Use computers to analyze/manage data and information	5.1. Use computers to collect, analyze and interpret complex data.	
	5.2. Establish a formal system for computerized data/information collection, storage, access, retrieval, archiving and disposition.	
	5.3. Apply advanced computer skills, (e.g.,use of MS Word, Excel, PowerPoint, WinNonlin, etc.).	
	5.4. Use statistical analysis packages (e.g. SAS), data files and databases to organize data/information.	
	5.5. Use computers to analyze data, generate reports and create presentations, posters and manuscripts.	
	5.6. Use computers to conduct online literature search and review .	
6. Manage work activities	6.1. Utilize responsible practices which contribute to the cost-effective use of resources.	
	6.2. Maximize efficient use of resources (e.g., time, equipment, personnel).	
	6.3. Apply continuous quality improvement techniques and risk management processes.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
7. Establish effective working relationships	7.1. Work effectively with team members, collaborators, and others.	
	7.2. Ensure two-way communication.	
	7.3. Share current knowledge with new colleagues.	
	7.4. Recognize the skills and abilities of others.	
	7.5. Show respect.	
	7.6. Accept and appreciate different ways of doing things.	
8. Encourage team-building	8.1. Facilitate team planning efforts.	
	8.2. Work towards measurable objectives.	
	8.3. Implement changes, as required.	
	8.4. Assign responsibilities appropriately (level, background/experience, expertise).	
	8.5. Empower people.	
	8.6. Promote accountability.	

A Pharmacologist must be able to:

I. Administer subcontractor relationships

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1.Develop subcontractor relationship	1.1. Define requirements and selection criteria.	
	1.2. Identify subcontractors that meet the requirements.	
	1.3. Select subcontractor.	
	1.4. Develop contract and put into place.	
2. Monitor subcontractor performance	2.1. Establish reporting schedule and template.	
	2.2. Review subcontractor performance to contractual requirements/performance indicators.	
	2.3. Discuss areas requiring corrective action with the subcontractor.	
	2.4. Agree on course of corrective actions and expected results.	
3. Manage issues and risks on a proactive basis	3.1. Identify emerging issues and risks.	
	3.2. Determine impact of subcontractor non-compliance on research plan/objectives.	
	3.3. Quantify the financial impact of each risk/issue.	
	3.4. Develop mitigation strategies and plans for each emerging risk/issue.	
	3.5. Maintain productive relationships with subcontractors.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.6. Assess effectiveness of corrective actions.	
4. Authorize payment to subcontractors	4.1. Review delivered products/services to contract requirements.	
	4.2. Review invoice for accuracy and completeness to business requirements.	
	4.3. Approve invoices for payment.	
5. Report on subcontractor performance	5.1. Prepare a report on subcontractor performance to contract requirements.	
	5.2. Outline impact of subcontractor performance on overall research plan and objectives.	
	5.3. Develop options appropriate to subcontractor compliance and impact on research plan.	
	5.4. Present key findings to the executive team.	
	5.5. Obtain approval for planned actions.	
	5.6. Work with the subcontractor to execute planned actions as appropriate.	

A Pharmacologist must be able to:

J. Supervise team members

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Recruit team members	1.1. Develop and maintain job descriptions.	
	1.2. Post jobs.	
	1.3. Interview candidates.	
	1.4. Hire personnel.	
	1.5. Orient new personnel.	
2. Assign and monitor work and responsibilities	2.1. Assign tasks and responsibilities appropriately (based on level, background/experience, expertise).	
	2.2. Provide clear instruction as to what is to be done, approach to be used, procedures/guidelines that are applicable to the work to be done.	
	2.3. Define expectations of team members in terms of work quality and outcomes, in line with job descriptions and corporate guidelines.	
	2.4. Communicate expectations regarding work quality and outcomes to team members.	
	2.5. Recognize work efforts that meet or exceed expected results.	
	2.6. Address situations where work quality, outcomes and assumption of responsibilities do not meet expectations.	
3. Identify team member development needs	3.1. Monitor performance.	
	3.2. Identify weaknesses and strengths.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.3. Explore team member expectations and interests regarding development options.	
	3.4. Support team member development goals and objectives.	
	3.5. Follow up on progress, improvement and achievements.	
4. Evaluate team member performance	4.1. Utilize a standard review process, as prescribed by company policies and guidelines.	
	4.2. Assess performance to key performance criteria (actions and objectives agreed upon during prior discussions of performance).	
	4.3. Solicit team member perspective on performance relative to agreed upon actions and objectives.	
	4.4. Review performance assessment with the team member.	
	4.5. Identify skills development needs as required.	
	4.6. Discuss and explore points of difference, and achieve consensus on actions and objectives moving forward.	
	4.7. Create a record of the performance assessment and agreed upon plan of action.	
	4.8. Obtain team member sign off on the performance assessment record.	
5. Address other human resource (HR) responsibilities	5.1. Contribute information to maintain personnel files.	
	5.2. Counsel personnel.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	5.3. Investigate workplace complaints, infractions or incidents.	
	5.4. Discipline personnel.	
	5.5. Dismiss personnel.	

A Pharmacologist must be able to:

K. Apply professional practices

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Comply with established policies, procedures and protocols	1.1. Maintain confidentiality (e.g., data, records, intellectual property, client information).	*Personal Information Protection and Electronic Documents Act* (PIPEDA)
	1.2. Practice and adhere to Good Laboratory Practices (GLP).	
	1.3. Follow established corporate protocols and procedural documentation (e.g., policies, procedures, standard operating procedures (SOPs), test procedures).	
2. Comply with all applicable regulations, legislation and Good Clinical Practices (GCPs)	2.1. Know and understand applicable rules, regulations and legislation.	
	2.2. Practice and adhere to legislative/regulatory requirements (e.g., Workplace Hazard Management Information System (WHMIS)).	Workplace Hazard Management Information System (WHMIS)
	2.3. Review relevant literature.	
	2.4. Identify and document requirements.	
	2.5. Work within regulatory framework.	
	2.6. Identify situations that do not align with the regulatory framework.	
	2.7. Determine appropriate corrective action(s).	
	2.8. Determine impact of the conformance to the regulatory framework and the impact on the research/trial plan and objectives.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	2.9. Report identified situations on non-conformance, estimated impact and proposed corrective actions.	
	2.10. Implement approved corrective actions.	
	2.11. Update research/trial plan(s) if necessary.	
	2.12. Monitor conduct to ensure proper.	
3. Demonstrate scientific and laboratory knowledge and skills	3.1. Apply the principles of standard precautions.	
	3.2. Adhere to Good Laboratory Practice (GLP) protocols.	
	3.3 Understand the theories/practicalities of conducting in vitro and in vivo techniques and protocols.	
	3.4. Analyze data and information, including pharmacokinetics (PK), pharmacodynamics (PD), and statistical data.	
	3.5. Define the clinical pharmacology characteristics (pharmacokinetics, and pharmacodynamic) of materials under study.	
	3.6. Identify appropriate models to quantify pharmacological effects being studied.	
	3.7. Translate study data to pre-clinical models.	
4. Demonstrate medical and research and development (R&D) experience	4.1. Apply knowledge of the clinical research settings and clinical trial monitoring, as required.	
	4.2. Comply with regulatory authorities on clinical pharmacology issues.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	4.3. Apply medical and scientific principles and concepts including preclinical pharmacokinetics, PK/PD relationships, metabolism, bio-analytical processes and toxicokinetics.	
	4.4. Exploit knowledge of global pharmaceutical regulatory requirements where appropriate (Food and Drug Act (FDA), International Conference on Harmonization (ICH) etc).	
	4.5. Use understanding of regulatory statistical requirements to provide statistically sound experimental design and data analysis input to submission documents.	
	4.6. Apply experience working with health data to create study reports submission data summaries and other contributions to regulatory documents.	
5. Take appropriate safety measures	5.1. Use appropriate personal protective equipment (e.g., mask, gloves, laboratory coat, etc.).	Workplace Hazard Management Information System (WHMIS)
	5.2. Utilize laboratory safety devices in a correct manner (e.g., biological safety cabinets, fume hoods, laminar flow cabinets, safety pipeting devices, safety containers and carriers, safety showers, eye washes).	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	5.3. Apply the principles of working with hazardous chemical or biological material regarding reagent preparation, storage and disposal and equipment cleaning and disinfecting (as per WHMIS and related legislation).	
	5.4. Take the appropriate actions to minimize the potential hazards/dangers related to disinfection/sterilization methods, biological samples, radioactive materials, equipment and laboratory supplies.	
	5.5. Label, date, handle, store, and dispose of chemicals, dyes, reagents and solutions according to Workplace Hazard Management Information System (WHMIS) and existing legislation.	Workplace Hazard Management Information System (WHMIS), Material Safety Data Sheets (MSDS)
	5.6. Seek appropriate first-aid treatment by mobilizing emergency response (e.g., external and/or internal response, such as an Emergency Response Team) to respond to incidents such as chemical injury, traumatic injury, electrical shock, burns, radioisotope contamination.	
	5.7. Respond appropriately to fire emergencies.	
	5.8. Report incidents related to safety and personal injury (e.g., needle stick injuries), in a timely manner to the appropriate personnel.	
6. Ensure quality of work practices	6.1. Perform quality control activities and tests (internal and external).	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	6.2. Assess results of quality control activities and tests (internal and external).	
	6.3. Utilize statistics and indicators to monitor the acceptability of results based on established quality control ranges.	
	6.4. Investigate statistically significant deviations from established quality control ranges.	
	6.5. Maintain appropriate documentation (e.g., document laboratory reporting errors and corrective measures taken).	
	6.6. Report significant variations from quality control ranges to the appropriate personnel Research Manager.	
7. Demonstrate professional integrity	7.1. Report findings and results accurately and honestly.	
	7.2. Respect confidentiality (e.g., data, records, intellectual property, client information).	
	7.3. Take responsibility for actions and decisions.	
	7.4. Accept accountability for outcomes of actions and decisions.	
	7.5. Maintain high standards in practice.	
	7.6. Apply relevant internationally accepted protocols and practices, regulations, and legislation.	
	7.7. Follow rules and regulations administered by regulatory bodies, such as Health Canada, Agriculture and Agri-Food Canada.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	7.8. Demonstrate openness, transparency and fairness.	
	7.9. Show respect for team members, peers and other individuals.	
	7.10. Act with regard to corporate ethics and values.	

A Pharmacologist must be able to:

L. Demonstrate personal competencies

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Demonstrate leadership	1.1. Focus on goals and objectives.	
	1.2. Demonstrate commitment.	
	1.3. Promote and demonstrate ethical behaviour and integrity.	
	1.4. Demonstrate balanced judgment.	
	1.5. Show and promote mutual respect.	
	1.6. Promote trust and honesty.	
	1.7. Promote accountability.	
2. Demonstrate critical thinking/problem solving	2.1. Identify the problem.	
	2.2. Apply logical and methodical approach to identify and assess the cause(s) of the problem.	
	2.3. Develop and assess options to address the problem.	
	2.4. Apply knowledge, training and creativity to determine the appropriate course of action.	
	2.5. Oversee implementation of the selected course of action.	
	2.6. Evaluate the effectiveness of the selected course of action.	
3. Set priorities	3.1. Reference critical information when setting priorities.	
	3.2. Establish criteria to facilitate priority setting, such as risk, time-sensitivity, investment required, etc.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.3. Consider available resources and redistribute work/assignments, as appropriate.	
	3.4. Maintain awareness of time-sensitive issues and critical deadlines.	
	3.5. Keep goals and objectives in mind.	
	3.6. Multi-task where possible and practical.	
	3.7. Communicate priorities to team members/relevant personnel.	
	3.8. Review and adjust established priorities as appropriate.	
4. Organize work	4.1. Think ahead and anticipate.	
	4.2. Plan work schedule according to tasks and availability of equipment.	
	4.3. Demonstrate effective time management.	
	4.4. Set priorities and objectives.	
	4.5. Identify and manage resources needed to complete work.	
	4.6. Establish processes/systems/methodologies to enhance effectiveness.	
	4.7. Determine the information/data to be collected.	
	4.8. Recognize where templates and standard forms would facilitate data and information management.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	4.9. Develop hard copy and/or electronic templates/forms (or update existing templates and form) to facilitate standard and consistent collection of information and data.	
	4.10. Support use of the templates/forms with standard operating procedures (SOPs), help aids, education and examples.	
5. Demonstrate attention to detail	5.1. Establish and monitor a reminder/bring forward system to ensure trial stays on schedule.	
	5.2. Address follow-ups/issues in a timely manner.	
	5.3. Ensure deadlines are met.	
	5.4. Implement document control strategy supported by procedures and appropriate storage/retrieval/security system(s).	
	5.5. Maintain accurate, detailed records with appropriate back-up/recovery plans.	
	5.6. Validate analytical results.	
	5.7. Maintain up-to-date content in the management information system(s).	
6. Build networks internally and externally	6.1. Communicate well, clearly, and in a timely manner both verbally and in writing.	
	6.2. Listen.	
	6.3. Ensure awareness of differences, treat everyone fairly/equitably and accommodate to special needs.	
	6.4. Recognize the skills and abilities of others.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	6.5. Use various approaches in response to different individual styles.	
	6.6. Take advantage of networking opportunities.	
7. Communicate well and clearly	7.1. Demonstrate effective communication skills (written and oral).	
	7.2. Use appropriate terminology.	
	7.3. Understand nuances.	
	7.4. Translate, simplify, and explain terms and concepts when speaking not only with parties who understand clinical trial/scientific terminology, but also those who may not.	
8. Embrace continuous learning and development	8.1. Allocate time for continuous learning.	
	8.2. Identify opportunities for continuous learning.	
	8.3. Build on 'lessons learned' from past research efforts.	
	8.4. Keep abreast of relevant science and technology.	
	8.5. Nurture the ability and enthusiasm to learn new skills and techniques (e.g. technical and management skills).	
	8.6. Efficiently learn new skills and have the technical competence to do so.	

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