

Chapter 5

I. Qualification of suppliers and outsourced activities

An outsourced activity is an activity which is given to third parties. It must be clearly defined and agreed through SLA – Service Level Agreement - **or a written contract**, in order to avoid any misunderstanding that could affect the integrity of the product.

The qualification of the suppliers is a basic requirement in this kind of activity. Critical suppliers – those that can potentially **affect** the quality of the product – must be qualified and periodically checked through the risk analysis .

The logistic provider shall only use qualified suppliers, according to the GDP criteria. The qualification of suppliers:

- **Should be performed before any transport activity and cross-docking**
- **(and it) should be monitored according to a defined procedure**

Finally, the results should be documented, periodically rechecked and discussed in the management review.

The responsibilities of the contract giver are:

- **The assessment of the contract acceptor's competence through audit**
- **(and) providing all the necessary information to carry out the contracted operations**

The responsibilities of the contract acceptor are:

- **To have proper premises and equipment, adequate procedures and knowledge and competent personnel**

- **Do not let the subcontracting of activities without prior approval of the contract giver**
- **(and) to forward important information that can influence the quality of the product**

2. Self-inspections

Self-inspections have the scope to monitor the implementation of all the appropriate procedures, according to the **GDP** and **CEIV** principles; they also have to propose necessary corrective actions. There should be implemented a self-inspection program in compliance with the guidelines and procedures. It's also important to know that audits conducted by outside experts or consultants do not replace the self-inspections.

Self-inspections should be recorded and carried-out by competent personnel. Any irregularity will require the implementation of a **CAPA procedure – Corrective Action Preventive Action.**