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溫度測繪評估

Temperature Mapping

裕利股份有限公司

張富文資深品保經理

2013-09-17

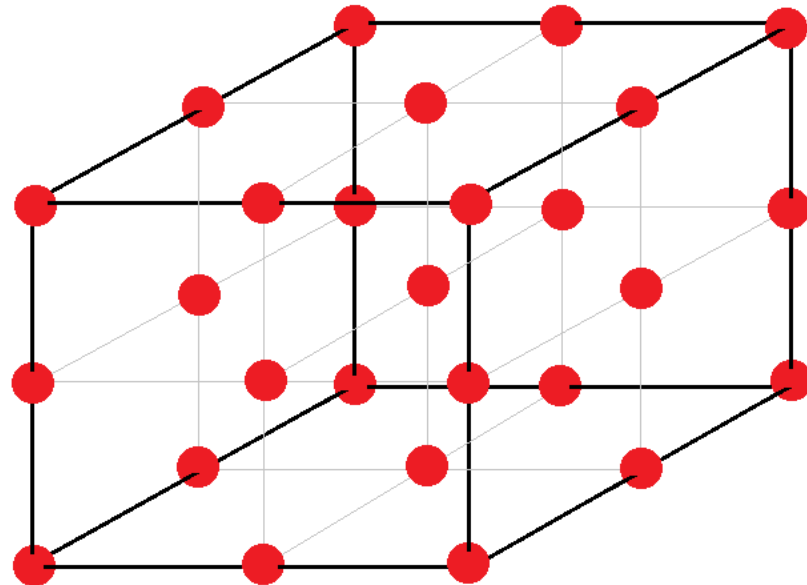
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Temperature Mapping

Temperature Mapping is the processes of recording and mapping the temperature in a 3 dimensional space.

Mapping grid



Guidelines and Requirements

PIC/S Guide to GMP for Medical Products, Part 1,

3.19. Storage areas should be designed or adapted to ensure good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature limits. Where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored.

Guidelines and Requirements

USP/General Chapters: <1079> GOOD STORAGE AND SHIPPING PRACTICES

ESTABLISHING TEMPERATURE PROFILES

Temperature profiles can be compiled by using a suitable number of thermometers or other temperature recording instruments. They should be placed throughout the warehouse in divided sections and should record the maximum and minimum temperatures during a 24-hour period for a total of three consecutive 24-hour periods.

Guidelines and Requirements

EU Guidelines on Good Distribution Practice of Medicinal Products for Human Use

3.2.1. Temperature and environment control

An initial temperature mapping exercise should be carried out on the storage area before use, under representative conditions. Temperature monitoring equipment should be located according to the results of the mapping exercise, ensuring that monitoring devices are positioned in the areas that experience the extremes of fluctuations.

9.4. Products requiring special conditions

Guidelines and Requirements

我國藥品GDP 規範(草案)

3.14 儲存區應在代表性的條件下進行溫度測繪，且應考慮到季節性變化。應在開始使用前進行初步的測繪。應依照風險評估演練結果，或每當設施或溫度控制設備有重大修改時，重複進行測繪演練。溫度監控設備應依照測繪演練結果設置。

9.20 使用冷藏車時，則在運送時所使用的溫度監測設備應定期或至少每年進行維護及校正。這包括代表性條件下的溫度分布，且應考量到季節變化。如被要求，應提供客戶溫度資料，以證明產品在運送時維持在規範的溫度儲存條件內。

Guidelines and Requirements

其他

ASTM D3103 - 07e1 Standard Test Method for Thermal Insulation Performance of Distribution Packages

Mapping Processes

1. Establish a validation plan
2. Consider areas at risk
3. Develop a validation protocol
4. Set up data loggers distribution
5. Select suitable devices
6. Conduct test
7. Retrieve data and analysis
8. Remediation
9. Documentation



Mapping Processes

1. Establish a validation plan

- Regulatory compliance
- Quality commitment
- Risk-based approach



Mapping Processes

1. Establish a validation plan(cont'd)

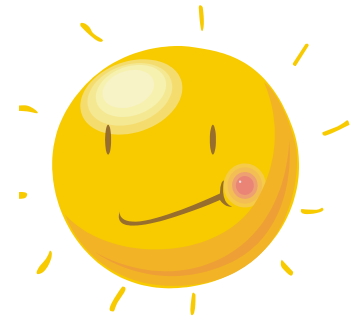
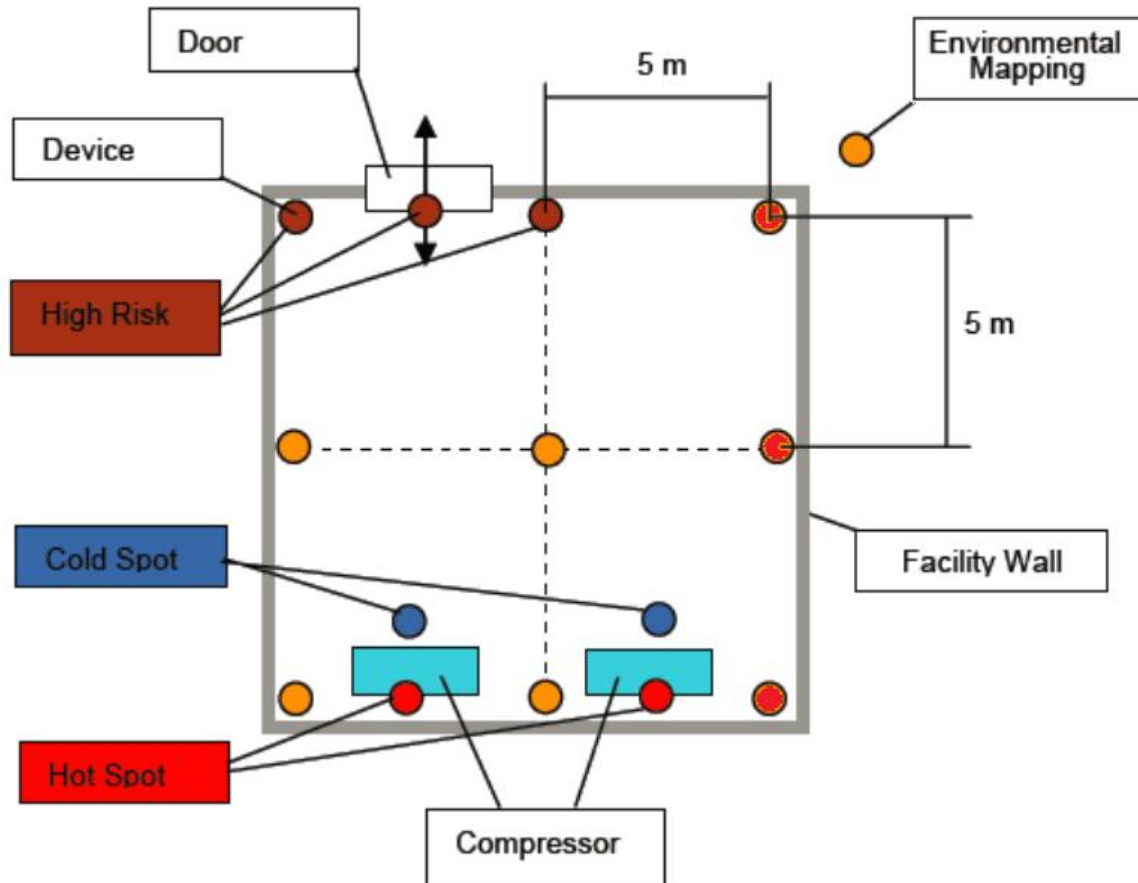
Validation Master Plan:

- Objective
- Roles/Responsibilities
- Activities
- Schedule
- Resources
- Procedures



Mapping Processes

2. Consider areas at risk



Mapping Processes

3. Develop a validation protocol

Inc (ZPI) Taiwan, R.O.C.		Title: Validation for AC3 area-temperature mapping Doc. No. VP-014 Rev. No. 1 Attachment: I Date: 2012.03.10 Page 1 of 10	
Validation Document		Validation Document	

Validation for AC3 Area- Temperature Mapping ,

Written by: _____

Title: Amy Liu Name: _____ Date: _____

Quality Assurance Assistant

Reviewed by: _____

Title: Janus Yuan Name: _____ Date: _____

Warehouse Manager

Approved by: _____

Title: Seven Chang Name: _____ Date: _____

Senior Quality Manager

Change Record

Revision Number	Date	Responsible Person	Description of Change
1	2012-03-10	Amy Liu	Initial Release

Distribution List

Position/Name	Department/Division	Notes
Dept. Manager	Warehouse, QA	

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Mapping Processes

4. Set up data loggers distribution



TL – Top level
ILn – Intermediate levels
LL – Lowest level

A mapping grid has always at least 2 levels.

Mapping Processes

5. Select suitable devices



TempTale®4 Dry Ice



TempTale®4 Humidity

- Brand
- Data Capacity
- Sampling Rate
- Monitoring range and Accuracy
- Size
- Battery Life
- Calibrations
- Software

Mapping Processes

6. Conduct test

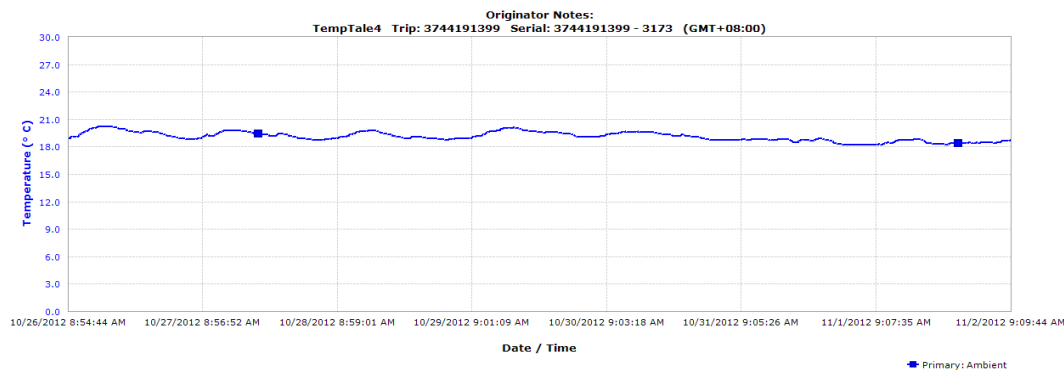
➤ Interventions



Mapping Processes

7. Retrieve data and analysis

2012-11-1 3:24 AM	19	2012-11-1 3:25 AM	18.7	2012-11-1 3:26 AM	17.7	2012/11/1 03:30	17.2	2012/11/1 03:30	17.6	2012/11/1 03:30	19.1	2012-11-1 3:23 AM	18.6	2012-11-1 3:23 AM	18.7	2012-11-1 3:23 AM	
2012-11-1 3:39 AM	18.9	2012-11-1 3:40 AM	18.7	2012-11-1 3:41 AM	17.7	2012/11/1 03:45	17.1	2012/11/1 03:45	17.7	2012/11/1 03:45	19.1	2012-11-1 3:38 AM	18.6	2012-11-1 3:38 AM	18.7	2012-11-1 3:38 AM	
2012-11-1 3:54 AM	18.9	2012-11-1 3:55 AM	18.6	2012-11-1 3:56 AM	17.6	2012/11/1 04:00	17.1	2012/11/1 04:00	17.7	2012/11/1 04:00	19.1	2012-11-1 3:53 AM	18.6	2012-11-1 3:53 AM	18.7	2012-11-1 3:53 AM	
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2012-11-1 4:39 AM	18.9	2012-11-1 4:40 AM	18.7	2012-11-1 4:41 AM	17.7	2012/11/1 04:45	17.1	2012/11/1 04:45	17.6	2012/11/1 04:45	19.2	2012-11-1 4:38 AM	18.6	2012-11-1 4:38 AM	18.7	2012-11-1 4:38 AM	
2012-11-1 4:54 AM	18.9	2012-11-1 4:55 AM	18.7	2012-11-1 4:56 AM	17.8	2012/11/1 05:00	17.1	2012/11/1 05:00	17.6	2012/11/1 05:00	19.2	2012-11-1 4:53 AM	18.6	2012-11-1 4:53 AM	18.7	2012-11-1 4:53 AM	
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Mapping Processes

8. Remediation

- Removing product from problem areas (such as hot spots near ceilings).
- Changing work practices (such as keeping doors open or closed).
- Changing racking or shelving configurations. Repositioning racks or shelving to improve air circulation.
- Changing the location of heating devices.



Mapping Processes

8. Remediation(Cont'd)

- Adding air conditioning.
- Improving ventilation.
- Installing more or larger-capacity fans.
- Adding humidification or dehumidification.
- Installing an HVAC control system.



Mapping Processes

9. Documentation



Mapping and Monitoring

From mapping study we may collect the following information:

- *The impact of interventions*
- *Identification of hot and cold spots,*
- *Variation of temperature at a single point,*
- *Temperature variation across the area,*
- *Length of time of any temperature excursions.*

Mapping and Monitoring

- Monitoring is the continuous long term recording process on the identified *hot and cold spots*. Additional points may be considered.
- Temperature mapping is very different from routine monitoring. One of the key differences is the number of points the temperature is measured at in the temperature controlled area.

- The End -

實作練習

1. 試描繪出倉庫溫度測繪點
 - 在一白紙上畫出自己倉庫平面圖
 - 約略說明倉庫長、寬、高
 - 約略標示貨架區、出入口、設施設備安裝位置等
 - 約略標明空調系統配置
 - 在繪製好的圖上標出溫度測繪點
 - 與學員分享與說明自己的測繪點圖

實作練習

2. 試擬定年度確效或驗證計畫

- 可參照投影片(第11頁)內容撰寫
- 與學員分享與說明確效或驗證計畫