

# **A Comprehensive Guide to GMP: Good Manufacturing Practices**

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# **A Comprehensive Guide to GMP: Good Manufacturing Practices**



## **What are Good Manufacturing Practices?**

Good Manufacturing Practices or GMP is a system that consists of processes, procedures and documentation that ensures manufacturing products, such as food, cosmetics, and pharmaceutical goods, are consistently produced and controlled according to set quality standards. Implementing GMP can help cut down on losses and waste, avoid recall, seizure, fines and jail time. Overall, it protects both company and consumer from negative food safety events.

GMPs examine and cover every aspect of the manufacturing process to guard against any risks that can be catastrophic for products, such as cross-contamination, adulteration, and mislabeling. Some areas that can influence the safety and quality of products that GMP guideline and regulation address are the following :

- Quality management
- Sanitation and hygiene
- Building and facilities
- Equipment
- Raw materials
- Personnel
- Validation and qualification
- Complaints
- Documentation and recordkeeping
- Inspections & quality audits

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## What are the 5 Main Components of Good Manufacturing Practice?

It is paramount to the manufacturing industry to regulate GMP in the workplace to ensure consistent quality and safety of products. Focusing on the following 5 P's of GMP helps comply with strict standards throughout the entire production process.



### People

Comprehend roles and responsibility



### Products

Clear specifications at every phase of production



### Processes

Properly documented, simple, and consistent



### Procedures

Guidelines for undertaking critical processes



### Premises

Cleanliness and equipment calibration at all times

1. **People** - All employees are expected to strictly adhere to manufacturing processes and regulations. A current GMP training must be undertaken by all employees to fully understand their roles and responsibilities. Assessing their performance helps boost their productivity, efficiency, and competency.
2. **Products** - All products must undergo constant testing, comparison, and quality assurance before distributing to consumers. Manufacturers should ensure that primary materials including raw products and other components have clear specifications at every phase of production. The standard method must be observed for packing, testing, and allocating sample products.
3. **Processes** - Processes should be properly documented, clear, consistent, and distributed to all employees. Regular evaluation should be conducted to ensure all employees are complying with the current processes and are meeting the required standards of the organization.
4. **Procedures** - A procedure is a set of guidelines for undertaking a critical process or part of a process to achieve a consistent result. It must be laid out to all employees and followed consistently. Any deviation from the standard procedure should be reported immediately and investigated.
5. **Premises** - Premises should promote cleanliness at all times to avoid cross-contamination, accidents, or even fatalities. All equipment should be placed or stored properly and calibrated regularly to ensure they are fit for the purpose of producing consistent results to prevent the risk of equipment failure.

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## 10 Principles of GMP

The basic principles of good manufacturing practices help ensure product quality is consistent and safe to use. Incorporating these will determine the scope and standards needed to pass GMP Auditing. The 10 principles of GMP are the following:

- **Create** Standard Operating Procedures (SOP) for processes and design specifications for facilities and equipment
- **Follow** the SOP and specifications
- **Validate** the SOP and specifications
- **Document** everything
- **Monitor** the facilities and equipment
- **Employ** competent and qualified personnel
- **Protect** products against contamination
- **Control** components and processes that are related to the product
- **Ensure** quality in operations, manufacturing, logistics, and distribution
- **Perform** periodic audits with certified auditors

## Regulations of GMP

GMP regulations are mandated by manufacturers' respective national government to regulate the production, verification, and validation of manufactured products and ensure that they are effective and safe for market distribution.

For example, in the United States, GMP is enforced by the US FDA through Current Good Manufacturing Practices (CGMP) which cover a broader range of industries such as cosmetics, food, [medical devices](#), and prescription drugs. The FDA conducts facility inspections to assess if a manufacturing company complies with CGMP regulations. If any serious violations are found during the inspection, FDA recalls all products, which is problematic for manufacturers in terms of both profit and business operations.

The quality of manufactured products is highly regulated as it can pose negative health risks to consumers and even the environment. Poor hygiene, temperature-control, cross-contamination, and adulteration in any step of the manufacturing process are some examples of how a manufactured product that doesn't follow GMP regulations can bring fatal consequences to consumers. [See GMP regulation and preamble sources by country here.](#)

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## Standards of GMP

GMP standards are developed to enhance the safety of manufactured products, especially pharmaceutical goods, and to ensure consumers get the highest quality possible. Adherence to GMP standards not only positively impacts the reputation of manufacturing companies but also reduces batch recalls and negative reports from consumers. Below are 4 measures you can follow to uphold GMP standards:

1. **Quality team** - Have a team of skilled workers that will focus on improving current manufacturing procedures and complying with GMP. Members will perform quality assessments on operations to identify problems and develop appropriate corrective measures. Part of the team's responsibility will also be performing scheduled monitoring of instruments, equipment, processes, and staff skills.
2. **Validation** - Validation is the documented act of demonstrating instruments, processes, and activities that are regularly used or done. This is done to check if they function according to expectations. GMP can involve a number of things to be validated, but it's good to focus on the following processes:
  - Process validation
  - Cleaning and sanitation validation
  - Computer system validation
  - Analytical method validation
3. **Surprise Audits** - A surprise audit every now and then can help gain a more accurate insight into what goes on in the facility. Identify real root causes of non-compliance and take action before it progresses into a larger issue. [Read more about best practices in doing GMP audits.](#)
4. **Compliance Training** - Providing compliance training to staff is the best way to ensure compliance with GMP standards. Help staff gain a better understanding of GMP and continually improve operations or systems in place to ensure standards are GMP-compliant. All employees should receive training on recordkeeping, sanitation, proper equipment handling, and labeling, and SOPs to minimize errors and maintain compliance.

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## GMP Guidelines and Basic Concepts

GMP guidelines are a set of principles that help manufacturers implement an effective manufacturing process and ensure that quality is built into the organization and the processes involved. GMP guidelines are customarily flexible, with countries having their own legislation to comply with local GMP guidelines and principles. But almost all regulations are derived from the basic concept and guidelines which are:

### Quality management

The principle of quality management is to ensure that manufactured products are fit for their intended use, comply with requirements and does not place consumers at risk due to inadequate safety, quality, or efficacy measures. To achieve this quality objective, quality assurance, good manufacturing practices, quality control, and quality risk management should be comprehensively and correctly implemented.

**Quality Assurance** - The system of quality assurance aims to ensure that manufactured products are designed and developed in a way that meets the requirements for Good Manufacturing Practice.

**Good Manufacturing Practice for Products** - As a part of quality assurance, good manufacturing practice is concerned with production and quality control. It aims to mitigate the risks that are inherent in the production process. Its basic requirements according to WHO's Good Manufacturing Practices for Pharmaceuticals can be found [here](#)

**Quality Control** - [Quality control](#) is a part of Good Manufacturing Practice that focuses on sampling, specification, and testing. It checks the organization, documentation, and release procedures to ensure that products go through the required tests before being released for sale or supply.

**Quality Risk Management** - Quality risk management is a systematic process of assessing risks that can affect the quality of the product. According to its principles, quality risk management should ensure that:

- The evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the patient and users;
- The level of effort, formality, and documentation of the quality risk management process is commensurate with the level of risk. c) The general quality risk management process and integration into the product quality can be referred to in ICHQ9.

### Sanitation and hygiene

Sanitation and hygiene are vital in every aspect of the manufacturing process. It covers anything that can cause contamination such as personnel, the premises, equipment, containers, and production materials. All potential sources of contamination should be identified and eliminated with a comprehensive sanitation and hygiene program.

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## Building and facilities/premise

As a principle, the premises should be situated in an environment that is suitable for its operations and one that is free from risks of contamination of materials and products. The premises should also be designed to minimize errors in operations and should be easy to clean and maintain.

## Equipment

Same with the premises, equipment should be designed, located, and maintained to function according to its intended use. Additionally, it should be cleaned and stored according to procedures. In the event of a defect or malfunction, it should be removed or labeled as defective.

## Raw materials

All materials used for production should be stored properly according to the appropriate conditions which are set by the manufacturers. There should be a proper stock management system implemented to ensure that all incoming materials are correct and of high quality.

## Personnel

The success of GMP compliance heavily relies on the people implementing it. For this reason, it is vital that all personnel are qualified and trained to do the job. They should be aware of the principles of GMP and receive continued training, hygiene instructions, and other tools relevant to their needs. Respective managers should be clear on job descriptions for each worker to avoid misunderstandings and reduce the risk of issues like overlapping responsibilities.

## Validation and qualification

Qualify systems, premises, and equipment if they are fit/ready for their intended use and validate if processes and procedures can repeatedly produce high-quality products. Critical steps in the manufacturing process should be verified to ensure that product quality is consistent and maintained at a high level.

## Complaints

Handling complaints is also part of GMP, therefore all manufacturing companies should have a well-designed GMP complaint system. Ideal complaint handling should have a ready solution to provide for all contingencies.

## Documentation and recordkeeping

Good documentation and record keeping are an essential part of the quality assurance system and are required in compliance with GMP requirements. Accurate recordkeeping can help managers and supervisors keep track of the historical record of manufacturing procedures and corrective measures implemented.

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## FAQs About GMP

### **What is the Difference Between GMP and cGMP?**

Good Manufacturing Practices (GMP) and current Good Manufacturing Practices (cGMP) are, in most cases, interchangeable. GMP is the basic regulation promulgated by the US Food and Drug Administration (FDA) under the authority of the [Federal Food, Drug, and Cosmetic Act](#) to ensure that manufacturers are taking proactive steps to guarantee their products are safe and effective.

cGMP, on the other hand, was implemented by the FDA to ensure continuous improvement in the approach of manufacturers to product quality. It implies a constant commitment to the highest available [quality standards](#) through the use of up-to-date systems and technologies.

### **Who is Responsible for GMP Compliance?**

The ones primarily responsible for GMP compliance are those in the quality team, this includes executives such as chiefs of quality control, directors of quality, and facilities managers, or those directly involved in quality-specific jobs such as quality control inspectors and quality assurance managers. They are in charge of ensuring that standards, requirements, and protocols are followed.

GMP audits are accomplished by certified auditors and regulated by agencies such as Food and Drug Administration (FDA), however, facilities are encouraged to do their own audits.

### **What is a GMP Audit?**

A GMP audit is a third-party audit conducted to assess if an organization is compliant with regulations and industry standards on acceptable good manufacturing practices. It helps identify areas for improvement on GMP compliance and also provides guidance on how to become compliant.



# GMP Compliance and Your Organization



GMP compliance is crucial in the manufacturing industry. Providing quality-assured products can secure the health and safety of the public.

Robust processes and easy-to-use systems that enforce and monitor standards can strengthen GMP compliance in your organization. With technological advances in the industry, food manufacturers have more opportunities to transform reactive company culture, into a proactive, predictive workforce equipped for continuous improvement.

**Utilize digital tools such as [iAuditor by SafetyCulture](#), a mobile inspection app, and sensors to move your GMP beyond compliance. With iAuditor you can:**

- create, customize, and use mobile-ready GMP audit checklists anytime, anywhere;
- attach photos and make annotations within the app;
- set and notify scheduled GMP audits;
- [integrate](#) existing software systems; and
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