

Competency-Based Position Description Template

Program/Department: *[State or Local]* Public Health Laboratory

Position Title: Quality Manager

Reports to: Laboratory Director *[or other designee]*

Previous Incumbent: None

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.

Essential Job Duties:

- Serves as subject matter expert in quality management systems, providing leadership and guidance to staff to ensure that quality policies, processes, and procedures are established, current, and followed by all laboratory staff
- Ensures compliance with laboratory accreditation, regulatory standards, and information management policies
- Coordinates the internal audit process, external assessments, and proficiency testing programs
- Recommends best practices to improve project outcomes or laboratory functions; facilitates laboratory improvement activities
- Analyzes data, identifies trends, monitors prevention and corrections of quality deviations, and develops management reports utilizing technical knowledge and laboratory experience
- Monitors customer satisfaction and performance metrics
- Ensures compliance with personnel competency processes and identification of training needs; designs and implements training programs specific to the quality system
- Establishes processes and policies for effective and professional communication between laboratory staff and among other stakeholders
- Oversees document control systems and processes
- May supervise others and provide input into financial, safety, and procurement decisions

Job Position Competencies:

Quality Management Systems (40% of duties)

QMS 01.00 Organization: ensures that the laboratory's organizational structure is committed to achieving and maintaining quality

- Demonstrates actions consistent with quality concepts and good professional practice (C)

- Explains how the laboratory's organizational structure ensures quality (C)
- Advocates for a culture of quality, safety, and ethics (P)
- Requests resources to support the QMS (C)
- Analyzes quality measures to evaluate the costs of maintaining quality (C)

QMS 02.00 Customer focus: ensures that customer needs, expectations, and requirements are consistently met

- Responds to internal and external customer inquiries and feedback (C)
- Adheres to roles and responsibilities in meeting customer needs, expectations, and requirements (C)

QMS 04.00 Personnel: ensures recruitment and retention of a qualified, well-trained, and competent workforce

- Ensures each position has the required competencies, education, training, skills, experience, and where applicable, certification and licensure (P)
- Facilitates orientation and end-of-employment processes (P)
- Facilitates training and evaluation processes (P)
- Evaluates individual competence assessment plans (P)
- Participates in continuing education and professional development opportunities (C)
- Participates in the ongoing performance evaluation process (C)
- Participates in recruitment and retention planning (C)

QMS 06.00 Laboratory equipment: ensures that laboratory equipment selection, installation, use, maintenance, and troubleshooting meet performance standards

- Describes processes and procedures for equipment installation qualification, operational qualification, and performance qualification (B)
- Describes processes and procedures for the maintenance, troubleshooting, and service and repair of equipment (B)
- Describes calibration of instruments and equipment (B)

QMS 07.00 Process management: ensures that operational processes meet organizational requirements

- Applies workflow processes according to laboratory policies, processes, and procedures (C)
- Participates in process control procedures (C)
- Develops method validation and performance verification processes and procedures (P)

QMS 08.00 Documents and records: ensures that there is an effective system to control and manage documents and records

- Applies the policies, processes, and procedures for controlling and managing documents (C)
- Applies the policies, processes, and procedures for controlling and managing records (C)

QMS 09.00 Information management: ensures the confidentiality, security, and integrity of generated and disseminated information

- Complies with policies, processes, and procedures for maintaining confidentiality of internally and externally derived information (C)
- Complies with policies, processes, and procedures for securing information (C)

QMS 10.00 Nonconforming event management: ensures that processes are in place for detecting and managing nonconforming events

- Investigates NCEs, including the creation of a corrective action plan (P)
- Performs analysis of records and reports of NCEs to identify trends (P)
- Assesses NCE investigations and root cause analyses to improve processes (P)
- Responds to product recalls and technical bulletin notifications (C)

QMS 11.00 Assessments: ensures that processes are in place to perform internal audits and external assessments

- Develops the quality assessment plan (P)
- Develops the processes and procedures to select, enroll, and participate in external assessments (P)
- Develops the processes and procedures for internal audits (P)

- Develops processes and procedures for determining pre-examination, examination, and post examination quality indicators (P)
- Develops the processes and procedures for collecting and analyzing quality indicator data (P)

QMS 12.00 Continual improvement: ensures mechanisms for continuous quality improvement

- Develops the processes and procedures of the CQI program (P)
- Documents staff compliance with CQI activities that support the CQI monitoring, evaluation, and review processes (P)
- Develops corrective action processes and procedures to address quality improvement (P)
- Develops the processes and procedures related to preventive action (P)
- Implements the change management process, including communication of changes made to established policies, processes, and procedures (P)

Management and Leadership (15% of duties)

MLD 1.00 General management: ensures sound management of laboratory operations

- Exemplifies the mission, vision and values for the laboratory (P)
- Coordinates laboratory program structure to meet organizational needs (C)
- Coordinates program activities according to laws and regulations related to laboratory operations (C)
- Evaluates the quality of services for continued quality improvement (P)
- Identifies strategies and activities to improve customer service (P)
- Uses basic project management concepts and tools (B)
- Analyzes data to assist in the monitoring and evaluation of program effectiveness (C)

MLD 2.00 Policy development: ensures the development, implementation, and review of internal policies

- Compiles important issues, lists of stakeholders, and various options and solutions for internal policy development (C)
- Ensures staff compliance with laboratory-wide policies (P)
- Develops amendments or updates to internal policies (C)

MLD 4.00 Human resource management: ensures effective management of human resources

- Maintains a process to ensure that staff meet licensure requirements (C)
- Evaluates the competency assessment program (P)

MLD 5.00 Leadership: models leadership behavior

- Serves as a role model of ethical and professional behavior by consistently conforming to the highest standards and practices (C)
- Communicates information and feedback to colleagues and management staff (C)
- Leads cross-functional teams to accomplish projects (P)
- Participates in activities to support the laboratory's goals (B)
- Participates in staff recognition programs (B)
- Leads critical thinking activities to achieve improvements in laboratory processes (P)
- Applies systems thinking when approaching projects and problem solving (C)
- Provides input into strategic thinking and decision-making processes (C)
- Leads the development of change management initiatives with the laboratory (P)
- Identifies gaps in engagement with external stakeholders to support the activities of the laboratory (P)

Communications (10% of duties)

COM 1.00 Communication techniques: deploys formal written and oral communication strategies

- Applies logical structure to written communications (C)
- Applies language and tone in oral communications tailored to target audience (C)

COM 2.00 Active listening skills: displays active listening skills when interacting with others

- Summarizes the dialogue to show understanding (C)
- Exhibits active listening during the dialogue exchange (P)
- Provides counterpoints while being respectful of disagreements (C)

COM 3.00 Comprehension of materials: demonstrates comprehension of written documents and directions

- Applies knowledge acquired from written text to situations (C)

COM 5.00 Communication professionalism: ensures professionalism in communication with customers and stakeholders

- Displays professional demeanor in all situations with customers and stakeholders (C)

COM 6.00 Professional reports: prepares professional written reports and oral presentations

- Creates drafts of written reports (C)
- Creates drafts of oral presentations (C)

General Laboratory Practice (10% of duties)

GEN 1.00 - General technical and laboratory practice knowledge: demonstrates general knowledge and skills related to the scientific and technical components of laboratory testing

- Applies basic scientific and laboratory concepts and theories related to the specific testing that is conducted in work area (B)
- Instructs others in fundamental mathematical and statistical concepts and practices (C)
- Instructs others in model laboratory practices (C)
- Ensures utilization of established paper and electronic documentation methods or systems (P)
- Serves as a role model, consistently conforming to the highest scientific standards and practices (C)

GEN 5.00 - Examination: performs steps in the examination phase of testing

- Oversees the policies, processes, and procedures related to QC activities, including staff compliance (E)

GEN 6.00 - Postexamination: performs steps in the postexamination phase of testing

- Oversees the policies, processes, and procedures related to QC evaluation activities (E)
- Oversees the policies, processes, and procedures related to QA (E)

GEN 7.00 - Regulatory Compliance: complies with regulations and guidelines governing laboratory testing

- Ensures staff compliance with regulatory requirements and guidelines related to laboratory testing (P)
- Monitors to ensure the PT and alternative assessment program meets regulatory requirements (P)
- Ensures staff compliance with reporting of PT and alternative assessment results (P)
- Evaluates method validation and performance verification results (P)
- Instructs staff in policies, processes, and procedures regarding protected information (C)

Ethics (5% of duties)

ETH 1.00 Professional Code of Conduct: adheres to policies and principles governing professional ethics and rules of conduct when working in a public health

- Exemplifies integrity in interactions and activities (C)
- Serves as a role model of ethical behavior by consistently conforming to the highest ethical standards and practices (C)
- Identifies methods to improve stewardship of resources (C)

ETH 2.00 Scientific Code of Conduct: adheres to policies and principles governing scientific ethics and rules of conduct when working in a public health laboratory

- Instructs others in policies, processes, and procedures regarding scientific integrity of test results and findings (C)
- Serves as a role model of scientific ethical behavior and rules of conduct by consistently conforming to the highest scientific standards and practices (C)

Safety (5% of duties)

SDR 1.00 Documents and record keeping: ensures staff compliance with agency quality management system (QMS) and statutory, regulatory, accreditation, and licensing requirements for documentation and recordkeeping in relation to the health and safety management systems

- Describes procedures for safety document management (B)
- Ensures restricted or confidential safety documents are not disclosed (C)

Workforce Training (5% of duties)

WFT 1.00 Content: gathers training content

- Conducts needs assessments (C)
- Implements established science and technology content (C)
- Implements training for emerging training topics (C)
- Collaborates with subject matter experts to gather content (C)

Chemistry (5% of duties)

CHM 4.00 Examination: performs chemistry examination procedures

- Ensures the QC program adheres to regulatory requirements (E)

CHM 5.00 Postexamination: performs chemistry postexamination procedures

- Oversees the policies, processes, and procedures related to QC evaluation activities (E)
- Oversees the policies, processes, and procedures related to QA (E)

CHM 6.00 Regulatory compliance: ensures regulatory compliance

- Analyzes NCEs for corrective actions and documentation (P)
- Monitors to ensure the PT and alternative assessment program meets regulatory requirements
- Evaluates method validation and performance verification results (P)
- Creates processes and procedures for the development and validation of LDTs (P)

Microbiology (5% of duties)

MCB 1.00 Concepts and techniques: adheres to policies and principles governing actions and behaviors that are essential when working in a microbiology laboratory

- Describes basic microbiological concepts and theories (B)

MCB 4.00 Examination: assesses microbiological samples during the examination phase

- Ensures the QC program adheres to regulatory requirements (E)

MCB 5.00 Postexamination: performs postexamination procedures of microbiological testing

- Oversees the policies, processes, and procedures related to QC evaluation activities (E)
- Oversees the policies, processes, and procedures related to QA (E)

MCB 6.00 Regulatory compliance: ensures regulatory compliance

- Analyzes NCEs for corrective actions and documentation (P)
- Monitors to ensure the PT and alternative assessment program meets regulatory requirements (P)
- Evaluates method validation and performance verification results (P)

Minimum Education and Experience Requirements:

- 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, microbiology, biochemistry, molecular biology, biology, immunology)
- More than 3 years of recent related laboratory work experience in a certified (e.g., CLIA, CAP, EPA, NELAC) clinical, public health or environmental laboratory
- Equivalent combinations of directly related education and experience may be considered on a case-by-case basis
- Special consideration will be given to applicants with Certifications in Quality or demonstrated experience directly related to the job duties