

Contract Manufacturing Project Manager

National Occupational Standard Summary



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Definition of occupation | **Contract Manufacturing Project Manager**

The Contract Manufacturing Project Manager leads and coordinates cross-functional projects from product design to delivery, including technology transfer to the client if required while partnering with internal and external resources. The Contract Manufacturing Project Manager supports the account managers/designated departmental representatives in all aspects of client contact and coordinates the project through the scope, schedules, and budgets to meet client needs, including planned and unplanned adjustments. They may recruit, engage, manage, inform, and actively collaborate with legal, logistics, technical development, manufacturing, and regulatory and quality departments and interface with other Project Managers. They work with the business development team to perform technical assessments, budget development, project proposals, contract negotiations, and statement of work development while managing stakeholder relationships and resource allocations. Contract Manufacturing Project Managers must think critically and broadly, be effective problem solvers/identifiers, and employ effective communication, leadership, and team building/efficient meeting skills to evaluate impacts and reorganize and manage continually changing project needs.

Contract Manufacturing Project Managers work for Canadian biotechnology companies of different sizes (small, medium, large) and in various biotechnology areas, such as:

- Agriculture
- Aquaculture
- Bioenergy
- Bio products
- Biosciences
- Food processing
- Forestry
- Genomics
- Human health
- Product manufacturing
- Life Sciences
- Medical devices
- Nanotechnology
- Nutraceuticals
- Pharmaceuticals

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Level of education, training or designations requirements

Typical Education Required	Secondary	College	Bachelor	Master	PhD
Typical Starting Experience	0-5 yrs.	5-10 yrs.	10-15 yrs.	15-20 yrs.	20+ yrs.

- Experience and potentially professional certification in project management
- Bachelor's degree in sciences or engineering (Bio Engineering, Mechanical Engineering and/or Biochemistry, Biotechnology/Pharmaceuticals, or relevant discipline) is preferred
- Background in development, manufacturing, supply chain, and/or vendor/contract management
- Project Management accreditation (PMP) Is preferred
- Team management and leadership skills
- Understanding of and/or experience/degree in Regulatory Affairs and Quality Assurance

This role works in the following subsectors:

Applicable To	Bio-Health	Agri-Bio	Bio-Industrial	Bio-Energy
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The level of complexity of the role is:

Span of Complexity Levels	Foundational	Operational	Specialist/ Management	Expert/Executive
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CONTRACT MANUFACTURING PROJECT MANAGER COMPETENCY SUMMARY

Competencies	Complexity Level Required			
	1 Foundational	2 Operational	3 Specialist/ Manager	4 Expert/ Executive
Core				
Professional Accountability				
Technical Awareness				
Technical				
Project Initiation				
Project Plan Development				
Scope Management				
Budget and Cost Management				
Project Team Management				
Risk Management				
Project Quality Assurance				
Project Management of Change				
Project Reporting				
Project Communication				
Project Close-Out				
Industry Regulatory				
Ensure Regulatory Compliance				
Document Management				
Personal and Professional				
Problem Recognition/Solving				
Service Excellence				
Attention to Detail				

Core competencies

Professional Accountability

Demonstrates personal accountability, adequate project work habits, initiative to deliver scheduled work to produce high-quality results, and a professional project presence.

Technical Awareness

Applies a wide range of technical knowledge, comprehension, and judgement in driving decisions or solving technical issues during the project.

Technical competencies

Project Initiation

Implements the transition plan to guide the hand-off between business development and the technical project team in order to ensure the delivery of product cost, schedule, and quality.

Project Plan Development

Uses the scope, manufacturing plan, technical specifications, quality standards, method of execution, and resources to develop a detailed project execution plan in order to deliver a project within schedule and budget.

Scope Management

Monitors and manages the execution of work and avoidance of scope creep by adhering to product design specifications as approved by the client/product owner in order to ensure the delivery of the project in compliance with contract standards.

Budget and Cost Management

Develops a budget, cost control baseline and cash flow management strategy by applying estimating, forecasting, and project finance principles ensuring that project execution is within the approved budget and projections.

Project Team Management

Aligns team members' skills, competencies, and strengths with the project objectives ensuring all team members perform work collaboratively at the expected level of excellence.

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Risk Management

Contains and minimizes the negative impacts of risks within the project by analyzing all the manufacturing work processes to identify potential risks and ensure the implementation of mitigation plans to deliver the product as planned.

Competency in this role is demonstrated when the individual:

Project Quality Assurance

Uses the Quality Management plan to monitor the execution of the contract manufacturers' Quality Assurance and Quality Control (QA/QC) processes in order to ensure product quality.

Project Management of Change

Ensures the quality of project deliverables through the timely communication of directives on managing the impacts of changes to the project scope, technology, manufacturing process, and/or design standards.

Project Reporting

Implements project reporting best practices to effectively inform project stakeholders, enabling decision-making about objectives, contractual arrangements, and regulatory requirements in order to ensure deliverables are in strict accordance with client and regulatory requirements.

Project Communication

Applies knowledge of the different stakeholders' information needs and communication methods in order to implement a communication plan that ensures all project stakeholders are informed to act in support of the project goals.

Project Close-Out

Implements project close-out plan to ensure the review of deliverables against contracted standards and requirements in order to obtain sign-off on completion of project endpoints and obligations and finalize project close-out.

Industry regulatory competencies

Ensure Regulatory Compliance

Consults and collaborates with applicable regulatory authorities and experts to identify regulatory requirements, plan for compliance, and ensure meeting reporting and permitting requirements for maintaining the project schedule.

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Document Management

Establishes and/or follows the document management procedures to enable the identification, safe storage, and retrieval of those documents which individually and collectively permit evaluation of the conduct of the project when the project may result in any changes to the environment or to health, social, or economic conditions to potentially occur in Canada.

Personal and professional competencies

Problem Recognition/Solving

Recognizes when there is a problem and identifies the nature of the problem in order to collect and review relevant information, make decisions, and select and implement actions which solve the problem.

Service Excellence

Builds a successful track record of superior personal and organizational service delivery in diverse environments by collecting and sharing information around service expectations that results in innovative service enhancing initiatives.

Attention to Detail

Consistently applies mental focus and pays attention to their duties, ensuring that work is accurate and error-free to achieve results or accomplish tasks/objectives.

USE NATIONAL OCCUPATIONAL STANDARDS TO:

- ✓ Build a job description
- ✓ Plan professional development
- ✓ Map career progression and succession planning
- ✓ Benchmark compensation

View the full National Occupational Standards at biotalent.ca/NOS

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