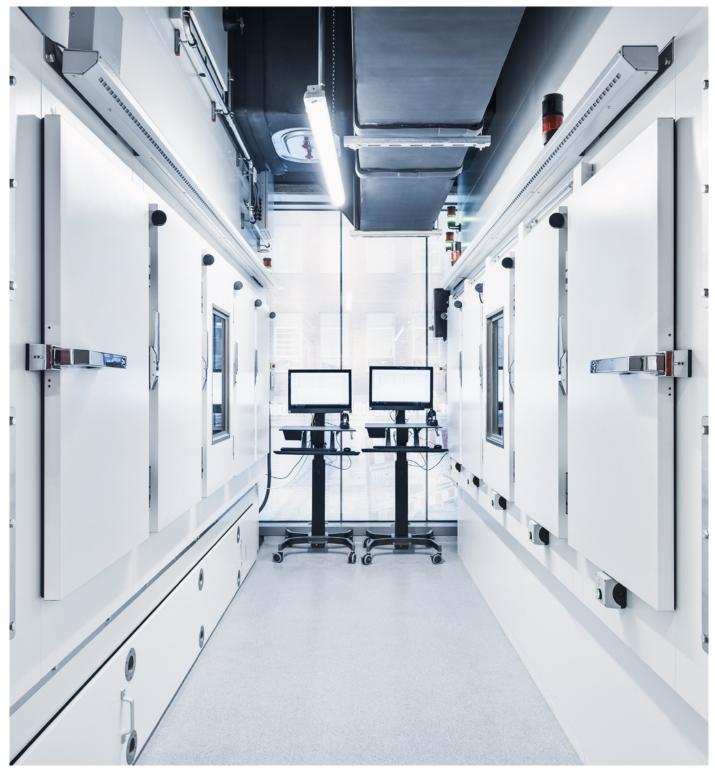
Solution Guide

Secure Storage Environments





Pharmaceutical storage

Quality control plays a central role in the pharmaceutical industry. Manufacturers must observe specific guidelines during production and aim to ensure compliance with specified hygiene, temperature, and climatic conditions. This can be quite challenging to maintain especially considering the vastly different requirements one product might have to another in terms of temperature, humidity and lighting.

It's critical to consider industry-specific factors, otherwise the stored goods risk being exposed to natural elements or unauthorized personnel and can become damaged, expired, contaminated or degraded and often must be discarded or cleaned – a costly and time-consuming task.

Kardex offers numerous solutions to keep pharmaceutical products protected. These controlled environment solutions reduce floor space by 85% and increase productivity by reducing the walk and search time commonly associated with manual pick systems.



Compliance with climate and cleanroom requirements



Error-free workflow



100% traceability



Reduce floor space by up to 85%

Cleanroom environments

Kardex units provide particle-free environments, meeting the conditions in compliance with cleanroom classes EN-ISO 5 to 8 (or classes 100 to 100,000). To reduce air particles as much as possible, the <u>Vertical Lift Module (VLM) Kardex Shuttle</u> is equipped with roller-based trays which do not produce dust. In addition, the VLM air conditioning solution (ACS) is equipped with dual access doors to reduce exposure to dust, dirt, particles, germs and other harmful pollutants. Controlled air streams can also ensure cleanroom conditions are maintained inside the unit.

- Constant temperatures +/-1 K
- Cleanroom classifications ranging from EN-ISO 5 to 8 (5 on request)
- Positive/negative pressure



Benefit from dust-free storage to fulfill any product requirements

Low humidity / Dry environments

Automated storage and picking solutions can also be used in dry room applications, providing a relative humidity at or below 5%. In addition to a sealing system and an airlock in the access opening, a dehumidification device is designed for use with the VLM and VCM to ensure humidity levels are maintained within the unit.

- 10% relative humidity (r.h.) through nitrogen purging
- 5% r.h. adsorption drying
- ESD-compatible design



Keep humidity levels low to protect your goods

Temperature-controlled storage

Many stored goods are vulnerable to temperature changes. They quickly become contaminated if temperatures are not properly managed. This applies to a very vast range of products, all of which require storage at constant temperatures.

The Vertical Lift Module Kardex Shuttle and the <u>Vertical Carousel Module (VCM)</u>

<u>Kardex Megamat</u> both come equipped with an integrated air conditioning system to protect stored goods. The automated storage systems can maintain a consistent temperature (+/- 1). Additionally, Kardex clima solutions feature temperature mapping, heated and insulated switch cabinets and humidity control to maintain peak performance levels.

- High performance of the components at constant temperatures between -30 to +55 degrees Celsius (-22 and +131 degrees Fahrenheit)
- Constant temperatures +/-1 K
- Humidity control



Control temperature and humidity as needed to protect sensitive items



Fire, gas & explosion protection

Whenever highly flammable gas or particles are present in the air, dangerous incidents can unpredictably occur. This is why scrutinous plant planning, designing, and construction are so critical.

The earlier a dangerous incident is detected, contained, and extinguished, the less damage caused to the warehouse and the stored goods. Kardex units are planned and designed taking into account the explosion protection classes and with sophisticated early detection and prevention capabilities.

Understanding the pharmaceutical industry needs, Kardex offers a special feature for retained samples. The gas value measurement option offers the possibility to automatically activate fans when a critical value is exceeded. The gas values are then neutralized, and the gas concentration is returned to its normal range. Kardex will customize a solution based on your needs. We offer a wide spectrum of features including

- Residue-free fire extinguisher and aspirating smoke detector (ASD)
- Fire protection gates and sprinkler technology
- OxyReduct®, a fire prevention system that reduces oxygen
- Acceptance testing for fire protection services in accordance with Vds or FM Global requirements



Prevent all goods and storage systems from damage

Overview

Kardex will customize a solution based on your needs. The table below shows the various options for temperature controlled, dry and cleanroom environments based on the product type.

		Temperature controlled		Dry environment	Clean environment
Kardex Shuttle	500	-4 to +131 F	-20 to +55 C	<5%	ISO 6 to 8
	700	-4 to +131 F	-20 to +55 C	<5%	ISO 6 to 8
Kardex Megamat	180	+35 to +104 F	-2 to +40 C	< 5%	ISO 8
	350	+35 to +104 F	-2 to +40 C	<5%	ISO 5 to 8
	650	-22 to +104 F	-35 to +60 C	<5%	ISO 5 to 8







Best practice in the pharma industry

Take a look at this customer example from Kardex to learn more about the different options and storage environments that are possible. Kardex dives deep into their customers' warehouses to understand the challenges and tailor automated solutions.

Merck – a customized solution saves 60% floor space

Merck is a leading science and technology company in the pharmaceutical and chemical industry. They partnered with Kardex to help with a newly constructed research center in Germany. Merck wanted to create a cool and deep-freeze storage area that was accessible from a room-temperature area.

Kardex implemented a customized solution that included three standard Vertical Lift Module Kardex Shuttles modified for chilled conditions. The solution inclided laser pointers and position indicators to show an item's exact position. It also included a refrigeration unit, a back-up cooling unit, and drying device to prevent humidity.

Project highlights

- A 60% reduction in floor space
- Improved ergonomics for plant workers
- Air-conditioned units with direct access from a room temperature area



Conclusion

Pharmaceutical storage checklist – what are your key requirements?

Before making any final decisions for new solutions, it's important to check they meet your specific criteria. Read through the top 10 pharmaceutical storage requirements below. Rank these based on what is most important to you and then use this as a checklist when interviewing a new intralogistics partner.

\checkmark	Control over temperature and humidity levels
✓	Knowledge and experience working with pharmaceutical regulations: GXP, GDP, GAMP 5, FDA
<u></u>	100% guarantee against dust particles and pollutants such as microorganisms, spores and germs
<u></u>	Sophisticated security access features for personnel
<u></u>	Specialized prevention and detection features for fires, explosions and gas incidents
✓	Inventory control and traceability back to the product origin
✓	Automated storage and retrieval optimizing floor space and providing fast and reliable order picking
<u></u>	Worker safety and ergonomics
<u> </u>	Buffer storage for efficient production flow
<u> </u>	Seamless hardware and software integration