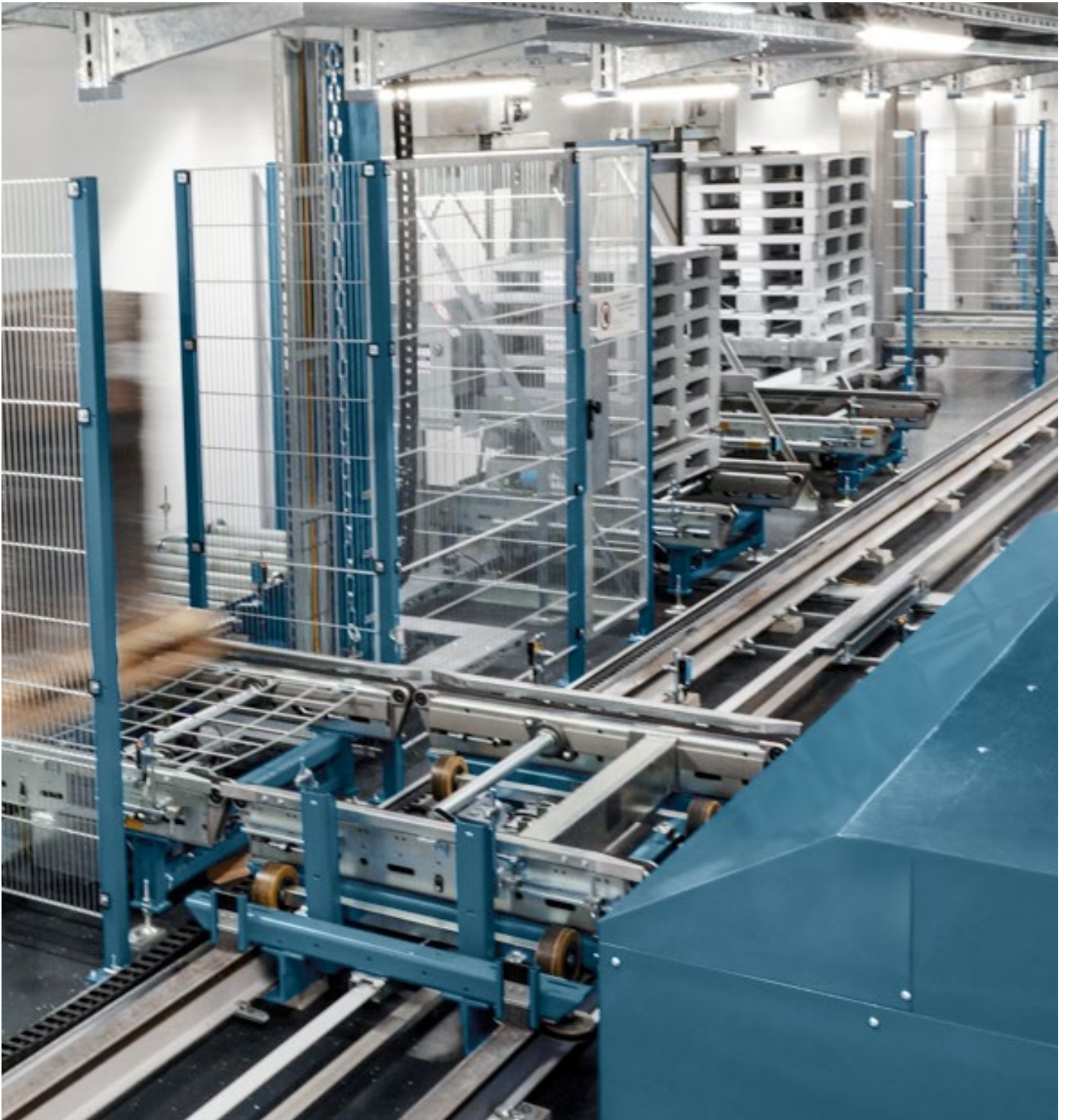


White Paper

Pharmaceutical Logistics to Order



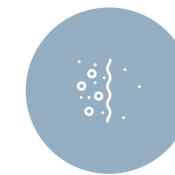


Automation – the critical factors

In pharmaceutical logistics, planning, extending, and refurbishing automated warehouses require expert industry-specific knowledge. The key focus is on the GMP, GDP, and GAMP 5 sets of rules which define the technical acceptance processes and regulations concerning hygiene, climate, and temperature control. When selecting the right supplier for hardware and software, in addition to basic performance figures, all-around competence regarding performance components is critical.

In the pharmaceutical industry, quality assurance plays an important role as every error can directly impact consumers' health. Therefore, drug manufacturers must ensure they fully comply with regulations not only in their own production facilities, but also along the entire supply chain. The basis for this compliance consists of the GMP, GDP, and GAMP 5 sets of rules. The latter relates primarily to automated systems and is considered the standard set of rules for validating computer-supported systems in the pharmaceutical industry. GMP stands for Good Manufacturing Practice and was established together with Good Distribution Practice (GDP).

Pharmaceutical logistics warehouse 3 critical factors



Complying with hygiene regulations as efficiently as possible



Managing consistent temperatures



Monitoring various storage zones efficiently

Hygiene: clean and smooth surfaces

Most of the pharmaceutical industry's production takes place under clean room conditions, which influences upstream and downstream logistics. A clean room is a controlled work area with exceptionally high environment and employee standards. There should be as few as possible airborne particles in a clean room to prevent contamination and manufacturing defects. Pallets, transported via automated conveying systems from goods receipt or a high-bay warehouse to the production area, travel through low-pressure airlocks close to the critical areas. Extraction systems remove dust particles to minimize the risk of contamination.

For example, the high-bay warehouse at PharmaSwiss's Serbian distribution center in Belgrade uses high speed doors to keep clean rooms safe, clean, and separate from gray and black zones. The load-carrying devices that arrive with deliveries are replaced fully automatically by hygienically safe plastic pallets. The Kardex constructed and installed their fully automated high-bay warehouse. At 24 meters-high, it stores 4,840 pallets in a minimum floor space.

Clean room storage located between a high-bay warehouse and a production area also achieves high-efficiency levels. Boehringer Ingelheim microParts GmbH adopted this concept for the manufacturing of drug atomizers under clean-room conditions. They extended their two-aisle high-bay warehouse, featuring approximately 1,800 storage spaces, with a clean room storage facility in the form of a MTower lifting beam warehouse. With the MTower, storage and retrieval of load units take place using a vertically mobile lifting beam on which a distribution shuttle moves horizontally. The load unit is picked up by the telescopic fork mounted on the distribution vehicle. In the construction, only silicone-free materials and stainless steel were used.

As early as the planning stage, it must be ensured that the conveying and racking technology can be easily cleaned. Profiles with smooth and tapered surfaces and as few openings as possible ensure low build-up of dirt right from the beginning.



Integrated high-speed doors keep the clean rooms safe and clean and separate them from the grey and black zones.

Temperature: mapping in all zones

The pharmaceutical industry's frequently used sensitive raw materials and products often require special climatic conditions. Depending on the production stage and product type, a high-bay warehouse will require different temperature zones.

On a smaller scale, vertical lift systems are appropriate here. The compact lift systems at Merck KGaA's research building in Darmstadt stage, prepare, manage, and store pharmaceutical research substances. Due to the special requirements the research substances place on warehousing conditions, Merck KGaA installed a refrigerated and deep-freeze storage area. The lab employees working in an area with room temperature must have access to the refrigerated storage area. This solution, provided by Kardex, is based on three standard Shuttle XP devices housed in insulation cells. The operators in the room-temperature lab area have direct access to the climate controlled storage area.



In the Merck research building in Darmstadt, the lab employees working at room temperature have direct access to the climate-controlled storage area.

Climate management right from the start

For all pharmaceutical warehouses, temperature fluctuations must not exceed defined limits. It is much easier to control a warehouse's temperature with a volume of 125 m³ than a building with several thousand cubic meters. The level of filling of the warehouse also plays an important role. Due to changing airflows, a well-filled warehouse will have a different temperature profile to that of an almost empty building. The arrangement of racks, partitioning walls, shelves, or pallets also influences the air circulation. Another factor is the position of goods within the warehouse.

The time of year also affects the warehouse temperatures. Various warehouse openings are also relevant including gates at loading ramps, doors, and windows. These all can quickly change prevailing temperatures. The same applies to light entry sources in the form of window fronts and glass domes and roofs. It is important to consider how heating, ventilation, and air conditioning systems affect warehouse conditions.



Factors influencing warehouse temperatures



Facility size



Fill-level



Position



Time of year



Hardware and software qualifications

GMP controls not only ongoing processes in manufacturing and logistics, but also planning and approving new plants. It covers the creation of functional specifications and tender specification documents in addition to hardware and software qualifications. The Factory Acceptance Test (FAT), mandatory in the pharmaceutical industry, is essential here. In the course of this preliminary acceptance, the customer inspects the plant components at the manufacturer's premises and accepts the associated documentation. Both the subsequent Site Acceptance Test (SAT) at the deployment location and the plant must be in working order at this early stage.

This becomes challenging when different suppliers provide the hardware and software. In these cases, full functional tests as part of the FAT are all but impossible because not all the components can be brought together at this stage. This is typically only possible during a SAT.

Added to this is the fact that the customer must visit different manufacturers for the preliminary acceptance, which takes up time and costs. For this reason, when selecting a supplier, companies should focus on providers who offer a complete A-Z range of services including design, storage and retrieval machine construction, and software programming. During this phase, they should also insist on a central contact partner responsible for project management from beginning to end.

Finally, all additional services such as the calibration of sensors and user training should be considered in the selection of the optimal supplier. The same applies to an evaluation system set-up, which can test all interfaces between the machine controls, the warehouse management system, and the materials management or production planning systems.

Additional factors influencing the interior climate



Fittings



Gates, doors, windows



Artificial light



Air conditioning



Supplier selection checklist



Industry experience and available references



All components from a single source



Central contact person for the entire project execution



Broad range of solutions

Summary: When planning automated warehouses for pharmaceutical logistics, there are three critical factors to consider. First, the plant must not only comply with strict hygiene regulations, but they must actively facilitate this through the use of appropriate materials, free spaces, and surfaces. Second, there must be consistent temperature management and efficient monitoring of different storage zones. Lastly, when selecting a supplier, companies should require that one source delivers all components.