# Pre-Clinical/Clinical or Field Trial Project Manager

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.

**Learn more about the role of a Pre-Clinical/Clinical or Field Trial Project Manager by downloading the full skills profile for free at www.biotalent.ca/profiles.**

**BioTalent** Canada™

**Building skills for Canada's bio-economy**

# Pre-Clinical/Clinical or Field Trial Project Manager

## BioTalent Canada's Bio-economy Skills Profiles

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

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

## Who can use these profiles?

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

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

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

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

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

## Validated by industry

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

## Information you can trust

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

## Understanding the bio-economy

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

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

## Get started today

Even before you download the full **Pre-Clinical/Clinical or Field Trial Project Manager** Skills Profile, get a sense of the information it contains and how you might use it in your work. Attached here is a quick-reference checklist that summarizes the core skills required for the position and the common tasks associated.

**Go to www.biotalent.ca/profiles and download the complete Pre-Clinical/Clinical or Field Trial Project Manager Skills Profile.**

**In addition to a bachelor or master's degree in life or medical sciences,** a Pre-Clinical/Clinical or Field Trials Manager has extensive hands-on experience working in pre-clinical, clinical or field environments— and may have project management training and experience as well.

Building on these, a **Pre-Clinical/Clinical or Field Trials Manager** must be able to:

## A. Institute a project management infrastructure

- [ ] 1. Establish a project management office
- [ ] 2. Establish stakeholder relationships
- [ ] 3. Organize the project team
- [ ] 4. Develop standard project processes/procedures/protocols
- [ ] 5. Oversee development of standard trial documentation
- [ ] 6. Apply information management protocols
- [ ] 7. Set up trial database(s)



## B. Develop a consolidated trial project plan

- [ ] 1. Define detailed timelines
- [ ] 2. Develop individual trial project plans
- [ ] 3. Integrate trial project plans
- [ ] 4. Set clear accountability for trial deliverables
- [ ] 5. Establish trial budgets

## C. Implement the trial project plan

- [ ] 1. Launch trial
- [ ] 2. Track progress of individual trials
- [ ] 3. Manage trial timelines
- [ ] 4. Oversee trial risk management

- [ ] 5. Monitor trial budgets
- [ ] 6. Oversee trial data integrity
- [ ] 7. Oversee vendor performance
- [ ] 8. Manage Investigator relationships

## D. Communicate performance to plan

- [ ] 1. Evaluate progress to plan
- [ ] 2. Prepare budget reports
- [ ] 3. Prepare the consolidated trial report and communicate to the Executive team

## E. Conclude the trial project

- [ ] 1. Oversee site closures
- [ ] 2. Preserve data integrity
- [ ] 3. Identify lessons learned
- [ ] 4. Prepare final reports
- [ ] 5. Prepare final information for inclusion in the registration dossier
- [ ] 6. Complete project closeout

## F. Demonstrate accepted management capabilities

- [ ] 1. Apply accepted management principles and techniques
- [ ] 2. Identify and protect intellectual property
- [ ] 3. Protect sensitive/confidential information
- [ ] 4. Administer subcontractor relationships
- [ ] 5. Use computer applications to analyze/manage data and information
- [ ] 6. Encourage team-building

## G. Supervise project team members

- [ ] 1. Recruit team members
- [ ] 2. Assign work and responsibilities
- [ ] 3. Identify team member training needs
- [ ] 4. Evaluate team member performance
- [ ] 5. Address other human resource (HR) responsibilities

## H. Apply professional practices

- [ ] 1. Comply with established policies, procedures and protocols
- [ ] 2. Comply with all applicable regulations, legislation and Good Practices (GxP)
- [ ] 3. Demonstrate project management experience

- [ ] 4. Demonstrate scientific experience
- [ ] 5. Demonstrate regulatory knowledge and understanding
- [ ] 6. Negotiate fairly
- [ ] 7. Demonstrate professional integrity



## I. Demonstrate personal competencies

- [ ] 1. Demonstrate leadership
- [ ] 2. Act upon strategic planning capabilities
- [ ] 3. Influence decisions
- [ ] 4. Build networks internally and externally
- [ ] 5. Solve problems
- [ ] 6. Set priorities
- [ ] 7. Communicate effectively
- [ ] 8. Embrace ongoing learning