

Room Mapping of Temperature and Humidity

Mapping in general

Temperature and humidity levels that are out of specifications can cause damage to ingredients during production or to the final product during storage. Knowing correct temperature and humidity levels at all times is especially important for pharmaceutical and food production companies. Regulatory organizations (see table below) require food and drug products to be stored and/or produced under appropriate conditions. Temperature and humidity levels are critically important in order for the material to retain its identity, strength, quality and purity.

The best way to understand the temperature and humidity characteristics of a room is to conduct a proper and complete mapping exercise. The mapping process consists of placing dataloggers in various strategic places in a room



and accurately monitoring the different parameters over a chosen time span. Depending on the room structure, storage configuration and the placement of product in the room, extremes of temperature are likely to occur. Mapping provides a detailed picture of the temperature and humidity levels of the entire room over time and even year to year as the seasons change. Based on the final room map of temperature and humidity, food and drug manufacturing companies are able to place the sensors in the proper locations and choose a suitable monitoring system that complies with regulations as well as protects product during production or storage.

Overview of the mapping process

Depending on the size of the room and the internal and external influences, choose the most appropriate measurement points that will characterize the temperature and humidity profile.

Small rooms: For chambers or rooms with dimensions of (LWH) 5m x 2m x 5m or smaller best practices dictate at least 9 points of measurement. The 9 points should include each corner and one point in center of the room.

Large room: For rack warehouses or any large space, the first step is to prepare a grid diagram

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Common Global Regulators

Food and Drug Administration (FDA)
United States Pharmacopeia (USP)
World Health Organization (WHO)
Int. Conf. on Harmonization (ICH)

Guidelines

Good Distribution Practice (GDP)
Good Manufacturing Practice (cGMP)

Overview of the mapping process

(continued)

depicting the location of each sensor. When mapping a rack warehouse, each shelf row should be mapped. Best practice recommends placing a sensor horizontally every 10 to 15m.

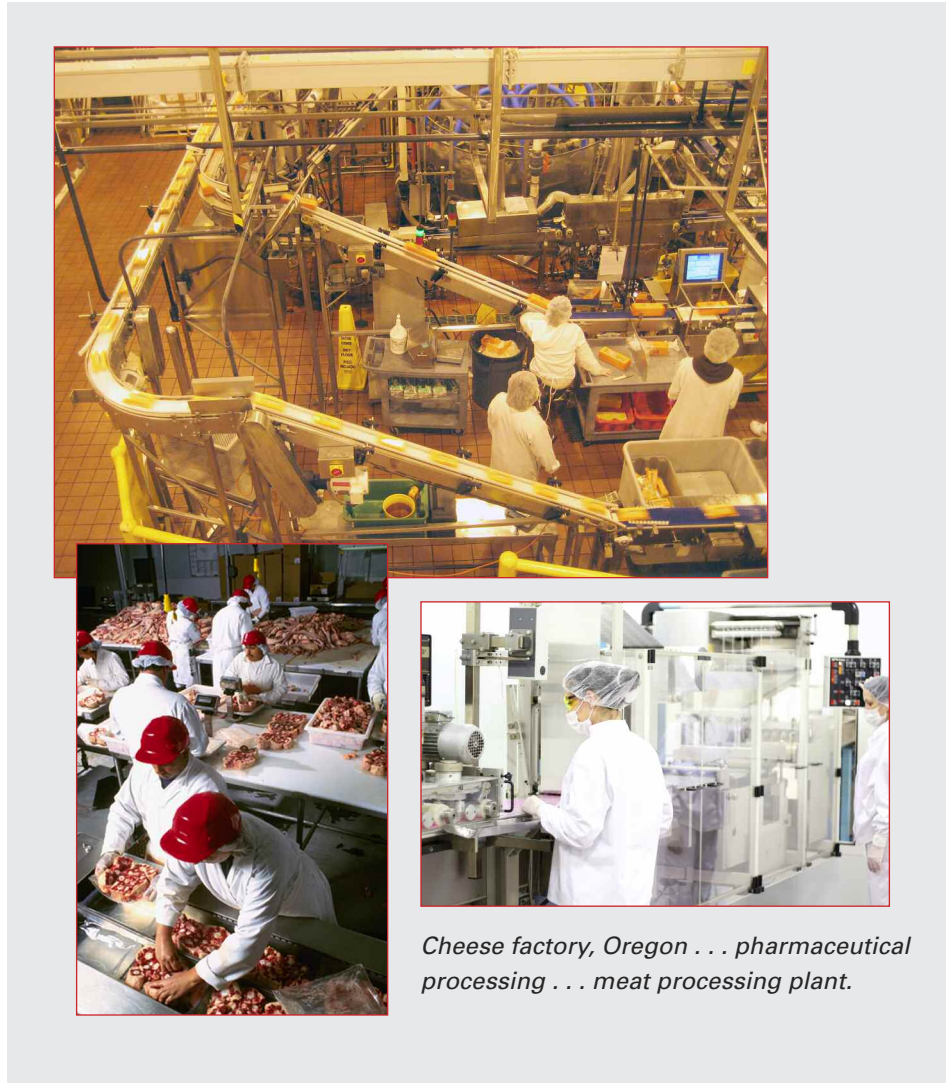
Vertically, best practices recommend measuring the lowest shelf and the top shelf. If the shelving is higher than 10m, add measurement points with a vertical spacing of 4...6m.

In addition to the mapping points as mentioned above, internal and external influences on temperature or humidity such as windows, loading docks, doors or ventilation outlets should be measured and recorded.

Additionally, don't forget to place a data logger outside to monitor exterior conditions. Seasonal differences will have a direct effect on the HVAC system and, therefore, to the internal temperature and humidity. It is highly recommended that mapping be performed during the different seasons.

Other recommendations

A logging interval of 10min is usually adequate to give enough resolution for a thorough analysis of the mapping data. Before placing the loggers, make sure the devices are acclimatized for at least 2 hours. Duration of the mapping study should be a minimum of 2 weeks and conducted under normal operating conditions.



Cheese factory, Oregon . . . pharmaceutical processing . . . meat processing plant.

Conclusion

Mapping is an extremely powerful tool for compliance with regulations as well as saving costs due to improved efficiency. The key to compliance and efficiency is a proper mapping study that ensures correct placement of data loggers used for the continuous monitoring system. Make sure to document all aspects of the mapping operation as well as the assumptions and

decisions regarding final placement of monitoring instruments. Calibration of both the mapping instruments and the continuous monitoring instruments is a critical aspect of proving an effective and compliant process. Once the mapping project is complete, the work is not over. Best practices advise continuous monitoring and continuous improvement.