# Laboratory Management

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## Introduction

Laboratory management is the integration and coordination of organisational resources so that quality laboratory services can be provided as effectively and efficiently as possible.

**Note**

Organisational resources include: personnel, equipment, money, time and space.

The goal of lab management is to guide laboratory personnel to deliver their assigned duties within limited time and resources.

Running a laboratory is similar to running a business. A laboratory is made up of personnel with diverse skill sets, all working together as a team. A laboratory requires financing so that resources can be made available. Generally, a lab should have a plan with clear goals, and ways to achieve them. Most importantly, a lab needs someone to run it—someone who gives directions and makes all lab activities possible.

### Essential skills for laboratory management

A laboratory manager needs to have a certain understanding and knowledge of quantitative methods and analysis, but also needs to posses the following skills:

1. Setting lab objectives
2. Designing long-term plans
3. Overseeing lab operations and relevant regulations

4. Assigning tasks, monitoring and evaluating staff progress, performance, and customer satisfaction
5. Developing and administering the budget
6. Reviewing regulatory requirements

### Internal Processes

Lab management includes the monitoring of several internal work processes that are crucial for the day-to-day functioning of the lab. Some examples:

1. Inventory management
2. Shared equipment reservation
3. Equipment maintenance
4. Resources acquisition and management
5. Waste management
6. Information management

## Quality Management in the Laboratory

A quality philosophy has to be in all activities with high degree of assurance of meeting regulatory, accreditation and customer requirements.

The aim of having quality assurance in a laboratory is to ensure that the customer's requirements are understood and agreed.

Ways to ensure quality in a laboratory:

1. Laboratory personnel must be properly trained.
2. Standard operating procedures (SOPs) need to be available and adhered to.
3. The analytical methods used must be validated to ensure that the methods will produce correct results.
4. Instruments used must be calibrated.

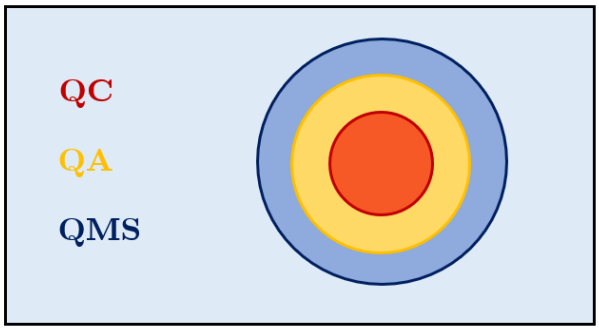
**Definition**

Calibration is the comparison of measurement values delivered by a device under test with those of a calibration standard of known accuracy.

5. The appropriate reagent grade and concentration is used.
6. The reagents are within stability and/or expiry date provided.
7. The working environment and glassware are kept clean from any contaminants.
8. Good Documentation Practices (GDP) are followed.
9. Logging the use of equipment and chemicals to achieve traceability.
10. Proper labelling of solutions and glassware.
11. Following the required safety precautions.

## Quality as a Target

To bring the quality philosophy into the lab's path of workflow you have to look at different aspects of quality.




### Quality Control (QC)

- The Lab's activities are pre-analytic, analytic and post analytical; if we think of the lab's quality as a target, quality control only hits the centre, i.e. the analytical methods.
- Quality control is the innermost circle of the target since the targets for each and every lab test is accuracy and high confidence.

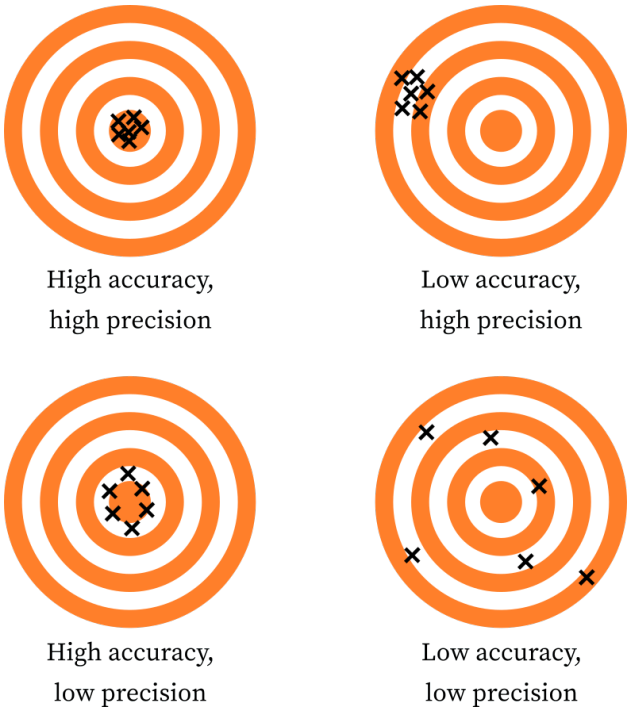
- QC is done by method control.
- The frequency of QC is specified by regulations, accreditation standards, manufacturer's operator manuals, package inserts and authorities.
- Regular QC checks reveals when a method, equipment or procedure is not working as expected.

*What is the difference between accuracy and precision?*

Accuracy and precision are alike only in the fact that they both refer to the quality of measurement, but they are very different indicators of measurement.

**Definition**

The term **accuracy** indicates that a measure meets all its standards while **precision** indicates that the measurement values are very close to each other but not necessarily close to the required value or true value. Thus, one can deduce that a set of *measurements can be precise and not accurate but not accurate without being precise.*



e.g. Specification: 8 blue 5cm petals and 1cm yellow centre, quantity = 100.

Quantity: 100 flowers

**Accurate** (meets specs)

Quantity: 100 flowers all the same

**Precise** but not accurate (they are all the same but do not meet the specs.)

### Quality Assurance (QA)

- Having a system (including appropriately trained personnel) that is designed to assure that analysis or manufacture is carried out to an agreed standard.
- Having the lab's entire workflow functioning is particularly important in processes that cross over functional or departmental lines. Therefore, QA is bigger than QC and covers all the pre-analytic, analytical and post-analytic processes.

### Quality Management System (QMS)

- The quality management system is the outermost ring of the target, which encompasses all the management activities needed to ensure that the laboratory's workflow proceeds smoothly to provide laboratory services to clients.
- A QMS includes both QC and QA, as well as the management activities.
- A QMS provides a framework for building quality principles and practices into all laboratory operations, starting with test ordering and proceeding through delivery of test reports

## 12 Quality Essentials

### 1. Organization

The type and size of the laboratory is what determines the configuration of the laboratory's QMS.

The laboratory should state in writing its policies, goals and objectives for each of the QMS essentials and relate them to the bigger organisation's quality goals.

### 2. Personnel

Quality begins and ends with people, A quality problem is rarely an individual employee's fault but most frequently comes down to faulty work processes.

Quality policies, goals and objectives do not ensure the accuracy and timeliness of laboratory test results. Laboratory personnel need to:

- be properly trained to perform their tasks.
- demonstrate ongoing competence by carrying out tasks right the first time.
- know how their job fits into the organisation

It is important that the lab defines qualifications, licensing and experience to ensure that the employee is fit for the job description. Periodic evaluation of laboratory personnel is also of great importance.

### 3. Equipment

It is important that the equipment used is monitored frequently and maintained as well as possible.

1. Schedules for calibration and preventive maintenance are incredibly important. Equipment use must be logged on a daily basis.
2. Temperature controlled equipment need to be logged frequently.
3. Lab records of all installations, calibration, maintenance, use, troubleshooting, service and repair activities are required to be maintained for the life of the equipment's use and for specified times after decommission.

### 4. Purchasing and Inventory

Purchasing and Inventory is not always taken care or by laboratory personnel and if so, there would be a specific person in charge of this task. In most cases contracts and purchasing of good is done by the purchasing department, especially for larger organisations.

Incoming supplies must always be inspected and their performance (e.g. equipment) has to be verified. Any the supplies and reagents need to be stored according to manufacturer's requirements or directions.

There also needs to be an effective and efficient process for managing inventories in the laboratory so that stock can be kept up to date.

### 5. Process Control

Monitoring performance is essential, it makes it possible to correct problems before they affect the output, and to continuously improve processes to meet changing needs and technology. Routine process controls include: QC of test methods and reagents, Reviews of QC results, identifying non-conformities. Proficiency testing is another example of a process control. This is when laboratories compare their methods and procedures with each other and test the ability to get the same results. Regulations require that all labs participate in proficiency testing for specific tests. One common process control performed by a lab's computerised system (LIMS) is the comparison of current results with previous stored results to detect and differences.

### 6. Information Management

A laboratory information management system (LIMS) is a software-based solution with features that support a modern laboratory's operations. The LIMS stores a wide range of information including: laboratory results (archive), trending of previous laboratory results, reagent preparations and logs, specification sheets, COA certificates, investigation reports and a track record of personnel who have entered results, validated results and released results.

### 7. Documents and Records

Documents include approved information and define the QMS for external inspectors and internal staff. Records capture the results or outcomes which are stored or archived for a specified amount of time, depending on the laboratory. Both must be controlled to provide evidence that regulations and standards are being met.

## 8. Occurrence management (Non-conformance management)

Laboratories need to have a process for detecting, reporting, evaluating and correcting deviations and non-conformance in its procedures, products or services. - Non-conformances need to be identified at the earliest of stages and acted upon. - Any complaints received are considered as non-conformances.

*Investigation and Corrective Action*

- Non-conformances need to be recorded on a database for traceability of the resolution process, so that it can be reviewed and investigated and classified accordingly.
- Immediate action needs to be taken on realisation of the non-conformance.
- This is followed by a corrective action, which might result in changes to the process.
- It is important that all employees are informed of any changes, this is usually communicated by a circulation of an updated SOP. Training must be provided if the change is significant.

*Process for Non-conformance reports*

1. Accession number is provided to all non-conformance reports.
2. The report is then forwarded to personnel who will be involved in the investigation.
3. After investigation is complete and the root cause and required corrective action (if any) is identified, the report is returned to the quality officer who opened the report.
4. The quality officer documents the outcomes of the investigation on the LIMS.

## 9. Assessments and Process Improvement

Quality assurance within any company needs to be cyclical in nature. A very important way of ensuring quality assurance within the organisation is through audits which may either be external or internal.

An essential element of Laboratory QMS is an Internal Audit. The organization's employees perform the internal audit as a way of self-assessment.

It identifies gaps or non-compliances (NCs) and suggests corrective actions to eliminate undesirable situations. As a result, internal audits help increase

the overall efficiency and reliability of the test procedure and its result.

**Note**

**Internal audits** are held by authorised personnel within the company and are very often used in order to prepare the company for upcoming External Audits.
**External audits** are held and inspected by external auditors (e.g. clients or organisations such as ISO and the MMA (Malta Medical Authority)).

Internal audits are usually held on multiple occasions throughout the year and might even be unannounced to the employees. External audits are not held so often but are still carried out annually.

Audits help pinpoint improvements that can be made in the laboratory. There are other things which can indicate improvements; non-conformance trending, customer feedback, monitoring quality indicators, external compliance inspections, report from other departments.

### 10. Process management

A process can be described as a set of interrelated resources and activities which transforms input into outputs.

Process control is a set of activities that ensures that a given work process will keep operating in a state that is continuously able to meet processes goals without compromising the process itself.

**Note**

**Validation**: New processes need to be validated before they start being implemented. The process of validation challenges all activities in a new procedure in order to provide a high degree of assurance that process will work as intended when applied.
When a method is validated, all lab personnel need to be re-trained on the modified process before it is put to use.

### 11. Customer Service

The customer or client is the entity or person that receives and must be satisfied with a product or service provided. Results should always be accurate and timely. Having a customer focus means understanding the customer's

expectations and designing the lab's workflow to meet those requirements as well as regulatory and accreditation requirements.

### 12. Facilities and Safety

The allocated space for the laboratory should be designed to provide for efficient workflow and effective ergonomics. All regulatory, accreditation and larger organisation requirements for current and planned space need to be met.

Authorities often require an environmental control program which addresses all significant environmental issues for facility management and maintenance such as temperature control, electrical safety, fire protection and so forth.

Training is of high importance when it comes to safety.