

Pre-Clinical/Clinical or Field Trial Project Manager

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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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 of a pre-clinical/clinical or field trial project manager.

Occupational Definition

The pre-clinical/clinical or field trial project manager oversees and coordinates development and trial projects, championing the project from beginning to end. In this role, a pre-clinical/clinical or field trial project manager assumes project management responsibilities for assigned clinical studies, manages all aspects of multiple trials and trial sites and ensures the safety of the participants involved in the trial(s). Responsibilities include contributing to product design, trial design, developing the supporting project infrastructure, coordinating the various trial activities and evaluating progress and results. They monitor trial data and oversee the day-to-day management of activities associated with assigned trials from concept to completion of final study report. This includes liaising with and ensuring reporting to regulatory bodies and coordinating approvals for the trial's implementation. They are responsible for developing budgets, timelines and quality guidelines. They liaise with vendors and other external stakeholders such as contract research organizations (CRO) and investigators. They also manage staff and train others in aspects of procedure and protocols and oversee the accuracy and completeness of the trial data and records. Pre-clinical/clinical or field trial project managers work for Canadian biotechnology companies of different sizes (i.e., small, medium, large) and in various biotechnology areas, such as:

- Agriculture
- Aquaculture
- Bioenergy
- Bioinformatics
- Bioproducts
- Biosciences
- Environment
- Food Processing
- Forestry
- Genomics
- Human Health and Animal Health
- Industrial
- 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

A pre-clinical/clinical or field trial project manager oversees the conduct of pre-clinical/clinical/field trials (trials) in support of the development of pharmaceuticals and other biotechnology products for use by humans and in animals. A pre-clinical/clinical or field trial project manager participates in the development of the trial project plan; and its execution; coordinates staff and staff training, materials and supplies availability for trial sites; oversees data collection and storage, and performs regular reviews of the trial's progress. They may also oversee the administration of trial project budgets, resources, and reporting requirements. A pre-clinical/clinical or field trial project manager's activities may include coordinating approvals for a trial implementation; liaising with stakeholders; and ensuring that required reporting to stakeholders and regulatory bodies is completed. They are also responsible for developing trial project budgets, timelines and quality guidelines. They liaise with vendors and other external stakeholders such as contract research organizations (CRO) and investigators, ensuring that the required information is exchanged in a timely manner.

Pre-clinical/clinical or field trial project managers work closely with all members of a trial project team – ensuring required training is provided and completed, identifying issues that might delay the project and making recommendations to improve time lines for project completion. They are also responsible for ensuring all trial site activities are conducted in accordance with the regulations and guidelines related to Good Clinical Practice (GCP) and the ethical treatment of humans/animals in a study or trial. They must also ensure trial site activities/operations meet the regulatory regimes as are applicable to international trial sites when trials they are managing cross international borders. At the completion of a trial, the pre-clinical/clinical or field trial project manager is responsible for overseeing the closure of trial sites and ensuring the integrity of the trial data through secure archiving. They are also required to prepare final reports on the trial project process: evaluating performance against objectives, identifying lessons learned, and completing budget reviews and analysis.

A pre-clinical/clinical or field trial project manager must possess strong leadership competencies, be able to use persuasion and influence to direct the progress of a project and to establish effective working relationships across functions in an organization. A high level of professional integrity must be demonstrated as should their commitment to ensuring protocols and processes are followed throughout a trial project.

Often faced with challenging situations, a pre-clinical/clinical or field trial project manager must be able to solve problems effectively – working with others to identify solutions and opportunities for improvement. They must be flexible and adaptable when confronted with changing priorities or objectives, able to maintain composure under stressful situations in order to ensure the success of a project. As well, they must be adept at negotiating fairly with a view to achieving their desired/required outcome. Communication skills are very important in this occupation. Pre-clinical/clinical or field trial project managers interact and collaborate with clinicians, investigators, clinical research associates, scientists, management, and other project stakeholders A pre-clinical/clinical or field trial project manager must be able to effectively communicate project objectives, progress, issues and concerns to stakeholders and

project team members both verbally and in writing. They must also be well-organized, able to set and manage priorities, make informed decisions and identify and manage expectations.

The pre-clinical/clinical or field trial project manager occupation requires a minimum of a bachelor's degree education in science or a medical field. Some employers insist on a master's degree. The preferred areas of concentration include chemistry, biology, pharmacology, psychology or business administration. Prior work experience in a clinical testing environment is preferred. Many pre-clinical/clinical or field trial project managers possess nursing degrees or diplomas combined with relevant experience – having transitioned into the occupation through employment as a clinical research associate. Frequent advances in clinical trial protocols, trends and practices and changes to regulations and standards require a pre-clinical/clinical or field trial project manager to commit to continuous learning and self-improvement. They are expected to maintain and enhance their knowledge of the project field, and project management practices, staying current with legislative/regulatory changes, technological advances and other events affecting their practices or area of specialization. Pre-clinical/clinical or field trial project managers require a knowledge and understanding of medical terms, a general sense of disease states, and ability to interpret and translate complex medical data. The occupation also requires a strong capacity for mathematics – to support the review and assessment of quantitative trial data, and effectively audit clinical trial results and outcomes. They also need to have a good understanding of the legislation, regulations and protocols related to trials including Good Clinical Practice (GCP).

Based on job postings, many employers require a minimum of 3-5 years of experience working in a clinical trial or medical setting and identify experience as a clinical study coordinator or clinical research associate as an asset. Many pre-clinical/clinical or field trial project managers gain this experience through prior employment that includes nursing, part-time employment in clinical research facility, student work terms (during college or university studies), or employment with university research facilities.

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		

Pre-Clinical/Clinical or Field Trial Project Managers need strong oral communication skills to manage the project team as well as to liaise with regulators, vendors and external stakeholders such as contract research organizations. They also need well developed problem solving skills and be able to plan and organize complex projects that may involve multidisciplinary experts working in different sites around the world.

Language Benchmarks

The majority of communications tasks associated with the required competencies and activities of a competent pre-clinical/clinical or field trial project manager were found to be between Canadian Language Benchmark levels 8 – 11. 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 Pre-Clinical/Clinical or Field Trial Project Manager must be able to:

A. Institute a project management infrastructure

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Establish a project management office	1.1. Establish Terms of Reference for the project management office (PMO).	
	1.2. Develop governance framework.	
	1.3. Define role and responsibilities of the PMO staff.	
	1.4. Obtain Executive management approval.	
	1.5. Communicate the roles and activities of the PMO.	
2. Establish stakeholder relationships	2.1. Review scope of trials to be managed.	
	2.2. Research internal stakeholders (research teams, other department, committees, research programs or lines of business).	
	2.3. Identify external stakeholders (regulatory bodies, clients, associations, interest groups etc).	
	2.4. Research stakeholder priorities, positions, concerns and issues.	
	2.5. Identify key individuals associated with each trial.	
	2.6. Obtain stakeholder support.	
3. Organize the project team	3.1. Confirm project scope and depth.	
	3.2. Assess work to be done.	
	3.3. Define the project team structure.	
	3.4. Obtain Executive team approval to proceed.	
	3.5. Solicit team members from the stakeholder population.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.6. Educate team members regarding their roles and responsibilities on the project team.	
4. Develop standard project processes/procedures/protocols	4.1. Develop protocols for status reporting.	
	4.2. Develop protocols for risk management.	
	4.3. Develop the issue management process and supporting standard operating procedures (SOPs) (including corrective and preventative actions).	
	4.4. Develop the standard operating procedures (SOPs) for managing trial budgets.	
	4.5. Circulate draft documents for review and feedback.	
	4.6. Update processes/procedures in light of review feedback.	
	4.7. Obtain Executive team approval to implement protocols and procedures.	
5. Oversee development of standard trial documentation	5.1. Contribute to the clinical/field protocol study design.	
	5.2. Contribute to the development and documentation of processes and standard operating procedures (SOPs) to support the trial protocol.	
	5.3. Coordinate and integrate the development of trial document/templates/forms across different trials.	
	5.4. Review and provide feedback on draft guidelines and policies to support trial protocols, i.e., prepares standard operating procedures (SOPs), Terms of Reference (TORs_, etc.	
	5.5. Review and provide feedback on the design of information and data collection forms to be used in the trial e.g. Informed Consent Forms (ICFs), Case Record Forms (CRF).	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
6. Apply information management protocols	6.1. Obtain training on corporate policies and guidelines for information/record management.	
	6.2. Communicate requirements for information management to the project team.	
	6.3. Ensure information management protocols are followed.	
7. Set up trial database(s)	7.1. Solicit input on information/data needs from stakeholders.	
	7.2. Define trial data and information requirements.	
	7.3. Integrate data requirements into trial documents/templates/forms.	
	7.4. Create, write and document edit checks pertaining to ensuring data quality.	
	7.5. Create databases to support multiple projects/trials.	
	7.6. Develop standard operating procedures (SOPs) for data management and data collection.	
	7.7. Communicate the existence and planned use of the trial databases.	
	7.8. Educate stakeholders on the use of the trial databases.	
	7.9. Establish security appropriate to protect the integrity of the database(s) and data stored in them.	

A Pre-Clinical/Clinical or Field Trial Project Manager must be able to:

B. Develop a consolidated trial project plan

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1.Define detailed timelines	1.1. Seek clarity regarding timelines and senior management expectations.	
	1.2. Share timeline expectations with stakeholders and obtain feedback.	
	1.3. Manage expectations based on feedback.	
2. Develop individual trial project plans	2.1. Discuss project plan requirements with stakeholders.	
	2.2. Offer assistance for development of their trial project plans	
	2.3. Reinforce use of standard project plan framework and standard operating procedures (SOPs).	
	2.4. Contribute to overall trial design/planning process.	
	2.5. Receive copies of final trial project plans.	
	2.6. Seek appropriate approvals.	
3. Integrate trial project plans	3.1. Align timelines.	
	3.2. Identify dependencies.	
	3.3. Clarify milestones.	
	3.4. Highlight points of convergence/divergence.	
	3.5. Define the critical path.	
	3.6. Work with plan owners to address and adapt individual plans.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.7. Finalize timelines, milestones, dependencies, risks etc.	
	3.8. Develop key performance indicators.	
	3.9. Review the integrated project plan with executive team.	
	3.10. Advise plan owners of executive team feedback.	
	3.11. Make adjustments as needed.	
	3.12. Obtain executive team approval.	
	3.13. Share the final approved integrated project plan with all stakeholders.	
4. Set clear accountability for trial deliverables	4.1. Identify trial deliverables in the integrated plan.	
	4.2. Confirm scope of deliverables with key trial stakeholders.	
	4.3. Clarify stakeholder responsibility and accountability for deliverables.	
	4.4. Communicate expectations for deliverables management.	
	4.5. Explain key performance indicators for the deliverables.	
5. Establish trial budgets	5.1. Identify resources (budget, equipment, people) needed to conduct the trials.	
	5.2. Estimate the value of resources and level of investment needed for each trial.	
	5.3. Consolidate the individual trial resource requirements into a single budget estimate.	
	5.4. Identify and address areas of overlap/duplication.	
	5.5. Identify resources that can be shared across more than one trial.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	5.6. Identify gaps in the resource requirements estimates.	
	5.7. Review the proposed budget with key trial stakeholders.	
	5.8. Refine the consolidated trial budget.	
	5.9. Present the consolidated trial budget to the executive management team.	
	5.10. Address concerns/issues.	
	5.11. Obtain approval for the level of resources requested.	
	5.12. Back out individual trial budgets based on the approved consolidated budgets.	
	5.13. Communicate budget/approved resourcing levels to trial stakeholders.	

A Pre-Clinical/Clinical or Field Trial Project Manager must be able to:

C. Implement the trial project plan

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1.Launch trial	1.1. Lead the launch meeting.	
	1.2. Motivate team members and summarize expectations.	
	1.3. Reinforce mechanisms and frequency of consultations and address gaps.	
2. Track progress of individual trials	2.1. Monitor trial workloads and resource utilization.	
	2.2. Reassess trial scope to ensure trials are carried out according to established plan and budget.	
	2.3. Meet regularly to review trial activities and progress and management strategies.	
	2.4. Ensure issues and risks are managed as they emerge.	
	2.5. Assist with resolution of technical and operational problems as needed.	
	2.6. Review completion of deliverables.	
3. Manage trial timelines	3.1. Verify that trials are on schedule and keeping to approved timelines.	
	3.2. Investigate variances to the approved timelines.	
	3.3. Offer direction with regard to corrective actions to address variances.	
	3.4. Identify potential risks/issues that may impact timelines.	
	3.5. Develop contingency plans to mitigate potential risks/issues.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.6. Make critical decisions in order to manage timelines to plan.	
	3.7. Make recommendations to improve timelines for trial completion.	
	3.8. Seek appropriate approvals to implement decisions and recommendations.	
4. Oversee trial risk management	4.1. Identify, qualify and quantify trial risks.	
	4.2. Identify the risk/benefit/cost proposition.	
	4.3. Communicate risks to senior management in a timely manner.	
	4.4. Seek appropriate advice and counsel.	
	4.5. Develop and seek appropriate approvals to action contingency/remedial plans.	
	4.6. Implement 'Go/No Go' decision making as dictated by circumstances and risk assessment.	
5. Monitor trial budgets	5.1. Review reports on trial budgets.	
	5.2. Assess resource utilization and 'burn' rate for each trial.	
	5.3. Forecast resource utilization and requirements through remainder of each trial.	
	5.4. Identify potential resource shortfalls.	
	5.5. Develop options for addressing anticipated shortfalls.	
	5.6 Seek management approval.	
	5.7. Reallocate resources as approved.	
	5.8. Assess impact on consolidated trial budget.	
6. Oversee trial data integrity	6.1. Review reports on database edit programs.	
	6.2. Communicate current edit failures and corrective action to trial staff.	
	6.3. Ensure appropriate security measures for read, write, review, and edit access are followed.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	6.4. Confirm that database access granted is in line with position requirements.	
	6.5. Ensure that database access is monitored and maintained in a timely manner.	
7. Oversee vendor performance	7.1. Review reports on various vendor performances.	
	7.2. Identify those vendors having difficulty meeting commitments.	
	7.3. Assess impact of vendor performance on overall project plan and objectives.	
	7.4. Work with identified vendors to develop a plan of action for meeting commitments.	
	7.5. Indicate how effectiveness of corrective actions will be measured.	
	7.6. Monitor to assess effectiveness of vendor corrective actions.	
	7.7. Make decision regarding ongoing relationship with the vendor based on assessed effectiveness.	
	7.8. Readjust sourcing/supply arrangements to existing or new vendors.	
	7.9. Advise trial staff of decisions related to vendors.	
8. Manage Investigator relationships	8.1. Maintain communication channels with Investigators.	
	8.2. Confirm and act to address Investigator's requirements for the trial.	
	8.3. Review Investigator performance.	
	8.4. Provide support to Investigators having difficulty.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	8.5. Assess impact of investigator performance on both individual and consolidated trial plans and objectives.	
	8.6. Advise trial team of decisions affecting ongoing Investigator participation in their trial.	

A Pre-Clinical/Clinical or Field Trial Project Manager must be able to:

D. Communicate performance to plan

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Evaluate progress to plan	1.1. Review status/progress reports for each trial.	
	1.2. Evaluate progress and performance to established performance indicators.	
	1.3. Identify gaps.	
	1.4. Assess impact of gaps on each trial plan and objectives.	
	1.5. Identify appropriate corrective actions.	
	1.6. Assess impact of corrective actions on individual trial plans and objectives.	
	1.7. Review evaluation findings and corrective actions with key stakeholders.	
	1.8. Develop preferred course of action for each trial.	
2. Prepare budget reports	2.1. Access necessary information for budgeting and forecasting.	
	2.2. Assess performance against budget parameters/targets for each trial and for the consolidated trial plan.	
	2.3. Identify variances in actual vs. planned budget and funding.	
	2.4. Discuss elements contributing to the variances.	
	2.5. Outline steps taken/planned to address variances.	
	2.6. Describe any reallocation of resources across the different trials and impact of same.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	2.7. Provide budget forecasts for remainder of individual trial and consolidated plan.	
	2.8. Highlight anticipated overages/shortfalls.	
	2.9. Request additional investment as appropriate.	
3. Prepare the consolidated trial report and communicate to the Executive team	3.1. Compile progress/results for all trials against consolidated trial plan.	
	3.2. Prepare report and presentation for senior management.	
	3.3. Manage expectations and socialize report findings.	
	3.4. Present report and recommendations to Executive management.	
	3.5. Communicate approval of recommendation and Implement the recommended course(s) of action.	
	3.6. Update trial plans as per approvals	

A Pre-Clinical/Clinical or Field Trial Project Manager must be able to:

E. Conclude the trial project

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Oversee site closures	1.1. Ensure that unused trial products and trial equipment are returned from closing trial sites.	
	1.2. Reconcile all trial product inventories .	
	1.3. Confirm receipt and verify trial documentation/files from closed trial sites.	
2. Preserve data integrity	2.1. Confirm database(s) for closed trial sites have been locked down on requested date.	
	2.2. Verify data in database has not been corrupted.	
	2.3. Confirm appropriate security access and protocols to ensure data integrity.	
3. Identify lessons learned	3.1. Conduct a 'lessons learned' session.	
	3.2. Identify what worked well and what didn't work well.	
	3.3. Gather suggestions/ideas for improvements and corrective action.	
	3.4. Circulate for review and feedback including input from those unable to participate.	
	3.5. Update the session report based on review feedback/contributions.	
4. Prepare final reports	4.1. Complete final evaluations of individual trials and consolidated trial initiative progress and results.	
	4.2. Determine final budget and expenses for each trial and the consolidated trial initiative.	
	4.3. Document final assessment of Investigators and vendors supporting the trials.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	4.4. Prepare Lessons Learned report including recommendations for enhanced management of future trials.	
	4.5. Distribute reports in accordance with company policies and procedures.	
5. Prepare final information for inclusion in the registration dossier	5.1 Compile technical information to align with Regulatory requirements for the preparation of the Common Technical Document (CTD) and/or Technical Dossier.	
	5.2. Circulate for review and assessment by appropriate experts	
	5.3. Update the compilation to reflect expert assessment	
	5.4. Forward updated compilation for management decision-making.	
6. Complete project closeout	6.1. Ensure Accounts Receivable and Accounts Payable records are transferred to Finance department.	
	6.2. Support project team members to take on new roles.	
	6.3. Archive project records/data in accordance with information management protocols.	
	6.4. Transfer knowledge to stakeholders who are taking on ongoing responsibilities of the project.	
	6.5. Celebrate project completion.	

A Pre-Clinical/Clinical or Field Trial Project Manager must be able to:

F. Demonstrate accepted management capabilities

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Apply accepted management principles and techniques	1.1. Align management and leadership style with the corporate culture and objectives.	
	1.2. Ensure that project team uses accepted management principles and techniques.	
	1.3. Create opportunities for information sharing across the project team e.g. regular meetings, governance structure.	
	1.4. Comply with corporate policies and guidelines.	
	1.5. Align to the organizational procedures and structures in place to achieve corporate goals.	
	1.6. Plan and implement strategically.	
	1.7. Ensure the execution of strategies and tactics.	
	1.8. Establish the appropriate controls for evaluating performance.	
2. Identify and protect intellectual property	2.1. Understand corporate policies, guidelines and procedures pertaining to intellectual property.	
	2.2. Support the ongoing generation of work with potential to be intellectual property.	
	2.3. Ensure that all necessary steps are being taken regarding intellectual property.	
3. Protect sensitive/confidential information	3.1. Identify those clinical trial records which meet the definition of sensitive personal information under the *Personal Information Protection and Electronic Documents* Act (PIPEDA).	
	3.2. Assure maintenance of confidentiality of the information.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.3. Communicate confidential information appropriately to those who have a functional 'need to know'.	
	3.4. Store and secure confidential information in observance of applicable laws and company policies/procedures.	
4. Administer subcontractor relationships	4.1. Review delivered products/services to contract requirements.	
	4.2. Review and approve invoice for accuracy and completeness to business requirements.	
5. Use computer applications to analyze/manage data and information	5.1. Use databases to organize data/information.	
	5.2. Use software applications to analyze data, manage projects, generate reports and create presentations, posters and manuscripts.	
6. Encourage team-building	6.1. Facilitate team planning efforts.	
	6.2. Work towards measurable objectives.	
	6.3. Implement changes, as required.	
	6.4. Assign responsibilities appropriately (level, background/experience, expertise).	
	6.5. Empower people.	
	6.6. Promote accountability.	

A Pre-Clinical/Clinical or Field Trial Project Manager must be able to:

G. Supervise project team members

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Recruit team members	1.1. Develop and maintain job descriptions.	
	1.2. Interview candidates.	
	1.3. Hire personnel.	
	1.4. Orient new personnel.	
2. Assign work and responsibilities	2.1. Assign work and responsibilities appropriately (level, background/experience, expertise).	
	2.2. Provide 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 training needs	3.1. Identify training needs for regulatory requirements, standard operating procedures (SOPs) and processes.	
	3.2. Identify weaknesses and strengths.	
	3.3. Explore team member expectations and interests regarding development options.	
	3.4. Support team member development goals and objectives and follow up on progress.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.5. Maintain training records.	
4. Evaluate team member performance	4.1. Utilize a standard review process, as prescribed by company policies and guidelines.	
	4.2. Obtain training on reviewing team member performance, if necessary.	
	4.3. Assess performance to key performance criteria (actions and objectives agreed upon during prior discussions of performance).	
	4.4. Review performance assessment with the team member and explore points of difference.	
	4.5. Create a record of the performance assessment and signed-off plan of action.	
5. Address other human resource (HR) responsibilities	5.1. Counsel personnel.	
	5.2. Investigate workplace harassment, complaints, infractions or incidents.	
	5.3. Discipline personnel.	
	5.4. Dismiss personnel.	

A Pre-Clinical/Clinical or Field Trial Project Manager must be able to:

H. 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).	
	1.2. Practice and adhere to Good Laboratory Practices (GLP).	
	1.3. Practice and adhere to legislative/regulatory requirements (e.g., Workplace Hazard Management Information System (WHMIS)).	
	1.4. 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 Practices (GxP)	2.1. Know and understand applicable rules, regulations and legislation.	
	2.2. Review relevant literature and appropriate regulatory web sites on a timely basis.	
	2.3. Identify and list essential document requirements.	International Organization for Standardization (ISO)
	2.4. Work within regulatory framework.	
	2.5. Work with Quality Assurance in situations that do not align with the regulatory framework.	
	2.6. Support appropriate corrective action(s).	
	2.7. Report identified situations on non-conformance, estimated impact and proposed corrective actions.	
	2.8. Support the implementation of the approved corrective actions.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	2.9. Update research/trial plan(s) if necessary and get approval.	
3. Demonstrate project management experience	3.1. Manage projects of varying complexity including multi-site projects.	
	3.2. Show understanding of budgeting in the planning and oversight of projects.	
	3.3. Apply in-depth specialty knowledge to complete projects of broad scope and complexity.	
4. Demonstrate scientific experience	4.1. Apply knowledge of the clinical research settings and clinical/field trial monitoring, as required.	
	4.2. Interact with regulatory authorities.	
	4.3. Apply scientific principles and concepts	
	4.4. Provide input to sound trial design and data analysis.	
	4.5. Apply statistical analysis experience to create reports, submission data summaries and other contributions to regulatory documents.	
	4.6. Apply knowledge of competitive science-based research and intellectual property to clinical and field studies.	
5. Demonstrate regulatory knowledge and understanding	5.1. Apply knowledge of the clinical regulatory framework and progression.	Health Canada, Agriculture Canada, Food and Drug Administration (FDA), International Conference on Harmonization (ICH), Environmental Protection Agency (EPA), International Organization for Standardization (ISO), Organization for Economic Co-operation and Development (OECD)
	5.2. Apply knowledge of global regulatory requirements where appropriate.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	5.3. Use understanding of regulatory requirements to provide sound input to project plans.	
	5.4. Apply experience working with regulatory agencies and different regulations/legislation as appropriate.	
6. Negotiate fairly	6.1. Define the best approach to promote a position.	
	6.2. Articulate the position with clarity.	
	6.3. Understand the positions of the other parties.	
	6.4. Develop a structured analytical approach to identified issues to reach consensus.	
	6.5. Achieve an outcome that is mutually accepted by all parties.	
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. Adhere to rules and regulations administered by regulatory bodies, such as Health Canada, Agriculture and Agri-Food Canada.	
	7.8. Maintain confidentiality (e.g., data, records, intellectual property, client information).	
	7.9. Demonstrate openness, transparency and fairness.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	7.10. Show respect for team members, peers and other individuals.	
	7.11. Act with regard to corporate ethics and values.	

A Pre-Clinical/Clinical or Field Trial Project Manager must be able to:

I. Demonstrate personal competencies

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Demonstrate leadership	1.1. Look at the big picture.	
	1.2. Focus on goals and objectives.	
	1.3. Demonstrate commitment.	
	1.4. Promote and demonstrate ethical behaviour and integrity.	
	1.5. Show and promote mutual respect.	
	1.6. Promote trust and honesty.	
	1.7. Set an example.	
	1.8. Accept accountability.	
2. Act upon strategic planning capabilities	2.1. Anticipate future trends and developments.	
	2.2. Align research objectives with organizational direction and goals.	
	2.3. Consider the consequences and future implications of plans and actions.	
	2.4. Recommend actions or options to mitigate or prevent negative consequences.	
	2.5. Develop contingency plans.	
3. Influence decisions	3.1. Define the best approach to promote a position.	
	3.2. Articulate the position with clarity.	
	3.3. Understand the positions of the other parties.	
	3.4. Promote the benefits of preferred position.	
4. Build networks internally and externally	4.1. Communicate well, clearly, and in a timely manner.	
	4.2. Listen.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	4.3. Ensure awareness of differences, treating everyone fairly/equitably and accommodates to special needs.	
	4.4. Recognize the skills and abilities of others.	
	4.5. Use various approaches in response to different individual styles.	
	4.6. Champion the project, build interest throughout its lifecycle and target new opportunities across networks for impact.	
5. Solve problems	5.1. Identify the problem and the causes of the problem.	
	5.2. Understand the science or the technology relevant to the problem or issue.	
	5.3. Involve experts and professionals in the problem-solving exercise	
	5.4. Apply knowledge, training and creativity to determine and implement the appropriate course of action.	
6. Set priorities	6.1. Reference critical information when setting priorities.	
	6.2. Establish criteria such as risk, time-sensitivity, investment required, etc. to facilitate priority setting.	
	6.3. Consider available resources and redistributes work/assignments, as appropriate.	
	6.4. Maintain awareness of time-sensitive issues and critical deadlines.	
7. Communicate effectively	7.1. Demonstrate an ability to clearly articulate complex issues orally and in writing.	
	7.2. Explain point of view clearly and concisely.	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	7.3. Deliver and adapt message for appropriate audiences and translate, simplify and explain terms when speaking with non-specialists.	
8. Embrace ongoing learning	8.1. Identify opportunities and allocate time for ongoing education and learning.	
	8.2. Build on 'lessons learned' from past project management efforts.	
	8.3. Keep abreast of relevant science and technology.	
	8.4. Stay current with trends and practices in project management.	

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