DETAILED PROCEDURE AND GUIDELINES

ON

TEMPERATURE MAPPING STUDY & QUALIFICATION OF

COLD ROOMS, WAREHOUSES, VANS, TRUCKS, REEFERS, REFRIGERATORS & BOXES

FOR

PHARMACEUTICAL INDUSTRY

Revision History:

Revision no.	Date of issue	Description
0	16 Nov 2014	Original Issue
1	2 Jan 2015	Sl. No. 3 and subheadings added. Sl. No. 5 and subheadings added. Sl. No. 7 and subheadings added.

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Temperature mapping study and Temperature qualification study are carried out generally in pharmaceutical industry. There are different kind of medicines and vaccines which need to be stored and transported at certain temperatures. Majority of these medicines and vaccines are under two categories viz. Those to be stored between 2 to 8 Degree Centigrade and those to be stored between 15 to 25°C.

It is important for the efficacy of the medicine that the same be stored and transported at the recommended temperature limits as above. If the medicine or vaccine goes above these temperature limits, the medicinal properties will be gradually lost and most importantly the products will not show any indication that it has been compromised. In such case the ultimate distributor and user will be unaware of the efficacy of the medicine.

The storage is done in warehouses, cold rooms or refrigerators and transportation is carried out in boxes, vans, reefers and containers.

The whole set of study is carried out to analyze the temperature distribution in a warehouse, cold room, refrigerator, van or reefer trucks to find out whether the temperature inside such facility is always maintained between the desired temperature.

1. Temperature Mapping Study / Temperature & Humidity Mapping study

This article brief about mapping study for Temperature & Humidity

1.1. Temperature Mapping Study / Temperature distribution analysis

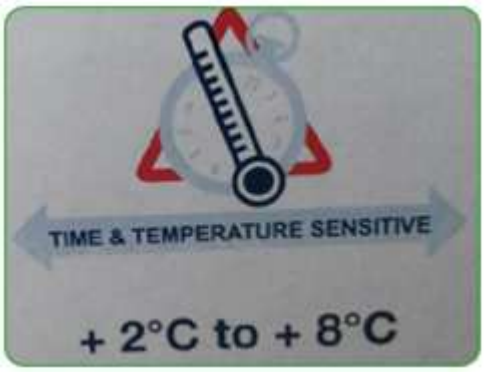
Firstly we will explain about temperature mapping study and thereafter about temperature & humidity distribution.

1.1.1. Why would you require Temperature Mapping Study (aka Temperature Distribution study)?

If you are involved in manufacturing, transportation, storage or distribution of medicines and vaccines, you will be interested to know more about temperature mapping study. In all these cases your medicine is kept inside an enclosed area such as a warehouse, cold room, temperature controlled van, reefer truck, refrigerator, insulated boxes etc.

In such cases you need to ensure that the temperature inside the enclosed area is within the desired limits. eg. If you want to keep the medicine between 2 to 8 °C and you are keeping inside a cold room, how do you ensure that all the entire cold room is between these temperature limits? You might be keeping the medicine at one shelf inside the cold room. You will not have any idea whether this particular place is within the limits. Generally you will have an indicator connected to the cooling unit to display the current temperature. This display picks up the temperature just from one sensor placed at a certain location near the duct opening of the cooling unit, based on which the cooling unit has its switch ON and OFF cycles.

This might be indicating a temperature between 2 and 8 °C. Most of us tend to believe that this displayed temperature is the temperature across the entire cold room.



However how about various shelves and corners of the cold room where you are keeping your medicines which are far away from this particular sensor?

How does a third party like an auditor can check whether the entire cold room is under correct temperature?

How can you ensure that the display at the front door is exact in relation with the corresponding sensor?

How do you know about the variations when a door is opened? The sensor might be far away from the door and hence may not reflect any variation. However it really happens that the area near the door suddenly goes above 8°C.

All these doubts can be clarified only through a temperature mapping study.

1.1.2. How do we carry out temperature mapping study?

In principle a temperature mapping study involves recording the temperature of the cold compartment under various conditions. The data will be recorded for days or weeks as per the nature of the asset. Numerous temperature data loggers will be placed inside the testing area at various heights and data will be continuously recorded. Depending on the nature of the property, the following conditions will be tested:

a. Testing under empty conditions to analyze the distribution of temperature when there are no loads in the area.
b. Testing under 60% loaded condition to analyze the distribution when the area is loaded up to 60% of full capacity.
c. Testing under 100% loaded condition to analyze the distribution when the area is loaded in full capacity.
d. Door opening test to understand the effects on temperature during and after a door opening.
e. Power failure test to analyze the effects in the event of a power failure.
f. Startup test to check the time required for stabilizing of the temperature inside the area.
g. Recovery test to check the time taken for temperature recovery after a door opening.

1.2. What is temperature and humidity mapping study?

The methodology is same as a temperature mapping study. However in this case humidity also will be recorded for the same duration and will be analyzed. If there are dehumidifiers already installed, the settings of the same also will be recorded to compare against the actual results. Nowadays for many of the storage areas, humidity also is important and hence need to be included in the study.

1.2.1. Do you require a temperature mapping or temperature & humidity mapping?

As mentioned earlier, this need to be decided by the manufacturer of the medicines or as per your internal quality policy. For a warehouse, generally it is preferred that humidity also be included in the study because a warehouse is directly affected by the external ambient conditions. For a cold room the humidity can go to extreme high levels of up to 100% because of its nature of operation. Generally the door of the cold room opens to a warehouse which is at a higher temperature. Since the cold room is at a lower temperature, it will attract the moisture and hence will always have a higher humidity. Hence irrespective of the medicine being kept in the cold room, it is ideal that the cold room be analyzed for humidity as well. However this can be decided by you and your pharma manufacturer.

We recommend that for warehouses and cold rooms temperature and humidity mapping study need to be carried out. For vans, reefers, refrigerators and boxes, only temperature mapping study might be sufficient unless otherwise specified.

1.2.2. What is the recommended humidity level for storage of medicines?

This generally depends on the type of medicine and the packaging being kept in the storage area either for cold room or warehouse. Hence this is generally recommended by the medicine manufacturers. Generally most of the manufacturers are recommending that the humidity should be maintained under a maximum limit of 65% under all conditions.

1.2.3. How to reduce the humidity for cold rooms and warehouses for medicine storage?

Humidity can be reduced mainly utilizing dehumidifiers. These are electrical devices which absorb humidity from the air and convert it into water. The water thus extracted can be removed either manually or automatically. In the automatic method there is a water pump attached to the dehumidifier which will pump the water to an external outlet. In the manual method the water gets filled up in a try underneath and has to be manually drained periodically.

In order to decide the number and type dehumidifiers, special calculations need to be carried out considering the present temperature, humidity, desired humidity etc.

Generally for ware houses, desiccant type and for cold rooms, rotary type dehumidifiers have to be used.

1.3. Documentation required prior to commencement of a mapping study

The customer has to provide the layout drawing of the asset including details and locations of cooling units and dehumidifiers if any.

Based on these documents a protocol will be prepared by us which has to be reviewed and approved by the customer.
The tests will be carried out by us based on this protocol prior to commencement of the temperature mapping study.

1.4. Acceptance criteria for the mapping study?

The results of the distribution study will be either pass or fail. Also it can be fail or pass with some deviations. The criteria for acceptance of the study will be defined in the protocol and typical ones are as under:

a. All readings of the data loggers should be within the desired limits of temperature & humidity
b. Mean Kinetic value should be within desired limits (We do not encourage this criteria unless insisted by the client. However we will indicate the value in our reports)
c. During door opening tests, the values should be within limits and should return to normalcy within the desired duration as defined in the protocol.

1.5. How to decide the sampling interval of data collection for the mapping study

Sampling interval is the frequency of data recording of the data loggers. Generally the data loggers can be programmed to record the data at different intervals such as 10seconds, 30 seconds, 1 minute etc. If the sampling interval of a temperature data logger is programmed for 5 minutes it means that the temperature is recorded every 5 minutes.

Sampling interval of data collection should be kept ideally as follows for a temperature mapping study:

a. 3 minutes for 2-8 °C assets such as cold rooms, vehicles, boxes, refrigerators etc.
b. 5 minutes for 15-25°C vehicles.
c. 10-15 minutes for warehouses maintained at 15-25 °C

This is mainly based on the goods to be stored inside the asset. Eg. If a medicine which should not go above 8°C for 2 minutes is stored inside a refrigerator, it means that you should keep a sampling interval of at least 1 minute. For a medicine which is permitted to go above 8°C for 10 minutes, a sampling interval of 3 minutes is sufficient.

This also depends on the range of the temperature. 2-8 °C is a very narrow range and can go above this range even for minor fluctuations. Hence ideally a sampling interval should not be more than 3 minutes.

For a warehouse, 15-25 °C is a wider range and the rise in temperature will be slow. Hence a sampling interval of 10 minutes is sufficient.

1.6. How to use the results of temperature mapping study

From the summary of the reports of a temperature mapping study, the following details will be useful for your practical applications

1. When you decide to place monitoring devices such as data loggers or real time monitoring devices, those should be placed in Hot and cold points. Hot and cold points will be mentioned in our reports.
2. The report will indicate the duration within which the temperature will exceed the permitted levels upon door opening. eg. if such duration is 5 minutes, you should take care that the door opening should be for a very short duration.
3. The report will indicate the duration within which the temperature will exceed the permitted levels in the event of power failure. So in case of a power failure, you should not open the door and should be in closed condition if you expect that power will be restored within such a duration. If you do not expect power restoration within such a duration the medicines should be shifted to an alternate facility such as a temperature controlled van or reefer.

1.7. Temperature mapping study / Temperature & Humidity mapping study for various assets

Brief details of the study for various kind of assets are detailed hereunder

1.7.1. Temperature mapping study of Reefer trucks & vans

For all type of vehicles, primarily the following tests are carried out:

a. Distribution analysis under empty conditions (24 hours)
b. Distribution analysis under 60% loaded conditions (24 hours)
c. Distribution analysis under full load conditions (24 hours)
d. Power failure test
e. Door opening test

The percentage loading can be decided by the client as per his usual loading pattern.

1.7.2. Temperature mapping study of a ware house

For a warehouse the following tests are carried out as part of a temperature mapping study

a. Temperature and humidity distribution analysis is carried out under loaded conditions.
b. Door opening tests to analyze the effects

For an existing warehouse it will be difficult to carry out other tests such as empty test, power failure test etc. since it may be difficult to remove the existing goods form the warehouse. For

a warehouse the distribution analysis is carried typically for 7-14 days. The tests should also include holidays so that the patterns can be analyzed.

Sampling interval of data collection should be kept ideally at 10-15 minutes.

1.7.3. Temperature mapping study of Cold room

For all type of cold rooms, primarily the following tests are carried out:

a. Distribution analysis under empty conditions (24 hours)
b. Distribution analysis under 60% loaded conditions (24 hours)
c. Distribution analysis under full load conditions (24 hours)
d. Power failure test
e. Door opening test

The percentage loading can be decided by the client as per his usual loading pattern. Sampling interval will be generally kept at 3 minutes.

1.7.4. Temperature mapping study of a refrigerator

For refrigerators, primarily the following tests are carried out:

a. Distribution analysis under empty conditions (24 hours)
b. Distribution analysis under 60% loaded conditions (24 hours)
c. Power failure test
d. Door opening test (for different durations such as 60 seconds, 120 seconds, 180 seconds etc., since for a refrigerator the door opening will be more frequent compared to other assets)

The percentage loading can be decided by the client as per his usual loading pattern. Sampling interval will be generally kept at 1-2 minutes.

1.7.5. Temperature mapping study of a shipping box

For shipping box, the following tests are carried out:

a. Distribution analysis under empty conditions (24 hours)
b. Distribution analysis under 60% loaded conditions (24 hours)
c. Power failure test (for active cooling boxes)
d. Door opening test
e. For active boxes, the tests will be conducted inside a van as well as inside a warehouse

The percentage loading can be decided by the client as per his usual loading pattern. Sampling interval will be generally kept at 3 minutes.

1.8. Reports generated in Temperature Mapping study

The reports of a mapping study will include the following details:

a. Temperature distribution – Pass /Fail
b. Humidity distribution – Pass /Fail
c. Hot and cold points of the asset. These will be the hottest and coldest points of the area. Data loggers need to be placed in these areas
d. Analytical graphs for all the tests
e. Any recommendations for improvement
f. Time taken to reach the desired temperature after start up
g. Duration for which the temperature remains within the limits after a power failure
h. Duration within which the temperature exceeds the limits during a door opening

2. What is Temperature Qualification study? (or Temperature & Humidity Qualification study)

Temperature qualification study is a very detailed sequence of tests and analysis to ensure that the asset is designed and installed in such a way that it is capable of maintaining the desired temperature. After these series of test and verification the asset is certified to be qualified for achieving and maintaining the desired levels of temperature and humidity levels. The various tests covered under the qualification process in general are as under:

a. Design qualification process – to verify the equipment are designed to generate the desired temperature and humidity conditions
b. Installation qualification process – To verify whether the installation is carried out as per the design and as per the installation procedures recommended by the respective manufacturers of critical equipment.
c. Operation qualification process – To verify that the operations are carried out as per the recommended procedures of the manufacturers of the critical equipment
d. Document verification – To verify whether all documents are maintained by the user including SOP, calibration certificates etc.
e. Temperature mapping study (and Humidity if required) – This test is more or less same as defined in the first part of this article.

2.1. Difference between Temperature mapping study and Temperature qualification study

In a temperature mapping study, only distribution of temperature & humidity are analyzed. This study makes sure that the distribution is always within the permitted range of temperature and humidity as applicable. However the mapping study does not check various criteria such as SOP, whether installation has been done correctly, whether the machines are working as per the design, whether written procedures are maintained, whether these written procedures are sufficient etc. All such parameters are covered in a temperature qualification study.

A temperature qualification study incudes mapping study, but not vice versa.

2.2. How to decide whether you need Temperature Mapping study or Temperature Qualification Study?

If you want to check only distribution of temperature & humidity, a mapping study is sufficient. If you want to check whether the whole asset is designed, installed and operated correctly, it is desirable to carry out a temperature qualification study.

A qualification study is considered to more of international acceptance. An auditor from another part of the world may not be familiar with various installation and operational parameters of the asset. If an asset is qualified the asset is considered to be a fully satisfactory system.

2.3. Do you require a Temperature qualification study or Temperature and humidity qualification?

Please see our explanation for similar query under temperature mapping study.

If your major parameter is only temperature, they you may limit to a temperature qualification study. If you also require humidity, a temperature & humidity qualification study will be required.

2.4. Advantages of a Temperature qualification study over a mapping study

The temperature qualification study is considered more of international acceptance. So if your clients and suppliers are from various countries it is preferred to have a qualification process done. As an example each country has their own type of design, installation and operation procedures for a cold room. Hence your client from another country may not be familiar with such parameters in your country. If a temperature qualification study is carried out on this cold room, the client need not check any details at all since the cold room is fully qualified to ensure full compliance to keep a temperature between 2-8°C

2.5. Documentation required prior to commencement of a qualification process

Prior to commencement of a temperature qualification study, we require the following document/details from the customer.

a. The customer has to provide the layout drawing of the asset
b. All details of cooling units such as sl. nos., details of sensors, operation manuals, design drawings etc. have to be provided.
c. Similar details of dehumidifiers also have to be provided.
d. All details of temperature monitoring systems (if any) to be provided.

Based on these documents a protocol will be prepared by us which has to be reviewed and approved by the customer.
The tests will be carried out by us based on this protocol.

2.6. Reports of a Temperature qualification study

The reports of a temperature qualification study will contain the following details in general. Please note these may vary depending on the nature of the asset.

a. Design qualification process – Pass or Fail
b. Installation qualification process – Pass or Fail
c. Operation qualification process – Pass or Fail
d. Document verification – Pass or Fail
e. Empty mapping study – Pass or Fail
f. Loaded mapping study – Pass or Fail
g. Power failure test results
h. Recovery test results
i. Start up test results
j. Hot and cold points
k. Deviation if any
l. Recommendations
m. Corrective actions

If all the above tests are passed satisfactorily during the temperature qualification study, we issue a certificate indicating that the asset is fully qualified. The details of the asset will be indicated in the certificate.

3. How to carry out a Qualification study

This section briefly describes method of qualification study for certain assets. You may once again note that a mapping study is part of a qualification study. But the qualifications process involves certain other procedures as explained in previous sections.

3.1. How to carry out qualification of a box

Box is one such item which will require a qualification because box goes through daily tough handling and hence a mapping study alone will not be sufficient to test its efficiency. Also for boxes we recommend a shorter validity of one year for a qualification. As the box goes through tougher conditions, it is preferred to have the qualification done once every year.

Active boxes

For active boxes, qualification includes the following:

- Define a Thermal profile based on general operating conditions
- Test the box against this thermal profile
- Check installation and operation of the cooling units
- Verify the calibration of the sensors and the cooling units

Passive box

For passive boxes, there are not may tests compared to active boxes.

For passive boxes, generally qualification need to be done only on a sample piece and not on every box. Especially there are many types of single use passive boxes and hence one from each design need to be qualified to prove the efficiency of the box.

In order to carry out the study more efficiently, it is desirable to know the operating environment conditions that the box undergoes for each customer.

3.2. How to carry out qualification of a Cold Room

For a cold room, the following verifications need to be done.

- Verify the calibration records
- Check the installation of the cooling units, sensors, location of sensors
- Check entire operation of the cooling units, control panel and associated circuitries
- Check the maintenance procedures of the cooling units

3.3. How to carry out qualification of a Van or reefer

For a van or reefer, the following verifications need to be done.

- Verify the calibration records
- Check the installation of the cooling units, sensors, location of sensors
- Check entire operation of the cooling units, control panel and associated circuitries
- Check the maintenance procedures of the cooling units

4. Reasons for failure of a Mapping study

Common reasons for failure of a temperature mapping study or a humidity mapping study are listed here:

4.1. Reasons for failure of mapping study of a van

We are mentioning of small and medium sized vans. There are many reasons for failure of these vehicles during a temperature mapping study and temperature qualification. The main ones are listed here:

a. The temperature shown in the display unit of the cooling unit may not be matching with actual inside temperature. Probably the sensor is reading is not correct. This can happen for many reasons. Over a period of time the accuracy of the sensor may be

lost. Eg. the display unit might be showing 5°C and the driver will be confident that the cold cabin is at 5°C. However it is possible that the inside temperature is at 7°C. In order to avoid such a situation place a data logger next to the sensor of the cooling unit and record for few hours. Set the cooling unit at desired temperature. After couple of hours download the data and analyze. The graph will be in continuous up and down cycles. Check the highest and lowest temperature of these cycles. If these values are close to the set point, it means that the sensor and display unit are working correctly. Eg. if the set point is 5°C, the highest and lowest readings should be 7°C & 4°C. (This varies based on the type of cooling unit, programmed setting of upper and lower cut off limits etc. However this will give an indication about correlation of the displayed temperature and actual sensor temperature.

b. Temperature goes to extreme low and high points at all cycles. Eg. The set point is 5°C. However the temperature goes regularly to 9°C and 3°C regularly. This happened because the cooling unit is programmed accordingly. ie. It has a high cut off at 4°C above the set point and low cut off of 2°C below the set point. This can be programmed for 2°C for both high and low cut off points. Thereafter the higher & lower cut off will be 7 & 3°C respectively. (This feature is based on the manufacturer and models of the cooling unit)
c. Temperature on one end of the vehicle goes beyond limits. This happens mainly in vehicles which has one cooling unit and having fan only at one end. It is possible that the other end of the cold cabin is not properly receiving the air. If the fan unit is not producing strong air flow it may happen. Otherwise air flow ducts will have to be provided from the cooling unit to the other end of the cooled cabin. Thus the air will be divided through multiple ducts and distributed at front and rear end of the vehicle.
d. Temperature goes high at certain points during loaded test. This may happen mainly due to limited air flow. During a loaded test (and during actual loaded conditions), goods should not be placed directly in front of the air flow. Also sufficient space should be left on all sides and on the top for efficient air flow.

4.2. Reasons for failure of mapping study of a cold room

General reasons for failure of a cold room are as under:
The display unit fixed at the outside of the cold room may not be displaying the correct temperature of the cold room.
The loading and distribution of the shelves may not be uniform thus hindering proper airflow
Humidity may be higher than the permitted levels
The positioning of the cooling units may not be in perfect location thus affecting uniform distribution
Air curtains may be required at the doors

4.3. Reasons for failure of mapping study of a Ware house

For warehouses the most common reasons for failure are:

a. The number of cooling units or the capacity of the cooling units may not be sufficient

b. The location of the ducts may not be proper

c. Humidity may be higher than desired levels

4.4. What is the validity period of a temperature mapping study and temperature qualification study?

There are no general rules applicable for the same. However for a new facility we suggest that the study report can be considered valid for a period of 3 years.

If any modifications are carried out related to shape and layout of the asset, modification or replacement of cooling units, rearrangement of racks etc., the original report cannot be considered valid. The reasoning is that any of these changes will affect the distribution of temperature and humidity.

5. Reasons for failure of a Qualification study

Even if a mapping study is successful, the qualification may fail for other reasons. Few of the major reasons are listed here. Such reasons are pointed out as deviations in the report and most of the minor deviations can be closed after rectifications. However sometimes it may happen that the deviation might be major and may require major rectifications and retesting for successful qualification.

5.1. Reasons for failure of qualification study of a van

Major reasons for failure of a van are:

- Failure to maintain proper calibration reports
- Control panel of the cooling unit of the van is not working properly
- The equipment are not installed as per manufacturer's recommendation
- The equipment are not operated as per manufacturer's recommendation
- There are no clear written instructions to the operators for proper operation of the vehicle

5.2. Reasons for failure of qualification of a cold room

Major reasons for failure of a cold room are:

- Failure to maintain proper calibration reports
- Control panel of the cooling unit including condenser, evaporator of the cold room is not working properly
- The equipment are not installed as per manufacturer's recommendation
- The equipment are not operated as per manufacturer's recommendation

- There are no clear written instructions to the operators for proper operation of the vehicle

5.3. Reasons for failure of qualification of a passive box

Major reasons for failure of a passive box are:

- Proper written procedures are not available for instructions of operation
- Proper identification including serial numbers are not available

5.4. Reasons for failure of qualification of an active box

Major reasons for failure of a passive box are:

- Failure to maintain proper calibration reports
- Control panel of the cooling unit including condenser, evaporator of the cold room is not working properly
- The equipment are not operated as per manufacturer's recommendation
- There are no clear written instructions to the operators for proper operation of the vehicle

6. How to improve the results of the test and eliminate chances of failure?

It is ideal that before carrying out the actual study, you may carry out a trial study with few number of data loggers to analyze the data. This trial study will help you to evaluate major problems if any. For all contracts being undertaken by us, we carry out a trial study before commencement of the actual test. This will save valuable time and money for the customer.

6.1. Advantages of a trial study

Major advantage of conducting a trial study are:

a. Saving time and money – After conducting a full test you may end up with some deviations. In such case you will have to carry out a retest after undertaking the corrective actions. By this time you may be in the midst of a climate change and hence will have to wait for the next season. If a trial study is planned properly, this can be avoided.
b. Correct settings for cooling units – sometimes just by changing the settings of the cooling units you may have better results. You may not have noticed this so far because your current recording devices were not placed at the correct hot and cold points.
c. Requirement of dehumidifier – In many cases humidity distribution was not properly analyzed and hence may require installation of dehumidifiers. This is a process involving time and money and hence if understood at the proper stage, suitable actions can be undertaken.

6.2. How to carry out a trial study?

Before commencing the actual tests, we will sent you some data loggers for placing at certain locations as per the drawings. The data need to be collected for a certain duration and the data loggers have to be returned. We will analyze the data and will provide suitable recommendations. Generally we include one trial study in our scope to assist customers (To be finalized at the time of finalizing the order)

7. What is Validation? What is difference from Qualification?

Validation is often confused with Qualification and often used interchangeably. It may not cause a problem while the terms validation is qualification is used interchangeable. We have seen especially the following terms being used:

a. Validation of boxes – This is generally qualification of the boxes only unless defined separately. If the data logger used in the boxes need to be validated, that is a separate procedure and is not covered under qualification of the box. Please see d, e & f under this section for more details.
b. Validation of cold rooms – This also refer to qualification only. If the data logger or real time monitoring system used in the cold room need to be validated, that is a separate procedure and is not covered under qualification of the cold room. Please see d, e & f under this section for more details.
c. Validation of vans, reefers etc. - This also refer to qualification only. If the data logger or real time monitoring system used in the vehicle need to be validated, that is a separate procedure and is not covered under qualification of the van or reefer. Please see d, e & f under this section for more details.
d. Validation of real time temperature monitoring system – This is not part of qualification and is done separately. In simple terms real time monitoring system consists of electronic components, software, cloud server, local server etc. and it need to be verified that all such components are working correctly ensuring correct recording and readings across all these channels. Also this has to meet CFR Part 11 standards. This whole process is known as validation of the system. Once the system is validated, you can be sure that the readings produced at different points of the hardware and software are all the same.
e. Validation of a data logger – This also is in line with Sl. d above, but applicable for the data logger and its software
f. Validation of a software used to monitor the system.- This also is in line with d & e above. This is generally applicable for any software, but in our context we are referring to any software used for monitoring of temperature or humidity. Eg. If a customer is using disposable data loggers (or any other data loggers) regularly, the report is generated using its software. The software is installed in a computer. Now how do we know as a user that the software is correctly producing all reports from the data logger? If there is an error in the software, the readings and reports will not be correct. If the software is validated, we can be sure that the reports are 100% correct. In this is a onetime procedure for the software, until a major revision is carried out.

8. Documents related to Mapping study & Qualification

a. Case study of a temperature qualification study on a cold room : http://bit.ly/14056T5
b. Protocol / SOP for Temperature qualification study of cold room : http://bit.ly/1zYJyno
c. Protocol / SOP for Temperature mapping study of warehouse : http://bit.ly/1Ah2StI

NB: For ease of understanding, we generally mentioned about temperature throughout the article. However all mentions about Temperature mapping study are equally applicable for Temperature & Humidity mapping as well. Similarly all mentions of a Temperature qualification study are equally applicable for Temperature & Humidity qualification study.
Also temperature mapping study is known as Temperature distribution analysis.