Chapter 1

1. Quality management

In order to be GDP compliant, the quality system of a logistic company must define **responsibilities, processes and risk management's measures**. In addition, it has to be monitored and documented during any process. These supervisions are also extended to **the activities of procurement, holding and exportation** of medicinal products.

The quality system should ensure that:

- **Medical products are stored and managed in compliance with GDP requirements**
- **Products are delivered to the consignee according to the timetable**
- **Management responsibilities are clearly defined, that is: the shipper has the task of packing and protecting the medical products, according to the shipping method; the logistic provider is responsible for transporting the medical products according to the shipper's instructions.**
- **Records are made at the same time as the operations**
- **Any deviation from the established procedures is documented**
- **Corrective and preventive actions are adopted**

Following the GDP rules is fundamental in order to protect medicinal products from temperature's changes, caused by the different weather conditions while they are travelling around the world. The missed conservation of a stable temperature will cause visible and invisible alterations to the medical product.

The **visible alterations** are:

- **Contamination**
- **Crystallization**
- **Freezing**
- **Denaturing**
- **Bacterial growth**
- **Deterioration of the packaging**

The **invisible alterations** are:

- **Ineffectiveness**
- **Infection and patient safety**
- **Cost of the product withdrawal**
- **Loss of sales**
- **Brand damage**
- **Regulatory implications**

2. Quality risk management

In the management of pharmaceutical products each activity has to be analyzed on the basis of risks, to identify the critical points of the system and undertake the migratory actions. The risk analysis can be realized in different ways; it is a systematic process that serves to evaluate and monitor the potential risks associated with the integrity of the medical product. It has to be applied both proactively and ex post.