Chapter 3

1. Documentation

The written documentation should have these basic requirements:

- **It should be understandable and complete; all the activities carried out should be approved, signed and dated by the responsible person**
- **Any alterations should be signed and dated by the responsible person and they should be in compliance with the quality management**
- **All employees should have easy access to the necessary documentation for their task**

  Lastly, all documents about the transport and storage of pharmaceutical products, should be retained, at least, for five years.

2. Operations

All the activities performed by the logistic provider should ensure that the quality of the pharmaceutical product is preserved and that the transportation is carried out according to the written information on the package and on the documentation.

A subcontracting to third company is possible only after a qualification of that company.

The basic rules of the storage, also called cross docking

- **Medical products should be stored separately from other products that may alter them**

- **Medical products should be stored in regularly cleaned areas and should be protected from the access of unauthorized people**
- **Medical products should be protected from the harmful effects caused by light, temperature, damp and other external factors**
- **Storage and handling activities should avoid spillage, breakage and contaminations**
- **Medical products in destruction should be handle according to the national regulation by following written procedures**
- **Medicines which are dangerous or under quarantine should be clearly marked and should be held separately from the others medical products**

3. Complaints

Complaints must be managed according to an established procedure. They must follow the logic of **Non-Compliance and CAPA**; finally, they must be recorded.

It's also necessary to appoint a responsible person to handle complaints; this person will have at its disposal a sufficient number of trained personnel. Complaints will be documented and periodically verified; lastly, they will be discussed in the management review.