

# WHITE PAPER

## GMP

Good Manufacturing Practices

Smart way of manufacturing goods.



**Global**  
Standards

*Success through management excellence*

# Adverse Drug Reactions



Good Manufacturing Practice (GMP) is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any food and pharmaceutical production that cannot be eliminated through testing the final product.

**GMP covers all aspects of production from the starting materials, premises, and equipment to the training and personal hygiene of staff. Detailed, written procedures are essential for each process that could affect the quality of the finished product. There must be systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process - every time a product is made.**

GMP refers to the Good Manufacturing Practice Regulations promulgated by the US Food and Drug Administration under the authority of the Federal Food, Drug, and Cosmetic Act (See Chapter IV for food, and Chapter V, Subchapters A, B, C, D, and E for drugs and devices.) These regulations, which have the force of law, require that manufacturers, processors, and packagers of drugs, medical devices, some food, and blood take proactive steps to ensure that their products are safe, pure, and effective. GMP regulations require a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mixups, and errors. This in turn, protects the consumer from purchasing a product which is not effective or even dangerous. Failure of firms to comply with GMP regulations can result in very serious consequences including recall, seizure, fines, and jail time.

GMP regulations address issues including record keeping, personnel qualifications, sanitation, cleanliness, equipment verification, process validation, and complaint handling. Most GMP requirements are very general and open-ended, allowing each manufacturer to decide individually how to best implement the necessary controls. This provides much flexibility, but also requires that the manufacturer interpret the requirements in a manner which makes sense for each individual business.

GMP is also sometimes referred to as "cGMP". The "c" stands for "current," reminding manufacturers that they must employ technologies and systems which are up-to-date in order to comply with the regulation. Systems and equipment used to prevent contamination, mixups, and errors, which may have been "top-of-the-line" 20 years ago, may be less than adequate by today's standards.

#### **GMP Covers and Requires:**

- **Record Keeping**
- **Personnel Qualifications**
- **Equipment Verifications**
- **Sanitation**
- **Cleanliness**
- **Process Validation**
- **Complaint Handling**


## BENEFITS OF GMP


- Manufacturing facility must maintain a clean and hygienic manufacturing area.
- Controlled environmental conditions in order to prevent cross contamination of food or drug product from adulterants that may render the product unsafe for human consumption.
- Manufacturing processes are clearly defined and controlled. All critical processes are validated to ensure consistency and compliance with specifications.
- Manufacturing processes are controlled, and any changes to the process are evaluated. Changes that have an impact on the quality of the drug are validated as necessary.
- Instructions and procedures are written in clear and unambiguous.
- Operators are trained to carry out and document procedures.
- Records are made, manually or by instruments, during manufacture that demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the food or drug was as expected. Deviations are investigated and documented.
- Records of manufacture (including distribution) that enable the complete history of a batch to be traced are retained in a comprehensible and accessible form.
- The distribution of the food or drugs minimizes any risk to their quality.
- A system is available for recalling any batch from sale or supply.
- Complaints about marketed products are examined, the causes of quality defects are investigated and appropriate measures are taken with respect to the defective products and to prevent recurrence.



[info@globalstandards.com.pk](mailto:info@globalstandards.com.pk) | [www.globalstandards.com.pk](http://www.globalstandards.com.pk)

+92-21-32434937 | +92-333-7913076 | +92-306-2708496 | +92-332-3246990

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