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A REVIEW ON GOOD MANUFACTURING PRACTICES

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ABSTRACT

In 1968 the WHO committee discussed in detail about the specification for pharmaceutical preparation and published are explained in Good Manufacturing Practices under the section 16 production is a good practices in quality control under section 17. These are in promulgated by the commissioner of the federal food and drug administration (FDA) under section 701(a) of the federal food, drug and cosmetics Act. In these methods used to control manufacturing, processing, packaging do not conform to uniformity with current good manufacturing practices. In Good Manufacturing Practices the most important parameter is validation ,to maintain standard operating procedures (SOPs), and also quality control parameters. The records must be maintained demonstrating that all the required sampling and testing procedures are carried out in Good Manufacturing practices.

INTRODUCTION

In 1968 the WHO expert committee revised the text and discussed in detail about the specifications for pharmaceutical preparations and published as to add to its twenty second report. The first version in 1969 recommended by the World Health Assembly on the quality of pharmaceutical products of the WHO certification scheme, moving in international commerce in resolution WHA 22-50, accepted the GMP text as an integral part of the scheme at the same time[1].

The certification scheme has been extended to includes :-

- For food producing animals, veterinary products has to be administered.
- The control done by legislation in both the exporting member state and importing member state, when the starting materials for use in dosage forms.
- In every operation of manufacturing (or) operating related to it, a set of practices to be followed, to get a zero defect product of assured called as "Good Manufacturing Practices."(GMPS)

The main objectives involved in the GMP are:-

- ✓ The cross contamination and mix up should be avoided.
- ✓ Drugs has to be produced in reproducible quality of predefined studies.
- ✓ As science and technology develops, good manufacturing practices also changes and fairly known as current GMPS.
- ✓ Under section 701(a) of the federal food ,drugs and cosmetics act specifies that a drug is deemed adulterated and these are promulgated by the commissioner of the federal food and drug administration.
- ✓ Current good manufacturing practise, it includes the methods used in (or) the facilities (or) the controls used for, its manufacture, processing, packing ,(or) holding are not operated (or)administered in conformity of these practices.
- ✓ The main aim of the good manufacturing practices are drug must meet the quality and purity characteristics.
- ✓ The producing good quality medicine , medical devices(or)active pharmaceutical products are the ultimate goals for safeguarding the health of the patient.

2) GUIDELINES FOLLOW A FEW BASIC RULES:-

These are "few basic principles which follow all guidelines"

The process which is controlled and clearly defined called manufacturing processes. The evaluation can be done, if any changes to the process can be controlled. Instructions and procedures which include in good documentation practices are written in clear and unambiguous language[2]. To carry out document procedures, operators have to be trained.

To minimize any risk to their quality by the distribution of drugs. If the complete history of a batch to be traced and retained in a comprehensible and accessible form by maintaining the records of manufacture including distribution.To recall any batch of drug from sale (or) supply there was a system available.

3) Application of Current Good Manufacture Practise Regulation:-

i. Drug of the biological products are to be regulations for human use and considered as a supplement not to displace each other, unless these regulations provide explicity [3].

ii. A person who engaged only in some operations subject to the regulations, that a person needs to comply with only those regulations that are applicable to the operations in which he/she engaged and not in others.

4) Quality management in drug industry:-

Aspect of management function in drug industry at large, that determines and implements "Quality Policy" (i.e) regarding quality, overall intention and direction called as "Quality Management."

The basic elements of quality management are:-

- The organizational structure, procedures processes and resources are an appropriate infrastructure encompassing the "Quality System."
- To ensure adequate confidence of a product (or) service which will give, satisfy requirements for quality and totality of these actions is termed as "Quality Assurance."
- The interrelated aspects of quality management are quality assurance, good manufacturing practise and quality control[4].

Fig: 1 Flow chart of Good Manufacturing Practice

5) DEFINITION OF QUALITY, QUALITY CONTROL, QUALITY ASSURANCE:-

i. Quality:-

Totality of features and characteristics of a product (or) service that bear on its ability to satisfy stated (or) implied needs defined as quality, according to the international standard organization(ISQ). "Quality is meeting the standards" by the quality expert, Philip crosky.

The requirements (or) needs involve conforming to specifications in terms of design, reliability, stability. To design, design, reliability and stability are the requirements (or) needs involve conforming specifications in the pharma industry.

The ultimate objective aim of satisfying the customer was done by appropriate sampling and testing procedures.

ii. QUALITY CONTROL:-

Quality control can be defined as one of the practical techniques for securing quality of the manufactured product and also covers all the activities[5]. Inspection for defects, includes "design analysis", "statistical sampling." Finished products and evaluation of raw materials can be done by the adequate documentation before release.

FUNCTIONS OF QUALITY CONTROL

1. **It Should Approve :-**
   - i. Starting materials, intermediate products, packaging materials and active pharmaceutical ingredients are the methods done by specifications and testing.
   - ii. Procedures about sampling.
   - iii. Regarding instructions about sanitation and hygiene must be maintained.
   - iv. For rejected batches (or) recovered materials, procedures done by reprocessing.
   - v. To assure that no errors have occured , production records has to reviewed by the authority[6].
2. For the release (or) rejection of starting materials, active ingredients, packaging material and intermediate products it should be done by feeling responsibility.
3. Stability of active pharmaceutical ingredients is monitored by making sure.
4. Related to the quality of active pharmaceutical ingredients, the investigation of complaints should be responsible.
5. Related to quality control, the responsibilities of procedures should be in writing and should be followed.

iii. QUALITY ASSURANCE:

Only by sampling, testing and release of materials and quality cannot be ensured. Whether the facilities and equipments are used in order, production department uses adequate systems and procedures are adequately documented and the quality control department does its job adequately and completely by following these methods, quality assurance can be ensured.

Planning, communication, control of work operations, audit, training, etc. are the activities have a well thought out system requires the company by the Total Quality Management [7]. The product failures are bound to be minimum, if the production department pays adequate attention to details and does not make shortcuts, according to the ISO 9000 standards. Commitment, system and documentation are the basic requirements of the quality standards.

6) GOOD MANUFACTURING PRACTICES FOR PHARMA PRODUCTS:-

A part of quality assurance is good manufacturing practise, which ensures that product are consistently produced and controlled to the quality standards. Diminishing the risks are primarily aimed by the good manufacturing practices, in any pharmaceutical production[8].

Essentially 2 types of risks are there, they are:-

1. Cross contamination (In particular of unexpected contaminants)
2. Mix-ups (confusion)

For example:-Under good manufacturing practise putting/placing/pasting the false labels on the containers.

- In the light of experience, all manufacturing processes are clearly defined and systematically reviewed.
- The validation and qualification should be performed in good manufacturing practices.
- Specifically, instructions and procedures are written in clear and unambiguous language, which are applicable to the provided facilities.
- To carry out procedures correctly, operators must be trained.
- The products minimizes any risk to their quality by the proper storage and distribution.
- To recall any batch of product from sale (or) supply a system is available.
- The causes of quality defects investigated, when complaints about marketed products are examined and to prevent recurrence, appropriate measures have to be taken in respect of the defective product

7) VALIDATION[9]:-

Validation is one of the most important parameter of good manufacturing practise. Production of drug of reproducible quality will ensure a process of proper validation.

MAJOR REASONS FOR VALDATION ARE:-

1) QUALITY ASSURANCE:-

By routine quality control testing quality cannot be assured, because of the limitation of statistical samples and the limited facilities of finished product testing [9]. To meet the predetermined criteria, validation checks the accuracy and reliability of a system (or) process. High degree of assurance provides a successful validation, in each unit a consistent level of quality is maintained of the finished product from one batch to another batch.

2) ECONOMICS:-

Due to decrease in the sampling and testing procedures and there are less number of product rejections and retesting, these are due to successful validation. These are all leads to cost-saving benefits.

3) COMPLIANCE:-

Validation is essential for compliance to current good manufacturing practices.

TYPES OF VALIDATIONS:-

1) PROSPECTIVE VALIDATION:-

Prior to the distribution of a new product, this type of validation is conducted by the establishment of documented evidence of what a system does (or) what its purports to do based upon a plan.

2) RETROSPECTIVE VALIDATION:-

It is based upon the review and analysis of the existing information, by the establishment of documented evidence of what a system does (or) what it purports to do. Based on accumulated data of production, testing and control this is conducted in a product which is already distributed.

3) CONCURRENT VALIDATION:-

It is based on information generated during implementation of the system, the establishment of documented evidence of what a system does (or) what are purports to do.

4) REVALIDATION:-

Revalidation of the validated process, should be done whenever there is a major change in the process (or) in the equipment used (or) any environmental conditions. Guidelines on "General principles of total quality control in drug industry" formulated by the pharmaceutical manufacturers association, in 1967

8) HANDLED MATERIALS AS PER GUIDELINES OF GMP [10]:-

- To produce finished products for patients use from a combination of materials (starting and packaging)is the main objective of a pharmaceutical plant.
- Starting materials, packaging materials, gases, solvents, process aids, reagents and labeling are the materials included.
- Water should be suitable for its intended use in the manufacture of pharmaceutical products.
- Materials not used for operations it should come into direct contact with the product such as cleaning, lubrications of equipment and pest control.

- After receipt(or) processing all incoming materials and finished products should be quarantined immediately until they are released for use (or)distribution.

9) GOOD PRACTICES IN QUALITY CONTROL:

A part of good manufacturing practices is quality control which includes sampling, specification and testing, organization, documentation and release procedures. From production the independence of quality control is considered as fundamental. Quality control function should be maintained by the each manufacturer. Under the authority of a person with appropriate qualifications and experience, having one (or) several control laboratories at his/her disposal, being considering quality control function should be independent of other departments [11].

QUALITY CONTROL BASIC REQUIREMENTS ARE:-

- By the personnel approved of by quality control department, samples of starting materials, packaging materials, bulk products, and finished products must be taken by methods.
- Validation and qualification must be performed.
- The finished products, ingredients should comply with the qualitative and quantitative composition as described in marketing authorization.

CONCLUSION

Finally we concluded that GMP is mainly involved in the standard operating procedures, manufacturing of various dosage forms to get desirable products, quality control. To maintain document and also stability studies as per the GMP guidelines. In pharmaceutical industry GMP required with are involves to specification in terms of design, reliability, stability, appropriate sampling and testing procedure are satisfying to the customer.

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