



Review on Current Good Manufacturing Practice for Finished Pharmaceuticals

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ABSTRACT:

A manufacturing authorization holder must manufacture pharmaceutical goods in such a way that they are fit for their intended use, meet the requirements of the Marketing Authorization, and do not endanger patients owing to insufficient safety, quality, or efficacy. The achievement of this quality aim is the responsibility of top management and necessitates the cooperation and dedication of employees from many departments and at all levels within the organisation, as well as suppliers and distributors. To accomplish the quality goal consistently, a completely planned and well executed system of Quality Assurance Incorporating Good Manufacturing Practise, Quality Control, and Quality Risk Management is required. It should be thoroughly recorded and its efficacy should be checked. each component.

Keywords: current Good Manufacturing Practice. Quality control. Quality assurance, authorized

OBJECTIVES:

1. Discuss the significance of preserving a contaminant-free environment.
2. To define quality and examine the importance of quality products in terms of safety and efficacy.
3. Describe the necessary things defined by the federal code and cGMP.
4. Research validation concepts and their significance in the industry from a quality standpoint.
5. To comprehend the ramifications of low quality. .

CONTENT:

INTRODUCTION:

Current Good Manufacturing Practise is abbreviated as cGMP. cGMP is defined as "a quality assurance component that ensures products are consistently produced and controlled to the quality standards appropriate for their intended use and legal requirements." Thus, cGMP is concerned with both production and quality control issues. cGMP provides detailed instructions for creating material and product requirements, as well as testing and replication methods. The drug regulatory bodies across the world, such as WHO, M.H.R.A. (UK), T.G.A (Australia), M.C.C. (South Africa), U.S.F.D.A, and others. Provides guidelines based on their specifications. cGMP requires that all personnel be trained. It includes detailed guidance on the necessary facilities and equipment. cGMP talks about how you should regulate material quality at every level. It also continues discussions.

Current good manufacturing practice for finished pharmaceuticals

1. General Provisions
2. Organization and Personnel
3. Buildings and Facilities

4. Equipment
5. Control of Components and Drug Product Containers and
6. Production and process controls.
7. Packaging and labelling controls
8. Holding and distribution
9. Laboratory control
10. Records and reports
11. Returned and salvaged drug products

1. General provisions

Scope and definitions:- The regulations in this section outline the minimal current good manufacturing practise for preparing drug products for human or animal administration. The cGMP requirements apply to pharmaceutical items. If OTC medications are normally advertised, the criteria under these rules should not be implemented.

2. Organization and personnel

It is concerned with the duties of a quality control unit. The applications and duties of QA should be in writing, and suitable laboratory facilities for testing and component approval should be available.

Personnel qualifications

Each individual who supervises, manufactures, processes, packs, or holds a drug product must have education, training, and experience. There must be a sufficient quantity of qualified workers..

Personnel responsibilities

Personnel involved in the creation, processing, packing, or storage of a drug product must wear clean attire appropriate for the tasks at hand. To protect drug goods from contamination, protective clothing such as head, face, hand, and arm covers must be worn. Personnel must maintain appropriate cleanliness and health behaviours. Only personnel authorised by supervisory staff are permitted to enter restricted access sections of buildings and facilities. Any individual who is found to have an obvious sickness or open lesions at any time (through medical examination or supervisory inspection) is prohibited from having direct contact with components..

3. Buildings and facilities

Any structure or structures used in the production, processing, packaging, or storage of a drug product must be of enough size, construction, and location to permit cleaning, maintenance, and appropriate operations. Any such structure must have enough room for the orderly positioning of equipment and materials to avoid component mix-ups. Operations must be carried out in clearly defined zones of sufficient size. There must be distinct or demarcated zones, as well as other control methods..

Facilities to be provided

1. Smooth, firm surfaces on the floors, walls, and ceilings that are readily cleaned
2. An air supply that is positive-pressure filtered using high-efficiency particle air filters, regardless of whether the flow is laminar or non-laminar.
3. A monitoring system for environmental conditions
4. A method for cleaning and disinfecting the space and its equipment in order to maintain aseptic conditions
5. A technique for maintaining any aseptic equipment used to manage the conditions
6. Appropriate lighting
7. Enough ventilation.
8. Potable water must be delivered under continuous positive pressure in a plumbing system devoid of flaws that might lead to medication product contamination.
9. Pre-filters and particle matter air filters must be utilised in air filtration systems.

10. Sewage, rubbish, and other waste entering and exiting Floors, walls, and ceilings of smooth, hard surfaces that are easily cleanable
11. An air supply that is positive-pressure filtered by high-efficiency particle air filters, regardless of whether the flow is laminar or non-laminar.
12. A monitoring system for environmental conditions
13. A system for cleaning and disinfecting the space and its equipment in order to maintain aseptic conditions
14. A technique for maintaining any aseptic equipment used to manage the conditions
15. Appropriate lighting
16. Proper ventilation.
17. Potable water must be delivered under continuous positive pressure in a plumbing system free of faults that might lead to medication product contamination.
18. The usage of air filtration equipment, including pre filters and particulate matter air filters, is required.
19. Sewage, garbage, and other rubbish in and around the building and immediate vicinity must be disposed of in a secure manner. Any building used in the manufacture, processing, packing, or holding of a drug product shall be maintained in a clean and sanitary condition.
20. Any structure utilised in the production, processing, packing, or storage of a drug product must be kept in excellent repair..



4. Equipment

The equipment employed must be of proper design, size, and location to allow operations for its intended purpose as well as cleaning and maintenance. Surfaces that come into touch with components, in-process materials, or medicinal products must not be reactive, additive, or absorptive. To prevent malfunctions or contamination, equipment and utensils must be cleaned, maintained, and, depending on the nature of the medicine, sanitised and/or sterilised at suitable intervals.



Types of equipment's:

Automatic, mechanical, or electrical equipment or other forms of equipment, including computers or linked systems that will properly execute a purpose. Appropriate controls must be applied to computer or associated systems. Filters for liquid filtration used in the production, processing, or packaging of injectable medicinal products intended for human use must not include fibres.

5. Control of components and drug product containers and closures

Written procedures detailing the receiving, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures must be in place. Bagged or boxed components of drug product containers or closures must be stored off the floor and in sufficient space to allow for cleaning and inspection. Each container or grouping of containers containing components, drug product containers, and closures should be visually checked upon arrival and before acceptance for adequate labelling as to contents, container damage or broken seals, and contamination. Each lot of components, drug product containers, and closures should be restrained from use until the quality control unit has sampled, tested, or inspected the lot and released it for use. Each shipment's representative samples

6. Production and process controls

Written production and process control procedures should be followed to ensure that the drug products possess or are represented to possess the identity, strength, quality, and purity that they possess or are claimed to possess. The batch must be designed to contain at least 100 percent of the labelled or defined quantity of active component. Weighing, measuring, and dividing processes for components must be properly overseen. A second person must inspect each container of component delivered to production. Actual yields and percentages of theoretical yield must be calculated at the end. All compounding and storage containers, processing lines, and main equipment involved in the manufacture of a drug product batch must be labelled.

7. Packaging and labelling control

Written procedures must be in place that specify the receipt, identification, storage, handling, sampling, examination, and/or testing of labelling and packaging materials. Records must be kept for each shipment received of each individual labelling and packaging material, stating receipt, examination or testing, and whether approved or refused. Any labelling or packaging materials that fulfil the relevant stated standards may be authorised and allowed for use. Labels and other labelling materials for each particular medication product, strength, dosage form, or quantity of contents must be stored separately and labelled appropriately. Printing devices on or linked with manufacturing lines used to imprint labelling on the drug product unit label or case must be monitored to ensure that all imprinting corresponds to the print defined in the batch production. Identification and management of unlabeled full drug product containers placed aside for future labelling processes to avoid mislabelling of individual containers, lots, or sections of lots. Package tamper-evident requirements- If an OTC drug product (excluding a dermatological, dentifrice, insulin, or lozenge medication) is available to the public while held for sale, the maker and packer must package the product in a tamper-evident packaging. Exemptions from packaging and labelling standards might be requested. New drug products for experimental use are excluded from the provisions of this section if they fulfil adequate criteria or specifications as evidenced by stability studies conducted during their use in humans. During the finishing process, packaged and tagged items must be checked.

8. Holding and distribution

Drug items should be stored under suitable temperature, humidity, and light conditions. A method of distributing a medicinal product's oldest approved stock first. Deviation from this criteria is allowed if it is transitory and reasonable. A method that allows the distribution of each lot of a drug product to be easily determined in order to ease its recall if necessary.

9. Laboratory controls

Laboratory controls must include the development of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures to ensure that components, drug product containers, closures, in-process materials, labelling, and drug products meet appropriate identity, strength, quality, and purity standards. There must be an acceptable laboratory assessment of satisfactory compliance for each batch of medicinal product. Any sampling and testing plans must be documented in writing, including the sample technique and the quantity of units per batch to be tested. The firm's test techniques' accuracy, sensitivity, specificity, and repeatability must be developed and recorded. Drugs that do not fulfil set standards or specifications, as well as any other applicable quality control criteria, will be rejected.

A sufficient number of batches of each medicinal product must be examined in order to identify a suitable expiration date, and a record of such data must be kept. Each batch of medicinal product claiming to be sterile and/or pyrogen-free must undergo adequate laboratory testing to ensure compliance with such criteria. A reserve sample that is adequately labelled and representative of each lot in each shipment of each active component must be kept. Animals employed to test components, in-process materials, or medicinal products for conformity with defined requirements must be kept and regulated in a way that ensures their appropriateness for their intended use. If there is a plausible risk that a non-penicillin drug product has been exposed to penicillin cross contamination, the non-penicillin medication product must be recalled.



10. Records and reports

Individual equipment logs must include a documented record of significant equipment cleaning, maintenance (excluding regular maintenance such as lubrication and adjustments), and usage, as well as the date, time, product, and lot number of each batch produced. Each shipment of each lot of components, drug product containers, closures, and labelling; the name of the supplier; the supplier's lot number, and so on must be noted. A distinct inventory record for each component, drug product container, and closure, as well as a reconciliation of the usage of each lot of such component for each component. Master production and control records for each medicinal product, including each batch size thereof, must be generated, dated, and signed to ensure consistency from batch to batch. For each batch of medicinal product manufactured, batch production and control records must be created. The quality control unit must evaluate and approve all drug product manufacturing and control records, including those for packing and labelling. Laboratory records must contain comprehensive data from all tests performed to ensure compliance with set requirements and standards. Distribution records must include the product's name and strength, as well as a description of the dosage form, the consignee's name and address, the date and quantity sent, and the lot or control number of the medicinal product.

11. Returned and salvaged drug products

Drug products that have been exposed to unsuitable storage conditions, such as temperature, humidity, smoke, fumes, pressure, age, or radiation as a result of natural catastrophes, fires, accidents, or equipment failures, should not be salvaged and reintroduced to the marketplace. Records of returned drug products must be kept and must include the drug product dosage form's name and label potency, lot number (or control number or batch number), cause for return, amount returned, date of disposition, and ultimate disposition of the returned drug product.



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CONCLUSION:

cGMP is a manufacturing and testing practise that aids in the creation of high-quality products. Many nations have passed laws requiring pharmaceutical businesses to adopt cGMP protocols, and they have developed their own cGMP rules to go along with their legislation. The fundamental ideas of all of these standards are more or less identical to the ultimate aims of protecting the patient's health and creating high-quality medications.

Only through thorough development and execution of a QA system, as well as practical application of cGMP, can quality objectives be met. Effective cGMP implementation necessitates great attention and knowledge of the many components of cGMP that must be implemented from the beginning of the manufacturing building and product development to the end of production.