

Quality Control Policy GMP and GDP

As well as being a Pharmaceutical Logistics Operator, Logista Pharma is authorised by AEMPS, (the Spanish agency for medicine and healthcare products), as a laboratory for the repackaging and re-labelling of medicines.

Logista Pharma, in accordance with Law 29/2006 (26th of July) for the guarantee and reasonable use of medicines and healthcare products, and that which is set out in the GxP regulations, has a Quality Guarantee System common to all facilities. This Quality Control System involves the whole organisation and forms the basis for our activity.

Operations carried out in the facilities guarantee the quality, effectiveness and security of the product at all times throughout the supply chain until reaching the patient. In order to achieve this:

- Approved, standardised working practices and procedures are set out and distributed, in a controlled manner, to the personnel concerned.
- Relevant and continued training of all personnel in order to guarantee their correct preparation and skills.
- All equipment, operations, facilities and IT systems connected with medicine quality are calibrated and validated: scales, probes, warehouse management systems, climate control systems, temperature monitoring systems, ...
- In order to guarantee validity, a change management system has been successfully implemented at corporate level for any change carried out in the facilities, equipment, IT applications and documentation.
- A risk identification, evaluation and analysis system is in place for the activities, systems and equipment used by LPH, allowing us to have a continuous improvement process and to identify critical points on which to focus our validation and verification processes.
- Our facilities have temperature control and humidity monitoring, with data recorded and checked daily.
 - Early warning and alarm systems that notify the personnel responsible of any important variation in temperature.
 - 24/7 maintenance contract for the climate control systems
 - Contingency Plan: electricity supply and calibrated, wireless probes.
- IT management systems which control aspects such as:
 - Stock levels
 - Analysis of stock status (quarantine, pre-expiry date, out of date, rejected, ...)
 - Storage of products based on their nature and/or status:
 - Thermolabiles, hazardous goods, cytotoxic, psychotropic, ...
 - Return, destruction, product sample area, ...
 - Track and trace for movements and users for all operations
 - Sales order management: Using the FEFO (First Expiry First Out) system and guaranteeing traceability from batch to end client. Product withdrawal support
 - Communication with the laboratories about all operations

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- Daily back up of the management system database□
- The repackaging and re-labelling process is carried out in compliance with GMP□
- Internal audits and inspections are carried out annually in order to detect problems, abnormalities □ and opportunities for improvement.□
- A system for the management of suppliers is in place, in which minimum requirements which □ must be met with are established.□
- Identification, recording and follow up of incidents and claims.□
- Recording and evaluation of Quality levels as defined in the KPI's (Key Performance Indexes)

This Quality Control system is headed by a corporate quality control unit, with qualified personnel in every facility, guaranteeing a high level of quality and service in all operations. Logista Pharma works hard on a daily basis in the search for solutions and opportunities for improvement, responding to the trends and demands of the sector.