

Case study – Cold room Temperature & humidity mapping study, validation and qualification

Scope

The scope of qualification was to carry out temperature and humidity mapping study, validation and qualification of one cold room of approximately 600 sq. mtr for a temperature range of 2-8 Deg Centigrade for one of the biggest Pharmaceutical distributor in United Arab Emirates.

Process

The entire study was carried out jointly by Cryopak, USA and Vacker UAE.

Approximately 100 data loggers were uniformly distributed across the entire cold room to record temperature and humidity.

As lot of parameters could not be checked during normal working days, the tests were started on weekend holidays.

Prior to the commencement of the qualification process, a protocol was written and verified by the customer and their third party auditor and approved. The protocol covers the entire procedure and sequence of the test activities. Also same involves verification of all Standard Operating Procedures (SOP).

All the sensors and cooling units were checked at various temperature levels to check their effectiveness.

Validation of their system involved validating their existing system of data collection including temperature & humidity. The validation process is carried out for ensuring compliance with 21 CFR part 11

Power failure tests were carried out to check the duration for which temperature remains within the limits after a power failure. This study is for information only and not for qualification. This particular cold room lasted for 5 hours before temperature reached 8 Degree Centigrade .

Thereafter temperature recovery test was carried out to understand the duration taken to attain the desired level of 4 Degree Centigrade. This test also is carried for information so that customer will aware of the duration in cases of emergency.

As the cold room was already loaded with medicine, we could not carry out the tests beyond 8 Degree Centigrade, however various other tests were carried out evaluate the entire cold room.

The whole tests and temperature and humidity mapping lasted for around 36 hours. During the recording of temperature and humidity, all other normal activities were taking place such as loading, unloading, opening of doors etc. and were recorded for analysis.

Temperature mapping study is the major part of the entire process identifying the hot and cold spots of the entire room. The hot and cold spots occur for various reasons and can be eliminated or reduced by various means. Potential reasons for the same will be identified during the process.

Results

Results of the study included the reports and recommendations including:

- a. Temperature mapping study indicating hot and cold spots inside the cold room
- b. Areas of the cold room where temperature was exceeding limits
- c. Permitted door opening duration. In this case if one of the doors was opened for more than 3minutes, the temperature exceeding the limits
- d. Rearrangement of racks to improve air circulation
- e. Recommendations for improving humidity levels.
- f. Recommendations to be included in the Standard Operating Procedure (SOP)

Similar qualification was carried out for the same customer for their trucks, refrigerators, freezers and reefers.

