

Quality-Control Specialist

Reports to: Team Leader or Supervisor



Main Duties

may vary from one company to another

- **Analyzes samples:** performs chemical, physical, and microbiological measurements; interprets test results and assesses their compliance; forwards the results.
- **Verifies analytical reports:** verifies the comprehensiveness of the tests as well as compliance of supporting documents, and ensures follow-up of abnormalities.
- **Participates in investigations pertaining to non-compliances:** identifies abnormalities and determines the cause; establishes corrective and preventive actions, and ensures follow-up.
- **Participates in the validation process and method transfer:** develops and validates analytical methods; drafts validation and transfer protocols for analytical methods; executes protocols; drafts reports; ensures the implementation of methods and follow-up.
- **Takes part in the qualification of laboratory equipment:** evaluates equipment needs; drafts and executes protocols; drafts equipment qualification reports; and manages equipment maintenance and requalification.
- **Performs laboratory-related activities:** conducts support activities necessary for the laboratory's operation; establishes standard operating procedures and manages standards and reagents.

Evolution of the Profession

- While company mergers may impact procedures and methods, the role of the Quality-Control Specialist remains the same.
- Computerized laboratory operations are a challenge as more sophisticated integrated applications interface with laboratory information-management systems (LIMSs).¹
- In microbiology, the advancements of automated identification systems mean fewer manipulations.
- The use of computerized systems requires a greater degree of meticulousness, rigour, and control on the part of analysts while conducting their tests.

Best Practices

- Keep knowledge up to date to remain proficient.
- Attend conferences as well as continuing-education and development activities.

Main responsibilities

Test Sample²

- Takes regulatory requirements into consideration.
- Safely and properly handles products.
- Accurately applies laboratory techniques.
- Accurately verifies calculations for various tests.
- Carefully analyzes data.
- Accurately interprets the results.
- Accurately assesses result compliance.
- Identifies out-of-specification trends or results.
- Comprehensively records information.

Verification of Analytical Reports

- Records appropriate references for tests conducted.
- Ensures that test results are recorded for each specification test.
- Rigorously reviews methodologies employed based on specifications.
- Maintains rigorous monitoring of and full compliance with requirements, methodologies, and references.
- Carefully checks records according to directives.
- Productively and effectively reviews reports.
- Ensures that analytical reports comply with standards and regulations.

Participates in Investigations Pertaining to Non-compliance

- Identifies compliance issues.
- Verifies compliance and procedures at each stage of testing, as well as compliance of in-coming material.
- Properly classifies abnormalities based on possible causes.
- Rigorously analyzes data.
- Formulates pertinent hypotheses.
- Confirms hypotheses.
- Determines possible and verifiable causes.
- Establishes corrective action / preventive action (CAPA).
- Drafts clear change requests.
- Resolves investigations.
- Takes into account all components related to the implementation of corrective measures.
- Precisely plans activities.
- Conducts appropriate follow-up of actions undertaken.
- Identifies challenges or obstacles to implementation.

¹ Computerized laboratory-management system (CLMS) used in large companies.

² The Quality-Control Specialist measures the physicochemical and microbiological properties of raw materials; packaging components; bulk and finished products as well as stability studies.

Qualifications

The Quality-Control Specialist has:

- A college diploma in laboratory techniques or
- A bachelor of chemistry, biochemistry, biology, or microbiology or a related discipline.
- Several years of experience in the pharmaceutical industry or a related field.

Employers are seeking candidates who possess the following skills and attributes:

- Ability to work independently.
- Ability to adapt to change.
- Analytical skills.
- Ability to work as part of a team.
- Ease of communication.
- Proficiency in commonly used software (Word, Excel, PowerPoint, Outlook), specialized software, and computer equipment.
- Fluency in French and English (written and spoken).
- Meticulous work habits and manual dexterity.
- Scientific rigour and respect for procedures.
- Keen observational skills and attention to detail.
- Organizational and planning skills.

Career-Path Options

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

- Senior Analyst.
- Product-Quality Associate.
- Product-Development Analyst.
- Research, Development, or Regulatory-Affairs Associate.
- Team Leader, Supervisor, or Coordinator.
- Department Head.

Some may opt for the quality assurance department, holding such positions as Information Officer, Reviewer, or Auditor.

Competencies	Behavioural Indicators
Interpersonal Relationships Ability to interact with colleagues and professionals.	<ul style="list-style-type: none"> • Correctly evaluates unforeseen situations. • Adapts behaviour to situations and individuals. • Is receptive and attentive. • Communicates clearly and effectively.
Teamwork Ability to work cooperatively with team members.	<ul style="list-style-type: none"> • Is cooperative and committed. • Actively contributes to the team. • Coordinates activities with those of other team members. • Provides solutions to problems and situational changes.
Information Analysis Ability to recognize different tests and take various regulations into account.	<ul style="list-style-type: none"> • Interprets national and international pharmacopoeia requirements. • Matches methodology to analytical techniques based on required tests. • Reviews documents pertaining to applicable regulations, good laboratory practices, and good manufacturing practices. • Ensures compliance with standards and regulations.
Problem Solving Ability to solve various problems pertaining to analytical tests.	<ul style="list-style-type: none"> • Adopts a rigorous approach to problem solving. • Adapts to unforeseen situations. • Assesses the urgency of situations. • Makes realistic and appropriate decisions. • Follows up on compliance issues until final resolution.
Compliance Control Ability to ensure compliance with regulatory requirements, good laboratory practices, and good manufacturing practices.	<ul style="list-style-type: none"> • Is very proficient with regulatory requirements, good laboratory practices, and good manufacturing practices. • Properly monitors procedures and methodologies. • Judiciously detects non-compliant situations. • Proposes relevant and realistic solutions. • Ensures the integrity and compliance of analytical reports and products based on standards and regulations. • Maintains consistent follow-up and adheres to established timelines.