



Logista

PHARMA

PARTIAL MANUFACTURING
AND SECONDARY CONDITIONING
SERVICE

In addition to certifications for the storage and distribution of pharmaceutical products and good distribution practices (GDP) certification, Logista Pharma is authorised as a **Partial Manufacturer of Medicines and Secondary Conditioning**, by the **Spanish Agency of Medicines and Medical Devices (AEMPS)**.

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This authorisation allows Logista Pharma to offer its customers services that require activities entailing the **handling of the secondary packaging** of a medicine, such as labelling, shrink-wrapping, the assembly of displays, packaging, package inserts, etc. Here are some examples:



- Assembly of displays
- Safety-seal coupons
- National code labels
- Change of package inserts
- Shrink-wrapping/Packs

Logista Pharma has over **18 years of experience** in performing such activities, guaranteeing the **100% effectiveness** of the process.

To maintain this level of success, Logista Pharma has suitable facilities that follow strict procedures based on **compliance with European GMP regulations.**

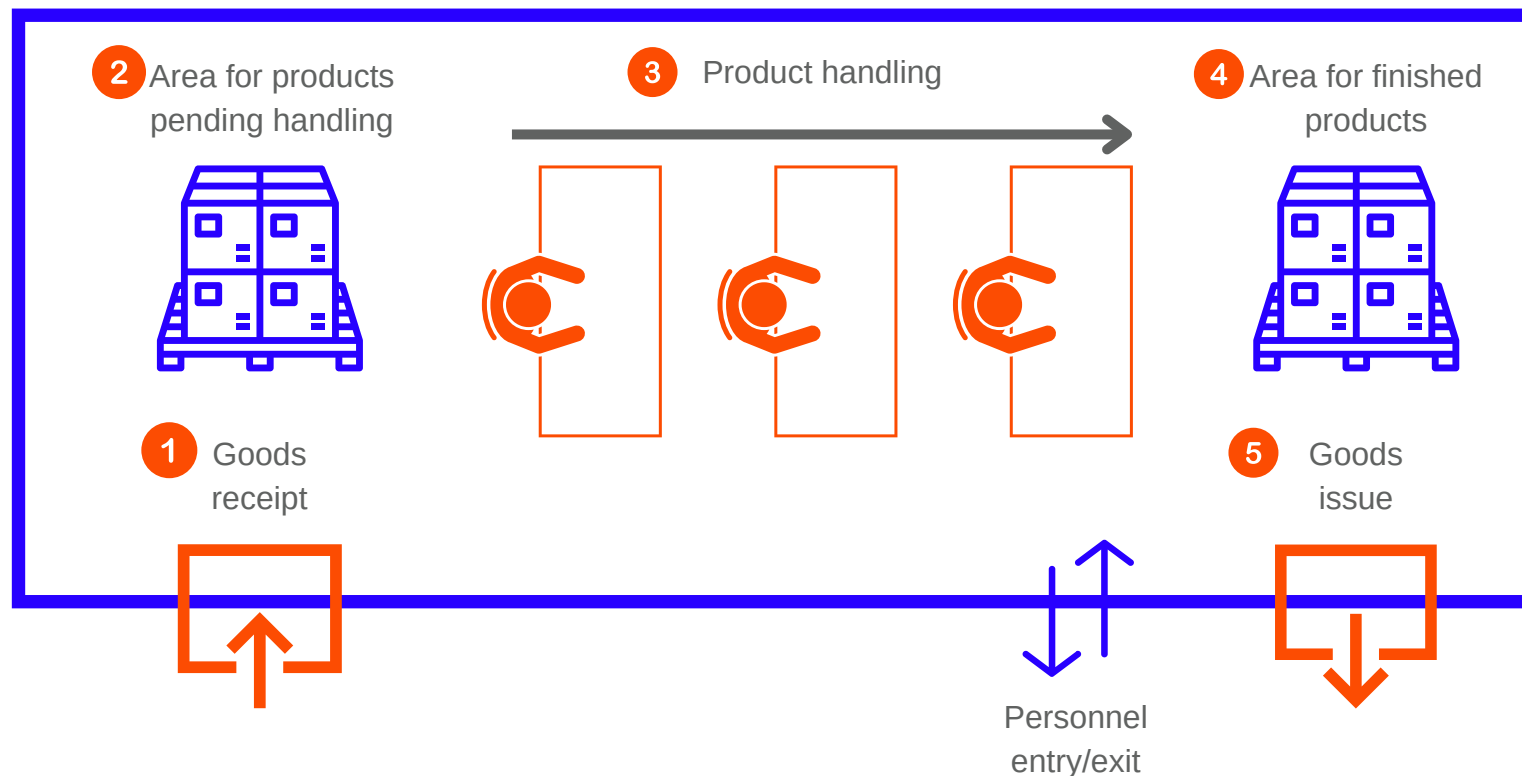




At our Leganés facilities, we have a 150 m² **clean room**, and 210 m² at Piera warehouse, at a controlled temperature of between 15 °C and 25 °C, equipped with Closed-Circuit Television (CCTV) cameras. In addition to the clean room at the Leganés centre, we have partial manufacturing and handling rooms at our centres in Piera (Barcelona) and Dos Barrios (Toledo). More than 600 m² dedicated to handling management.

When performing handling or partial manufacturing tasks, the main goal is to **avoid cross-contamination**. Only one item/batch is handled at a time in the clean room, thus creating a single batch.

To this end, procedures clearly establish both the **flow of goods** and the **flow of personnel**, as well as the **specific clothing** that must be worn by handling operators.



Partial Manufacturing activities require specific documentation. The procedure followed at Logista Pharma establishes 4 **necessary documents:**

- 1 Conditioning material control sheet
- 2 Partial Manufacturing Order (PMO)
- 3 Partial Manufacturing Guide
- 4 Certificate of Batch Conformity / Release

Throughout the whole process, **Quality Control** and the allocated staff member perform a strict control of the activity:

Check of the material to be handled against the PMO.

Line clearance is performed, ensuring that the room is ready to use for future handling.

BEFORE

DURING

AFTER

Process control at the start, after each hour and at the end of handling.



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