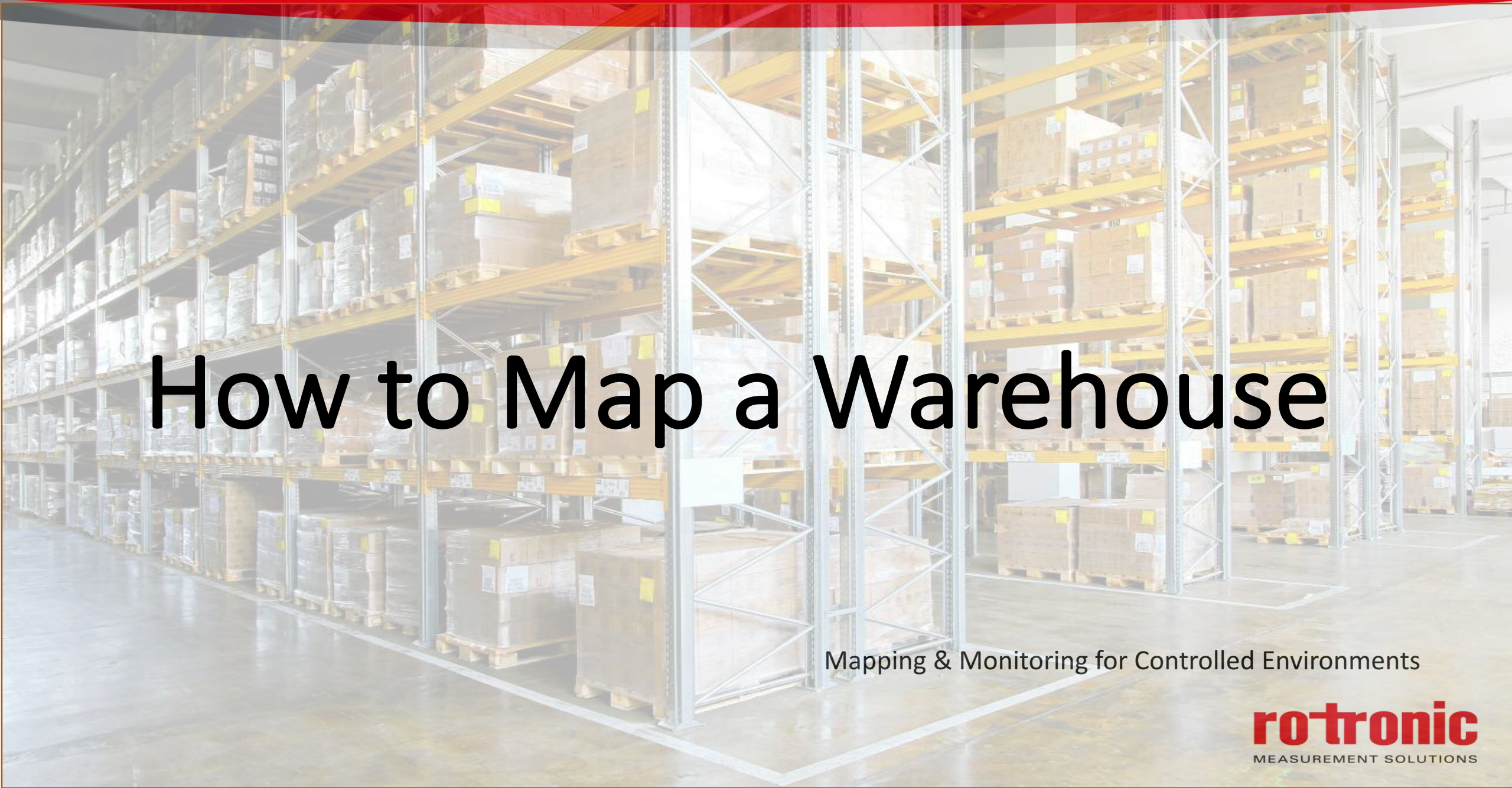

How to Map a Warehouse

Mapping & Monitoring for Controlled Environments

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Webinar Presenters & Humidity Experts

Bruce McDuffee

Steve Chenal

Agenda & Takeaways

Agenda

- Regulations & Guidance Overview
- Step 1 – Space Assessment
- Step 2 – Prepare the Protocol
- Step 3 – Conduct the Mapping
- Step 4 – Prepare the Report
- Summary & Questions

Takeaways

- Understand the high level process
- Learn what questions you should be asking

Regulations & Guidance

Regulation and Guidance USP (United States Pharmacopeia)

- USP Chapter 1079 – Good Storage and Distribution Practices
  - describes good storage and distribution practices to ensure that drug products reach the end user (practitioners and patient/ consumers) with quality intact.

“Drug product storage areas are required to maintain the product temperature between the limits as defined on the product label. “

Regulation and Guidance USP (cont.)

- USP Chapter 1118 Monitoring Devices – Time, Temperature, and Humidity
  - Provides background on the science and technology of temperature and humidity monitoring

Regulation and Guidance EU

- EC Guidelines - Good Distribution Practice of medicinal products for human use (5 November 2013)

- *“Suitable equipment and procedures should be in place to check the environment where medicinal products are stored. Environmental factors to be considered include temperature, light, humidity and cleanliness of the premises.*
- *An initial temperature mapping exercise should be carried out on the storage area before use, under representative conditions. ”*

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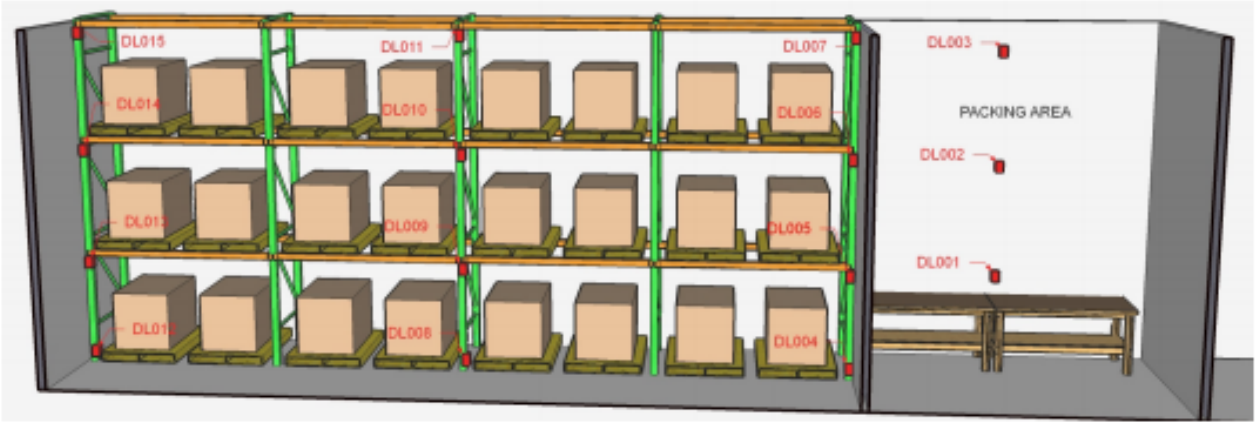
Regulation and Guidance WHO

- World Health Organization (WHO)
  - Technical Report Series, No. 961, 2011
  - Supplement 8 - Annex 9: Model guidance for the storage and transport of time and temperature-sensitive pharmaceutical products (May 2015)

Regulation and Guidance FDA

- Food and Drug Administration
  - **“Storage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected.”**



Space Assessment

Space Assessment

- What type of HVAC is present?
  - Heating
  - Air conditioning

Space Assessment

Potential high variance areas:

- Windows
- Doorways
- Exterior walls
- Anything that may create heat/cool zones
  - compressor
  - fans
  - etc.
- HVAC ducts
- Lighting
- Rack heights

Space Assessment and Begin to Prepare the Protocol

- Consider the mapping report details *before* starting the mapping.

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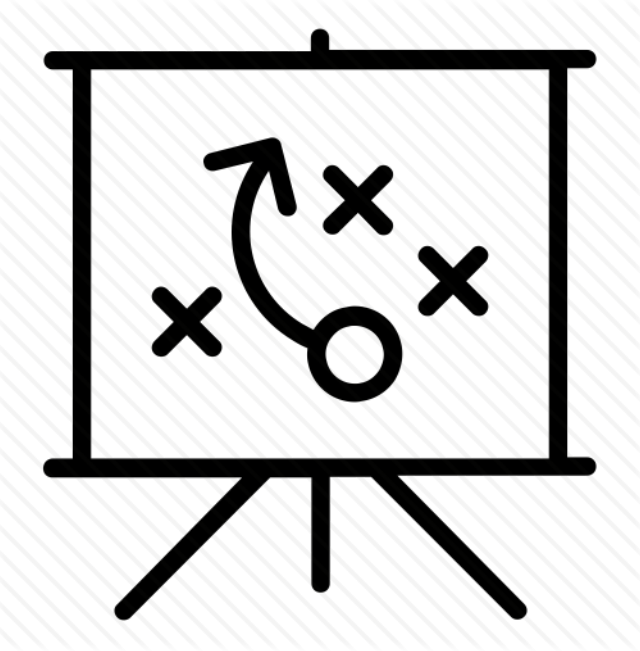
Prepare the Protocol

Prepare the Protocol

- Many room mappings fail due to a poorly prepared protocol
- Keep the protocol simple and targeted as possible



Prepare the Protocol

The mapping protocol should contain the following sections:

a. Approval page and change control history

b. Acronyms and glossary

Prepare the Protocol

c. Description and rationale
d. Scope
e. Objectives

Prepare the Protocol

f. Methodology
g. Mapping report template
h. Annexes as needed

Prepare the Protocol

- Special Calculations
- MKT Calculation
  - a simplified way of expressing the overall *effect* of temperature fluctuations during storage
- High Low Data
- Mean Temperatures
- Leverage reporting from the data collection software to enhance the final report

Comments & Questions

Please type your questions into the chat box at the lower left portion of your screen.

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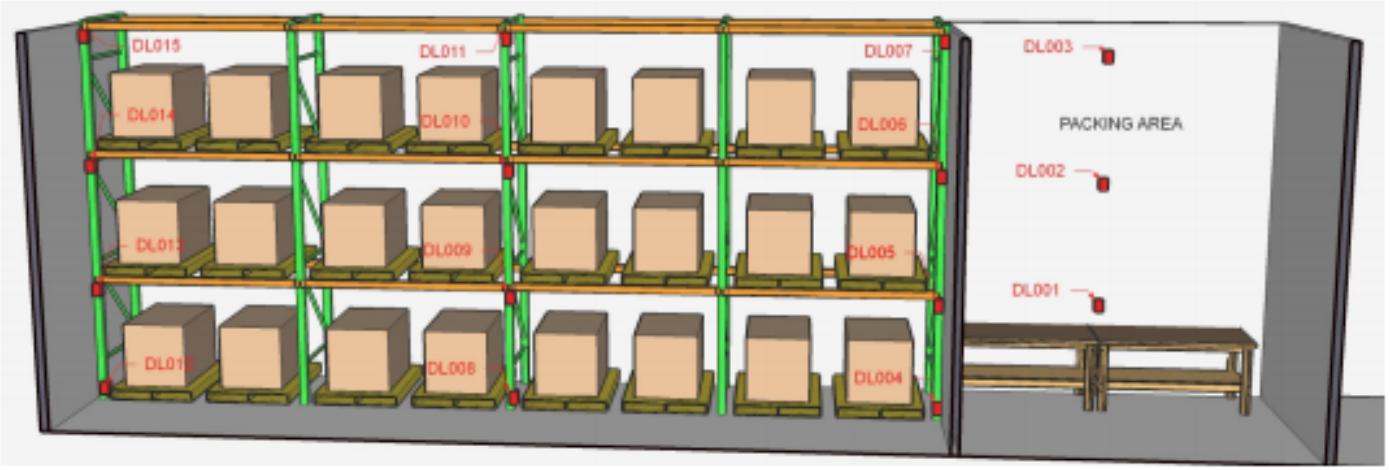
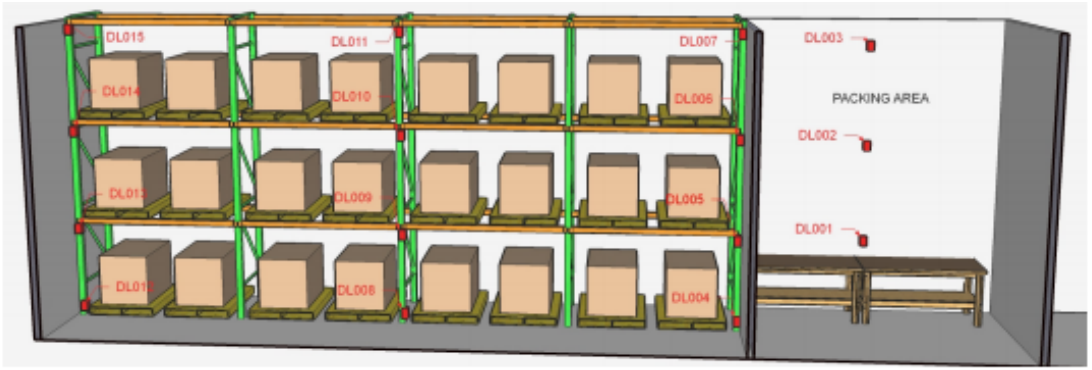


Conduct the Mapping

Conduct the Mapping

- Follow the defined mapping protocol
- Place and document the placement of loggers
- Ensure that each logger can be identified



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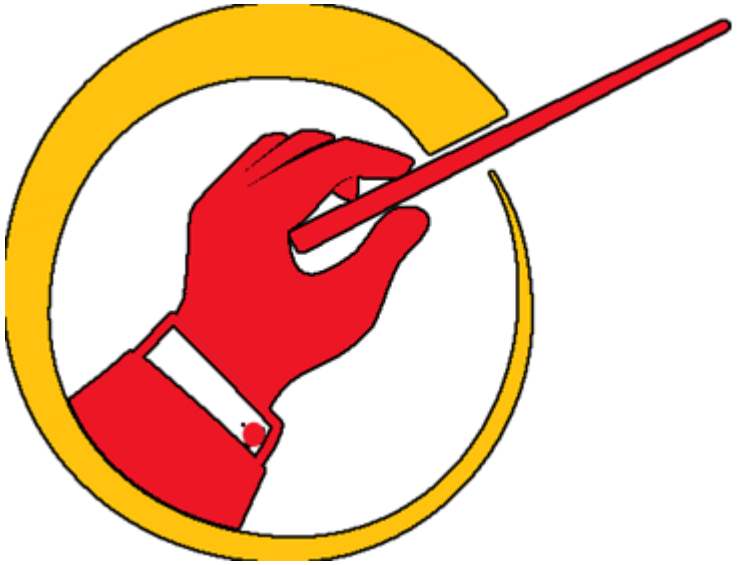
Conduct the Mapping



- Ensure that logger memory will be available for the entire length of the mapping
- Ensure that the loggers are active and logging
- Check data logger battery level

Prepare the Mapping Report

Prepare the Mapping Report

The mapping report should include the following sections:

a. Introduction
b. Summary
c. Conclusions and recommendations
d. Report annexes

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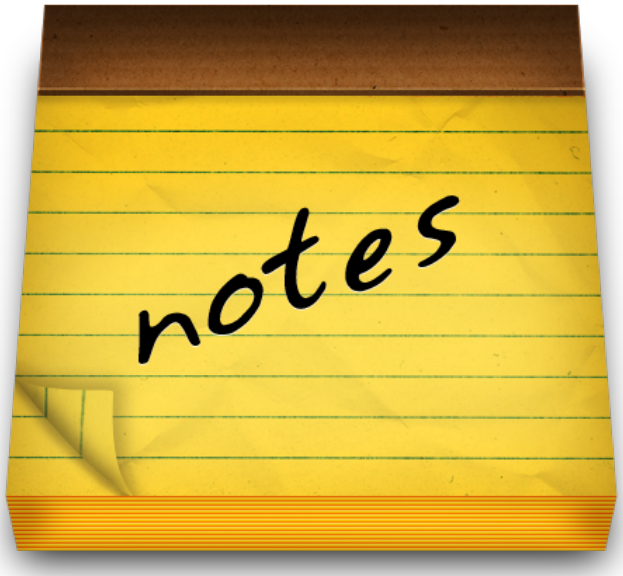
Prepare the Mapping Report [cont.]

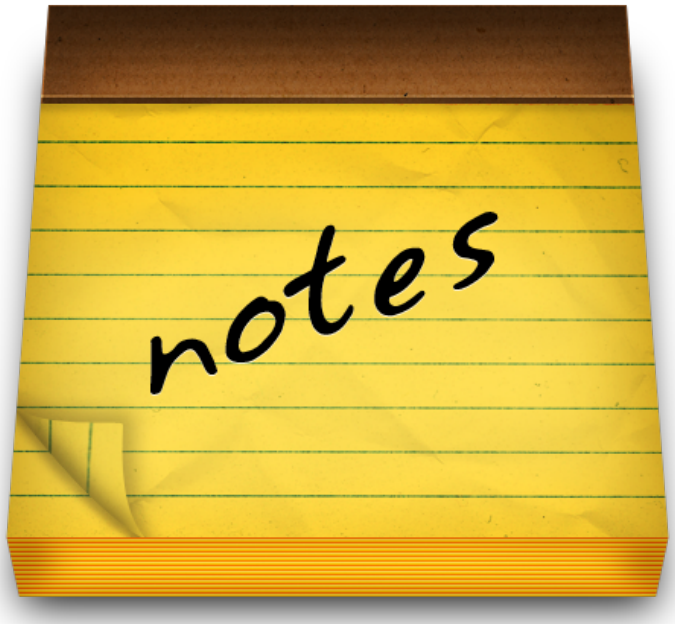
d. Report annexes including:
   - the site survey, showing logger locations
   - the raw data
   - spreadsheet data and related temperature graphs for every EDLM used in the mapping exercise
   - raw results of the data analysis, including hot and cold spots
   - key documents any other supporting material
   - deviation reports, including corrective and preventive action forms, if required: this may include a recommendation for partial or total re-mapping
   - calibration certificates for all loggers used

Some Notes about the Mapping Report



- Again: Leverage reporting from the data collection software to enhance the final report
- Include mean , minimum and maximum data (hot and cold spots)

More Notes about the Mapping Report



- The report should include any anomalies or deviations
- Recommendations should be included for any required changes

Summary and Takeaways

- Regulations & Guidance Overview
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Rotronic Academy

- Resources for cGMP mapping
- Resources for environmental monitoring

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Next Webinar

How to Choose an Environmental Monitoring System

Thursday, January 12th 1:00PM EST

www.rotronic-usa.com/webinars

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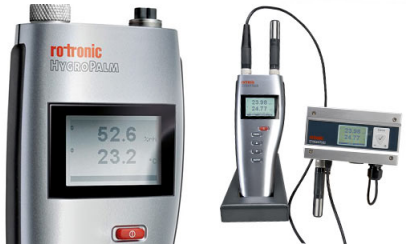
Mapping and Monitoring for Controlled Environments



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