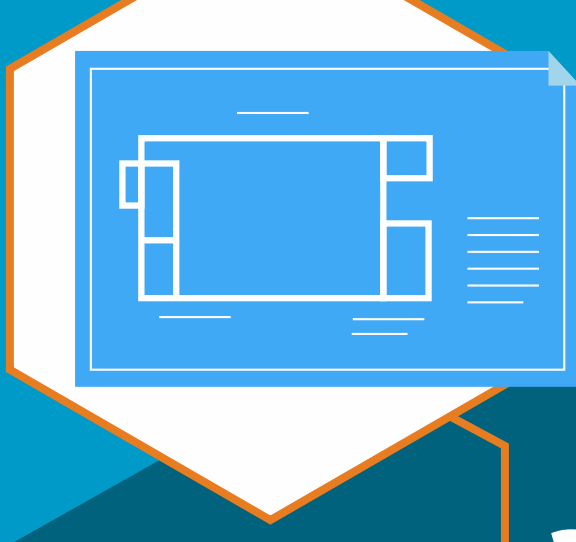


9 Steps to GxP-compliant Warehouse Mapping

1 Create a validation master plan

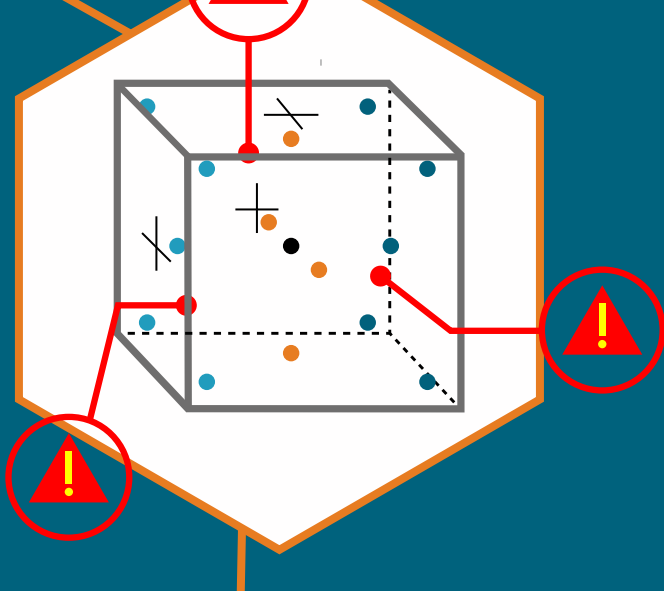
Establish a validation plan that takes a risk-based approach. Where will environmentally sensitive products and materials be stored?



2 Identify areas at risk

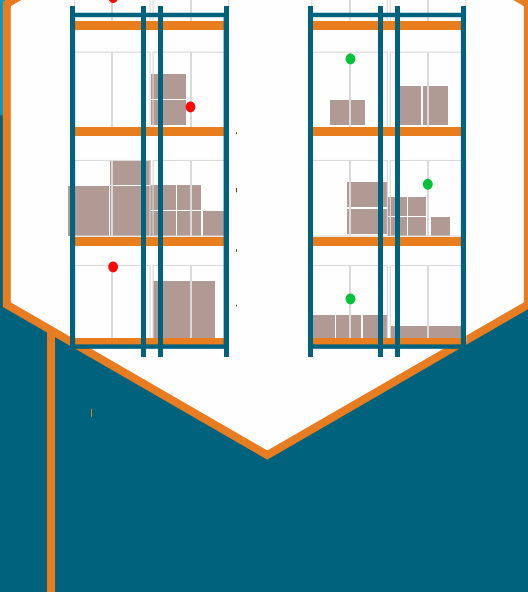
Identify risk from variations in temperature and humidity. Account for :

- Volume of space
- Temperature gradients
- Energy sources (heaters, AC, fans)
- Shelving layout
- HVAC control locations
- High traffic areas
- Seasonality
- Location to external exposure



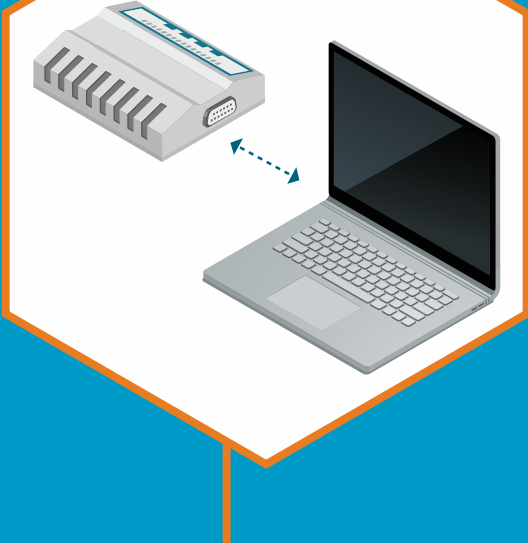
3 Develop protocol information

Based on identified risks, make decisions on what your data needs are for your mapping study.



4 Determine sensor distribution

How can we create a uniform distribution of sensors that will give us a full understanding of the environment? Take into consideration external walls, windows, lighting, and any type of air circulation. Storage shelf capacity has an effect on airflow and temperature gradients. Will humidity have an adverse effect on products? Consider using both temperature and humidity sensors.



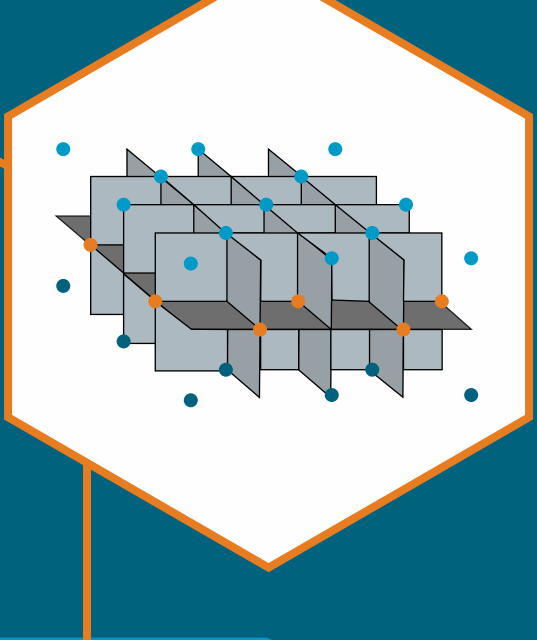
5 Select suitable technology

Choose equipment designed for mapping studies.

- Software that meets all 21 CFR Part 11 & International standards
- Temperature only
- Temperature and Humidity
- High-accuracy measurement range
- Long-term stability
- Traceable calibration
- Clear, comprehensive and accessible records

6 Set up mapping equipment

Setup sensors where planned



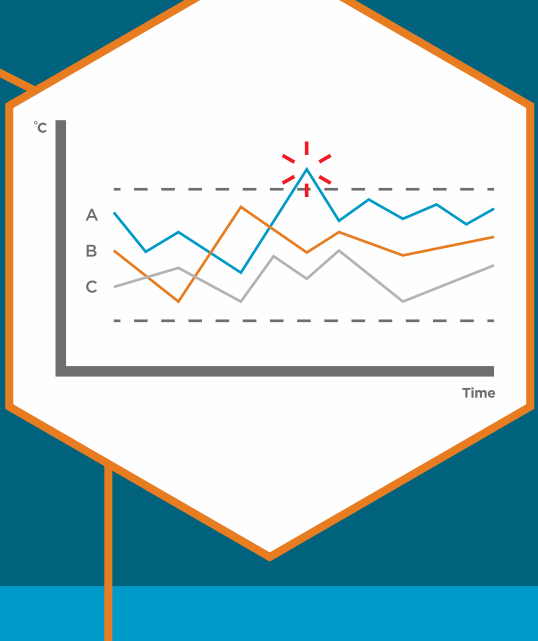
7 Test and review data

Conduct a test and look at data for these points :

- Dates and times
- Calculated values (temp. min/max, avg.)
- Review trends over time
- Instrument settings
- Traceable calibration
- Calibration info
- Review and approve report

8 Make modifications

Identify locations where products may be exposed to unacceptable conditions, then make adjustments to storage locations. Don't forget to modify your validation protocol in light of results from initial mapping test.



9 Document and schedule mapping study

Conduct and document a mapping study for approval then plan out mapping schedule.



Have you successfully mapped your facility? Take action and read up on all **9 steps for validation mapping studies.**

[READ ABOUT VALIDATION MAPPING](#)

[GET TO KNOW CONTINUOUS MAPPING](#)