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A review on good manufacturing practice

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Abstract
Good Manufacturing Practices (GMP) are a crucial element of quality assurance, ensuring that products are consistently produced and controlled to meet established quality standards suitable for their intended use and regulatory approval. GMP guidelines set the minimum requirements that manufacturers of pharmaceuticals, food, cosmetics, medical devices, and dietary supplements must adhere to, safeguarding consumers by minimizing potential risks. These practices ensure that every stage of production from raw material procurement to final product distribution is conducted in a standardized and controlled manner. In the United States, GMP regulations are enforced by the FDA under 21 CFR, emphasizing the importance of compliance across all relevant industries.

Keywords: GMP, quality assurance, pharmaceuticals, medical device

Introduction
Good Manufacturing Practices (GMP) are a systematic approach designed to ensure that products are consistently produced and controlled according to established quality standards. The system is aimed at minimizing risks inherent in pharmaceutical production that cannot be eliminated solely by testing the final product. GMP ensures that raw materials used in drug manufacturing are of known and standardized quality, and are free from contamination [1]. Historically, numerous tragic incidents related to unsafe or ineffective drugs resulted in significant loss of life, highlighting the urgent need for regulatory oversight. In response, the FDA established guidelines to ensure that products reaching the market are manufactured under stringent GMP conditions [2].

As a key component of quality assurance, GMP ensures that all products are consistently produced and controlled to meet the quality requirements necessary for their intended use and as mandated by marketing authorization. The primary objective of GMP is to mitigate risks during pharmaceutical production, particularly those associated with incorrect labeling, cross-contamination, or mix-ups. Manufacturers are responsible for ensuring that their products are safe, effective, and of high quality. Risk assessment has therefore become an integral part of the World Health Organization's recommendations for quality assurance. Inspections of pharmaceutical manufacturing facilities form another essential aspect of the GMP framework, serving either to enforce compliance or to grant approval for the production of specific pharmaceutical products, usually in connection with marketing authorization applications. Furthermore, to prevent the circulation of counterfeit medicines, inspections also monitor the quality of pharmaceutical products throughout the supply chain, from production to delivery to the end user [3].

History [4]
Good Manufacturing Practices (GMP) were incorporated into the Drugs and Cosmetics Act of 1940 and formally included in Schedule M in 1988. The schedule provides guidelines for pharmaceutical manufacturing units in India to ensure that medicines are produced according to standardized quality requirements. The last amendment to Schedule M was made in June 2005. It outlines GMP standards covering various aspects of pharmaceutical production, including company premises, quality control systems, laboratory testing, production processes, equipment cleaning, housekeeping, prevention of cross-contamination, and other related practices. On 28th December 2023, a revised version of Schedule M was implemented, placing greater emphasis on the quality management system of pharmaceutical

products, reflecting a shift toward more comprehensive and systematic quality assurance throughout the manufacturing process.

Objective [5]

1) Ensure Product Safety and Quality

- **Consistency in Production:** GMP ensures that products are manufactured with consistency and reliability, which is critical for patient safety and consumer trust.
- **Preventing Contamination:** It minimizes the risk of contamination (e.g., microbial, chemical, physical) and ensures the safety of pharmaceutical products.
- **Quality Control:** Through continuous monitoring, testing, and validation of processes, GMP ensures that all manufactured products meet predefined quality standards, from raw material acquisition to finished product release

2) Compliance with Regulatory Standards

- **Regulatory Compliance:** GMP is designed to align with the requirements of various regulatory agencies such as WHO, US FDA, EMA.
- **Avoid Legal Issues:** By adhering to GMP guidelines, manufacturers avoid legal consequences, product recalls, and sanctions due to non-compliance.
- **Inspection Readiness:** Manufacturers must be prepared for audits or inspections by regulatory bodies at any time, ensuring they maintain the required standards in every phase of production.

Components of GMP [6-7]

1) Quality Management System (QMS)

- **Documentation Control:** Written procedures, batch records, and SOPs must be established, followed, and updated regularly.
- **Risk Management:** Identification of risks associated with product quality and control measures to mitigate them.
- **Corrective Actions and Preventive Actions (CAPA):** A process for identifying, investigating, and correcting deviations.
- **Continuous Improvement:** Ensuring processes are continually improved based on monitoring and feedback.

2) Premises & Facility Design

- **Cleanliness and Maintenance:** Production areas should be clean and well-maintained to prevent contamination. This includes regular cleaning schedules and inspections.
- **Separation of Areas:** There should be clear separation of different areas (e.g., raw material storage, production areas, finished product storage) to avoid cross-contamination.
- **Environmental Control:** Facilities should have appropriate air filtration, lighting, temperature, and humidity control systems.

3. Equipment & Utilities

- **Equipment Qualification:** Equipment used in production must be validated (IQ, OQ, PQ) to ensure proper operation and accuracy.
- **Maintenance & Calibration:** Regular maintenance and calibration schedules must be established and adhered to.
- **Sanitization and Cleaning:** To ensure cGMP, the all equipments must be sanitized and cleaned.

4) Raw Materials & Supplier Management

- **Material Sourcing:** Raw materials should be obtained from approved suppliers who provide valid Certificates of Analysis (COA).
- **Storage & Handling:** Materials must be stored in controlled conditions to prevent degradation, contamination, or mixing.
- **Supplier Qualification:** A robust supplier qualification process should ensure that all suppliers meet GMP.

Fig 1: Components of GMP

GMP Guidelines [9]

Quality Management

Quality Assurance (QA): This encompasses all factors that, individually or collectively, impact the quality of a product. QA ensures that products are systematically designed and developed to consistently meet predefined quality standards and requirements.

Quality Control (QC): This involves testing raw materials as well as the final products and in-process samples to check whether they are meeting the predetermined quality standards.

Training & Hygiene

- **Training:** All employees should be properly trained on GMP principles and the particular operations they perform.
- **Hygiene:** the employees must have high standards of personal hygiene to avoid contamination.

Facilities and Equipment

Design and Maintenance: Facilities should be designed such that cross-contamination is avoided; all equipment must be well equipped and maintained with excellent efficiency in working.

Documentation

- **Standard Operating Procedures (SOPs):** SOPs should be established for every activity that is performed in the manufacturing.
- **Batch Records:** All the batches made should be documented with extremely fine details so that any problem that arises can be traced out easily.
- **Change Control:** Any change in the manufacturing should be documented, justified and approved and should be allowed only after proper approval.

Production

- **Process Validation:** It is ensuring that there is a manufactured product which meets specifications consistently.
- **In-Process Controls:** It is checking products during production in order to ensure that they meet specifications.
- Packaging and Labelling: It ensures that the final product is correctly labelled and packed in order not to have mix-ups and traceability.

Quality Control (QC)

- **Testing: The proper & reailble testing of products is** important to ensure quality.
- **Stability Testing:** Ensures that the product stays within specifications for the shelf life

Complaints and Product Recalls

- **Complaint Handling:** All complaints shall be thoroughly investigated, and remedial actions taken accordingly.
- **Product Recalls:** An organization shall have a recall procedure for products not conforming to quality requirements or hazardous to health.

GMP Standards [10]

1) Quality Management System

A comprehensive quality management system is central to Good Manufacturing Practices (GMP), encompassing all stages of production from raw material acquisition to final product release. Its core purpose is to continuously monitor processes, assess risks, and implement corrective measures to ensure consistent and reliable product quality. The key elements in QMS under GMP are.

- **Policy and procedures:** Policies and procedures that guide how quality assurance and control of the organization should he put into action.

2) Personnel and Training Continue and training

Personal hyping and protecting against contamination by dressing and comporting Apportunity.

3) Premises and Equipment

GMP considers the physical space where the manufacturing process occurs important. The building and maintenance of premises and equipment, combined with adequate clean practices, reduce hazards from being formed.

GMP-compliant manufacturing facilities

- Are appropriately located and designed with efficient workflow and containment of hazardous substances.
- Are kept clean and regularly maintained.
- Use validated and calibrated apparatus/equipment to ensure proper and consistent manufacture.
- Separate rooms for each step of the production process. This is to help eliminate cross-contamination.

The role of GMP in quality assurance [11]

GMP serves as the inspiration of best assurance in production, with the aid of enforcing GMP, businesses can setup standardized techniques that assist prevent mistakes, contamination, and defects in products. The rule of GMP in QA consists:-

- **Establishing a robust quality management system:** Implementing Good Manufacturing Practices (GMP) necessitates the development of a comprehensive Quality Management System (QMS) that defines all procedures, responsibilities, and documentation essential for maintaining product quality. The system provides structured guidance on areas such as personnel training, equipment maintenance, process validation, and meticulous record-keeping to ensure consistent compliance with quality standards.
- **Ensuring consistency in production GMP emphasizes the importance of standardized operating procedures (SOPs):** These procedures ensure consistency in production processes, minimizing variability and reducing the likelihood of defects.
- **Promoting Employee competence and awareness:** Training is a critical component of GMP, ensuring that employees are competent in their roles and aware of their responsibilities concerning quality, Regular training and updates ensure that staff remain informed about new regulations, techniques, and quality requirements
- **Facilitating Regulatory Compliance:** Good Manufacturing Practices (GMP) ensure adherence to international regulatory standards, including those established by the World Health Organization (WHO), the U.S. Food and Drug Administration (FDA), and the European Medicines Agency (EMA). Compliance with these guidelines is essential for obtaining market

authorization and helps manufacturers avoid legal issues and financial penalties.

- **Enhancing Risk Management:** GMP places significant emphasis on proactive risk management, utilizing tools such as Hazard Analysis and Critical Control Points (HACCP), Failure Mode and Effects Analysis (FMEA), and other risk assessment methodologies. This approach allows potential hazards to be identified and mitigated early in the production process, thereby safeguarding product quality and patient safety.

GMP for Premises & Materials [12-14]

Fig 2: GMP Premises & materials

1) General Requirements

Pharmaceutical manufacturing facilities must be designed to support safe, efficient, and contamination-free operations. Buildings and premises should provide sufficient space for production, processing, packaging, warehousing, testing, and labeling, while allowing unhindered movement of personnel. The design must prevent mix-ups between different drugs, raw materials, intermediates, and finished products, and minimize the risk of contamination or cross-contamination. Structural features should prevent the entry of pests, rodents, and birds, and walls should be smooth, crack-free, and easy to clean and disinfect. Controlled environmental conditions, including proper air-conditioning, ventilation, lighting, and air-handling units, are essential to maintain appropriate temperature and humidity levels. Proper drainage systems should be in place, avoiding open channels, and routine cleaning and disinfection should be documented.

2) Water System

A reliable water treatment system is essential to provide purified water for all production processes except washing and cleaning. Water storage tanks must be cleaned regularly to prevent microbial growth, and records of cleaning and maintenance should be maintained.

3) Waste Disposal

Waste management must comply with the guidelines of the Environmental Pollution Control Board. Biomedical waste should be treated and destroyed according to Biomedical Waste Rules, 1996. Hazardous, flammable, or toxic materials must be stored safely, and records of storage and disposal should be maintained meticulously.

4) Warehouse Areas

Storage areas must be clean, dry, and maintained at controlled temperatures. The warehouse should remain free from pests and rodents and should be equipped with suitable bins and shelving. Walls and floors should be smooth and crack-free to prevent dust accumulation, and cleaning and painting activities should be documented. Narcotics, psychotropic substances, and other controlled drugs must be stored securely, while sterile materials should be handled and stored in aseptic areas. Regular inspections should ensure integrity of containers, and all activities must be recorded.

5) Ancillary Areas

Separate areas should be provided for personnel facilities, including restrooms, changing rooms, refreshment areas, and laundry facilities, which should not lead directly into production areas. Regular cleaning and disinfection must be documented.

6) Quality Control Areas

Quality control laboratories must be designed to prevent mix-ups and cross-contamination, with dedicated spaces for physicochemical, biological, and microbiological testing. Microbiology sections should include airlocks and laminar airflow systems, and routine cleaning must be documented.

7) Personnel

All manufacturing and testing operations must be conducted by qualified technical staff with appropriate training and experience. QA and QC personnel should have clearly defined roles and responsibilities, and staffing levels should correspond to workload requirements.

8) Sanitation and Health
All personnel must undergo medical examinations and be free from communicable diseases, skin infections, tuberculosis, or other conditions that may compromise product quality. Special considerations must be made for staff handling potent drugs, beta-lactam antibiotics, cytotoxic substances, or sex hormones, with periodic health checks and rotation of duties. Personnel should be trained in personal hygiene and prohibited from smoking, eating, or drinking in production, storage, and laboratory areas. Health monitoring and records must be maintained systematically.

9) Materials, Equipment, and Packaging
Raw materials must be procured from approved suppliers and labeled appropriately upon receipt, distinguishing quarantine, released, and rejected materials. Equipment should be constructed from smooth, non-reactive, and easily cleanable materials to prevent contamination. Packaging materials in direct contact with products must meet high-quality standards.

10) Validation
Validation is a critical component of GMP, ensuring that processes, equipment, and systems operate consistently and produce products meeting predetermined quality standards. Validation protocols, results, and conclusions must be thoroughly documented, and periodic revalidation should be conducted to confirm continued compliance.

11) Self-Inspection and Quality Audits
Management should establish expert teams to perform regular self-inspections and quality audits of production and QC areas. These evaluations identify gaps in GMP compliance, with documented corrective actions. Standard operating procedures (SOPs) should cover all aspects, including premises, personnel, storage, documentation, quality control, sanitation, complaints, validation, and product recall procedures.

12) Complaints and Product Recalls
All product quality complaints must be carefully reviewed, documented, and addressed. Serious adverse events should be reported to relevant authorities. SOPs should be in place for systematic product recalls, ensuring timely corrective actions.

13) Documentation
Comprehensive documentation is a cornerstone of GMP and QA, ensuring traceability and regulatory compliance. Key documents include:

- **Standard Operating Procedures (SOPs):** Step-by-step instructions for processes and procedures.
- **Test Methods:** Detailed instructions for product and material testing.
- **Policies:** Guidelines for GMP compliance.
- **Site Master File:** Complete information about the manufacturing site.
- **Quality Handbook:** Rules and regulations for internal compliance.
- **Batch Records:** Detailed records of production steps, in-process controls, deviations, and material usage.
- Prior to processing each batch, equipment and workstations must be cleaned and verified as suitable for use. All relevant information including product name, batch number, operator details, dates and times, equipment used, materials, yields, in-process control results, and deviations must be recorded accurately by designated personnel.

Importance of GMP [15-17]
The significance of Good Manufacturing Practices (GMP) stems from their role in guaranteeing that pharmaceutical, food, and cosmetic products are manufactured consistently, meeting stringent standards of quality, safety, and effectiveness. GMP protects consumers by reducing risks such as contamination, mix-ups, incorrect labeling, equipment failures, and human errors, which can lead to serious health consequences. By enforcing strict control over raw materials, equipment calibration, facility hygiene, validated processes, trained personnel, and documented procedures, GMP ensures that the quality product. GMP also builds organizational discipline, strengthens regulatory compliance, and enhances global acceptance of products by meeting international standards. Importantly, GMP helps companies avoid costly recalls, legal penalties, product failures, and reputation damage.
GMP extends beyond routine compliance, as GMP functions as a strategic quality system that strengthens the entire lifecycle of a product. One unique aspect of GMP is that it transforms manufacturing into a predictable, knowledge-driven process that prevents failure before it occurs. By integrating scientific understanding with controlled operations, GMP creates a manufacturing environment where every outcome can be traced back to a documented cause, enabling rapid root-cause analysis and continuous learning. GMP also plays a crucial role in protecting supply chain integrity by ensuring that materials, processes, and environments remain consistent regardless of geographic location or batch size. This harmonization builds global trust in a manufacturer's capability to deliver safe and reliable products. Moreover, GMP's emphasis on data integrity prevents manipulation or loss of information, ensuring that decisions are made on accurate, trustworthy evidence. Ultimately, the importance of GMP lies in its ability to transform quality from a final inspection activity into a proactive culture embedded in every step of production.
GMP establishes a systematic framework that controls every stage of production, reducing risks such as contamination, equipment malfunction, mix-ups, and human error. By enforcing strict standards for raw materials, facility hygiene, documentation, validation, and personnel training, GMP ensures that each batch of product meets predetermined specifications. Moreover, GMP minimizes costly recalls, legal consequences, and product failures, thereby safeguarding a company's reputation and ensuring long-term business sustainability. Ultimately, GMP transforms manufacturing into a controlled, transparent, and quality-driven process that continually enhances safety and operational excellence.

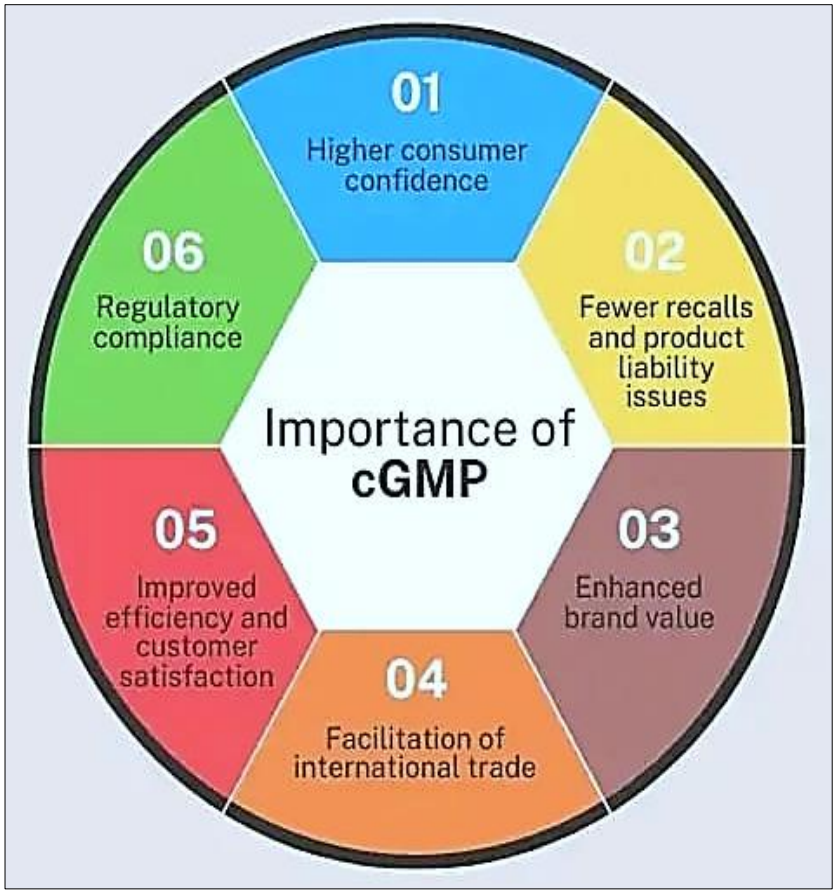

Fig 3: Importance of GMP

GMP also strengthens supply chain reliability by setting strict standards for vendor qualification, material traceability, and storage conditions, preventing substandard or counterfeit ingredients from entering manufacturing processes. Furthermore, GMP supports data integrity, requiring complete, accurate, and secure records that allow rapid identification of deviations and corrective actions. This transparency enhances regulatory confidence and enables smoother audits and international product approvals. In the broader sense, GMP is essential because it integrates scientific understanding with operational discipline, fostering a culture where continuous improvement and risk prevention become routine parts of manufacturing excellence.

Application of GMP [18]

1) Pharmaceutical Industry

- **Drug Manufacturing:** All the pharmaceuticals drugs, including prescription drugs, over the under drugs
- Biologic, and various are formulated using this process to ensure that the products are manufactured control conditions. This includes control over raw materials, manufacturing, packaging and Labelling practice in order to guarantee safety, purity, and potency
- **Active Pharmaceutical Ingredients (APIs):** GMP wed in the manufacture of APIs so as to meet exacting quality standards before taking place in the formulation of the final product
- **Clinical trials supplies:** Maintains stringent control over manufacturing, packaging, and distribution processes while ensuring the quality of the investigational drugs provided to clients during clinical trials.

2) Food and Beverage Industry

- **Food Processing and Manufacturing:** GMP guidelines ensure food is produced in a clean environment thereby not allowing contamination, promoting safety and quality in the supply of food. CMP compasses Personal hygiene, sanitation, equipment maintenance, and raw material handling
- **Packaging and Storage:** GMP is used to ensure food packaging materials do not contaminate the product, in clean storage conditions, and protect food from physical, chemical, or microbial hazards
- **HACCP (Hazard Analysis and Critical Control Points):** GMP is incorporated into HACCP programs to control specific food safety hazards and drive out regulatory compliance.

3) Medical Device Industry

- **Device Manufacturing:** GMP ensures that all types of medical devices, such as simple tools and others being complicated machinery, are manufactured according to the appropriate quality standards. This ranges from ensuring proper control over the design, manufacture, testing, packaging, and distribution of medical devices
- **Sterility Assurance:** The controls and validation of sterility processes are required strictly under GMP requirements to check contamination of sterile devices and prevent these from coming in direct contact with patients.
- **Traceability and Documentation:** GMP calls for thorough documentation and record-keeping to trace all medical devices from point of manufacture to the end user in order to enable recall where necessary.

4) Cosmetics and Personal Care Products

- **Manufacturing and Packaging:** GMP for Cosmetics develops the need to manufacture cosmetics in a place that eliminates contamination and mix-ups. This aspect concerns raw materials, production processes, equipment, and packaging materials.
- **Safety and Stability Testing:** The proper & effective testing must necessary for safety.
- **Labelling Compliance:** GMP needs accurate and compliant labelling of cosmetics to provide users with necessary information, such as ingredients, usage instructions, and safety warnings.

Conclusion

GMP represents a systematic approach to production and testing that guarantees high-quality, safe, and effective products. Compliance with GMP is mandated by law in numerous countries, with each nation defining regulations consistent with its legal system. GMP ensures quality and safety of a product from a wide number of industries, including but not limited to pharmaceuticals, food and beverages, medical devices, cosmetics, and biotechnology. GMP sets higher standards in manufacturing process, training of employees, facilities management, and documentation handling which are all liable to cause contamination, errors or defects resulting in risks to consumer health and safety. The GMP application maintains a good level of quality in the product, fulfils all the rules and regulations concerning the product, creates trust among the consumer, offers minimal waste and cost, and is available in the global market. However, challenges in implementing GMP include high costs, complexities, continuous updates to fulfil the changing standard requirements, and dealing with the error issue created by humans. Nevertheless, trends such as digital transformation, continuous manufacturing, risk management, and regulatory harmonization will determine what the future of GMP holds.

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