

PRINCIPLES OF GOOD LABORATORY PRACTICE (GLP)

*NEWBORN SCREENING
LABORATORY*

AND THE IMPORTANCE OF
QUALITY CONTROL

PROPER LABORATORY PRACTICE

- In the experimental (non-clinical) research arena, proper laboratory practice or GLP is a quality system of management controls for research laboratories and organizations to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of products in development for human or animal health (including pharmaceuticals) through non-clinical safety tests; from physio-chemical properties through acute to chronic toxicity tests.

ELEMENTS OF PROPER LABORATORY PRACTICE

Certification of
lab facilities

Certification of
analysis

Specimen /
Sample tracking

Reagent /
Materials
certification

Accountability

Statistical
procedure

Instrumentation
validation

Quality
assurance

Documentation
and its record

ELEMENTS TO QUALITY

- There are two main elements in this definition of quality. First, the commitment may be explicit such as a written contract or it may be implied in terms of the expectations of the average consumer of the product.
- Second, the performance of the product relates to the ultimate functions and services which the final product must give to the final consumer

For example- a watch should show accurate time or a ball point pen should write legibly on a piece of paper.

- According to ISO 8402: Quality Vocabulary, quality is the “The totality of features and characteristics of a product or service that on its ability to satisfy stated or implied needs

QUALITY ASSURANCE VS QUALITY CONTROL

Quality assurance is the maintenance of a desired level of quality in a service or product, especially by means of attention to every stage of the process of delivery or production

Quality control is a system of maintaining standards in manufactured products by testing a sample of the output against the specification

QUALITY CONTROL (QC): DEFINITION, IMPORTANCE AND TOOLS OF QUALITY CONTROL

Definition:

Quality is a relative concept. It is related to certain predetermined characteristics such as shape, dimensions, composition, finish, colour, weight, etc. In simple words, quality is the performance of the product as per the commitment made by the producer to the consumer. J. M. Juran (1970) who is considered the father of quality research has defined quality as “the performance of the product as per the commitment made by the producer to the consumer

QUALITY CONTROL

Alfort and Beaty defined quality control as:

“Quality control is the mechanism by which products are made to measure up to the specifications determined from the customer’s demands and transform into sales, engineering and manufacturing requirements. It is concerned with making things right rather than discovering and rejecting those made wrong. Quality control is a technique by means of which products of uniform acceptable quality are manufactured.”

ADVANTAGES OF QUALITY CONTROL (PART I)

- The brand products build up goodwill or image which ultimately increases sales.
- It helps the manufacturers/ entrepreneurs in fixing responsibility of workers in the production process
- Quality control also helps in minimizing the costs by increasing efficiency, standardization, working conditions, etc.

ADVANTAGES OF QUALITY CONTROL (PART 2)

- Enables the entrepreneur to know the cost of his / her product quite in advance which helps him in determining competitive prices of his product.
- The entrepreneur can confirm whether the product manufactured by him / her is in accordance with the standard set by the Government. It further facilitates the entrepreneur to take necessary actions to comply with the standard set.

METHODS/TOOLS OF QUALITY CONTROL:

Any variations in the quality of a product, i.e., standards set are mainly caused by variations in raw material, men, machines, methods, and procedures of production and inspection. In order to produce the quality products, these variations need to be checked and controlled. There are mainly two methods of quality control.

METHODS OF CONTROL

➤ **Inspection: C.L.I.A.**

➤ **Statistical Quality Control:**

- Under this method, the entire lot is, firstly, sampled on the basis of its specific characteristics and, then, is divided into three parts as mentioned below:
 - (i) Analysis of Samples
 - (ii) Use of Control Charts
 - (iii) Corrective Measures.

THANK YOU

- Questions?

