Quality Assurance Manager

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 GXP (i.e., GMP, GLP, GCP, 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.

Learn more about the role of a Quality Assurance Manager
by downloading the full skills profile for free at www.biotalent.ca/profiles.

BioTalent™ Canada

Building skills for Canada's bio-economy

Quality Assurance Manager

BioTalent Canada's Bio-economy Skills Profiles

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

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

Who can use these profiles?

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

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

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

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

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

Validated by industry

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

Information you can trust

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

Understanding the bio-economy

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

- 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

Get started today

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

Go to www.biotalent.ca/profiles and download the complete Quality Assurance Manager Skills Profile.

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Bio-economy Competency Profile Checklist

Quality Assurance Managers must have a solid understanding of operations and testing standards in quality-controlled labs as well as a science-related university bachelor's degree in life sciences, biology, chemistry, engineering or other related discipline. A master's degree is an advantage.

Building on these, a **Quality Assurance Manager** must be able to:

A. Implement Quality Management Systems

- 1. Develop quality manual
- 2. Benchmark best practices
- 3. Create quality policies
- 4. Create and implement deviation management system
- 5. Create and implement change management system
- 6. Create Corrective and Preventative Action (CAPA) system
- 7. Create and implement complaint system
- 8. Create batch record system
- 9. Create risk management system
- 10. Monitor Quality Management Systems
- 11. Collaborate on product design system
- 12. Create product recall system
- 13. Create site validation master plan

B. Provide quality leadership

- 1. Set Quality Assurance department goals
- 2. Interpret quality requirements
- 3. Provide quality and compliance support to project teams
- 4. Recommend quality and regulatory strategies
- 5. Facilitate risk analysis
- 6. Provide real-time quality advice on shop floor
- 7. Provide technical advice
- 8. Communicate status of essential quality requirements
- 9. Problem solve

C. Manage quality documentation

- 1. Manage documentation system
- 2. Create master document templates
- 3. Design and develop document life cycle databases
- 4. Review and approve quality documentation
- 5. Create archive system for quality documentation, as required
- 6. Archive obsolete documents
- 7. Archive study materials

D. Supervise quality staff

- 1. Establish staffing plan
- 2. Align Quality Assurance activities with management priorities
- 3. Coach and develop staff
- 4. Review quality staff work
- 5. Mentor quality attitudes
- 6. Evaluate quality staff performance

E. Maintain regulatory compliance intelligence

- 1. Provide input to reviews of proposed regulations
- 2. Attend quality and regulatory courses
- 3. Review regulatory inspection findings, warning letters and regulatory actions
- 4. Review quality and regulatory compliance publications
- 5. Conduct compliance gap analysis of other companies' observations

F. Manage non-conformances

- 1. Identify non-conformances
- 2. Develop system to manage non-conformances
- 3. Design and develop non-conformance tracking database
- 4. Collaborate with senior-level management to design process goals and set metrics
- 5. Set metrics for shop floor
- 6. Trend root causes
- 7. Trend non-conformance system performance
- 8. Follow up on non-conformances

G. Manage audits

- 1. Develop and implement system to manage audits
- 2. Design and develop observation tracking methods
- 3. Train in auditing practices
- 4. Perform audits
- 5. Obtain audit responses
- 6. Create Corrective and Preventative Action (CAPA) plans for audit findings
- 7. Close out audits
- 8. Maintain system for inspection readiness
- 9. Facilitate regulatory and quality compliance inspections
- 10. Prepare responses to regulatory and quality compliance inspections

H. Oversee training

- 1. Develop system for documenting training
- 2. Develop methods to track training
- 3. Create On-the-Job training matrix
- 4. Deliver quality-related training
- 5. Evaluate training effectiveness

I. Manage supplier/vendor quality

- 1. Review quality supplier management system
- 2. Participate in supplier qualification and selection
- 3. Qualify raw or starting materials
- 4. Assign supplier status
- 5. Collaborate in creation of supplier quality and technical agreements
- 6. Create system to manage supplier change notifications

J. Release product

- 1. Create a product release process
- 2. Assemble release protocol
- 3. Review and approve release protocol
- 4. Obtain regulatory authorization for product release, as required
- 5. Reconcile and close out batches
- 6. Develop load out procedures

K. Demonstrate personal competencies

- 1. Write effectively
- 2. Demonstrate an above-average ability to communicate in the language of the quality and regulatory compliance environment
- 3. Avoid conflicts of interest
- 4. Follow company policies and procedures for computer and internet use
- 5. Observe company confidentiality
- 6. Make decisions
- 7. Facilitate intra/inter-departmental understanding

L. Perform administrative functions

- 1. Recruit staff, as required
- 2. Manage staff access to required systems
- 3. Conduct performance reviews
- 4. Develop budgets
- 5. Manage budgets