Planning a Successful Warehouse Mapping Study

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The Importance of Thermal Mapping

Pharmaceutical, biological and medical device products require controlled environmental storage conditions. Degradation can occur when the storage environment of the product exceeds the range of safe conditions of the product. For example, some pharmaceutical materials need to be stored at ambient temperature to preserve the potency of the product. If the temperature of the storage environment goes outside that range, damage to the pharmaceutical material may occur. Thermal mapping of all storage areas is required to assess the environmental conditions stored pharmaceutical materials will be exposed to. This is especially true of warehouse storage due to large seasonal variations of environmental conditions.

Create a Plan

A critical step when temperature mapping warehouses is to determine the scope of the project. A number of factors must be considered when determining the scope; the number of mapping studies, study length, the temperature range acceptable for operation, quantity of sensors, sensor locations, storage envelope parameters, and any other information deemed important by the end user, all are critical pieces of information to ensure a successful mapping study whereas the storage envelope refers to a specific section of the warehouse designated for product storage. Parameters relevant to the storage envelope include storage rack numbers, storage rack dimensions, storage rack and product spacing, and thermal mass distribution.

Information about the geographic location of the warehouse or storage area is necessary for planning a mapping study. For example, warehouses located in a tropical environment will require more HVAC power to maintain ambient temperature and humidity during the summer months than

the winter months. This is due to the greater temperature difference between the outside and inside conditions of the warehouse. Warehouses located in colder environments will most likely require more HVAC power in the colder months for the same reason. This will be true for most ambient storage areas, as they are temperature controlled by facility HVAC systems. Airflow in storage areas is extremely important for temperature regulation. If air is not properly circulated throughout the storage area, a stratification effect can occur. This means there will be a distinct temperature

gradient, with temperatures increasing from the floor of the area to the roof. Warm air will become stagnant on the upper levels of the storage space during the summer months. Thermal conduction through the walls of the warehouse will transfer heat to any product stored up against it. The walls will also allow for the transfer of heat through convection and conduction throughout the warehouse.

Seasonal temperature swings will greatly affect the operation of the HVAC systems in place to regulate the temperature of the storage environment. It is required by the United States Pharmacopeia, Article 36, Chapter 1079, to perform two mapping studies; one in the winter, and one in the summer to capture warehouse environmental data for the most extreme outdoor low and high temperatures. Studies are usually performed under "As-Is" conditions for warehouses already in operation or previously qualified where the "As-Is" loaded condition is identified and documented with respect to current load.

Temperature mapping studies need to capture normal operation of the storage area as well as low foot traffic days to get the full range of temperature variations. Temperature excursions can occur during normal operation events such as opening a door, excessive foot traffic, product movement, and daily HVAC operation. For these reasons, warehouse mapping studies are run for a minimum of 7 consecutive days to demonstrate area uniformity during both weekdays and weekends.

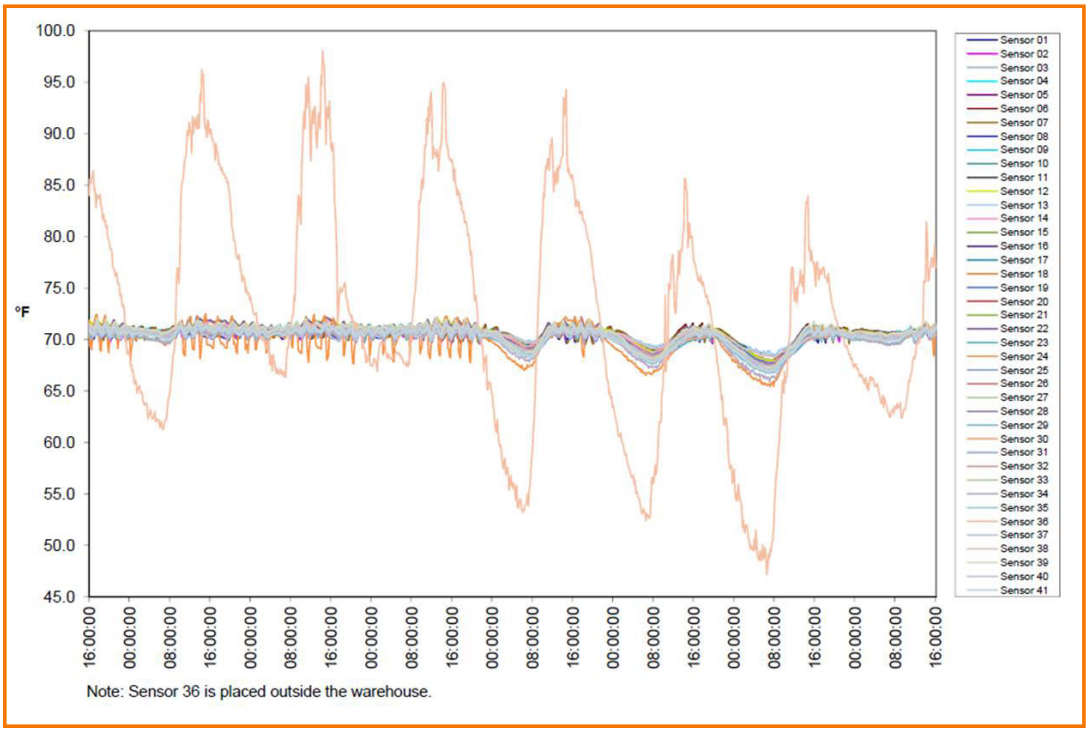

Fig. 1: This graph represents a Summer profile, 7 day thermal mapping study shown in Fahrenheit. Sensor 36 was located outside of the warehouse where it was exposed to the extreme seasonal temperatures.

Executing the Plan

Temperature ranges in the warehouse are defined with respect to the product in storage and the ability of the environmental control system to maintain the proper conditions. From this information, acceptance criteria for a passing mapping study can be determined. Mapping studies can also be performed to determine that the area mapped is suitable for a specific pharmaceutical material that requires a certain temperature and humidity range. For ambient temperature storage, a range of 15°C to 30°C is acceptable with brief excursions due to outside environmental variation.

Sensor locations and quantity will depend greatly on the size and shape of the storage area. Three sensors should be placed on all corners of the storage area, one at the top of the storage space, one in the middle of the storage space, one at the bottom of the storage space. Three sensors should also be placed in the center of the area and individual sensors should be placed next to all monitoring probes, thermostats, entrances, or any other sources that influence temperature. It may also be beneficial to place sensors in storage rack areas to capture temperature conditions next to product. An additional sensor should be placed in an area representative of outside temperature and humidity for reference purposes only. This is done to capture the outdoor temperature and humidity conditions the warehouse will experience throughout the mapping study.

Sensors should be labeled with unique identifiers to mark their location. A map with sensor locations allows anyone to easily determine locations of hot and cold areas in the warehouse. Well-documented sensor placement allows for consistency in each of the seasonal mapping studies. Dataloggers used for data acquisition must be calibrated and traceable to NIST or equivalent followed by a calibration-verification after the qualification. This ensures the dataloggers remained accurate within the application temperature range throughout the data collection process. Sensors should be secured to their locations for the entirety of the study.

Analyzing the Results

After the mapping has ended, the data is analyzed. Results from the mapping study should be compared to the acceptance criteria defined by the end user. In order for the warehouse to pass the qualification, the minimum and maximum temperatures during the study must be within the specified operating range. The humidity readings are typically recorded and utilized as a reference only. Because all of the sensors and locations are labeled, the minimum and maximum temperatures recorded will identify the coldest and the warmest locations in the warehouse as well as any non-conforming areas that fall outside of the specified operating range. With that information the end user can make key decisions with regards to product storage. One way to eliminate non-conforming areas is to demarcate those as outside the range, if any are identified. Monitoring sensors can be placed in locations that challenge the limits of the operating ranges so those areas are constantly monitored and can be addressed if an excursion occurs. The maximum and minimum temperature locations may vary depending on season, so monitoring systems sensor placement should account for seasonal extremes.

Another key tool used to analyze data for warehouse mapping is the Mean Kinetic Temperature (MKT). The MKT can be used to evaluate readings from a single datalogger if the temperature profile fluctuates in a distinct pattern, such as a sinusoidal wave with repeating temperature peaks and dips. The MKT will give an accurate mean temperature for a datalogger that experiences short excursions.

$$T_K = \frac{\frac{-\Delta H}{R}}{ln\left[\frac{\sum_1^n exp\left(\frac{-\Delta H}{R \cdot T_n}\right)}{n}\right]}$$

The Mean Kinetic Temperature is defined as:

TK is the mean kinetic temperature in kelvin; ΔH is the activation energy in kJ, R is the universal gas constant, n is the number of sample events, when the samples are taken after the same time period, and Tn is the temperature taken at a sample point n in kelvin. This equation weighs each data point against all of the other data points taken in a study, so small excursions from the normal operation of the storage area, such as product loading or movement, and door openings, will not have a great effect on the calculation of the mean temperature of a specific location of the storage space.

Conclusion

Pharmaceutical materials require controlled environmental storage conditions to preserve and protect the efficacy of the product. Thermal mapping of warehouse storage areas is essential to assess the environmental conditions the products will experience. Certain considerations need to be made prior to the mapping study. Mapping studies should be planned to capture seasonal temperature extremes and daily operations the storage area can experience. Sensors should be placed in locations to identify at risk temperature areas during mapping. Data collected through the study should be analyzed and compared to the acceptance criteria. Warehouse storage is a key step in many pharmaceutical product life cycles. Understanding all stages of the process is essential in successful pharmaceutical storage.

Citations

USP-NF. Good Storage and Distribution for Drug Products. USP 36 General Information / Good Storage and Shipping Practices. Retrieved September 14, 2018

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