# Good Distribution Practices for Pharmaceutical Products

## Introduction -

The pharma supply chain is getting complex day-in and day-out. Manufacturers are under pressure to place safe, quality and cost-effective drugs over the counter before their competitors. All this is to be done following regulations and best practices. The ultimate focus these days of all the companies is to maintain the quality of their pharma products throughout the entire supply chain including storing, handling of products and distribution too. Thus, to serve this purpose of maintaining the quality and identity, certain guidelines are formulated. In other terms, these are the practices that pharma companies should follow to meet specific safety and quality standards. Through this e-Book, we aim to touch the guidelines or say the Good Distribution Practices that each Pharma manufacturer must follow along their distribution cycle:

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## Here are some Good Distribution Practises that will help you in distributing your drugs effectively-

### Personnel

- All personnel involved should be trained according to their job tasks
- Key members should have enough experience to manage the drugs properly
- There should be competent personnel at every distribution stage to ensure product quality
- National regulations with qualifications and experience of personnel should be followed
- Dealing with hazardous pharmaceutical products such as hazardous chemical, risky fire
- Personnel hygiene should be maintained
- First-aid procedures and equipment for dealing with emergencies should be available
- Procedures designed should minimize the possibility of unauthorized possession
- Codes of disciplinary procedures in the distribution process should be implemented

## Quality management

- Proper documentation of quality policy in relevance to govt regulations should be made.
- They should cover the principles of quality assurance, embodied in the WHO guidelines.
- There should be a place to ensure traceability and quality of pharmaceutical products.
- Authorized procurement and release procedures should be in place.
- All entities in pharma supply chain should fall under national policies and legislation.
- Authorized SOPs for all administrative and technical operations performed should be stored at one place.
- Inspection and certification of compliance by external bodies is recommended.

## Containers and container labelling

- All drugs stored, should not have an adverse effect on the quality of the products.
- They should offer protection from external influences and microbial contamination.
- Labels should be clear, unambiguous, permanently fixed to the container and be indelible.
- Information on the label should comply with applicable national legislation.
- The labelling language should be easy to understand.
- Special transport and storage conditions should be stated on the label.
- Shipping containers should provide sufficient information on handling and storage conditions.
- Special care should be taken for using dry ice in containers.
- Written procedures should be available for the handling of damaged or broken containers.

## Dispatch

- Written proof for dispatch of products to person or entities.
- The supplier should be aware of the storage and transport conditions.
- The dispatch should be after a valid delivery order receipt or material replenishment plan.
- Records of dispatch should have all necessary details written in it.
- Delivery schedules and route planning should be planned on prior basis.
- Vehicles and containers should be loaded carefully.
- Pharma products should not be supplied or received after their expiry date.

## Transportation and  Products in Transit

- The manufacturer should communicate all relevant conditions for storage & transportation.
- General international requirements regarding safety, health and environmental, temperature should be observed.
- The process should not have a negative effect on quality of pharma products.
- Written procedures should be in place to investigate and deal with any violations.
- Products that are highly active or other dangerous drugs should be transported in safe containers and vehicles.
- Spillages should be clean as early as possible.
- Damage to containers during transit must be recorded and reported.

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