

## Quality Management System

### *What is a Quality Management System (QMS)?*

A QMS is a web of interconnected processes that uses resources to turn inputs into outputs. The input-output relationships glue all of the processes together, making it a *system*. The decision to implement a QMS has to be made by top management, because management's commitment is essential for the implementation and ongoing success of the system. The design and implementation of a QMS will vary depending on the type, size and output of the laboratory; each having their own objective. Generally the QMS is written to align with the requirements of an international standard, for laboratories this will be either ISO 17025 or ISO 15189.

### *Quality Objectives:*

In order for a QMS to be effective, the objectives must be measurable, reflect the laboratory's overall objectives, and be clearly defined. It must also be practical, reviewed regularly, measured for effectiveness, and accessible to all employees. Adjustments must be made to reflect major changes to the laboratory and its practices.

### *Quality Documents:*

A QMS consists of documented policies and procedures for establishment and effective implementation of the system, as well as, records to provide evidence that the system is in compliance. The documents include: Quality Manual (philosophy of the laboratory), Procedures (principles and strategy), Test Methods (SOP's), and Records (proof).

### *Advantages of a QMS:*

- Reduces costs and risks/errors
- Increases operational efficiency and productivity
- Provides ability to identify improvement opportunities
- Increases customer satisfaction
- Provides flexibility and ability to respond to market opportunities
- Allows effective and efficient use of resources
- Provides a system to enable control of all processes
- Increases competitiveness and industry reputation
- Provides employee participation and motivation of human resources

### *Implementing a QMS:*

Responsibility	Tasks
Management	<ul style="list-style-type: none"> <li>• Set objectives and goals of the QMS</li> <li>• Appoint a Quality Manager (QM) or Quality Team (QT) to develop and maintain the QMS</li> <li>• Set timelines and project scope</li> <li>• Allocate resources required for the development, implementation and on-going management of the system</li> <li>• Inform all staff and seek participation from all levels</li> </ul>

Management/QM/QT	<ul style="list-style-type: none"> <li>• Decide if a consultant is required for the project</li> <li>• Prepare a project plan and allocate resources</li> <li>• Assess an appropriate budget based on equipment, training, time and personnel required</li> <li>• Seek approval from management to procure required resources and attend any training</li> </ul>
QM/QT	<ul style="list-style-type: none"> <li>• Assess method for documenting the QMS</li> <li>• Design templates and documentation</li> <li>• Set timelines for the various tasks</li> <li>• Schedule individual departments and positions for development of policies and procedures</li> </ul>
QM/QT/Management	<ul style="list-style-type: none"> <li>• Develop QMS policies to reflect laboratory objectives</li> <li>• Start to develop procedures and work instructions (SOPs) with each department</li> <li>• Report to management any risks and improvement opportunities that have been found</li> <li>• Document any Quality Corrective Action Requests that might be identified (identified risk areas that require management attention and improvements)</li> </ul>
Management	<ul style="list-style-type: none"> <li>• Approve and issue the QMS</li> <li>• Operate the QMS for a minimum period of 3 months</li> </ul>
QM/QT	<ul style="list-style-type: none"> <li>• Carry out initial audits to ensure documentation matched processes</li> <li>• Ensure that “you do what you say you do”. If any deficiencies are found change processes or QMS to reflect what is actually done</li> <li>• Assess the effectiveness of the QMS and implement any changes that might be required.</li> </ul>
Management	<ul style="list-style-type: none"> <li>• Undertake management review of the QMS</li> <li>• Adjust resource requirements</li> <li>• Decide if accreditation assessment is required</li> <li>• Set accreditation assessment timelines</li> <li>• Appoint Accreditation Body</li> </ul>
QM/QT/Management	<ul style="list-style-type: none"> <li>• Continue to audit, review and assess the QMS at the agreed time intervals</li> <li>• Continue to assess risk areas and identify improvement opportunities</li> <li>• Continue to review policies and procedures and make amendments as required</li> <li>• Continue to measure effectiveness of QMS to the overall laboratory performance</li> </ul>