Quality-Assurance Specialist

Reports to: Director, Manager, or Supervisor

Pharmabio Développement
Comité sectoriel de main-d'œuvre des industries des produits pharmaceutiques et biotechnologiques

Main Duties

may vary from one company to another

- **Releases lots:** approves manufacturing and packaging master files; reviews batch records for manufacturing, packaging, testing, and deviations; ensures documents are in compliance; releases or rejects lots of raw materials, packaging components, imported bulk goods intended for production, and finished products intended for retail; issues appropriate certificates; assesses product returns.
- **Manages the stability program:** implements stability studies; establishes or confirms product expiry dates; drafts stability reports; recommends changes based on data analyses.
- **Ensures that customer complaints are handled:** analyzes customer non-medical complaints; identifies trends and tendencies with respect to lot, product, and type of complaint and determines the cause; drafts complaint reports; recommends changes based on investigations and trend analyses.
- **Manages control of changes:** helps evaluate change requests for equipment, primary and secondary components, processes, systems and various types of documents; monitors follow-up with parties involved; ensures that deliverables are compliant pursuant to the change; closes changes upon implementation.
- **Involved in activities geared towards procedural improvements and document approval:** reviews and approves product-quality failure and non-compliance investigations; performs follow-up on corrective and preventive actions pursuant to an incident; assists with process optimization; reviews standard operating procedures; assists with internal and external audits.
- **Participates in the annual product review:** reviews documents related to the products; compiles trend-analysis data and writes a trend-analysis report.

Evolution of the Profession

- Among other things, more sophisticated computer systems facilitate data traceability and availability, parallel as opposed to serial assessments, and the integration of different computerized systems to allow for:
  - an overview of quality systems such as procedures, CAPAs[1], investigations, and control changeovers;
  - trend reviews and more efficient monitoring;
  - improved document control and approval times.
- Regulatory agencies such as Health Canada and the FDA focus on investigations, control of changes, complaints, cross contamination, CAPAs, and risk management. Companies must document all decisions and deviations pertaining to corrective and preventive actions to avoid recurrences.

Best Practices

- Upgrade knowledge in order to remain proficient in the profession.
- Attend conferences as well as continuing-education and development activities.

Main responsibilities[2]

Lot Release

- Carefully reviews and approves product manufacturing and packaging batch files.
- Properly verifies investigation reports and change requests.
- Diligently verifies document completion and compliance.
- Adheres to standards, procedures, and quality agreements.
- Makes fair decisions about the release of raw materials and packaging components or the approval or rejection of raw materials, packaging components, and finished product.
- Respects prescribed timelines.
- Issues appropriate certificates.
- Scrupulously evaluates returns.
- Properly assesses the need to perform laboratory tests.
- Confirms return and proper disposal with the supervisor.

Change Management

- Helps evaluate change requests for equipment, primary and secondary components, processes, and various types of documents.
- Properly manages priorities according to deadlines.
- Obtains evaluations with support documents from concerned departments.
- Fairly assesses the impact of changes on the organization.
- Closely monitors different stakeholders.
- Meets approval dates.
- Complies with controlled documents.
- Approves change implementations.
- Ensures completion and/or monitoring of all identified regulatory activities.

Procedure Improvement and Document Approval Activities

- Actively assists in investigations into product-quality failure or non-compliance.
- Uses support documents to thoroughly review and approve investigations.
- Effectively manages priorities in order to implement corrective and preventive actions.
- Correctly applies CAPAs or change management.
- Appropriately applies principles of continuous improvement.
- Approves and ensures implementation of standardized operating procedures.
- Approves documents according to templates and required GMPs.
- Accurately assesses audit findings (production, installation, equipment, control laboratory, packaging, labelling, etc.).
- Provides inspectors with clear and comprehensive files (external audits).
- Responds with proficiency to questions from inspectors (external and internal audits).
- Actively engaged in the follow-up of audit observations.

[1] Corrective actions / preventive actions (CAPAs)
[2] As per the company's mode of operations.

Qualifications

Quality-Assurance Specialists have:

- A bachelor of chemistry, biochemistry, biology, microbiology, or a related discipline or
- A master's degree in one of these disciplines or a post-graduate diploma such as a *D.É.S.S. (Diplôme d'Études Supérieures Spécialisées)* in drug development or
- A college diploma in science
- In all cases, two to five years of experience in the pharmaceutical field.

Employers are seeking candidates who possess the following skills:

- Ability to manage priorities.
- Ability to work on multiple matters at once.
- Analytical and synthesis skills.
- Flexibility and diplomacy in interpersonal relationships.
- Fluency in French and English (written and spoken).
- Proficiency in the use of common and specialized software.
- Ability to meet deadlines.
- Communication skills.

Career-Path Options

With experience, depending on interests and training, Quality-Assurance Specialists can aspire to, among other positions, the following:

- Systems Quality-Assurance Specialist.
- Senior Quality-Assurance Specialist.
- Coordinator, Manager, or Supervisor.
- Internal Auditor.
- External Auditor.
- Trainer.

Competencies	Behavioral Indicators
Leadership Ability to take initiative and make decisions to achieve product-quality objectives.	• Communicates clearly and effectively. • Correctly evaluates the facts and unforeseen situations in order to make the best decisions. • Is proficient at negotiation and persuasion. • Adapts to individuals and situations when interacting with people. • Is receptive with an opened mind. • Establishes fruitful interpersonal relationships. • Makes decisions within a regulatory context.
Document Management Ability to ensure compliance of controlled documents.	• Cautiously analyzes data. • Verifies document completion for compliance with standards and specifications for pharmaceutical or biotechnological products. • Drafts reports within prescribed time frames and in accordance with regulations. • Approves required certificates.
Problem Solving Ability to implement relevant solutions to problems or situational changes.	• Adopts a rigorous approach to problem solving within a regulatory context. • Adapts to unforeseen situations. • Assesses the urgency of situations. • Makes realistic and appropriate decisions. • Follows up on compliance issues until final resolution.
Quality Assurance Ability to ensure compliance with good manufacturing practices and regulatory requirements.	• Is very proficient with regulatory requirements and good manufacturing practices. • Rigorously monitors compliance with good manufacturing practices, regulatory requirements, and company and industry standards. • Judiciously identifies non-compliance situations. • Proposes realistic and relevant actions. • Ensures product integrity and compliance based on standards and regulations. • Complies with established timelines.

Please refer to the *Quality-Assurance Specialist's Analyse de profession** and *Profil de compétences** for all additional information.
The Competency Profile was made through funding by *the Commission des partenaires du marché du travail.*
* This document has not been translated yet.

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