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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 Quality Assurance Manager.

Occupational Definition

Quality Assurance Managers provide quality leadership through implementation of Quality Management Systems (e.g., documentation management, management of non-conformances, change management, Corrective Action and Preventative Action (CAPAs), validation site master plan). Quality Assurance Managers develop investigational protocols and reports, coordinate the document review process and review actions taken to address complaint investigations, laboratory variances and supplier-generated investigations. They report on investigations and corrective actions for any non-conformances by ensuring that all quality-related procedures are implemented and followed. They take the lead role in internal and external audits and ensure records are properly maintained. They maintain the records of all batch review and G*X*P (i.e., G*M*P, G*L*P, G*C*P, etc.) documentation for all products and services (e.g., input materials, Active Pharmaceutical Ingredients (APIs), raw materials, in-process materials, by-products/ intermediates, final products, suppliers, contractors). They approve release of products. They review any material that is deemed defective and work with colleagues in all departments to manage the process of troubleshooting within those departments and to ensure compliance. They lead quality compliance authority inspections. They will often be responsible for the departmental budget and finance as well as human resources duties including the hiring of staff, employee performance evaluations and the training and mentoring of junior staff. Quality Assurance Managers may work for Canadian biotechnology organizations 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 and Animal 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

Quality Assurance (QA) Managers working in Canadian biotechnology companies perform a variety of functions, and their roles may differ greatly depending on the size of the company, scope of work and industry subsector. Major aspects of quality assurance may include: sanitation, hygiene, pest control, production procedures and shelf-life determination. Quality assurance management responsibilities may be classed into two (2) main spheres: Quality Assurance activities and Regulatory Affairs activities. QA activities include the development and implementation of sound quality strategies. In developing quality strategies, QA Managers play a critical role in supporting the various departments within their organization. In relation to regulatory affairs, QA Managers promote and uphold regulatory standards from external organizations such as Health Canada or the Canadian Food Inspection Agency (CFIA). QA Managers may also be responsible for the registration of products through regulatory bodies.

QA Managers maintain a number of working relationships on a daily basis. They often report to a company executive in regards to the status of quality assurance activities. As leaders, QA Managers must motivate, mentor, and set developmental goals for their quality assurance staff. They provide interdepartmental guidance and training in relation to quality assurance documents, procedures and standards. Depending on the size of the organization, QA Managers may also provide training and guidance to other sites and sister companies. Quality Assurance Managers may be required to travel in order to train off-site staff and perform assessments. They must often liaise, either onsite or offsite, with product vendors, regulatory bodies, and inspection agencies. Quality Assurance Managers balance their varied functions and responsibilities by diligently planning the execution of tasks and being responsive to the needs of the organization.

Quality Assurance Managers must have industry experience before carrying out their managerial duties. Quality Assurance Managers typically possess a Bachelor of Science (BSc.) in a natural science such as Chemistry, Biochemistry, Biology or Microbiology; although, a degree in Engineering may also be a relevant entry path into the field of quality assurance. It is also important for a QA Manager to obtain statistical training as it pertains to data analysis and trending. Due to managerial, supervisory and other business-related components of quality assurance management, a degree or a Master of Business Administration is complimentary to the occupation. A number of professional designations and accreditations are also complimentary to role of Quality Assurance Manager including, for example, ASQ (American Society for Quality), and CAPRA (Canadian Association of Professional Regulatory Affairs). Through experience and continuous education, Quality Assurance Managers must develop detailed knowledge of relevant Canadian and American Good Laboratory Practices, Good Manufacturing Practices and Good Clinical Practices regulations. Other related industry-specific knowledge includes applicable standards such as International Standard Organization (ISO) standards and Food and Drug Administration 21st Century initiatives (e.g., Quality by Design). It is beneficial also to have specialized knowledge in adverse event reporting, international trade certificates, auditing, and transportation of goods. Quality Assurance Managers must also demonstrate knowledge of business and managerial principles. Quality assurance management is also moving from paper-based to electronic media such as electronic databases, forms and reports that are currently being used more and more in industry.

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		

Thinking skills, including problem solving, decision making, and critical thinking, are the most important Essential Skills for the occupation. QA Managers must have the ability to be detail-oriented while considering a project in its entirety. QA Managers must be flexible and dynamic to provide creative ideas for mitigating problems and preventing re-occurrence. They should possess excellent oral and written communication skills, and the ability to organize and manage multiple priorities. A combination of collaboration and effective listening skills are important as QA Managers need to work with multiple individuals from diverse backgrounds to develop viable solutions.

Language Benchmarks

Quality Assurance Managers ensure that Quality Management Systems are implemented effectively by the company employees and will need an upper level language benchmark of CLB 10.

Competency Profile

A Quality Assurance Manager must be able to:

A. Implement Quality Management Systems

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Develop quality manual	1.1 Determine appropriate quality system to meet business needs	Food and Drug Administration (FDA) International Organization for Standardization (ISO) (e.g., ISO 9001, 17025, 13485) European Union (EU) Hazardous Analysis & Critical Control Points (HACCP)
	1.2 Determine regulatory/industry standards compliance requirements	
	1.3 Develop a scope for the manual	
	1.4 Develop terms, definitions and references	
	1.5 Develop documentation requirements	
	1.6 Establish management responsibility	
	1.7 Establish operational elements	
	1.8 Establish laboratory protocols	
	1.9 Establish sampling and testing protocols	
	1.10 Establish remediation elements (e.g., Corrective and Preventative Action (CAPA) system)	
	1.11 Establish product load out	

2. Benchmark best practices	2.1 Research quality system options, methods and resources (e.g., survey other companies; engage quality assurance experts)	cGXPs ISO standards
	2.2 Define Quality Assurance practices within the business model	
	2.3 Seek advice from regulatory authorities and auditors	
	2.4 Interpret relevant regulations and guidance	
3. Create quality policies	3.1 Facilitate creation of policies based on the standards that the business is going to implement	
	3.2 Seek approval from higher management or sign off on policies, as required	
	3.3 Develop a documentation hierarchy (e.g., policies, procedures)	
	3.4 Define authorities for documentation approval	
4. Create and implement deviation management system	4.1 Link to quarantine process for major deviations	
	4.2 Link to product disposition system (e.g., accept, reject, pending, on test)	
	4.3 Write procedure, as required	
	4.4 Create tracking system	
	4.5 Conduct risk assessment	
	4.6 Design data needs (e.g., depending on system being used, data may need to be pulled into a data warehouse)	
	4.7 Access system data	
	4.8 Do trend analysis	

	4.9 Review and approve the deviation reports	
	4.10 Communicate metrics and performance	
5. Create and implement change management system	5.1 Write procedure, as required	
	5.2 Create tracking system	
	5.3 Design data needs	
	5.4 Review performance of the change management system	
	5.5 Build in component for regulatory reporting assessments	
	5.6 Quarantine awaiting regulatory approval, as required	
	5.7 Evaluate and approve change	Seek customer approval, as required
	5.8 Organize inter-departmental teams to develop change implementation plan, as required	
	5.9 Communicate metrics and performance	
6. Create Corrective and Preventative Action (CAPA) system	6.1 Write procedure, as required	
	6.2 Create secure tracking system	Appropriate version control
	6.3 Design data needs	
	6.4 Review performance (i.e., closure)	
	6.5 Establish effectiveness measurement	
	6.6 Communicate metrics and performance	
	6.7 Conduct root-cause trend analysis	

7. Create and implement complaint system	7.1 Identify and classify complaint (e.g., physical customer complaints)	
	7.2 Write procedure	
	7.3 Create tracking system	Appropriate version control
	7.4 Design data needs	
	7.5 Review performance (i.e., closure)	
	7.6 Provide feedback to customer	
	7.7 Communicate metrics to senior management	
	7.8 Monitor trends of recurring complaints	
	7.9 Take action on recurring complaints	
	7.10 Interact with specialized product assessment experts e.g. pharmacovigilance, as required	
8. Create batch record system	8.1 Write procedure, as required	BQ 9000
	8.2 Create tracking system	
	8.3 Create templates	
	8.4 Create master documents (e.g., site master file, drug master file)	
	8.5 Issue copies for execution	
	8.6 Review and approve batch record once execution is completed, as required	
	8.7 Work with production managers to maintain batch record system	
	8.8 Reconcile issued documents [e.g., labels, batch production records (BPRs)]	

9. Create risk management system	9.1 Write procedure, as required	Failure Mode and Effects Analysis (FMEA) Newly released Guide 0001 for cGMP (October 2009 version of Drug GMP) ISO 13485 (medical devices) and ISO 17025 (testing and calibration labs)
	9.2 Create tracking system	
	9.3 Perform risk analysis (e.g., prospective, retrospective)	
	9.4 Use risk analysis tools, as required, for example: • Ishikawa • Fishbone • Paretto • Hazard Analysis and Critical Control Points (HACCP)	
	9.5 Seek to mitigate and prevent risks	
	9.6 Establish operational map for conducting risk assessments	
	9.7 Maintain risk management system to ensure the system will not impact quality regulations	
10. Monitor Quality Management Systems	10.1 Establish performance goals and objectives (e.g., organizational, departmental)	
	10.2 Convene design and output review meeting with management	
	10.3 Identify and review outputs of each quality system (e.g., risk analysis report)	
	10.4 Monitor performance and identify areas for improvement (e.g., extract performance data)	

	10.5 Implement and manage actions resulting from management performance review meeting	
	10.6 Inform management regarding areas for improvement (e.g., via dashboard)	
	10.7 Trend and communicate metrics (e.g., via dashboard)	
	10.8 Review quality system periodically for continuous improvement	
11. Collaborate on product design system	11.1 Write procedures, as required	
	11.2 Validate and verify processes, as required	
	11.3 Collaborate on design control process	
	11.4 Review specifications (e.g., raw materials, in-process materials, and final products) that will link to transfer from development to licensed manufacturing	
	11.5 Work with project manager to facilitate link to relevant departments (e.g., research and development (R&D), marketing, technology transfer)	
	11.6 Collaborate to develop product design database or product master file	
12. Create product recall system	12.1 Write procedures	
	12.2 Create tracking system (e.g., lot number assignment and traceability)	
	12.3 Create template recall and notification forms	
	12.4 Liaise with internal and external stakeholders	
	12.5 Establish communication policies	

13. Create site validation master plan	13.1 Write master plan	
	13.2 Create tracking system	
	13.3 Update master plan	
	13.4 Monitor master plan for timelines and milestones	
	13.5 Issue copies for execution	

A Quality Assurance Manager must be able to:

B. Provide Quality Leadership

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Set Quality Assurance department goals	1.1 Understand the business model	Company business model
	1.2 Assess management priorities	
	1.3 Apply the business model	
	1.4 Understand areas of risk	
	1.5 Ensure firm scope for deliverable	
	1.6 Communicate departmental goals to senior management as well as to staff	
	1.7 Continuously evaluate departmental goals	
	1.8 Integrate Quality Assurance goals with other departments' goals	
2. Interpret quality requirements	2.1 Understand the business model	Current Inspection findings Warning letters, FDA 483 forms Regulatory Body Guidance, for example: • International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) • Food and Drug Administration (FDA) • International Organization for Standardization (ISO) • BQ 9000 • European Union (EU) • Health Canada • Canada Food Inspection Agency (CFIA) • United States Department of Agriculture

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
		(USDA) • US Food and Drug Act
	2.2 Understand areas of risk	
	2.3 Understand operations and how quality requirements apply	
	2.4 Stay current with quality and regulatory requirements	
	2.5 Seek understanding and input from other departments	
	2.6 Examine how regulators are interpreting quality requirements	Review recent audit reports; participate in Health Protection and Food Branch Inspectorate (HPFBI)
3. Provide quality and compliance support to project teams	3.1 Participate on project teams	
	3.2 Understand scope of project	
	3.3 Develop quality plans for project, as appropriate	Apply QC Tools
	3.4 Review project documents at various stage gates or project milestones	
	3.5 Provide guidance on requirements	
	3.6 Lead teams, as required	
4. Recommend quality and regulatory strategies	4.1 Develop a quality strategy (e.g., for Information Systems)	
	4.2 Understand the business model	
	4.3 Stay current with quality regulations and guidance	
	4.4 Understand operations and how quality requirements apply	
	4.5 Assess risk	
	4.6 Evaluate options for strategies and assess whether quality and regulatory	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	strategies are meeting needs (e.g., find appropriate balance where business goals are being met and appropriate quality and regulatory standards are being met), as required	
	4.7 Define quality strategies as they pertain to product development (e.g., determine what standards apply at each phase of development)	
	4.8 Develop creative solutions to problems	
5. Facilitate risk analysis	5.1 Apply risk assessment models	
	5.2 Develop and follow procedures (e.g., who is involved?)	
	5.3 Build risk assessments into systems (e.g., validations, non-conformances)	
	5.4 Seek to balance quality and regulatory risks	
	5.5 Review risk mitigation actions	
	5.6 Report to senior management and staff, as required	Wear and promote wearing of appropriate Personal Protective Equipment
6. Provide real-time quality advice on shop floor	6.1 Establish a presence on the floor	
	6.2 Be available to respond to events as they occur	
	6.3 Assess risk of situations (e.g., safety, quality, regulatory)	Wear appropriate Personal Protective Equipment
	6.4 Use effective decision-making skills	
	6.5 Understand product and the process	
	6.6 Listen to shop floor concerns	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	6.7 Understand scope of problem and obtain all perspectives	Understanding of processing operations and equipment used
	6.8 Identify own limits and seek advice from subject matter experts, as required	
	6.9 Be decisive (e.g., stop production when required)	
	6.10 Observe activities on the manufacturing floor and communicate observations, as required	
7. Provide technical advice	7.1 Work with technical managers to provide advice, as required	
	7.2 Employ multi-disciplinary skill set and competencies	
	7.3 Demonstrate technical competence	
	7.4 Understand the product	
	7.5 Understand the manufacturing process	
	7.6 Understand the facilities (e.g., utilities)	
	7.7 Understand what is validated and the validation process	

	7.8 Provide input to validation master plan (e.g., plans and reports)	
	7.9 Access technology information on an ongoing basis	
	7.10 Provide technical and quality advice; for example: • In person • Via presentations • Via reviews of documents • Via written reports • Via correspondence (e.g., e-mail messages)	
8. Communicate status of essential quality requirements	8.1 Establish or access a system for extracting data and interpreting trends	
	8.2 Manage data	
	8.3 Communicate status of quality requirements, for example: • In person • Via presentations • Via reviews of documents • Via written reports • Via correspondence (e.g., e-mail messages)	
	8.4 Perform regular product reviews, as required (e.g., quarterly, annually)	
	8.5 Interpret quality metrics and communicate any major issues	
9. Problem solve	9.1 Use creativity	
	9.2 Utilize problem solving toolbox (e.g., Lean Six Sigma, KAIZEN)	
	9.3 Assess risk	
	9.4 Consider all perspectives (e.g., engage staff)	

	9.5 Seek solutions between business, quality, and regulatory risks	
	9.6 Assemble experts, as required, to resolve more difficult problems	
	9.7 Use project management tools for problem solving (lead and drive process to get results, e.g., Kepner-Tregoe approach to problem solving)	

A Quality Assurance Manager must be able to:

C. Manage Quality Documentation

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Manage documentation system	1.1 Determine whether documentation system is paper-based or electronic (e.g., WISDOM – Oracle database, Agile – product lifecycle management Oracle software solution)	Statistical Process Control (SPC) BQ 9000 ISO 9000
	1.2 Facilitate development of Standard Operating Procedures (SOPs)	
	1.3 Define controlled documentation versus non-controlled documentation	
	1.4 Define controlled records versus non-controlled records	
	1.5 Develop a documentation hierarchy (e.g., policies, procedures), as required	
	1.6 Develop permissions matrix for access to documentation	
	1.7 Develop and maintain version control and distribution	
	1.8 Provide access to controlled documentation, as required	
	1.9 Issue and reconcile good manufacturing practice (GMP) documents directly (e.g., batch record templates)	
	1.10 Implement and monitor documentation system	
2. Create master document templates	2.1 Develop process for developing,	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	reviewing and approving master document templates and issuing copies (e.g., collaborating with appropriate personnel)	
	2.2 Define which documents need to have templates developed (e.g., master batch record)	
	2.3 Ensure document templates will be created and conform to regulatory standard [e.g., with common technical documents (CTD)]	
	2.4 Ensure master document templates are updated and current approved version is available for use	
3. Design and develop document life cycle databases	3.1 Develop record retention policy	
	3.2 Create or use templates for each type of document (e.g., Standard Operating Procedures, forms, protocols)	
	3.3 Develop user requirements for the databases	
	3.4 Evaluate system risk	
	3.5 Evaluate and apply regulations and guidance	Food and Drug Administration (FDA), GMPs
	3.6 Ensure that Information Systems access tools for the design and development of document life cycle databases	Good Automated Manufacturing Practices (GAMP)
	3.7 Seek recommendations or follow company standards	
	3.8 Determine functional requirements and specifications	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	3.9 Ensure that system is developed, validated and verified	
	3.10 Ensure administration is available or in place to maintain the system	
4. Review and approve quality documentation	4.1 Provide regulatory, quality and technical input to master records	
	4.2 Establish and follow Standard Operating Procedures for the review and approval process	
	4.3 Establish metrics for document review and approval (e.g., right first time, document errors)	
	4.4 Seek approval from higher management or sign off on policies, as required	
	4.5 Link review and approval to other processes (e.g., link review of batch records to batch release process)	
	4.6 Evaluate and seek to minimize redundancies	
5. Create archive system for quality documentation, as required	5.1 Determine desired method for archiving documents (e.g., hard copies of documents, scanning and electronic filing, determine how long records will be retained)	
	5.2 Utilize available archiving tools	
	5.3 Develop system for indexing and locating files	

	5.4 Implement system for quick document retrieval (e.g., for readiness in regulatory inspections)	
	5.5 Manage off-site storage issues (e.g., mandatory fire safety of documents)	
	5.6 Seek professional services for hard copy storage, as required	
	5.7 Validate data integrity after archiving	
6. Archive obsolete documents	6.1 Maintain previous versions of quality documents and Standard Operating Procedures (SOPs)	
	6.2 Seek approval for retiring documents	
	6.3 Hold document for time outlined in quality system	
	6.4 Ensure approvals are filed with obsolete or retired documents	
7. Archive study materials	7.1 Establish and maintain official archive (e.g., quality manuals, standard operating procedures, site plans)	Good Laboratory Practice (GLP)

A Quality Assurance Manager must be able to:

D. Supervise Quality Staff

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Establish staffing plan	1.1 Evaluate management priorities	
	1.2 Define workload plan (e.g., ratio of quality to manufacturing personnel)	
	1.3 Assign staff according to competencies	
	1.4 Define job roles and responsibilities for quality staff	Ensure Standard Operating Procedures are available with work instructions
	1.5 Respond to organizational and management needs for quality or staff support	
	1.6 Define hierarchy or outline reporting structure in quality organizational chart, as necessary	
	1.7 Develop skills inventory of quality staff (e.g., to determine competencies available within quality department)	
2. Align Quality Assurance activities with management priorities	2.1 Assess workload priorities and resource requirements	
	2.2 Prioritize revenue generating work and compliance issues	
	2.3 Communicate with senior management and all staff	

	2.4 Respond to and manage priority requests among staff and departments	
	2.5 Utilize available tools to manage project activities and seek to meet critical project or production timelines and priorities	
3. Coach and develop staff	3.1 Assess staff competencies	
	3.2 Seek feedback from internal and external customer relations	
	3.3 Create development plans for individuals (e.g., to close skills gaps)	
	3.4 Set personal goals	
	3.5 Conduct one-on-one meetings	
	3.6 Lead or attend department meetings	
	3.7 Be available to staff	
	3.8 Provide external training development opportunities	
	3.9 Make external mentors available	
	3.10 Provide cross-training opportunities	
4. Review quality staff work	4.1 Review documentation (e.g., reports, investigations, presentations)	
	4.2 Provide constructive feedback and guidance	
5. Mentor quality attitudes	5.1 Lead by example	Promote professionalism and ethics
	5.2 Foster distinction between quality and compliance	

	5.3 Promote quality thinking time (e.g., ensuring adequate time to evaluate problems, to make decisions, to act on requests)	
	5.4 Promote quality by design	
	5.5 Promote continuous improvement	
	5.6 Act as mediator of ideas	
	5.7 Promote positive, solution-based thinking	
	5.8 Promote best practices and quality on the shop floor and understanding of consequences and effects when there are oversights	
	5.9 Promote understanding of the value of quality objectives	
	5.10 Listen and encourage questions	
	5.11 Encourage staff to acknowledge problems and issues as they arise	
	5.12 Promote understanding of the impacts of quality work on the business and other departments	
6. Evaluate quality staff performance	6.1 Review documentation (e.g., reports, investigations, presentations)	
	6.2 Provide feedback and guidance	
	6.3 Conduct or participate in periodic formal reviews	
	6.4 Manage internal and external customer relations and seek feedback	
	6.5 Establish staff development plans	
	6.6 Promote accountability and ethics	
	6.7 Evaluate suitability of job roles and responsibilities	

	6.8 Complete evaluation documentation and forward to Human Resources, as applicable	

A Quality Assurance Manager must be able to:

E. Maintain Regulatory Compliance Intelligence

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Provide input to reviews of proposed regulations	1.1 Establish system for scanning for proposed regulations	
	1.2 Collaborate with other departments when reviewing proposed regulations (e.g., regulatory, manufacturing)	
	1.3 Review and provide feedback and comments to influence direction	
	1.4 Provide formal, written input	
	1.5 Provide initial assessment of impact of regulations	
2. Attend quality and regulatory courses	2.1 Attend courses [e.g., through Parenteral Drug Association, Centre for Professional Innovation and Education Corps (CfPIE)], as required	
	2.2 Evaluate relevance of courses to management priorities	
	2.3 Communicate areas for application of knowledge	
	2.4 Apply new learning to quality activities	
	2.5 Share learning with quality staff and management (e.g., prepare report)	

3. Review regulatory inspection findings, warning letters and regulatory actions	3.1 Develop mechanism for accessing inspection findings, warning letters and regulatory actions (e.g., Food and Drug Administration (FDA) website)	
	3.2 Interface with staff from regulatory affairs or other specialists, as applicable	
4. Review quality and regulatory compliance publications	4.1 Review industry publications, such as: • *The Gold Sheet* • *The Grey Sheet* • *BioQuality* • Health Canada reports (e.g., *Summary of Audit Findings*)	
5. Conduct compliance gap analysis of other companies' observations	5.1 Understand the regulatory scope of other companies, if possible (i.e., to ensure comparisons are made between *like* companies)	
	5.2 Develop internal mechanism for performing gap analysis	
	5.3 Apply Corrective and Preventative Action (CAPA) to address gaps	

A Quality Assurance Manager must be able to:

F. Manage Non-Conformances

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Identify non-conformances	1.1 Conduct fails testing and certification to segregate non-conformances	American Society for Testing and Materials (ASTM) Standards
2. Develop system to manage non-conformances	2.1 Understand regulatory requirements, expectations and industry standards	Current inspection findings Warning letters FDA 483 forms Regulatory Body Guidances; for example: • International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) • Food and Drug Administration (FDA) • International Organization for Standardization (ISO) • BQ 9000 • European Union (EU) • Health Canada • Canada Food Inspection Agency (CFIA) • United States Department of Agriculture (USDA) • US Food and Drug Act • Industry Standards • American Society for Testing and Materials (ASTM) • Hazardous Analysis & Critical Control Points (HACCP)

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	2.2 Establish procedures to comply with requirements	
	2.3 Build in or link to Corrective and Preventative Action (CAPA) system	
	2.4 Coordinate experts to investigate, prioritize and resolve non-conformances, and utilize tools such as material review boards	
3. Design and develop non-conformance tracking database	3.1 Define user requirements	
	3.2 Evaluate and select tools in collaboration with Information Systems (e.g., ensure that database interfaces with existing systems)	
	3.3 Develop and validate database	
	3.4 Establish permissions for the database (e.g., QA authorizations versus initiator authorizations)	
	3.5 Implement and maintain tracking database	
4. Collaborate with senior-level management to design process goals and set metrics	4.1 Evaluate management priorities and objectives	
	4.2 Assist in setting appropriate process goals	
	4.3 Demonstrate value of process goals to senior-level management	
5. Set metrics for shop floor	5.1 Collaborate with department management, as required	
	5.2 Evaluate shop floor priorities and objectives	
	5.3 Design shop floor metrics (e.g., simple, visual metrics)	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	5.4 Demonstrate value of metrics to shop floor	
	5.5 Promote meeting shop floor metrics	
	5.6 Develop mechanism to respond to shop floor metrics that indicate negative trends	
6. Trend analysis of non-conformity root causes	6.1 When building non-conformity databases, define root cause categories	
	6.2 Develop data management system to extract the data	
	6.3 Define what is critical data	
	6.4 Carry out data analysis using statistical tools	
	6.5 Communicate trends to senior management and production areas	
	6.6 React to negative trends (e.g., CAPA)	
	6.7 Demonstrate ability to enhance reliability, as required	
7. Trend analysis of non-conformance system performance	7.1 Trend overall system performance	
	7.2 Trend closure rates (e.g., how fast the non-conformance is closed, when disposition has been assigned)	Refer to Standard Operating Procedures for non-conformance closure timelines
	7.3 Trend outstanding issues	

	7.4 Communicate trends to senior management and production areas, as necessary (e.g., Key Performance Indicators, dashboard)	
8. Follow up on non-conformances	8.1 Assign disposition (i.e., rework or reprocess, accept as is, re-grade material, scrap it)	
	8.2 Determine if a corrective action is required for each non-conformance	

A Quality Assurance Manager must be able to:

G. Manage Audits

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Develop and implement system to manage audits	1.1 Create procedures, for example: • Internal • External supplier • Third-party (e.g., customer, regulatory)	Company policy
	1.2 Create templates (e.g., agenda, checklist, report, executive summaries)	
	1.3 Ensure system is implemented according to defined timelines (e.g., number of audits per year)	
2. Design and develop observation tracking methods	2.1 Define objectives, scope and needs of tracking tool	
	2.2 Design tracking methods (e.g., reports, corrective actions, responses)	
	2.3 Utilize tools for audit tracking (e.g., databases, spreadsheets)	
3. Train in auditing practices	3.1 Provide auditors with direct training (e.g., through course, job shadowing)	
	3.2 Combine formal and on-the-job training of auditors	

	3.3 Utilize Standard Operating Procedures in training for managing and conducting audits (e.g., audits should be performed by persons other than those responsible for the area being audited)	
	3.4 Mentor by example to provide guidance on soft skills for auditing, for example, to: • Answer questions concisely when being audited • Not offer additional information that is not requested • Ask open-ended questions when conducting audits • Be conscious of body language	
	3.5 Train in report writing	
4. Perform audits	4.1 Know and apply auditing skills	Technical and interpersonal skills
	4.2 Promote continuous and open communication between auditor and auditee	
	4.3 Facilitate efficiency of auditing process	
	4.4 Be in control of the audit	
	4.5 Collect objective evidence	
	4.6 Ensure that high priority goals of audit are met	
	4.7 Communicate audit results to auditee (e.g., formal and informal wrap-up, formal letter, provide recommendations)	

	4.8 Perform periodic product reviews, as required (e.g., annual product audits)	
5. Obtain audit responses	5.1 Send official audit response request to auditor	
	5.2 Develop follow-up mechanism	
	5.3 When dealing with suppliers, communicate audit results to relevant departments	Observe company policies and procedures (e.g., regarding defined timeline for audit responses)
	5.4 For all audits, communicate audit results to senior management and relevant departments (e.g., executive summaries)	Highlight deficiencies and errors
	5.5 Track audit responses in tracking database	
6. Create Corrective and Preventative Action (CAPA) plans for audit findings	6.1 Create CAPA plans (e.g., for third-party and regulatory audit findings)	
	6.2 For internal audits, monitor CAPA plans related to audit findings	Provide assistance and guidance to departments, as required
7. Close out audits	7.1 For supplier audits, when response is obtained, close out immediately or after objective evidence is provided	
	7.2 When audit is closed out, provide response of closure to auditee	
	7.3 Set supplier status, using applicable internal mechanism	
	7.4 For internal audits, follow up on completion of CAPA projects	
	7.5 Maintain and update database to reflect closures	

8. Maintain system for inspection readiness	8.1 Define roles and responsibilities for maintaining inspection readiness	
	8.2 Set indicators to monitor system readiness for inspections, where applicable	
	8.3 Monitor Quality Management Systems which indicate inspection readiness (e.g., documents, deviations, change controls, complaints, recalls)	
	8.4 Ensure physical inspection of facilities to ensure they are well maintained	
	8.5 Be prepared for inspectors and auditors (e.g., internal audit before auditor arrives)	
9. Facilitate regulatory and quality compliance inspections	9.1 Define procedure for inspections	
	9.2 Define roles for inspections	
	9.3 Determine appropriate location for effective logistics (e.g., set up war room)	
	9.4 Train staff for inspection behaviour (e.g., compile audit *do*'s and *don't*'s)	
	9.5 Employ audit skills during inspections	
10. Prepare responses to regulatory and quality compliance inspections	10.1 Assess observations including risk level	
	10.2 Assign lead experts to address each observation	
	10.3 Carry out inter-departmental investigations and audits	
	10.4 Conduct root-cause analysis, as necessary	

	10.5 Examine inspection observations to ensure there is complete understanding	
	10.6 Apply all appropriate CAPA	
	10.7 Compile final observations	
	10.8 Communicate observations and have them reviewed by senior management	
	10.9 Send response to regulatory body or customer, within allotted timeframe	
	10.10 Follow up receipt of response	
	10.11 Utilize tools to track development of the response (e.g., database)	
	10.12 Provide ongoing updates of status of response for each observation to regulatory bodies, inspectors and senior management	

A Quality Assurance Manager must be able to:

H. Oversee Training

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Develop system for documenting training	1.1 Set and observe training policies	Company policies
	1.2 Create procedures to monitor and manage training system	
	1.3 Interpret regulations and guidelines	
	1.4 Standardize formats for documenting training (e.g., binders, training logs, databases)	
2. Develop methods to track training	2.1 Develop paper-based or electronic systems, as required	
	2.2 Establish tracking system for training (e.g., use ISOtrain training management software)	
	2.3 If possible, link training database to document management system	
	2.4 Monitor training system on an ongoing basis	
3. Create On-the-Job training matrix	3.1 Collaborate to define job roles and responsibilities, as required	
	3.2 Establish core training requirements and create training matrices for each job function	
	3.3 Monitor and update matrices, as required	
4. Deliver quality-related training	4.1 Create training material content and ensure normative references are available	American Society for Testing and Materials testing protocols

	4.2 Coordinate relevant Quality or On-the-Job training activities (e.g., Good Manufacturing Practice (GMP) training, Quality Management Systems training)	
	4.3 Deliver or organize 3rd party delivery of training programs	
5. Evaluate training effectiveness	5.1 Monitor trends of quality management system performance through, for example, Non-Conformance Reports, deviations	Modify training programs accordingly
	5.2 Carry out direct training evaluations through, for example: • Quizzes • Case studies • On-the-job performance • Test panels • Feedback forms	

A Quality Assurance Manager must be able to:

I. Manage Supplier/Vendor[1] Quality

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Review supplier's quality management system	1.1 Provide input to procedures to monitor and manage the supplier's quality management system	
	1.2 Create strategy for communication with the supplier	
	1.3 Create templates (e.g., vendor questionnaires)	
	1.4 Create or monitor database to track status of suppliers, for example: • Certified • Approved • Disqualified • Pending	
	1.5 Oversee categorization of suppliers (e.g., critical, sole-source, non-critical)	
2. Participate in qualification and selection of suppliers	2.1 Investigate suppliers using a range of methods (e.g., web site search, Food and Drug Administration site search, consult colleagues)	Purchasing Management Association of Canada (PMAC)
	2.2 Evaluate completed supplier questionnaire	
	2.3 Communicate with supplier to address quality compliance gaps	

[1] For the purposes of this Quality Assurance Manager Skills Profile, the terms 'Supplier' and 'Vendor' are used interchangeably.

	2.4 Link to supplier audit program, for example: • Determine whether an audit is necessary • Audit supplier qualification files	
3. Qualify raw or starting materials	3.1 Define required specifications (e.g., end use, chemical properties, level of purity, stage of process or product)	
	3.2 Provide guidance and direction to selection of suppliers for critical raw and starting materials (e.g., for GMP versus non-GMP materials)	
	3.3 Assess supplier's consistency (e.g., consistent quality and supply)	
	3.4 Conduct risk assessment	
	3.5 Evaluate and minimize raw risks related to raw materials	
	3.6 Obtain animal source information, as required (e.g., certificates of origin, BSE/TSE certification)	
	3.7 Review material test data, for example: • On more than one lot • Determine how lots are assigned	
	3.8 Link to specific site of production	
4. Assign supplier status	4.1 Review supplier evaluation, audit, history	
	4.2 Determine quality and purchasing aspects	
	4.3 Communicate status to supplier	
	4.4 Maintain approved supplier list	

	4.5 Monitor supplier for history of deliveries (e.g., timeliness, product quality versus requirements)	
	4.6 Monitor each delivery for timeliness, product quality versus requirements etc.	
	4.7 As issues arise, work with suppliers to resolve issues	
5. Collaborate in creation of quality and technical agreements with supplier	5.1 Develop procedures and templates for agreements (e.g., service provider, material provider, contract manufacturing)	
	5.2 Determine the scope of the specific areas where quality and technical agreements apply	
	5.3 Guide the scope of all quality agreements (e.g., per project)	
	5.4 Include change notification, expectations and requirements in agreements	
6. Create system to manage supplier change notifications	6.1 Create procedures to monitor and manage supplier change notifications	Refer to Purchasing Management Association of Canada (PMAC)
	6.2 Determine key contact point for supplier change notifications (e.g., manufacturing, quality)	
	6.3 Conduct assessments of potential impacts	
	6.4 Assess need for regulatory reporting resulting from supplier change notifications, as required	
	6.5 Collaborate with regulatory, and other departments, as required	

	6.6 Develop implementation plan based on supplier change notification (e.g., impact on product quality)	

A Quality Assurance Manager must be able to:

J. Release Product

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Create a product release process	1.1 Create procedures and protocols to monitor and manage product release	
	1.2 Collaborate with regulatory authorities to develop format for release of products	
	1.3 Develop control documents for the protocols to release products, as required	
2. Develop the release protocol	2.1 Collaborate with other departments (e.g., manufacturing, testing, regulatory affairs) to assemble information requirements	
	2.2 Comply with different types of requirements, depending on type of product, industry, company and regulatory authorities	
	2.3 Utilize checklists to document that the release protocol is followed	
	2.4 Submit product samples and documents to agencies and customers, as required (e.g., biologics)	
3. Review and approve release protocol	3.1 Provide quality and regulatory guidance	
	3.2 Utilize checklists to approve release protocol (e.g., confirm that there are	

	no outstanding non-conformance or Out Of Specification (OOS) investigations)	
	3.3 Coordinate input from other departments	
	3.4 Communicate findings associated with batch and release of product to departments for correction of minor deficiencies, as required	
	3.5 Carry out reconciliation activities (e.g., for raw materials, labels, yield)	
	3.6 Take sample and retain for appropriate period of time	
4. Obtain regulatory authorization for product release, as required	4.1 Collaborate with regulatory affairs, as required, to obtain authorization for market release	
	4.2 Give Quality Assurance department release for distribution	
5. Reconcile and close out batches	5.1 Ensure batch distribution is fully reconciled	
	5.2 Archive documents	
6. Develop load out procedures	6.1 Develop product release procedures to ensure product specifications are maintained	ISO shipping and loading protocols Industry standards (e.g., ASTM)
	6.2 Ensure verification of product and order prior to shipping	
	6.3 Ensure instructions are provided to shipping contractors (e.g., on temperature, timeliness, cleanliness of shipping vessel)	BQ 9000 ISO
	6.4 Record product verification	

A Quality Assurance Manager must be able to:

K. Demonstrate Personal Competencies

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Write effectively	1.1 Write clearly and concisely	
	1.2 Observe company standards and structures for content (e.g., for correspondence, faxing, reporting)	
2. Demonstrate an above-average ability to communicate in the language of the quality and regulatory compliance environment	2.1 Communicate verbally with diverse audiences	Note: English is the working language in the Canadian Biotechnology industry
	2.2 Speak with, for example: • Government officials • Customers/clients • Staff • Executive • Shop floor operators • Regulatory authorities	
	2.3 Use appropriate terminology	
	2.4 Understand nuances	
	2.5 Express complex concepts clearly, for example: • Synthesize • Speak to the level of audience understanding • Avoid jargon and acronyms • Avoid ambiguous words	
3. Avoid conflicts of interest	3.1 Understand company structure and regulations	Follow company policies and procedures (e.g., policies that define conflicts of interest within your

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
		organization)
	3.2 Operate within regulatory framework of the job description of quality	
4. Follow company policies and procedures for computer and internet use	4.1 Observe software application terms of use	Follow company policies and procedures
	4.2 Sign computer and internet use agreements, as required	
5. Observe company confidentiality	5.1 Sign and adhere to confidentiality agreements, as required	
	5.2 Participate in company training on confidentiality, as required	
6. Make decisions	6.1 Demonstrate and document logic and scientific rationale	
	6.2 Anticipate outcomes of decisions	
	6.3 Employ decision-making tools	
	6.4 Listen to all perspectives	
	6.5 Evaluate relevant data	
	6.6 Assess risk associated with decision	
	6.7 Consider management priorities	
	6.8 Act decisively and in a timely manner	
	6.9 Be calm, cordial, and kind; avoid unnecessary delay	
	6.10 Follow up on decisions to evaluate results	
7. Facilitate intra/inter-departmental understanding	7.1 Listen actively to perspectives and concerns from quality and other departments (e.g., marketing, manufacturing)	
	7.2 Disseminate information and understanding to relevant parties/staff	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	7.3 Be respectful of the opinions of others	
	7.4 Keep audience in mind to ensure their understanding	

A Quality Assurance Manager must be able to:

L. Perform Administrative Functions

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
1. Recruit staff, as required	1.1 Obtain approval and develop outlines for job advertisements	
	1.2 Develop interview guides	
	1.3 Arrange and conduct interviews	
	1.4 Give presentations to new students or potential job incumbents, as required	
	1.5 Network to assist in staff recruitment	
2. Manage staff access to required systems	2.1 Define job roles and responsibilities	
	2.2 Develop initial training packages (e.g., new employee orientation packages)	
	2.3 Ensure access to all systems and tools required to perform competently in the job (e.g., Information Systems, production process, laboratory)	
	2.4 Manage access on an ongoing basis (e.g., in response to promotion, change in department, change in job needs)	
3. Conduct performance reviews	3.1 Schedule performance reviews	
	3.2 Prepare for and perform reviews	
	3.3 Communicate clearly with staff	
	3.4 Set goals and objectives for performance	
	3.5 Suggest actions for improving	

TASKS	SUBTASKS	IMPORTANT ACTIONS / PERFORMANCE STANDARDS
	performance, as required	
	3.6 Follow up with staff after reviews to monitor performance improvement	
4. Develop budgets	4.1 Consider management priorities	
	4.2 Define quality departmental needs	
	4.3 Define quality compliance needs, as required	
	4.4 Articulate and justify departmental priorities	
	4.5 Compare costs of resources and needs (e.g., training courses, standards)	
	4.6 Consider consulting project expenses, as required (e.g., external expertise or additional resources)	
	4.7 Complete and submit forms for finance department, as required	
	4.8 Finalize budgets through management approval process, as required	
5. Manage budgets	5.1 Monitor actual versus planned	
	5.2 Report on budget performance	
	5.3 Justify/substantiate discrepancies	
	5.4 Adjust budgets and respond to changing management priorities, as required	