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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 Contract Manufacturing Project Manager.

## **Occupational Definition**

Contract Manufacturing Project Managers lead projects through project teams from concept to delivery while partnering with internal and external resources. The project manager supports the account manager in all aspects of client contact, and coordinates the project through budgets, timelines, and scope to meet client needs. They manage and actively collaborate with legal, logistics, technical development, manufacturing, regulatory and quality departments. They work with the business development team to perform technical assessments, budget developments, project proposals, contract negotiations, statement of work development, while managing stakeholder relationships. Contract Manufacturing Project Managers must think critically, be effective problem solvers, and must employ effective communication and leadership skills to manage continually changing project needs. CMPMs work for Canadian biotechnology companies of different sizes (i.e., small, medium, large) and in various biotechnology areas, such as:

- Agriculture
- Aquaculture
- Bioenergy
- Bioproducts
- Biosciences
- Environment
- Food processing
- Forestry
- Genomics
- Human health
- Industrial
- Life Sciences
- Medical devices
- Nanotechnology
- Natural resources
- 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

Many biotechnology companies seek the support of outside manufacturing companies to help them manage the challenges of internal and external start-up. These companies employ Contract Manufacturing Project Managers (CMPMs) to lead projects from concept to delivery while partnering with internal and external resources. CMPMs support their company's account manager in all aspects of client contact, and coordinate the project through budgets, timelines, and scope to meet client needs. They manage project teams and actively collaborate with legal, logistics, technical development, manufacturing, regulatory and quality departments. They work with the business development team to perform technical assessments, budget developments, project proposals, contract negotiations, statement of work development, while managing stakeholder relationships. Contract Manufacturing Project Managers must think critically, be effective problem solvers, and must employ effective communication and leadership skills to manage continually changing project needs. CMPMs work primarily for Canadian health biotechnology and pharmaceutical companies of different sizes (i.e., small, medium, large) but also in various other biotechnology-related areas, such as: agriculture, aquaculture, bioenergy, bioproducts, biosciences, environment, food processing, forestry, genomics, human health, industrial, life sciences, medical devices, nanotechnology, natural resources and nutraceuticals.

Through their various relationships, CMPMs must manage the companies' goals, the manufacturing process, and the customers' needs in the final deliverable. They work with company manufacturing departments to assist in determining resource requirements and to allocate discrete project goals amongst the departments required for the projects. They assist in maintaining budget forecasts and actual account figures/project quotes, as related to projects for the project management team. Through their various relationships, Contract Manufacturing Project Managers manage the companies' goals, the manufacturing process, and the customers' needs in the final deliverable.

CMPMs also participate in business development by informing prospective clients of manufacturing, development and analytical capabilities. They also collect custom project requirements and specifications from clients while building effective business relationships. They may travel nationally or internationally to build relations, conduct site visits, and monitor manufacturing activities.

CMPMs identify manufacturing constraints and develop the means to anticipate and alleviate them. They work to ensure that contract manufacturers operate in accordance within established standards and guidelines for product quality, safety, efficiency, inventory control, material handling and reporting. They ensure that vendors maintain up-to-date documentation for compliance with regulatory standards and may be required to develop and maintain scorecards to facilitate continuous improvement. They ensure that contract manufacturing agreements are in place, and in compliance within each area of assigned contract manufacturing.

CMPMs must have a team player mentality with an ability to collaborate and negotiate within cross-functional teams. They should be leaders and willing mentors with the ability to motivate and influence people who don't report to them. They should also have well developed research

and analytical skills, and a strong ability to identify, quantify and realize various opportunities. CMPMs should be detail-oriented and possess strong problem-solving and planning skills.

A CMPM should have excellent English verbal and written communication skills, and be comfortable presenting information to multidisciplinary internal and external audiences. Reading and writing skills related to the comprehension and communications of Good Manufacturing Practices are essential. CMPMs who are managing international manufacturing contracts may also find it beneficial to be conversant or fluent in the language used where manufacturing operations are taking place.

Current Canadian and American job postings reveal that employers are seeking Contract Manufacturing Project Managers who possess a B.Sc. (Bachelors of Science) or a M.Sc. (Masters of Science) in a natural science such as Chemistry or Biology. In addition, most employers prefer candidates who have a minimum of three (3) to five (5) years experience in project management. Such experience may be related to project costing, analysis, justification, and presentation of deliverables to client specifications. Certain employers also require that project managers possess Good Manufacturing Practices (GMPs) regulatory knowledge. CMPMs should also have knowledge of and abide by the project management standards set forth by reputable associations such as the International Project Management Association (IPMA).

## 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	

CMPMs need a combination of technical knowledge and interpersonal skills to manage multi-disciplinary teams. CMPMs must have strong communication and leadership skills to manage the continually changing needs of projects. They must also be highly effective problem solvers and critical thinkers.

### **Language Benchmarks**

A Contract Manufacturing Project Manager must be able to work with a project team to satisfy client requirements and will need an upper level language benchmark of CLB 9.

## Competency Profile

*A Contract Manufacturing Project Manager must be able to:*

### **A. Manage Projects**

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Manage project transition from business development	1.1 Manage hand off between business development and technical project team	
2. Create detailed project plan	2.1 Work with client, business development and purchasing personnel to develop and review project scope (e.g., inclusions, exclusions)	Project management training or certification
	2.2 Determine client expectations and requirements	
	2.3 Evaluate knowns and unknowns (e.g., using decision tree)	
	2.4 Evaluate risks and constraints versus technical capabilities (e.g., run trials)	
	2.5 Breakdown project tasks	
	2.6 Generate project visual (e.g., using appropriate software)	
	2.7 Coordinate development of project milestones and deadlines	
	2.8 Develop and track project timelines	
	2.9 Identify critical path lists and revisit periodically during the project	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	2.10 Follow up and act on critical path action items	
3. Coordinate project activities with key personnel and departmental heads	3.1 Monitor and communicate project milestones, deadlines and activity timelines	
	3.2 Influence internal management to obtain project buy in	
4. Manage internal project team	4.1 Assemble project team with relevant expertise	
	4.2 Identify stakeholders	
	4.3 Assign and delegate project tasks within internal project team setting	
	4.4 Continuously maintain line of communication	
	4.5 Ensure that timelines and milestones are being met	
	4.6 Assure individual workgroups are working in sync	
	4.7 Proactively address any issues across all functions on the project team	
5. Outsource specific tasks, as required	5.1 Seek appropriate subject matter expertise, as required	
	5.2 Write up request for proposal	
	5.3 Circulate request for proposal or purchase (RFP) to competent sub-contractors, as required	
	5.4 Select successful contractor	
6. Manage sub-contractors, if required	6.1 Coordinate adherence to corporate safety guidelines	Company safety policies and procedures

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	6.2 Develop contract for services including Quality Assurance agreement, confidentiality and manufacturing agreement	
	6.3 Continuously maintain line of communication	
	6.4 Ensure that timelines and milestones are being met	
	6.5 Communicate deviations from timelines and milestones to the project team	
	6.6 Schedule audit of premises by Quality Assurance personnel, as required	Necessity of premises audits may depend on criticality of service being provided
7. Evaluate and monitor performance outcomes	7.1 Provide input to or develop performance measuring metrics and Quality Assurance/Quality Control program, as required	Applicable regulatory standards
	7.2 Monitor performance including ability to meet deadlines and maintain milestones	
	7.3 Communicate performance and follow up on action items to achieve improvement	
	7.4 Ensure quality assurance and performance standards are met	ISO 9000, ISO 14000
	7.5 Reassign resources, as required, to meet project performance goals	
	7.6 Continuously re-evaluate project performance	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	7.7 Close project upon final agreement on acceptability of deliverables	

8. Manage scope of project	8.1 Manage project against scope to identify change orders	
	8.2 Manage stakeholder expectations	
	8.3 Have an intimate knowledge of the project contract or master service agreement	
9. Facilitate project troubleshooting activities	9.1 Facilitate resolution of challenges with both internal personnel and external stakeholders	
	9.2 Mentor technical staff and help them work through encountered challenges	
	9.3 Re-evaluate project goals in light of encountered challenges	
	9.4 Review past lessons learned to assist in troubleshooting	
10. Develop contingency and risk mitigation plans	10.1 Anticipate points where project may encounter issues	
	10.2 Manage risks around project's critical path	
11. Promote continuous improvement	11.1 Define continuous improvement within the context of the company	
	11.2 Suggest opportunities for improvements	
	11.3 Conduct lessons learned meetings	

A Contract Manufacturing Project Manager must be able to:

**B. Communicate**

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Articulate goal and vision of the project	1.1 Clarify goal and vision with senior management	Outline goal and vision using communication tools (e.g., status reports, action plans, presentations)
	1.2 Manage client expectations for the project	
	1.3 Communicate project goal and vision to internal team	
	1.4 Communicate effectively within the defined management framework (e.g., Matrix Management Model)	
	1.5 Promote goal and vision to stakeholders	
	1.6 Promote goal and vision to project team	
2. Facilitate open communication within the overall project team	2.1 Actively bring subgroups of the project team together	
	2.2 Balance communication strategies between external team setting and internal project team setting	
3. Facilitate open communication with the internal organization	3.1 Work within organizational hierarchy to seek buy-in for the project (e.g., lab time, equipment, resources)	
4. Promote interaction among work groups	4.1 Prioritize and integrate work groups and functions	

	4.2 Assure individual workgroups are communicating effectively and working in synchrony	
	4.3 Communicate directly and regularly with individuals and work groups	
5. Integrate inter-departmental technical skills	5.1 Identify external groups or individuals who may assist with evolving project issues	
	5.2 Liaise with different technical groups to reach consensus on project operations	
	5.3 Recognize and coordinate strengths and technical skills different groups bring to the project	
	5.4 Resolve any issues between departments and technical personnel	
	5.5 Maintain alignment of technical personnel on behalf of the client and the company for the duration of the project	
6. Coordinate communications with auxiliary professionals	6.1 Facilitate open communication with consultants, for example: <ul style="list-style-type: none"> <li>• Quality Assurance</li> <li>• Manufacturing</li> <li>• Engineering</li> <li>• R&amp;D</li> <li>• Regulatory</li> <li>• Intellectual Property/Legal</li> </ul>	

	6.2 Facilitate open communication with appropriate project team members and external contractors and suppliers, for example: <ul style="list-style-type: none"> <li>• Contract manufacturing organizations</li> <li>• Contract research organizations</li> <li>• Raw material suppliers</li> </ul>	
7. Chair project team meetings	7.1 Establish project meeting protocol (e.g., key participants, schedule of meetings, minutes, follow up)	
	7.2 Exercise good chairmanship, for example: <ul style="list-style-type: none"> <li>• Encourage participation</li> <li>• Be accountable and hold others accountable</li> <li>• Identify problems and ensure they are solved</li> <li>• Ensure a sense of order (e.g., keep agenda moving)</li> </ul>	
	7.3 Manage time and topics	
	7.4 Rely on technical team, as required	
	7.5 Be decisive	
	7.6 Create and circulate meeting minutes and action items efficiently and expediently	
8. Maintain regular communication with all project stakeholders	8.1 Determine the most appropriate mode of communication for the intended purpose	
	8.2 Communicate efficiently using various media, as appropriate (e.g.,	Maintain records of what was communicated and when

	teleconference, e-mail, face-to-face meeting, presentation)	
	8.3 Develop audience-targeted reports and communications	
	8.4 Communicate relevant project information (e.g., project progress, status, road blocks, budgets, milestones)	
	8.5 Observe proper business protocol in project communications (e.g., message recipients, disclosure, confidentiality)	
	8.6 Act as primary client contact for project-related issues	
9. Champion and maintain sense of urgency and act accordingly	9.1 Encourage continued team member buy in and feedback	
	9.2 Compare established critical path to actual project progress and identify specific issues	
	9.3 Communicate the importance and implications of maintaining planned project timelines	
	9.4 Demonstrate benefits and consequences	
	9.5 Demonstrate ability to prioritize	
	9.6 Ensure buy-in	

A Contract Manufacturing Project Manager must be able to:

**C. Oversee Financial and Operational Performance**

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Develop and propose budget	1.1 Work with logistics, purchasing, operations and finance personnel as resources when developing the budget	
	1.2 Estimate costs for resources (e.g., transportation, logistics, rentals, equipment)	
	1.3 Obtain input from subject matter experts (e.g., equipment supplier, service provider, managers, workers) to determine appropriate costs	
	1.4 Utilize cost-calculating software, as required [e.g., Materials, Resources and Planning (MRP)]	
	1.5 Identify timeline for budget funds allocation and cash flow requirements during the project	
	1.6 Identify operational constraints	
	1.7 Estimate any new capital expenditures required	
	1.8 Assemble required documents, as required	
	1.9 Conduct peer review of the cost roll up	
	1.10 Submit cost roll up to senior	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	management	
	1.11 Justify costs to management	
	1.12 Revise internal financial figures based on senior management feedback	
	1.13 Perform lessons learned of cost roll up	
2. Coordinate project purchasing	2.1 Work with key personnel (e.g., controller, purchasing department) on project purchasing	
	2.2 Arrange equipment and order supplies, as required	
	2.3 Manage how funds are spent during project, according to project scope	
3. Monitor financial performance	3.1 Compare estimated cost model to actual costs	
	3.2 Carry out comparisons at agreed milestones of the project	
	3.3 Redefine the project budget based on actual performance	
	3.4 Compare production versus targets	
	3.5 Manage scope of work for change order events	
	3.6 Forecast revenue streams based on project performance	
	3.7 Develop creative solutions to reduce costs and accelerate revenue	
4. Update program manager on financial targets and performance	4.1 Produce interim reports for senior management	



	4.2 Present spreadsheet and visual timeline to illustrate performance against project milestones	
	4.3 Redefine the project budget based on actual performance, as required	
5. Support business development activities	5.1 Contribute to technical assessments	
	5.2 Champion scope of work development	
	5.3 Finalize external proposal	
	5.4 Provide quotation or manufacturing supply agreement to client	
	5.5 Participate in contract negotiations	
	5.6 Meet and follow up with client, as required	
	5.7 Revise quotation periodically, as required (e.g., monthly, quarterly)	
6. Manage site visits to audit project	6.1 Determine nature of site visit	
	6.2 Identify appropriate team to lead site visit (e.g., Quality Assurance personnel, Regulatory Affairs personnel)	
	6.3 Provide support to facility tour	
	6.4 Compile report to address issues	
	6.5 Follow up on issues	
7. Implement changes for improvements and efficiencies	7.1 Once milestones are achieved, carry out project financial review	
	7.2 Act as change agent for continuous improvement within the organization	

	7.3	Work with subject matter experts and investors to determine possible improvements and efficiencies	Document possibilities and use as input to lessons learned meetings
	7.4	Make specific improvements to projects to align with financial objectives	
	7.5	Secure agreement among stakeholders to implement change	
	7.6	Drive specific identified changes, for example: <ul style="list-style-type: none"> <li>• Ask QA to improve a test method</li> <li>• Implement efficiencies to the manufacturing process</li> </ul>	

A Contract Manufacturing Project Manager must be able to:

**D. Comply with Regulations**

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Develop safety policies and standards	1.1 Participate on company safety committees (e.g., joint health and safety committees)	Provincial/territorial Occupational Health and Safety regulations
	1.2 Coordinate with appropriate personnel to develop safety policies and standards	
	1.3 Review and update facility-specific health and safety plans	
	1.4 Coordinate with designated health and safety representative	
2. Ensure compliance with safety policies and standards	2.1 Consider and account for safety aspects that are a part of the project design	Company policies and procedures Occupational Health and Safety Transportation of Dangerous Goods Regulations
	2.2 Ensure project teams are informed and aware of the dangers associated with their materials and activities	Material Safety Data Sheets WHMIS
	2.3 Ensure personnel are trained according to project scope	WHMIS PPE Provincial Boiler Safety Association
3. Assure environmental legislation compliance	3.1 Review and update facility-specific environmental policies and procedures	Federal and provincial/territorial regulations Foreign regulations, e.g. FDA, depending on where the product will be sold
	3.2 Ensure that project-specific environmental requirements are	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	explicitly stated in the project plan	
	3.3 Communicate environmental policies to set the facility standard	Federal and provincial/territorial regulations
	3.4 Ensure employees are working in observance of the environmental standard	Federal and provincial/territorial regulations
	3.5 Secure regulatory expertise, as required	Federal and provincial/territorial regulations Federal Pollution Report Municipal environmental regulations
	3.6 Communicate with regulatory bodies, as required	
	3.7 Follow up on issues to assure compliance	
	3.8 Complete regulatory reporting, as required	
4. Assure compliance with specific cGMPs (current good manufacturing practices)	4.1 Be familiar with applicable regulations	<p>Applicable regulations and standards may include, for example:</p> <ul style="list-style-type: none"> <li>- Legislations following Health Canada</li> <li>- Canadian Food Inspection Agency (CFIA)</li> <li>- US Food and Drug Administration (USFDA)</li> <li>- United States Pharmacopeia (USP)</li> <li>- European Union Pharmacopeia (EUP) legislations</li> <li>- ICH (International Conference on Harmonization)</li> <li>- GLP (Good Laboratory Practices)</li> <li>- Environmental compliance documentation</li> </ul>

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
		<ul style="list-style-type: none"> <li>- Environmental, health and safety legislations</li> <li>- Current Good Manufacturing Practices (cGMPs)</li> <li>- Hazard Analysis and Critical Control Points (HACCP)</li> <li>- Investigational New Drug Application(INDA)</li> <li>- Investigational Medicinal Product Dossier (IMPD)</li> </ul>
	4.2 Liaise with Quality Assurance/Quality Control departments, as required, to ensure quality expectations are met	
	4.3 Apply experience with regulations to assure product is made within regulatory requirements	
5. Develop and write Validation Master Plan (VMP), as required	5.1 Collaborate with process validation team (i.e., QA, QC and manufacturing departments) to develop the Validation Master Plan	
	5.2 If required, write the process validation protocols, for Installation Qualifications (IQ), Operational Qualifications (OQ), and Performance Qualifications (PQ)	
	5.3 Circulate validation plan for review and approval	
	5.4 Complete required documentation, as required	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
6. Review all documents and Standard Operating Procedures SOPs	6.1 Review all documents and SOPs to ensure alignment with regulations	Health, safety and environmental regulations BQ 9000 ISO 9000, ISO 14000 ISO 9001
7. Prepare summary regulatory reports, as required	7.1 Write process validation reports, if required	Process Validation reports are typically written and belong to the technical authority of the project
	7.2 Circulate reports for review and approval	
8. Participate in client and third party audits	8.1 Respond to requests for client audits, as required	
	8.2 Schedule audits with QA	
	8.3 Bring knowledge of whole project to audit discussions	
	8.4 Be factual and articulate in discussions with auditors	
	8.5 Be able to rationalize and justify the design of the process	
	8.6 Work with senior management to define roles and responsibilities during audits, as required	
	8.7 Observe organizational Standard Operating Procedures guiding site visits by external auditing personnel	CFIA USFDA Health Canada
9. Obtain sign off from Quality Assurance department	9.1 Obtain Quality Assurance approval that product or process is in compliance with standards	BQ 9000

A Contract Manufacturing Project Manager must be able to:

**E. Manage Client Relationships**

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Manage customer needs and expectations	1.1 Provide overall project guidance to clients (e.g., regulatory, process, quality, development)	
	1.2 Manage scope creep and revise project budgets, as required	
2. Facilitate presentations to clients and stakeholders	2.1 Manage technical team’s contribution to presentations	
	2.2 Convey confidence in company’s ability to meet client needs	
	2.3 Prepare presentation using technology, as necessary (e.g., PowerPoint presentations)	
	2.4 Carry out direct, on-site presentations for clients and stakeholders	
3. Provide progress and status reports	3.1 Compile information from all respective workgroups	
	3.2 Provide status report to clients and stakeholders in agreed-upon format	
4. Establish rapport with client	4.1 Collaborate with business development or account management personnel for all aspects of client relationship	

	<p>4.2 Be available to client, for example:</p> <ul style="list-style-type: none"> <li>• Be responsive</li> <li>• Be open to additional meetings</li> <li>• Be open to new ideas</li> <li>• Be respectful</li> <li>• Listen</li> </ul>	
	<p>4.3 Be honest, upfront and factual</p>	
	<p>4.4 Develop strong professional relationship with clients</p>	
<p>5. Facilitate conflict resolution</p>	<p>5.1 Collaborate with business development or account management personnel to resolve conflicts</p>	<p>Conflict resolution training</p>
	<p>5.2 Identify areas of conflict (e.g., conflicting priorities among project stakeholders)</p>	
	<p>5.3 Present alternatives or solutions</p>	
	<p>5.4 Obtain buy in to resolve conflict</p>	
	<p>5.5 Address unresolved conflicts through proper channels, as required</p>	

A Contract Manufacturing Project Manager must be able to:

**F. Demonstrate Technical Credibility**

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Apply scientific knowledge	1.1 Complete or oversee technical assessments	
	1.2 Coordinate or oversee R&D discussions	
	1.3 Interact with client	
	1.4 Understand scientific aspects of client’s product (e.g., clinical aspect)	
	1.5 Regulatory and quality requirements for project	
2. Apply multi-disciplinary technical skill set	2.1 Be able to apply a broad set of technical knowledge, experience and guidance in contract manufacturing projects	
	2.2 Apply skills sets in, for example: <ul style="list-style-type: none"> <li>• Research &amp; Development/Process Development/Preparation</li> <li>• Quality Assurance/Quality Control</li> <li>• Manufacturing</li> <li>• Operations</li> <li>• Regulatory</li> <li>• Engineering</li> <li>• Validation/Maintenance</li> </ul>	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
3. Apply experience	3.1 Relate experience from working with other products and platform technologies to the current project	
	3.2 Identify transferable scientific processes	
4. Stay current with technological developments and their applications to current projects	4.1 Attend conferences	
	4.2 Read industry publications (e.g., periodicals, journals)	
	4.3 Speak with vendors and suppliers	
	4.4 Speak with technical leads within the organization	

A Contract Manufacturing Project Manager must be able to:

**G. Demonstrate leadership**

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Assemble management team to meet project needs	1.1 Define management and technical skills required for project	
	1.2 Ensure individuals with the appropriate skill sets are working on project teams	
	1.3 Recruit and restructure, as required	
	1.4 Assemble functional managers	
	1.5 Communicate needs of the project to the functional managers and performance expectations	
	1.6 Secure cooperation and buy-in	
2. Develop and empower project teams	2.1 Assemble correct group of professional competencies as required by the project	
	2.2 Assign decision making authorities and responsibilities among functional leaders	
	2.3 Meet with and brief people on the project and the project management framework	
	2.4 Empower project team members to contribute and complete objectives	
	2.5 Monitor team members' activities	
	2.6 Lead in team building activities	
	2.7 Motivate team members for duration	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	of the project	
3. Manage project staff	3.1 Ensure required training is delivered on time to relevant project members, depending on project needs	OHS PPE WHMIS Process-specific training
	3.2 Monitor set goals versus performance and give ongoing feedback to project staff	PMP training Supervisory training
	3.3 Make yourself available to project teams for consultation and guidance for duration of project (i.e., be on call)	
	3.4 Help people prioritize their work	
	3.5 Emphasize health and safety hazards, technical risks and critical process parameters of the project	
4. Manage tasks with competing priorities	4.1 Resolve project conflicts	Training in project change management
	4.2 Make and communicate decisions on what tasks are of highest priority, in alignment with critical path	
	4.3 Address project issues/conflicts in order of overall priority and urgency	
5. Identify and manage process risk	5.1 Identify and quantify risks	Risk management training PMP training
	5.2 Take measures to minimize and avoid project risks	
	5.3 Balance risks against project milestones	

	5.4 Develop contingency plans to mitigate risk	
	5.5 Communicate risks and contingency plans to stakeholders	
6. Participate as an active team member	6.1 Be involved with all aspects of the project, as required	
	6.2 Fill in gaps, as needed	
7. Be decisive	7.1 Consider options, suggestions and ideas that have been presented	
	7.2 Apply rational, data-driven approach to decision making (e.g., be prepared to justify decisions)	
	7.3 Come to final decision and implement it in a timely manner to move forward with project activities	
8. Coach and mentor project team	8.1 Appreciate individuals' capabilities	
	8.2 Challenge and support team members	
	8.3 Instil confidence and trust	
9. Demonstrate emotional intelligence	9.1 Be proactive in addressing individuals' needs	
	9.2 Be responsive to team needs	
	9.3 Be aware of and address cultural, religious and generational diversity	
	9.4 Be a good listener	
10. Acknowledge team members' expertise	10.1 Appreciate technical complexity in any area of others' expertise	
11. Participate in performance reviews and appraisals	11.1 Give feedback to departmental managers on project team members' performance	Follow company policies and procedures

	11.2 Participate in formal performance reviews	Ensure performance review reports are sent to company's human resources department
	11.3 Communicate client feedback of project team to senior management	

A Contract Manufacturing Project Manager must be able to:

**H. Demonstrate Personal Competencies**

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Lead with confidence	1.1 Show and take initiative	
	1.2 Be accountable	
	1.3 Think critically and act objectively	
2. Work in fast-paced environment	2.1 Listen carefully	
	2.2 Maintain 'big picture' perspective	
	2.3 Stay focused on overarching goals and objectives	
	2.4 Make decisions with limited information, as required	Be prepared to justify the decision
	2.5 Respond appropriately	
	2.6 Monitor and check outcomes	
	2.7 Adjust, as required	
3. Demonstrate professional attributes	3.1 Listen	
	3.2 Be sensitive to peoples' concerns	
	3.3 Maintain a professional level of interaction (e.g., refrain from sharing personal views and commentary)	
	3.4 Provide solutions within team's capabilities	
	3.5 Acknowledge concerns	
	3.6 Demonstrate integrity	
	3.7 Show impartiality	
	3.8 Delegate in a responsible and diplomatic way, also ensuring expectations are understood	



	3.9 Assign tasks according to team member qualifications	
	3.10 Be assertive	
	3.11 Be supportive	
	3.12 Be solution-driven	
4. Be a quick learner	4.1 Be open to new ways of doing things	
	4.2 Be able to think on your feet	
	4.3 Be amenable and resourceful	
5. Be customer service focused	5.1 Put client needs first	
	5.2 Act as client advocate within the organization	
6. Continuously update skills	6.1 Participate in continuous learning opportunities (e.g., management courses, professional development courses)	
	6.2 Maintain applicable certification [e.g., Project Management Institute (PMI)]	