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Chapter 6

Pharmaceutical Manufacturing Plant And QC & QA

QUALITY CONTROL AND QUALITY ASSURANCE

→ The word quality generally has different meanings Quality can be defined as "fitness for use," "customer satisfaction, "doing things right the first time." or "zero defects" These definitions are accepted as quality that refers to degrees of excellence.

→ Quality is defined "an inherent characteristic, property [or attribute" Quality control is the science that keeps these characteristics or qualities within the limit range

→ The term quality control includes various techniques and activities of an organisation that are involved in monitoring and improving the business so that the products, processes or services meet the standard specifications.

→ Quality control also involves reviewing the processes and specifications and make recommendations for their improvement. It aims to identify and eliminate the causes of sub-standard performance by removing or reducing the various sources.

→ In a manufacturing or service environment, quality of design and quality of conformance are the two major categories of quality.

→ If a product is not designed properly, it will not function appropriately even if it complies with all the standard specifications.

→ On the other hand, if a product does not conform to excellent design specifications, it will not perform its intended function in a proper way.

Quality of Design

→ It refers to the level of characteristics that the designers specify for a product.

→ High-grade materials, tught tolerances, special features, and high performance are the characteristics related to the high quality product.

Quality of Conformance

→ After determining the quality of design, the product characteristics formed into drawings and specifications, which are used by the manufacturing engineers to develop manufacturing standards and design the operations as required for production.

Quality Assurance

→ The term quality assurance includes all the planned and systematic activities (in the form of an independent final inspection) required for assuring that a product or service will meet the specifications.
→ The difference between quality control and quality assurance is that the former makes quality product and the latter assures the same.
→ Quality assurance function should represent the customers and should not depend on the quality control function that forms integral part of the manufacturing operation.
→ Quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the product quality.

CURRENT GOOD MANUFACTURING PRACTICES (CGMP)/GOOD MANUFACTURING PRACTICES (GMP)

→ GMP is a part of quality management that ensures that products are consistently manufactured and analysed as the quality standards appropriate for use and as required by the marketing authorisation, clinical trial authorisation, or product specification.
→ GMP should be followed by the production department as well as by the quality control unit.
→ GMP is mainly concerned with the management and minimisation of the inherited risks in pharmaceutical manufacturing, thus ensures the quality, safety and efficacy of products.

Under GMP:

1) All the processes involved in manufacturing of pharmaceutical products clearly are defined, systematically reviewed for associated risks according to the scientific knowledge and experience.
2) Thus, GMP also ensures that current manufacturing process is capable of manufacturing pharmaceutical products of required quality that comply with their specifications
3) Qualification and validation of the product are performed
4) All required resources are provided, including
   i) A qualified and trained personnel,
   ii) Sufficient space and adequate premises,
   iii) Required equipment and services,
   iv) Appropriate materials, containers, and tabels,
   v) Approved procedures and instructions,
5) The personnel are trained to carry out all the manufacturing processes correctly.
6) During manufacturing processes, records are either made manually or by recording instruments to describe that the steps taken are as per the defined procedures and instructions, and even the quantity and quality of the product are as expected.
7) Any significant deviations are recorded and investigated with their root cause. Along with this, appropriate corrective and preventive measures are implemented.

8) Records of manufacturing and distribution are maintained in an accessible form so that the complete history of a batch can be traced.
9) Proper storage conditions and distribution of the products reduce any risk to their quality and takes account of Good Distribution Practices (GDP))
10) A system is available to recall any batch of product from sale or supply.

CONCEPT OF CALIBRATION AND VALIDATION

- Calibration is a set of operations that establishes relationship between the values indicated by an instrument or system for measuring (e.g., weight, temperature, and pH), recording, and controlling, or the values represented by a material measure and the corresponding known values of a reference standard, under specified conditions.
- Acceptance limits for the results of measuring should also be established.

General Principles of Calibration

- Calibration is the process of adjusting an instrument or equipment as per the manufacturer's specifications.
- Calibration is also defined as the process of issuing data including a report or certificate of calibration that ensures an end user of a product's conformance with its specifications.

Reason for Calibration of Instrument

- Almost all the equipment, including the electronic equipment, degrades with time.
- The equipment components lose their stability with age and shift from their specified standards.
- Normal handling can adversely affect calibration, and rough handling can throw a piece of equipment out of calibration even if it may appear to be physically well.
- Continuing calibration assures the equipment fulfils the specification required at installation and it should be frequently checked.
- Calibration is required after maintenance to ensure the equipment still follows the required calibration data.
- A well-designed and organised calibration programme proves to be beneficial for quality, productivity, and increased revenue.

General Principles of Qualification

- Qualification is the documented evidence that premises, systems, or equipment can achieve the predetermined specifications properly installed, and/or work correctly and give the desired results.
- Qualification is often a part or the initial stage of validation, but the individual qualification steps do not involve in the process validation.

General Principles of Validation

→ Validation is the establishment of documented evidence to provide a high degree of assurance that a planned process will perform according to the intended specified outcomes without failing.

→ These guidelines cover the general principles of validation and qualification, and also appendices on validation and qualification (e.g., cleaning, computer and computerised systems, equipment, utilities and systems, and analytical methods).

The following principles apply:

1) Execution of validation should be in compliance with regulatory expectations,

2) Quality, safety and efficacy should be designed and built into the product,

3) Quality cannot be inspected or tested into the product,

4) Quality risk management principles should be applied in determining the need, scope and extent of validation, and

5) On-going review should ensure that the validated state is maintained and opportunities for continuing improvement are identified.

Importance and Scope of Validation

- Validation is a systematic approach where it is confirmed that any process in a pharmaceutical facility will operate within the specified parameters as per the requirement.
- This is possible by collecting and analysing data.

- Validation assures that the processes will produce reliable and repeatable results within the predetermined specifications.
- Validation verifies whether or not a product in every pharmaceutical facility is conforming to the quality standards and compliance.
- It also establishes that the facility is following the CGMP guidelines set for the industry by the authorised regulatory bodies.
- Validation is thus a documented evidence of the process conducted as per the predetermined specifications.

Types of Validation

- Process Validation
- Cleaning Validation
- Method Validation:
- Computer system Validation

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