Quality Assurance in the Laboratory

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Introduction

Quality Assurance is the **process** which ensures that production quality meets the customer's needs and requirements.

Definition

In the context of an analytical laboratory, quality assurance can be defined as **specification compliance**. A laboratory tests products or substances to check if they comply with the **standard specification**.

In order to test the for a specification the procedure itself must be appropriate to give a correct result which is up to the customer's requirements. This is called method validation.

There are two main approaches to quality management in a laboratory:

Definition (Quality Control (QC))

Carrying out checks to determine whether manufactured products and laboratory tests are 'fit for purpose' and that laboratory staff are working correctly.

Definition (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.

Quality Control	Quality Assurance
Focus on fulfilling quality requirements (based on inspection of output)	Focus on Process
Achieved by sampling and testing	Achieved by improving processes
Emphasises required standards	Emphasises the customer
Elimination of defects *(ensuring any defects are found before they reach the customer)*	Builds quality in *(providing reliable product quality—without customers having to inspect continuously)*

Quality Assurance requires the entire manufacturing process or supply of service to be controlled so as to ensure that the customer/client receives the desired end product to the appropriate standard specification.

Definition

A **standard specification** is a set of predefined limits which are established through standardisation processes. The product has to pass these limits for it to be 'within specification'.

Quality standards are documents that provide requirements, specifications, guidelines, or characteristics that can be used consistently to ensure that materials, products, processes, and services are fit for their purpose.

Quality Assurance in Laboratory Analysis

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

E.g. If a laboratory is sent a sample of soil to be tested for lead, it would be agreed with the customer if they wanted the total amount of lead content or the amount of extractable content, or both.

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.

These points all make part of the QA process which needs to be regularly kept under check and audited, both internally and externally. This is important to ensure that all the requirements are being adhered to and that interpretation of results go through the four eyes principle. This is done to ensure that results are not out of specification (OOS), out of trend (OOT) or out of expectation (OOE).

E.g. If there is a colour test that needs to be carried out for a particular product, the result needs to be checked twice by QC, once by QA and another time by QP before the results are sent to the customer.

Important Quality Processes and Documents

Definition

Standard Operating Procedures: Detailed written procedures with instructions on how to achieve uniformity in the performance of a specific function.

Good Documentation Practices: A term used to describe standards by which documents are created and maintained.

Good Manufacturing Practices: The practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufactured goods.

Validation: The confirmation, through provision of objective evidence, that the specified requirements for a specific intended use or application have been fulfilled.

Audit: Systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which criteria (set of policies, procedures or requirements) are fulfilled.

Laboratory Quality Management System (LQMS): A standardized procedure and practice contributing to the overall quality of laboratory test results. The quality of a test result does not depend on a single step but requires quality in individual processes, resources, and overall organizational structure.