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A REVIEW ON GOOD MANUFACTURING PRACTICES (GMP)

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ABSTRACT :

Good Manufacturing Practices is part of quality assurance that ensures that products are regularly produced and checked to meet quality standards and marketing authorizations for their intended use. These standards set minimum standards for pharmaceutical or food manufacturers to provide quality, safe products for consumers and society.

Keywords: - Good Manufacturing Practices, quality assurance, Pharmaceuticals, quality.

Introduction: -

The GMP concept was created to monitor the production and packaging process in the pharmaceutical industry. The UK Department of Health and Medicines Agency is working with a number of partners to develop GMP guidelines, commonly known as the Orange Guides.

- •The initial version of the guide was released in 1971, outlining the manufacturing of drugs under the Medicines Act.
- •The second edition, consisting of 52 pages with five appendices, was published in 1977,
- •The third edition in 1983, which comprised 110 pages along with five appendices.

Need of GMP: -

The necessity of Good Manufacturing Practices (GMP) arises from the limitations of final product testing in ensuring quality, efficiency, and safety, as it may not always detect contamination or errors. GMP ensures adherence to predetermined specifications, minimizes contamination risks like microbial contamination, eliminates errors, and facilitates the production of consistent quality products.

Importance of GMP: -

Good Manufacturing Practice (GMP) is crucial in ensuring that pharmaceuticals, food, and other products are consistently produced and controlled to the quality standards appropriate to their intended use.
GMP provide a system of processes, procedures, and documentation to assure a product's identity, strength, quality, and purity. Adhering to GMP standards helps to minimize risks involved in pharmaceutical production, ensuring the safety and efficacy of products for consumers.

Backgrounds: -

Both the pharmaceutical industry and regulatory agencies tend to ignore the importance of drug safety until significant safety issues raise concern. Before 1937, the FDA had no regulatory authority for drug safety testing, allowing products to enter the market without safety testing. S.E. Emphasize the importance of safety precautions. Information about Massengill Corporation.

Principles: -

Good Manufacturing Practices (GMP) is a system and process that ensures that products are manufactured and maintained in accordance with quality standards. Key principles include maintaining a clean and hygienic production environment, implementing quality control systems and documenting all processes for traceability and accountability.

GMP for premises and materials: -

General requirement: -

- Location and Surrounding: -
- Production facility. Medicine storage area may require the foll owing precautions:
- Avoid the risk of external contamination toxic emissions.
- Building and Premises: -
- Buildings should be designed to allow production to operate hygienically must be compatible with other production. ›Don't risk confusion. › Production and distribution facilities should be well lit, well-ventilated and have appropriate ventilation equipment.

Warehousing housing: -

- This site has been specially selected and modified for good storage.
- The exclusion zones must have clear boundaries and be accessible solely to authorized individuals.

Production area: -

- Sex hormone, cytotoxic substances and beta lactometer •services lines shall be well designed and constructed.

Personnel: -

- Sufficient personnel must be employed.
- Personnel for QA and QC shall be qualified.

Clothing: -

- Requirement for specialized protective attire.
- Apparel must undergo cleaning.

Equipment: -

- Defective equipment should be removed from the production area and properly maintained.
- Appropriate measurement and measuring equipment must be available during the storage, production and operation of raw materials. This equipment must meet specified standards, accuracy and precision, and must be measured and analyzed in accordance with standard operating procedures (SOPs) and records.

Labels and Other Printed Material: -

- It is important to identify the medication and understand its use.
- Printed in bright colors and legible manner. Record of receipt.

Risk management: -

Identify, measure and reduce risks throughout the production process.

Quality Assurance: -

- Ensure basic security policies of quality assurance/quality control.
- Developing actions to solve existing problems.
- Wide ranging concept.
- Identify managerial responsibilities.
- Covers all matters that individually.

Quality Audit: -

- Make sure the company operates in accordance with GMP.
- Recall.
- Repeated rejection.

Quality Control System (QCS): -

- Quality control will include testing, documentation and release procedures.
- By sampling. Standards that are not limited to laboratory studies should be considered in all options.
- About good things. Other responsibilities of this department include the development, measurement, evaluation and implementation of all quality control systems and procedures.
- All products are shipped after approval by QC department. "All equipment and testing procedures must be calibrated and verified before use in routine testing. Equipment calibration and verification procedures should be performed regularly.
- Pharmacopoeias, reference standards, reference spectra, other reference materials and technical information (if required) must be available at the licensee's quality control facility.

Specifications: -

- For raw materials and packaging. -For packaged and sealed products. -For finished products.

Common problems in GMP Execution: -

1. **Organization:**

- Lack of Commitment.
- Lack of Execution Resources.

2. **Equipment: -**

- Not calibrated.
- No balance test before use.
- Rust Incorrect storage location.

3. **Layout and Construction: -**

- Protecting the environment is not enough.
- There is no quarantine.

4. **Documentation and recording: -**

- No signature, no counter check.
- Made Improper correction.
- No written procedure.
- Incomplete complaint record.

5. **Labelling: -**

- Status not defined clearly.
- Poor labelling control.
- Release label not kept securely.

6. **Validation: -**

- Insufficient evidence.
- Insufficient original documentation.
- No evidentiary process.

Conclusion: -

Good Manufacturing Practices (GMP) are important guidelines for the quality, safety and effectiveness of pharmaceuticals, foods and other products. By following GMP standards, companies can maintain consistency in their production processes, reduce the risk of contamination or errors, and ultimately produce quality products that comply with legal requirements. In general, GMP plays an important role in protecting public health and ensuring consumers have confidence in the products they use.

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