Unit-I

QUALITY IN ANALYTICAL CHEMISTRY

Sem-V

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Unit-I :QUALITY IN ANALYTICAL CHEMISTRY

- **1.1.1 Concepts of Quality, Quality Control and Quality Assurance**
- **1.1.2 Importance of Quality concepts in Industry**
- **1.1.3 Chemical Standards and Certified Reference Materials; Importance in chemical analysis Quality of material: Various grades of laboratory reagents**

1.1 Concept of Quality : Quality can be defined in various ways.

i. **Product based : Presence of Ingredient as per the requirement**

ii. **Manufacturer based: Capacity to satisfy the customer**

iii. **Value Based : Degree of excellence at acceptable price**

1.2 WHO Concept of Quality:

QC is concerned with GMP concerning with the sampling, specification, and testing and with the organization, documentation and release procedure which ensures that necessary and relevant tests are actually carried out and those material are not release for use, nor product is released for sale or supply until their quality has been satisfactory.

2 Concept of Quality Control:

The system which accept or rejects any activities or parameters which affects the quality of product and thus prevent quality deficiency.

Quality control is not confined to only laboratory operation but must be involved in all decisions concerning with the quality of the product.

3 **Division of Quality Control Laboratory:**

i. Physical

ii. Chemical

iii. Microbiological

iv. Biological

4 **Normal Operation to be Carried out in Quality Control Laboratory :**

i. The lab and instruments should be cleaned daily.

ii. All the apparatus and instruments should be calibrated on regular basis

iii. The samples arrived in the lab should be noted in incoming register.

iv. Humidity and temperature of the lab should recorded daily.

v. Log books should be filled correctly for every instrument used.

vi. The results of the tests should be recorded appropriately.

vii. Any fault in the instruments should be immediately reported to the Q.C manager.

5 Sample Handling IN QCL:

i. Procedure available for receiving, storage and handling of samples for analysis.

ii. Sample receiving procedure should be documented and keep it.

iii. Each sample having distinct identification number and information for its storage with handling and labeling.

iv. Storage condition facilities in laboratory like refrigerator and absence of light.

v. Detailed description of sub sampling of samples for analysis.

vi. Reserve samples should be retained for additional testing if quantity is adequate.

6 Quality assurance:

i. **All planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy the given requirements for quality.**

ii. Quality assurance ensures that quality control activities are being properly implemented .

iii. Quality Assurance prepares and provides necessary guidelines to quality control department so that given product quality is maintained as per customers requirements and satisfaction.

iv. Quality Control Chemist will analyze given product as per the Guidelines by QA department.

Scope of QA:

i. QC can not change or modify these Guidelines.

ii. The change in Guidelines are provided by QA

v. QA upgardes Guidelines to provide better service to the customers

7 Three systems of Quality Assurance in Analytical Laboratories

i. GLP

ii. Accreditation of a laboratory according to EN 45001 or ISO Guide 17025

iii. Certification According to Norms ISO of Series 9000

8 Five interdependent elements IN QA

i. Assurance: Assurance of measuring traceability of the obtained results•

ii. Evaluation : Evaluation of uncertainty in obtained results of measurement•

iii. Certified Material: Use of certified reference materials•

iv. interlaboratory comparisons: Participation in various interlaboratory comparisons•

v. Method Validation : “Validation of the applied analytical procedures

9 **Components of QC/QA System:**

i. Uncertainty

ii. Reference Materials

iii. Interlaboratory Comparisons

iv. Method Validation

v. Traceability

10 Elements of a Quality Management :

i. Documentation

ii. Standard Operating Procedures (SOP's)

iii. Quality Control samples

iv. External Quality Assessment Scheme

11 **Total Quality Management (TQM)** :

It is a concept created by W. Edwards Deming. It was originally introduced in Japan after World War II to assist the Japanese in re-building their economy. The main focus of TQM was is continuous quality improvement in the areas of product or service, employer-employee relations and consumer-business relations. Total Quality Management is a management approach that originated in the 1950s and has steadily become more popular since the early 1980s. Total Quality is a description of the culture, attitude and organization of a company that strives to provide customers with products and services that satisfy their needs. The culture requires quality in all aspects of the company's operations, with processes being done right for the first time to eradicate defects waste from operations.

Total Quality Management is a method by which management and employees can become involved in the continuous improvement of the production of goods and services. It is a combination of quality and management tools aimed at increasing the business and reducing losses due to wasteful practices. The quality of a library is defined and assessed from a perspective of different groups of people. Moreover, the quality of library services decides on the perception of the library within its parent organization (Gilbert, 1992).

- **Accreditation for Quality Sustenance:**
- Accreditation is the process in which certification of competency, authority, or credibility is presented.
- There are many Accrediting bodies /organizations which helps to maintain the quality of organization. These Accrediting bodies develops some parameters to check the quality management of an organization, these are called as Process standard/ or system standard.
- ***There are three principle groups which have prepared and published standards which are relevant to accredited analytical Chemistry laboratories.***

i. Good Laboratory Practices Standard developed by (OECD) Organization for Economic Co-operation and Development.

ii. ISO: International Standard Organization has produced range of standards as ISO 9000 series of quality standard widely accepted worldwide.

iii. NABL National Accreditation Board for Laboratories (NABL) Indian Government.

- **ISO : International Standard Organization:**
- ISO was developed by technical committee 176 of the International stanadrad organisation in 1887. They are implemented by more than a million organizations in some 175 countries.
- ISO 9000 contains general guidelines
- ISO 9001 and ISO 9002 are related to quality assurance standards intended to inform customers.
- ISO 9003 and ISO 9004 are related to establishment of Total quality system.
- ISO 14001 It helps organizations to implement environmental management.

Advantages of Implementing ISO 9000 series:

i) Quality at each stage of production and customer satisfaction.

ii) Uniform working methods ,continuous improvement and auditing.

iii) Increase in efficiency

iv) Doing the right thing at right time by right method

v) Identification and solving problems at an early stage

12 **Good Laboratory Practices:**

GLP may be defined as a body rules, operating procedures, and practices established by a given organization, that are mandatory with a view to ensuring quality and correctness in the results produced by a laboratory.

OR

GLP is a quality system concerned with the organizational process and conditions under which nonclinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

13 **GLP: Principles** of GLP apply to all non-clinical health and environmental safety studies required by regulations for the purpose of registering or licensing

14 Scope of GLP (OECD)

i. Pharmaceuticals
ii. Pesticides
iii. Food and feed additives
iv. Cosmetic products
v. Veterinary drug products and similar products'
vi. Industrial chemicals

15 Practice OF GLP:

i. Testing facility Organizational and Personal
ii. Quality Assurance Programme
iii. Facilities
iv. Apparatus, Materials Reagents
v. Test Systems
vi. Test & Reference Substances & SOP
vii. Performance of the study
viii. Reporting of Results
ix. Storage and retention of Records

16 ***i) Reference material*** **:** material, sufficiently homogeneous and stable with reference to specified properties, which has been established as fit for its intended use in measurement or in examination of nominal properties.

ii) Certified reference material: reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures.

17 Application of Reference materials

i. Validation of analytical procedures, where RMs are used to determine pre- cision and accuracy
ii. Interlaboratory comparisons, where they are applied as subject matter for studies
iii. Estimating the uncertainty of a measurement
iv. Documenting traceability

18 **APPLICATION OF CRM:**

i. Determination of validation parameters — first of all their precision and accuracy
ii. Examining the skills of an analyst or a laboratory

iii. Routine control of precision and accuracy of the performed determinations

iv. Laboratory accreditation

v. The quality control of performance of a given laboratory

vi. Estimating measurement uncertainty

vii. Monitoring and ensuring traceability

viii. Calibration of measuring instruments

19 **A Reagent** : A **reagent** is a test substance or compound that is added to a system in order to bring about a reaction or to see whether a reaction will occur.

20 A **"reagent-grade" :**A **"reagent-grade"** describes chemical substances of sufficient purity for use in chemical analysis, chemical reactions, or physical testing

21 **Guaranteed Reagent (GR) :GR** Suitable for use in analytical chemistry, products meet or exceed American Chemical Society (ACS) requirements where applicable. (EMD trademark)

22 **Analytical reagent (AR): AR** - The standard Mallinckrodt grade of analytical reagents; suitable for laboratory and general use. If the reagent also meets the requirements of the American Chemical Society Committee on Analytical Reagent, it will be denoted as an AR (ACS) reagent. (MBI trademark)

23 **Primary Standard:** Analytical reagent of exceptional purity that is specially manufactured for standardizing volumetric solutions and preparing reference standards.