The efficient planning of temperature-controlled storage for pharmaceutical products

ABSTRACT

Unlike the planning of conventional warehouses, additional criteria must be considered for storage and material flow planning in pharmaceutical companies. All areas must be qualified from the very start of planning — including the areas of climate control, documentation of storage conditions (e.g. monitoring system), as well as entrance and access control, and particularly for material flow changes in the production area. The following article examines the success factors for efficient and successful warehouse planning in climate-controlled areas for the pharmaceutical industry.

KEYWORDS: Temperature-controlled warehouse, logistics planning, facility qualifications in pharmaceutical industry, supply chain engineering.

In the pharmaceutical industry, products are associated with very high standards for temperature, storage conditions, clean-room standards, or compliance with the stipulations of the Narcotics Act. A consistent temperature control and storage must be provided for humans and technology in the daily logistics process as well as entrance and access control, and particularly for material flow changes in the production area.

The extensive requirements applicable in the area of climate control and storage planning make it impossible to address the essential core aspects of pharmaceutical warehouse planning and the associated special concepts and phases in greater detail — but the peculiarities of the various temperature zones and requirements associated with the processes will be discussed. An explanation of the fundamental concepts of warehouse construction can be found in the article “Warehouse Conceits” (see Stockmeier article “Professionalization” in TechnoPharm 2 No. 2 94-99 (2012)).

The logistics-related question of “make or buy” should also be raised during the initial conceptual planning phases. Especially when a direct connection with the production area is not needed or the product groups to be stored are small and fragmented, outsourcing to a service provider may very well be the most economical solution. The pharmaceutical sector lags behind other industries in this respect (see Miebach Outsourcing Study 2014, “Hype Gives Way to Professionalization”).

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Only if the key data, needs, transport flows, inventory peaks, and throughput peaks are made available in a timely manner (and not, for example, only once the fiscal year is over) the warehouse processes can be planned to react positively — and not reactively. This transparency of the logistics chain is also referred to as “supply chain visibility” (also see the article by Krebs/Schön about supply chain visibility in the pharmaceutical Industry in TechnoPharm 4 No. 2 102-109 (2014)). The higher the value of the products, the more important transparency is, especially for (capital-forming) inventory.

In this area, too, the requirements imposed must be fully complied with them. (or variable access times), as a result, if toxic or hazardous properties are present the requirement imposed must be fully complied with for both storage and transportation. Such requirements are especially relevant when it comes to the separation of inventory due to temperature requirements. It is forbidden to store some materials from hazardous categories, with various toxicity levels, and with other properties together, thus necessitating the establishment of different storage and fire compartments for each temperature range and group of products. The newly created subgroups can cause the minimum number of essential storage areas to multiply — which in turn directly influences the building as well as the logistics and production processes.

The most common temperature classes in the field of pharmaceutical products are ambient/room temperature (15-25°C), cool/cooled products (2-8°C), and frozen products (not exceeding -18 or -20°C or -25°C). Additional temperature classes become especially interesting, if, for example, at temperatures of 40°C or 70°C, limits of feasibility for humans or equipment are reached. From such special temperature ranges, there is also a trend towards a higher proportion of cooled products whose temperatures are constantly shifting to lower ranges (from ambient to cool for example) and for which compliance must be more carefully monitored (e.g. compliance with temperatures along the entire cold chain, without any disruption). Starting with the amendment to the GDP Guidelines in the fall of 2013, (subgroups) is a legal requirement to transport and store when it comes to compliance with temperature criteria. Since the transport area has since become a major focus, the potential of the immobile parts of the supply chain, the processes, and structures in the warehouse, have been given special attention in this article. Efforts are made to clarify this within the initial planning stages, before a warehouse goes into operation. Only those things that are taken into consideration during planning can later be optimally built and operated. It is for this very reason that the requirements for planning a new temperature-controlled warehouse are illustrated. The requirements applicable to existing warehouses and processes, with the only difference being that it is hard to make changes to the status quo once the warehouse has been “set in stone” so to say.

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A few typical requirements can be identified for this area as well. The most important are those that can only be converted with great difficulty later on or not at all. In general, climate control systems should be planned with some redundancy in order to prevent a full system outage in the case that individual components fail. Here the statement “100% redundancy” may sound positive for operational security but can also mean 100% more investments in this area. Gradual redundancy can reduce investments considerably here.

Truck docking stations are another example of this. Loading docks at existing properties can also be equipped with inflatable seals for temperature control later on. The loading ramps on logistics properties are, however, usually designed so that truck drivers must open the doors of the trailer before completing the docking process. This interrupts the cooling chain though, which is why temperature-controlled transports should always be opened only after docking. Corresponding loading bridges must be installed for this, which often requires substantial renovation work on the ramp or the loading yard.

Especially high-bay warehouses (which can easily reach 40 m) pose additional challenges, since they must be equipped with special climate control and ventilation systems in order to maintain the proper temperature (e.g. to avoid temperature stratification solved by high air exchange rates, jet nozzles, etc.). Since these aspects create considerable problems in the different seasons of the year, a simulation of the temperature distribution in such warehouses also makes sense when determining the configuration of the future monitoring system, especially since adjustments must be made for the differing heating and cooling situations (summer and winter scenarios).

A demanding topic for structural engineering and materials are the “ultra deep freeze” temperatures, e.g. lower than -40°C or even -70°C. Not only do these conditions affect the products being stored, but also the building itself and the equipment installed inside. After a certain setting time, for example, a temperature will establish itself in the walls between two neighboring deep freeze rooms – even when adequate insulation is used – that falls between the two temperature zones of the respective cells. This means that even the structure itself must be capable of withstanding the low temperatures for the duration of its service life. Especially when it comes to subsequent repurposing of warehouse areas for other temperature zones, these requirements for construction and cooling systems must be taken into account from the very beginning and only very few manufacturers have already obtained all the necessary expertise for this.

In order to be prepared for any future changes, every plan should be conceived as modulator as possible. This is because creating a “bespoke warehouse” fitting today’s needs will be insufficient after just a short period of time once changes arise – and changes occur in every project. This means that, particularly when it comes to material flows, special care must be taken of temperature controlled areas. Mixed good-in-and-good-out areas, meaning places where all temperature classes are processed, are an example of something conducive to process optimization. But this will only work if items are allowed to leave their temperature range for a limited time (e.g. Time-out of Refrigeration, TQR).

As soon as (even just single) items need to remain permanently within the cold chain, separate good-in and good-out must be built for this purpose. If the basic structure of material flows isn’t prepared to handle such changes, this results in interacting material flows with temperature locks along the logistics spine that slows down logistical handling and increases costs.

**SUMMARY**

For a temperature-controlled warehouse which is at the same time efficient and GxP-compliant, a process-oriented overall solution must be the focal point according to the principle “form follows function”. Responsibility for logistics and civil construction as well as HVAC should be placed in one hand. Therefore, a general planner must be involved in the project from the very beginning (starting already with the strategic or conceptual phase before detailed design). They will cultivate an awareness of the operative needs as well as the superordinate logistical and production-relevant goals of the company and incorporate these into the current project.

Continuity between the completion of planning and start of implementation is the key to successful implementation and efficient future operation without unfavorable surprises.

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**CHALLENGES ASSOCIATED WITH OPERATIVE USE**

A variety of different challenges can arise during operation, depending on the temperature range and process. Generally speaking, bringing warm products into a cold area (depending on the amount) stresses the cooling systems and neighboring products, which cannot be allowed to warm up through the transfer of heat.

Bringing cold products into a warm area, on the other hand, is more critical for the cold products. Increased humidity in the warmer temperature zones will result in the immediate condensation of moisture on the cold items, which will quickly warm them up while at the same time getting the surrounding cardboard packaging wet. In order to circumvent such impacts, the products can be warmed up in a controlled way in special conditioning chambers (and with dry air) so the packaging will remain in its original condition – and it is best if these chambers have already been taken into account accordingly for the structural planning and logistics processes.

**SUPPORT AND REVIEW OF PLANNING THROUGH STRESS TESTS USING MATERIAL FLOW SIMULATION**

To achieve an optimal distribution throughout the whole warehouse, the behavior of known secondary conditions, an extensive material flow and inventory simulation for future warehouse operation should always be used to validate planning. In the best-case scenario, production lines should also be integrated into the simulation. Even if a simulation extends the overall planning time, it minimizes the risk of unexpected situations. In order to achieve this, information such as historical and expected growth, product changes, and disturbance values (of a technical as well as a developmental nature) to generate a prediction that is as accurate as possible.

The structure of the logistics network, inbound as well as outbound, can also be entered for a simulation and encompasses production locations, suppliers, warehouses, and customers or product recipients.

**ABOUT THE AUTHOR**

Achim Sponheimer is a Partner at Miebach Consulting and Head of Pharma & Life Sciences. Before joining Miebach Consulting in 2005, he spent several years in Ireland and Germany in the distribution department of a worldwide consumer product manufacturer. Today, Miebach Consulting serves its clients with 24 offices around the world and develops logistics and production solutions and designs the structures for networks, processes and fulfillment centres throughout the entire supply chain.