- **Good laboratory practices**

  - Good Laboratory Practice is defined in the OECD Principles as "a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported." The purpose of the Principles of Good Laboratory Practice is to promote the development of quality test data and provide a tool to ensure a sound approach to the management of laboratory studies, including conduct, reporting and archiving.

  - The Principles may be considered as a set of standards for ensuring the quality, reliability and integrity of studies, the reporting of verifiable conclusions and the traceability of data. The Principles require institutions to assign roles and responsibilities to staff in order to ensure good operational management of each study and to focus on those aspects of study execution (planning, monitoring, recording, reporting, archiving) that are of special importance for the reconstruction of the whole study. Since all these aspects are of equal importance for compliance with GLP Principles, it is not permissible to partially implement GLP requirements and still claim GLP compliance. No test facility may rightfully claim GLP compliance if it has not implemented, and does not comply with, the full array of the GLP rules.

- **Good distribution practices**

  - Distribution is an important activity in the integrated supply-chain management of pharmaceutical products. Various people and entities are generally responsible for the handling, storage and distribution of such products. In some cases, however, a person or entity is only involved in and responsible for certain elements of the distribution process. The objective of these guidelines is to assist in ensuring the quality and identity of pharmaceutical products during all aspects of the distribution process. These aspects include, but are not limited to, procurement, purchasing, storage, distribution, transportation, repackaging, relabelling, documentation and record-keeping practices.

- **Good storage practices**

  - This guide is intended for those involved in the storage, transportation and distribution of pharmaceuticals. It is closely linked to other existing guides recommended by the WHO Expert Committee on Specifications for Pharmaceutical Preparations, such as:
    - Good trade and distribution practice (GTDP) of pharmaceutical starting materials;
    - • The stability testing of pharmaceutical products containing well-established drug substances in conventional dosage forms (information given in connection with regulation for marketing authorization);
    - Good manufacturing practices (GMP);

- The cold chain, especially for vaccines and biologicals;
- The International Pharmacopoeia.

The objective of this guide is to supplement the above-mentioned documents by describing the special measures considered appropriate for the storage and transportation of pharmaceuticals. However, they may be adapted to meet individual needs where necessary, provided that the desired standards of quality are still achieved.

- **Good manufacturing practices**

  - 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 pharmaceutical production that cannot be eliminated through testing the final product. The main risks are: unexpected contamination of products, causing damage to health or even death; incorrect labels on containers, which could mean that patients receive the wrong medicine; insufficient or too much active ingredient, resulting in ineffective treatment or adverse effects. 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.