Industry Guide

Smart Pharmaceutical Warehouses

kardex

Introduction

The pharmaceutical industry depends on warehouse solutions that are 100% reliable 100% of the time. Pharmaceutical manufacturers, hospitals and health care providers must adhere to strict government and industry regulations. Inefficient processes and unhygienic conditions are non-viable, and can have serious repercussions including supply shortages, expired medications, unnecessary costs and, ultimately, inadequate patient care.

Automation via the right intralogistics partner can transition your warehouse into a smart warehouse! Learn the top 10 reasons why automation is critical.

Eliminate errors & gain traceability

Maximize space & decrease costs

Meet climate, hygiene & industry requirements (e.g., GXP, GDP, GAMP 5, FDA, CGMP[1])

[1] https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations

10 Reasons automation is critical

Automation is gradually becoming indispensable in the pharmaceutical industry, particularly with regards to product development, manufacturing, warehousing, as well as pharma eCommerce. The following 10 reasons highlight the importance of automation, and how it is transforming the global pharma industry.

#1 Adhere to industry regulations with confidence

Pharmaceutical production takes place under strictly regulated conditions, which influences upstream and downstream logistics. Critical factors include temperature, humidity, ventilation, and hygiene.

If strategic planning doesn't take place at an early stage, mayhem can occur making it challenging to receive regulatory approvals. For example, if not well planned, conveying and racking technology might be difficult to clean. In addition, areas with smooth and tapered surfaces and too many openings can begin building up dirt right from the beginning.

How to transition into a smart warehouse
By automating a cleanroom environment, it decreases airborne particles and prevents contamination and manufacturing defects. Pallets transported via an automated conveying system to the receiving area or via a high-bay warehouse to the production area, travel through low-pressure airlocks close to sensitive areas. Extraction systems remove dust particles to minimize the risk of contamination.

#2 Enhance cleanroom production processes

Transferring raw materials into the cleanroom production area is a time and labor consuming task. Materials must be cleaned, placed on a cart and transferred through the cleanroom vestibule, waiting as one interlock closes before the other opens and the materials are transferred into the production area. Keeping the transportation cart clean is a challenge, not to mention the time it takes for the employee to gown before they can enter production. Then they return to the warehouse, ungown to organize the next set of materials required for production, only to clean the cart and re-gown again. It's a grueling process.

How to transition into a smart warehouse
Using an automated storage and retrieval system as a cleanroom passthrough saves time and frees up space within the production area. The unit has an access opening in the dirty area. For examples, materials can be cleaned and stored inside a Vertical Lift Module (VLM) Kardex Shuttle or Vertical Carousel Module (VCM) Kardex Megamat. Both units can maintain a cleanroom environment (from class 100 to 100,000).

When production is ready, the parts can be retrieved via a second access window within the clean manufacturing environment. Using a dual access automated storage unit, there is no need to pass the production inventory through a cleanroom vestibule, it's simply retrieved as it's needed in production – saving time and increasing worker productivity.

Similarly, automation can support kitting operations by storing clean kits of production materials for retrieval as needed in the clean manufacturing area. This allows the kitting function to take place inside the cleanroom as the kits are called for by the production schedule.

#3 Achieve consistent temperatures and audit-proof monitoring in various storage areas

Sensitive raw materials and products often require special climatic conditions which may not exceed defined limits. Depending on the production stage and product type, a warehouse will require different temperature zones.

The facility size, current capacity, time of year, and light sources (e.g., window and glass roofs) all impact the warehouse temperature and ventilation. Proper temperatures are critical to maintaining the quality of pharmaceutical supplies and proper ventilation will control airborne particles and help avoid product contamination.

How to transition into a smart warehouse
An experienced intralogistics partner will make sure these factors are efficiently controlled. For example, Kardex offers controlled environment solutions that provide constant temperatures between –35°C and +60°C, heated and insulated switch cabinet cabins, humidity control, ventilation management and rapid cooling areas for warehouses with various temperature zones. Kardex will control the opening of loading ramps, doors and windows and manage light sources.

#4 Expedite fully-traceable change parts

Many pharmaceutical manufacturing lines rely heavily on automation – and with automated manufacturing comes change parts. Change parts are commonly stored on small movable carts and often covered in plastic for protection. These carts are unorganized and take up valuable space within the production area. Sometimes all the change parts for one machine are on the same cart, which helps, but finding the right cart isn't always easy.

Changing a part can take hours – searching for the right cart, finding the right change part on the cart and then doing the physical change work on the production machine – and that's hours the production line isn't running. Managing change parts consumes valuable floor space and can be a drain on productivity.

How to transition into a smart warehouse
Managing change parts in an automated storage and retrieval solution will not only save space and time, it will also support change part traceability. The dynamic storage solution makes use of overhead space by storing parts from the floor to the ceiling. Compared to standard carts, automated storage technologies can recover 70–85% of currently occupied floor space.

The compact footprint allows the vertical storage unit to be located near the production line. Each tray can hold an organized set of change parts making the production line change over process faster and more efficient.

When a change part is needed, the worker simply enters in the change part name or scans a barcode and the part is delivered directly to the operator at an ergonomic access opening, no need to walk and search for the part. Further, pick-to-light technology will direct the operator to the exact location to ensure there is no confusion on what change part is needed.

Lastly, the inventory management software records the operator ID, part number and time the change part was removed from inventory. Returning a part is easy, the operator simply enters the part ID or scans a barcode and the unit directs the operator to a storage location. All transactions are documented, providing full traceability of who and when the change part was removed or returned to inventory.

The automated solution can operate in a clean manufacturing environment if required (meeting conditions in compliance with cleanroom classes ISO 5 to 8 or classes 100 to 100,000). This stops parts from leaving the clean environment, even if just for transportation to a clean storage area, preventing possible contamination and recleaning tasks.

#5 Manage R&D inventory securely

Research and Development (R&D) labs are focused on the future – making pharmaceuticals faster and cost-effective. With multiple projects, and often multiple lab teams, managing required R&D inventory can be a challenge. Often all R&D inventory is managed in one area on shelving accessible to all R&D staff. Misplaced parts or parts "borrowed" for different R&D projects can quickly stop a prototype in its tracks as the lab researcher looks for or reorders the missing part.

How to transition into a smart warehouse
Not only does an automated storage and retrieval system consolidate the inventory into a smaller footprint, it also secures the inventory by only allowing authorized personnel to access it. Through the inventory management software, specific trays or carriers can be assigned to specific lab or project teams. The unit can be set to require an operator login and based on the login only provide access to specific items stored in inventory. This easily prevents missing or borrowed parts.

#6 Find manuals and maintenance records quickly and easily

Due to the importance of these products, pharmaceutical manufacturers must adhere to strict maintenance and quality control guidelines as established by government officials (e.g. U.S. Food and Drug Administration, European Medicines Agency, etc). All maintenance and repair operations (MRO) parts (e.g., calibration equipment, instruments, tools, consumables and parts) must be kept on hand and readily available.

Technical manuals must also be cataloged, inventoried and easy to find when needed. Further, inspection and maintenance records must be meticulously recorded and kept throughout the lifetime of the production equipment. Manuals and maintenance records are often stored in an area separate from MRO parts – in binders on shelves in the corner – or worse in someone's desk.

How to transition into a smart warehouse
With automated storage technology, MRO parts and documentation can be combined and stored in one secure and organized area with fast access. Inventory management software can track the exact maintenance part that was used in which piece of production equipment – down to the SKU, lot and serial number. Automation keeps MRO, quality control logs and other manuals/ records organized and easy to find – giving pharmaceutical manufacturers peace of mind.

#7 Centralize all documents

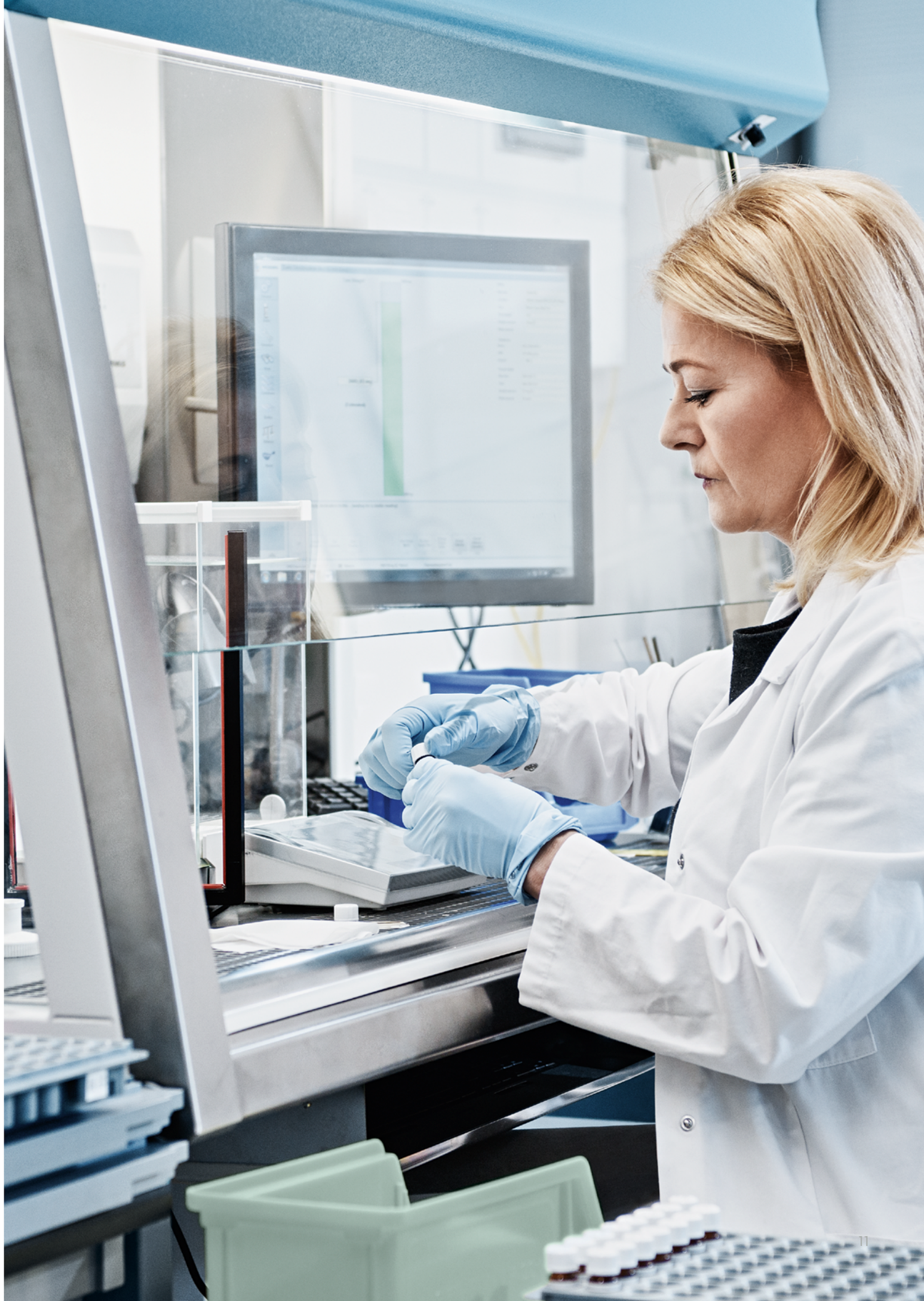
As a highly regulated industry, pharmaceutical manufacturers must keep detailed records of their manufacturing process for each pharmaceutical batch they produce. The FDA can require documents from a specific batch manufactured in the past to be presented within a specific number of minutes. These files are often stored haphazardly throughout the facility and hard to find. Inability to produce those documents can lead to serious fines.

How to transition into a smart warehouse
Use automation to centralize all required documents and labels in one compact and secure area. An automated filing unit can recover up to 70–85% of floor space compared to traditional filing cabinets or shelving. Additionally, every document or label can be identified and recorded as it is stored within the unit allowing operators to quickly and easily find them the minute they are requested.

#8 Ensures FDA approval

Pharmaceutical companies must receive approval from the FDA and comply with the Current Good Manufacturing Practices (GMP) and the Factory Acceptance Test (FAT). It's challenging to do this if the facility is not in order from an early stage and multiple suppliers are providing the hardware and software.

How to transition into a smart warehouse
Automation partners that provide a complete A-Z range of services, including hardware and software, simplify the planning and approval process for new plants. They provide a central contact for new facility design, storage and retrieval machine construction and software programming.



#9 Automate labels to improve accuracy and save space

Product labels are critical and require a high level of precision. Rolls of pre-numbered labels are loaded onto a machine that labels the current batch with the required regulatory information. If one dose is mislabeled, the entire batch must be discarded. Further, labels are adhesive and can be easily damaged if stored incorrectly.

Labels typically stored on shelving take up too much space and finding the correct roll can be difficult.

How to transition into a smart warehouse
Using automation to inventory labels provides higher accuracy rates, more control and saves space too!

#10 Reduce the sample storage area by 85%

Precision and accuracy are two key driving factors in successful pharmaceutical manufacturing as a faulty or defective product can directly impact a human life. For this reason, pharmaceutical manufacturers are often required to keep a sample of every lot or batch they produce. In the event of a complaint or safety issue the sample can be tested and checked to determine if there is a larger problem.

Further, samples must be protected against contamination, stored in the original packaging and in the recommended environmental conditions consistent with the product label for a specific time period. Maintaining samples is a costly challenge that requires additional floor space.

How to transition into a smart warehouse
Storing samples in an automated storage device can provide organization, traceability and save floor space. Samples can be easily organized into trays, carriers or totes within the machine and inventoried by lot, batch and serial number. By taking advantage of overhead ceiling height, the floor space required for sample storage can be reduced by 85%. When necessary, automated storage devices can be temperature and climate controlled to replicate the recommended storage environment for maintaining the samples.