

# Public Health Laboratory Recruitment Guide: Quality Manager Position Description



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## Job Position Summary

This leadership position oversees quality control, quality assurance and quality improvement within the overall Quality Management System (QMS) of the [Name of Laboratory] including the development, review, implementation, and communication of all laboratory quality processes. The Quality Manager provides guidance and consultation concerning quality processes for clinical, environmental, and food testing. This position also ensures compliance with local, state, and federal regulatory standards such as the Clinical Laboratory Improvement Amendments (CLIA), the NELAC Institute (TNI) and the International Organization for Standardization (ISO).

**Reports to:** [Laboratory Director, Deputy Director]

## Essential Job Duties

- Ensure compliance with laboratory accreditation, regulatory standards and information management policies by providing leadership and guidance to staff to ensure that quality policies, processes and procedures are established, current and adhered to by all laboratory staff.
- Oversee internal audit processes, external assessments, proficiency testing programs; document control systems; competency assessment; training and other quality processes.
- Identify training needs, as well as design and implement training programs specific to the quality system.
- Recommend best practices to maintain and improve project outcomes or laboratory functions; facilitate laboratory improvement activities.
- Analyze data, identify trends, monitor prevention and correction of quality deviations, and develop reports for management utilizing technical knowledge and laboratory experience.
- Monitor customer satisfaction and performance metrics.
- Identify and report quality issues and problems to management with recommendations for resolution.
- Establish processes and policies for effective and professional communication between laboratory staff and among other interested parties.
- May supervise others and provide input into financial, safety and procurement decisions.
- Work with the safety officer and security/biosecurity officer to align quality practices, including data analysis, monitoring of trends, prevention, corrections and continuous quality improvement.

## Job Position Competencies

### Quality Management Systems (50% of duties)

- Ensure that the laboratory's organizational structure is committed to achieving and maintaining quality, advocating for a culture of quality, safety and ethics, and analyzing quality measures to evaluate the costs of maintaining quality (QMS 01.00).\*
- Ensure that laboratory personnel and instrumentation meet performance standards (QMS 04.00, QMS 06.00, WFT1.00).\*
- Ensure that operational processes meet organizational requirements through the application of workflow processes or the development of method validation and performance verification processes and procedures (QMS 07.00).\*
- Ensure that there is an effective system to control and manage documents and records (QMS 08.00).\*
- Develop and ensure that processes and procedures are in place for detecting and managing nonconforming events, and performing internal audits and external assessments (QMS 10.00, QMS 11.00).\*
- Develop and ensure mechanisms for continuous quality improvement (QMS 12.00).\*

### **Laboratory Practice (20% of duties)**

- Demonstrate knowledge and skills related to the scientific and technical components of laboratory testing in order to oversee the policies, processes and procedures related to QA activities (GEN 1.00, GEN 5.00, GEN 6.00, CHM 4.00, CHM 5.00, MCB 4.00, MCB 5.00).\*
- Comply with regulations and guidelines governing laboratory testing, ensuring staff compliance and evaluating method validation and performance verification results (GEN 7.00, CHM 6.00, MCB 6.00).\*

### **Management and Leadership (15% of duties)**

- Ensure sound management of laboratory operations and the development, implementation and review of internal policies (\*MLD 1.00, MLD 2.00).\*
- Ensure effective management of human resources and model leadership behavior (MLD 4.00, MLD 5.00).\*

### **Communications (10% of duties)**

- Deploy formal written and oral communication strategies, display active listening skills, and demonstrate comprehension of written documents and directions (COM 1.00, COM 2.00, COM 3.00).\*
- Ensure professionalism in communication and prepare professional written reports and oral presentations (COM 5.00, COM 6.00).\*

### **Ethics (5% of duties)**

- Adhere to policies and principles governing professional and scientific ethics and rules of conduct, exemplifying integrity and serving as a role model of ethical behavior (ETH 1.00, ETH 2.00).\*

## **Requirements**

### **Education and Experience**

- Bachelor's degree in a biological, chemical or physical science related field (to include but not limited to medical or clinical laboratory science, medical technology, chemistry, environmental science, microbiology, biochemistry, molecular biology, biology, immunology, quality). An advanced degree may be substituted for experience.
- Minimum of 3-5 years of recent related laboratory work experience in a certified (e.g., CLIA, CAP, EPA, NELAC) clinical, public health or environmental laboratory.
- Must meet all state and federal requirements for education and experience as mandated in the final **[select all that apply: CLIA, TNI, ISO]** regulations.
- Equivalent combinations of directly related education and experience in quality assurance and quality management systems and quality improvement may be considered on a case-by-case basis.
- Be able to achieve proficiency in **[select all that apply: CLIA, TNI, ISO]** regulations within **[insert time frame]**.

### **Preferred Qualifications**

- Special consideration will be given to applicants with Certifications in Quality.
- Special consideration will be given to applicants with Certifications in Six Sigma or Lean.

### **Knowledge, Skills and Abilities**

- Extensive knowledge of quality management systems and quality improvement tools and techniques such as Six Sigma or Lean.
- Working knowledge of accreditation standards, practices and guidelines sufficient to advise and guide laboratory managers and supervisors as they implement and maintain accreditation.
- Working knowledge of computer and analytical software programs sufficient for evaluation of electronic data, data interpretation, and report development.
- A strong understanding of the principles, practices, and techniques of the various analytical areas of the laboratory.
- Advanced verbal and written communication skills necessary to effectively collaborate in a team environment, present and explain technical information, and provide advice to management.

- Excellent organization skills allowing the coordination of multi-faceted QA activities.
- Ability to manage complex projects independently and in a team environment, maintaining good working relationships with multi-cultural and multi-discipline staff.
- Ability to analyze and interpret written information and scientific data, compare against established requirements, identify potential discrepancies, and make suggestions for improvement.
- Ability to conduct and report quality assurance audits and reviews to determine compliance status and recommend corrective action plans.

\* Ned-Sykes, R., Johnson, C, Ridderhof, J, Perlman, E, Pollock, A, DeBoy, J. 2015. Competency guidelines for public health laboratory professionals. MMWR Suppl 2015;64(Suppl-1):1-81.  
<https://www.cdc.gov/mmwr/preview/mmwrhtml/su6401a1.htm>.