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Quality Management System in Testing Laboratories

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ABSTRACT

Testing laboratories provide vital services to their customers who expect accurate results produced at appropriate time and at reasonable cost. Adoption of the quality management system (QMS) by a laboratory would facilitate achieving these goals. The establishment of a QMS in compliance with the ISO 17025: 2005, the international standard for accreditation of testing laboratories, is accepted as optimal approach to assure quality in testing laboratories. This article summarizes the recommendations for accreditation according to ISO 17025 with implementation of a QMS including key aspects such as document control, control of records, internal audit, corrective and preventive action, management review and continual improvement.

INTRODUCTION

After the introduction of international standards for the quality management system (QMS), professionals of testing laboratories have shown increasing interest for understanding the QMS and attaining accreditation status for their services. The International Organization for Standardization (ISO) has developed an international standard, known as ISO 17025: 2005 'General requirements for the competence of testing and calibration laboratories', for the accreditation of testing laboratories to a wide range of testing environments^[1]. Compliance with this quality standard requires that the laboratory shall establish and maintain a systematic way to ensure and improve its performance. Compliance with the ISO 17025 provides a unique focus for assuring implementation of the QMS and technical competence of a laboratory. This article presents compliance requirements of the QMS as per ISO 17025 to be implemented in testing laboratories, such as a pharmaceutical testing laboratory.

Elements of the quality management system

The laboratory is a complex system, involving many steps of activity and many people. The complexity of the system requires that many processes and procedures be performed properly. Therefore, the QMS model, which looks at the entire system, is very important for achieving good laboratory performance. The QMS is defined as a 'management system to direct and control an organization with regard to quality^[2,3]. The QMS covers the laboratory activities, including drug sampling, analysis and reporting. The QMS consists of documentation of the laboratory policy and objectives, system procedures and instructions for assuring the quality of its results to meet safety and regulatory requirements and to satisfy the needs of the customers. A laboratory requiring ISO compliance must establish, document, implement and maintain a QMS, as well as maintain its effectiveness in accordance with the required compliance standard. The starting point for developing a framework for quality management of a laboratory lies in the introduction to ISO 17025. All essential elements of a QMS are covered by the ISO 17025 in two distinct sections: management requirements and technical requirements. The initial step of introducing good quality management in the laboratory

is the identification of the key elements of a quality system. These elements need to be integrated with the existing processes and organization, through documentation of standard operating procedures (SOPs) and definition of objectives and policies in a quality manual. A structured approach to the establishment, control, review and improvement of the QMS is presented in **Figure 1**.

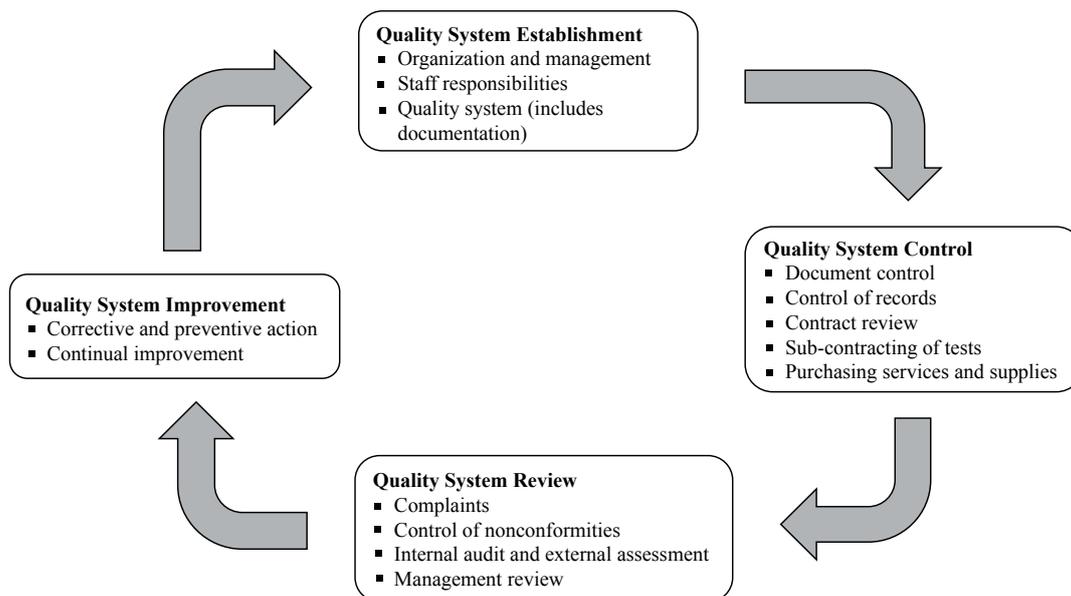


Figure 1. Approach for establishment and improvement of the QMS

Organization and responsibilities

The organization of which the laboratory is a part must be legally identifiable. For there to be an effective QMS, organizational structure capable of supporting the elements of the quality policy and quality objectives must be clearly defined^[3]. The organization should take into account applicable regulatory requirements, the size of the laboratory, the complexity of materials and products, and other critical activities when developing the QMS structure. The QMS should be designed to maintain its robustness, even when changes occur. Also the roles and responsibilities of the laboratory staff should be defined and conflict of interest should be identified. A quality manager has the responsibility of effective implementation of the QMS. Similarly, a technical manager is responsible for all the technical operations of the organization. There should be an appropriate number of personnel to avoid excessive duties being placed on one individual, which can compromise quality. The organization should establish job descriptions, with clearly defined responsibilities and authorities that are clearly understood by personnel.

Documentation

The QMS is all about documentation of laboratory policies, processes and procedures. The sequence of documentation required for establishing the QMS is illustrated in a pyramidal form in **Figure 2**. At the top of the hierarchy of the laboratory documentation is the quality manual which describes the road map to the whole documentation of the laboratory. It details the quality policy, the QMS requirements, organization structure of the laboratory, responsibilities of laboratory staff for management of the QMS and technical operations, management responsibilities and documented procedures for the QMS or reference to them.

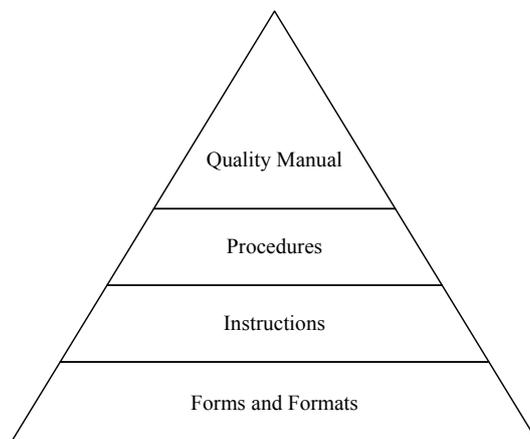


Figure 2. Hierarchy of QMS documents

The top management of the laboratory should declare its commitment to achieve quality in all aspects of the work of the laboratory. This statement constitutes the quality policy of the laboratory. All personnel of the laboratory are responsible for

adherence to the quality policy. The policy statement should include: the declaration of the commitment to quality and continual improvement in the performance of laboratory, statement that laboratory work will withstand scientific and legal requirements and statement on the commitment by the laboratory staff in ensuring compliance with the applicable standard *i.e.* ISO 17025. The quality policy may be subject to periodic review but is unlikely to change significantly unless the primary purposes of the laboratory were to change.

Quality manual also describes the procedures, commonly known as SOPs, for effective implementation of the QMS. SOPs are defined as 'detailed written instructions to achieve uniformity of the performance of a specific function ^[2] and constitute the second level in the hierarchy of documentation. In simple terms SOPs specify in writing who does the activity and when along with the way to carry out the activity. SOPs establish a systematic way of doing laboratory activities and ensure that activities are performed consistently by all laboratory staff.

This third level of documentation involves the practical day-to-day work instructions for ready reference at the site of actual work. Instructions are required to perform a section of a procedure and can be part of a procedure or can be referred to in a procedure and published separately. The advantage of having them separate is that any changes to instructions do not require a change to the procedure.

The final levels in the hierarchy of documentation are the forms. These forms and the records created using them are a crucial part of the QMS as they are the evidence that a procedure and related instructions have been carried out.

Document control

Document control is a mechanism by which the QMS documents are created, amended, reviewed, approved, distributed and archived to ensure that all laboratory staff uses the latest authorized versions. Documents must have the following key elements to be compliant: a unique identifier, version control where each update to the document must result in an incremental increase in the version number, a change history that summarises the changes made to a document each time it is updated, signatures from the preparer and approver of the document. Procedures must be in place to reflect the day-to-day management of all controlled documents. Documents within the QMS must be controlled so that only the current version is available to the staff while performing their duties. Invalid or obsolete documents should be promptly removed from all locations to prevent their accidental use. If documents are held and distributed electronically, they should be read-only versions which may only be edited by authorized staff.

Control of records

Records are special kinds of documents that provide evidence of activities performed. For this reason, they should be legible, clear, indelible, identifiable, traceable, and established immediately after performing an activity. Records may be categorized as quality and technical records. Quality records include audit reports, customer feedback, corrective and preventive actions, and management reviews. Technical records include the laboratory registers, equipment log books, data recording sheets and reports. The organization should have a written procedure for the control of records. These procedures should establish ways for identifying, storing, and protecting records, in order to avoid deterioration and damage. Records should be controlled and managed by assigning unique identifiers to individual record types. This ensures that they are traceable and retrievable. Records should be signed and dated by the person who performed the activity. Corrections to entries should be signed and dated, leaving the original entry legible. Electronic records and automated data-capture systems should meet the requirements for the control of records and should be validated.

Internal and external audits

ISO defines audit as "systematic independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled" ^[1,2]. Audits are a valuable tool for evaluating QMS effectiveness, along with regulatory inspections. Audits may be distinguished as internal and external audits. Internal audits are conducted by or on behalf of the organization itself. External audits (also known as external assessments) are performed by independent external organizations. The audit criteria, scope and objective should be clearly defined. Importantly, auditors should not be subjected to conflicts of interest that may adversely affect the audit, and for this reason auditors should not audit their own work. The organization should have a written SOP establishing the rationale for audits, which should include: responsibilities for the audit program, competencies of an auditor, frequency of audits, instructions for planning an audit, audit reports and follow-up. Audits should be performed at least once a year according to a schedule and discussed during management reviews.

Corrective and preventive action

A nonconformity is defined as 'a non-fulfilment of a requirement ^[4,2] and indicates that the work carried out by a laboratory is inconsistent with its QMS. Nonconformity can arise in two distinct ways: one, from an audit resulting from a problem in the conduct of a process and two, a proactive audit that produces nonconformity. All the nonconformities lead to the need for corrective and/or preventive action and thus contributing to the maintenance of quality or to continual improvement. Organizations should have a written SOP establishing the provisions for corrective and preventive actions as well as instructions for how they should be

handled within the organization. Root cause analysis should be performed to identify the cause of a critical deviation in order to implement corrective action. To overcome the identified problems, it is important to monitor the results of any corrective and preventive action taken and the results of such action are submitted for laboratory management reviews. The recognition of nonconformity and the implementation of corrective and preventive actions are essential elements in continually improving the laboratory's performance.

Management review and continual improvement

Management review is a crucial part of the QMS of the laboratory which is usually conducted once every twelve months to identify any potential sources of non-conformance or other opportunities for improvement in the QMS or technical practices. Management review shall take account of: previous management review reports, status of corrective actions taken and required preventive action, the outcome of recent internal audits, assessment by external bodies, feedback, complaints, nonconformities, returns, results of continuous improvement processes, quality policy and quality manual. Action plans for improvement shall be developed, documented and implemented, as appropriate. After action has been taken resulting from the review, laboratory management shall evaluate the effectiveness of the action through a focused review or audit of the area concerned. The results of action following the review shall be submitted to laboratory management for review and implementation of any needed changes to the QMS. Organizations should implement a systematic approach for performing QMS improvements. Management reviews, audits, regulatory inspections, and QMS planning initiatives are potential triggers for continual improvement activities and should be followed up by senior management. Findings and the actions that arise from management reviews shall be recorded, and laboratory staff shall be informed of these findings and the decisions made as a result of the review. Laboratory management shall ensure that arising actions are discharged within an appropriate and agreed-upon time. The outputs of the management reviews are recommendations for improvement of the system, processes, products, or services and demand for resources.

CONCLUSION

Establishing standardized operations for technical support and laboratory management leads to a well-organized laboratory with clear staff responsibilities and good communication framework. The adoption of the QMS leads to a greater degree of internal control, a good tracking system for all laboratory processes, an efficient and controlled documentation system and a reliable infrastructure for tracing errors and complaints. The adoption of key quality indicators helps in timely identification of system weaknesses and rapid resolution of problems. The adoption of standards also assists in reduction in operation costs and increased time savings. These cost savings come about largely because of increased staff competency. In addition, there has been a profound improvement in our performance on external quality proficiency testing, reduction in client complaint and sample rejection. Laboratory accreditation also gives a formal international recognition of quality laboratory services. To conclude, laboratory accreditation is the best way to demonstrate and attest competence and a worldwide tool to recognize testing laboratories. This would be of particular interest for pharmaceutical testing laboratories which operate under strict regulatory compliance.

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