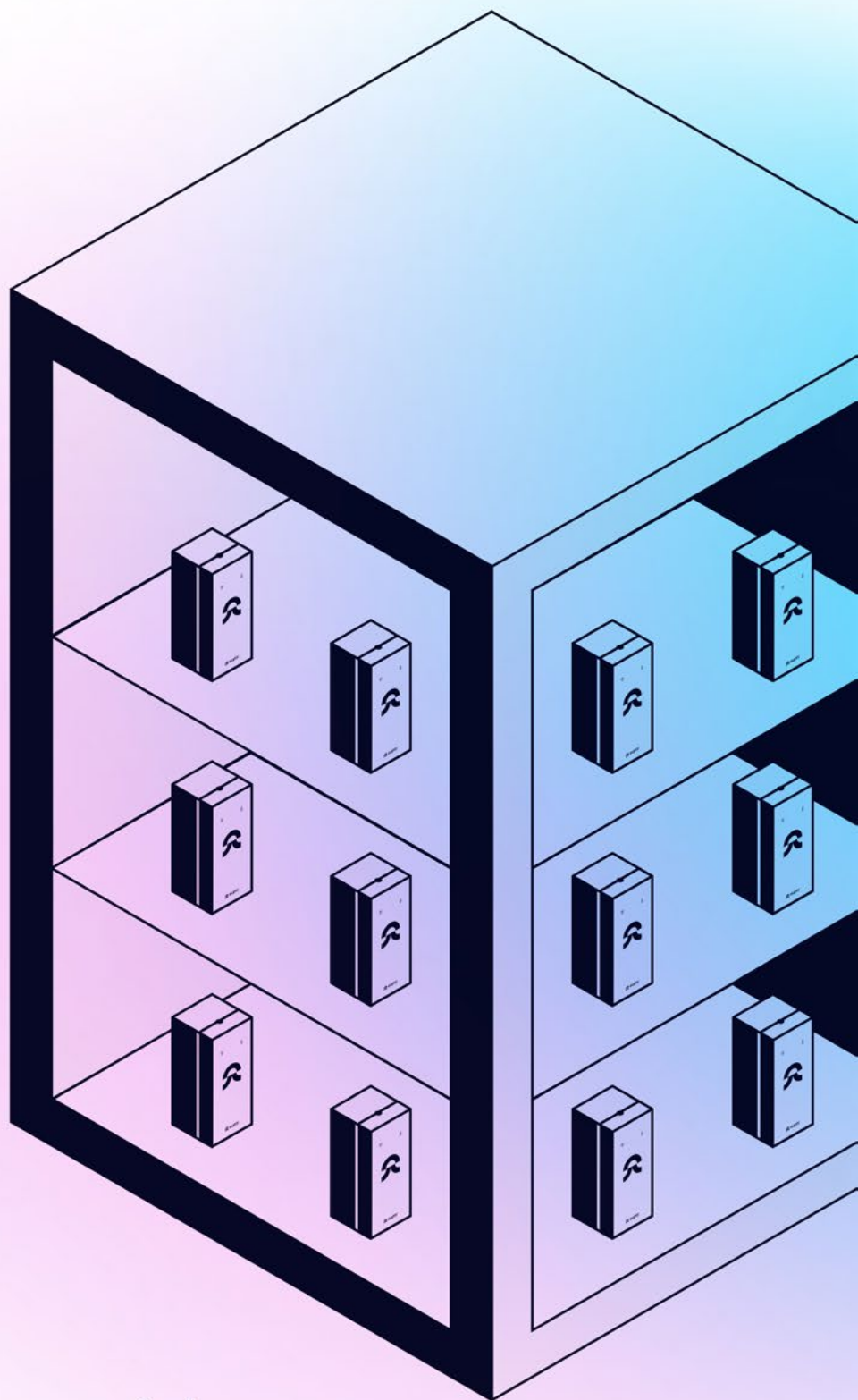




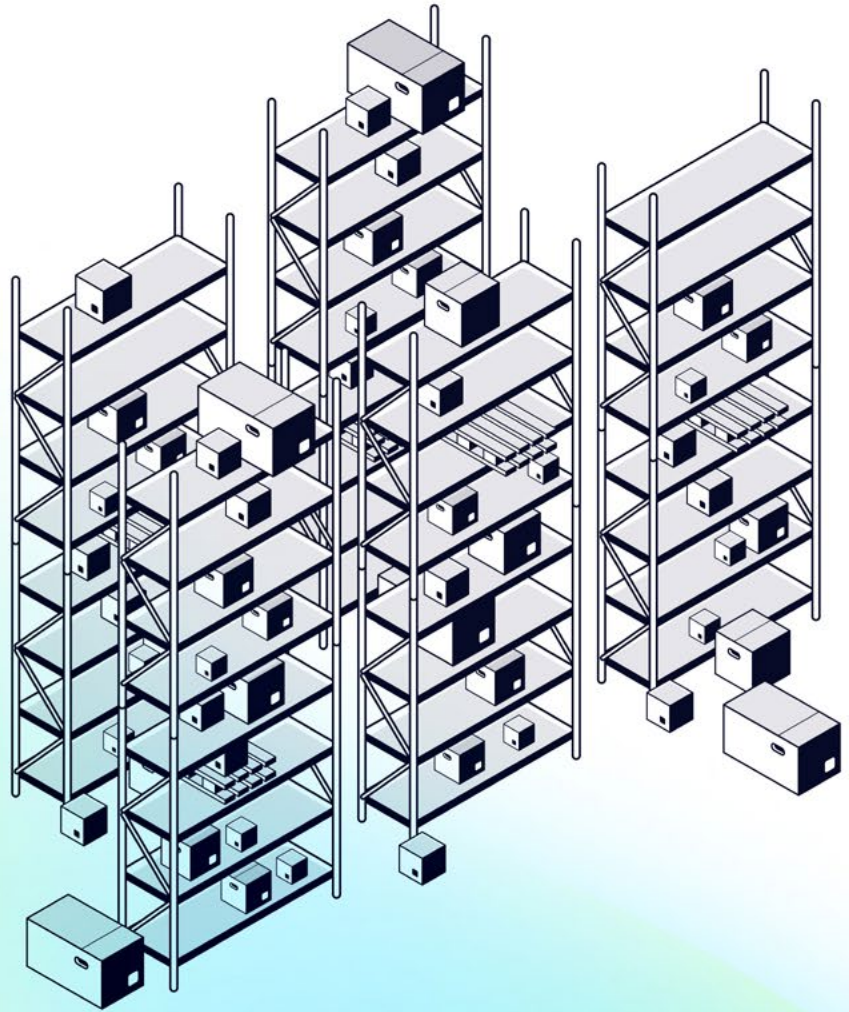
The ultimate guide to temperature mapping

E-book



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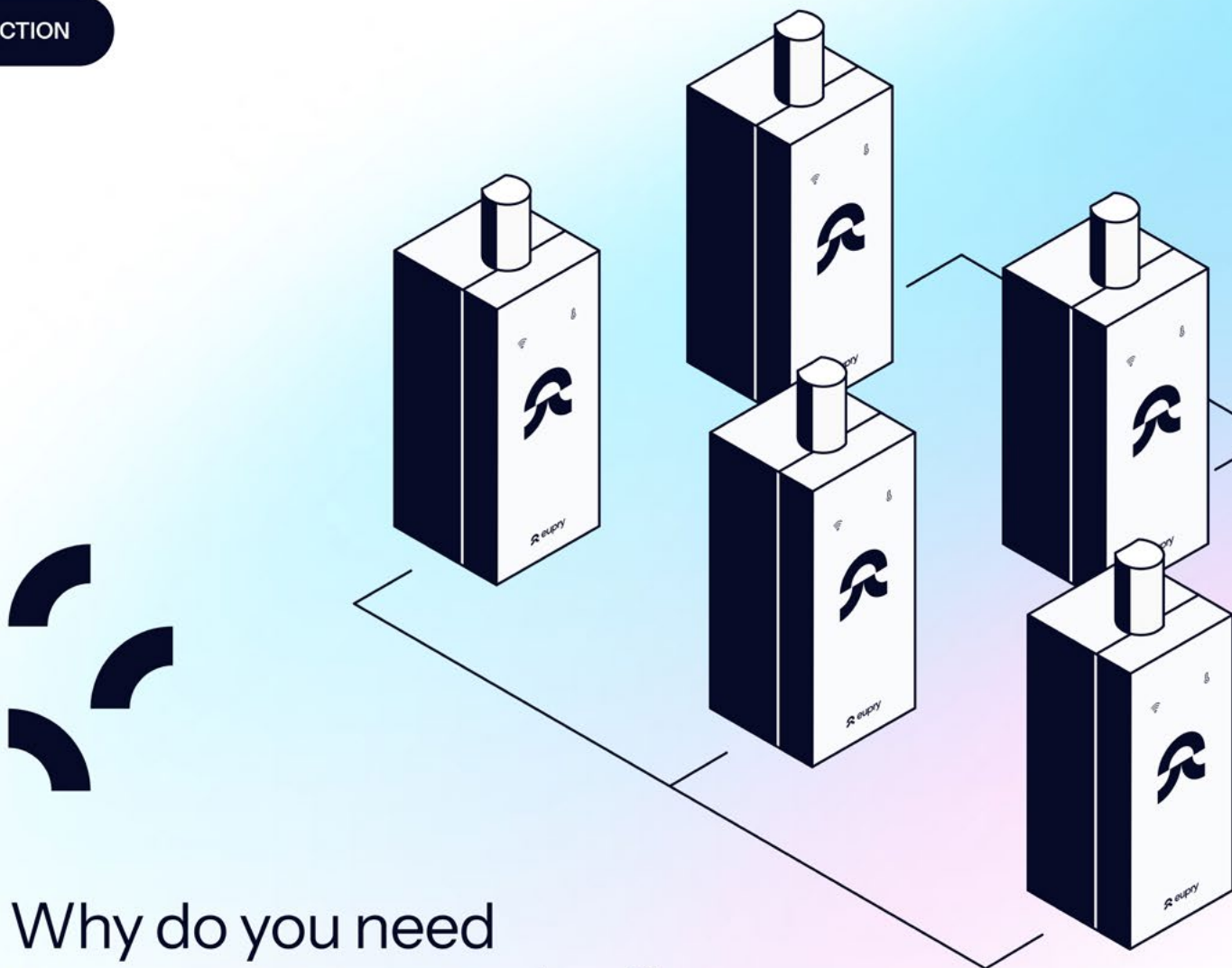


Introduction

Downtime, unnoticed failures, differing requirements: Temperature mappings are complex - especially working in the challenging environment of the logistics industry.

This handbook takes you through everything you need to know to conduct efficient, professional, and compliant temperature mapping within the pharma, biotech, and logistics.

Eliminate complications and gain solid confidence in your mapping study's quality - no matter the equipment type, number, and size.



Why do you need temperature mapping?

Mapping is a process carried out to prove that equipment meets the criteria set by authorities and auditors and to locate hot and cold zones.

In other words, a **temperature mapping study** documents that the equipment maintains temperatures within defined limits at all times. This is especially important to test and document when the warehouse is going to store sensitive medical products.

Inside a warehouse, the temperature can vary by significant margins due to factors such as external weather conditions, the absence of climate control systems in certain areas, and variations in insulation and ventilation.

After mapping studies, you will have a clear understanding of how the unit meets temperature requirements, and which zones can be used for storage and which cannot.

Last but not least, it will provide you with information on where to place your temperature monitoring equipment, to get a precise measurement of the temperature of the critical goods which ensures that you receive an alarm the minute temperatures deviate from the required temperature range.



Rent professional equipment tailored to temperature mapping

Save time by using Eupry's easy-to-use mapping kit with accredited DANAK ISO 17025 calibration and 21 CFR Part 11 compliance.



All the equipment you need

Receive a practical mobile box with all the data loggers necessary as well as any other equipment you need for your specific mapping.



Digital overview and reporting

Secure reliable results through automated data collection and easy digital reporting in the adjoining mapping software.



No calibration blockers

Pre-calibrated data loggers and automatically linked certificates in the software mean no manual pairings – and no waiting time.

Customers worldwide benefiting from Eupry



How does it work?



How is a temperature mapping performed?

Performing a temperature mapping of refrigeration equipment does not have to be complicated or time consuming. The most important thing is that the scope and complexity fit the equipment and what is stored in the equipment.

The 5 most important elements of mapping are:

1. Create a plan for the mapping study
2. Check the documentation of the measuring equipment
3. Set up your measuring equipment
4. Collect the data
5. Document and evaluate results

1. Create a plan

Before the mapping study, you must specify how to map.

We prefer detailing a standard operating procedure (SOP) with focus on answering the following questions:

- **How many places do you want to measure?**
- **Should the equipment contain goods during the mapping study?**
- **What are the acceptance criteria – i.e. what are the limits for the temperatures in the equipment?**
- **What kind of temperature mapping equipment will you use?**

The most important thing before you start the process is to find out what your limits are, so you have something to validate against, as well as how thoroughly you expect to carry out the mapping.

2. Check the documentation of the measuring equipment

You must check that the measurement equipment you use for mapping is **calibrated** and comes with a certificate documenting that the equipment is calibrated within a reasonable limit and timespan.

Typically, 0.5C precision and a maximum calibration interval of 1 year will be sufficient.

Additionally, make sure you can extract data when you have completed the mapping, e.g. by using a system where you can export reports within specific time periods.

Psst... **Eupry's wireless data loggers** automatically sends all data wirelessly, after which the data can be easily analyzed in our specialized validation software.

3. Set up your measuring equipment

Typically, the mapping will take place in the areas of the refrigeration equipment where high temperature fluctuations are expected.

This will usually be:

- **The front door far from the cooling element**
- **Close to the compressor at the bottom**
- **At the back panel where the cooling elements are located**

You can save time by assessing where the largest fluctuations will occur. You will never be able to find all extremes in the refrigeration equipment, so it is more important to choose locations that are representative.

Optimally, you have several pieces of measuring equipment, that you can install at the same time. If you only have a few or a single temperature data logger, you can instead move it from place to place and thus create an overview of the temperature extremes in the equipment.

Typically, it will be enough to measure in a 24-hour time span. This ensures that you catch both hot periods, often in the middle of the day, as well as the normal cooling cycle that the cooling equipment goes through.

To get a good picture of how your equipment performs under normal conditions, you can fill the equipment with goods. The mapping can also run without goods, but it will not provide a precise picture of how your equipment behaves under normal conditions.

During the mapping, it is important not to open the door(s) of the equipment as this may affect the precision of the temperature measurements.

4. Collect data

Whether you use multiple pieces of equipment or few pieces that you move around, it is paramount to collect data, which can later be compared.

If the goal of the mapping is to provide a credible picture of how your equipment is performing, it is important that the entire measurement period is included.

The data stored in the temperature data loggers have to be exported in order to document the measured data.

This is mostly done either by inserting the data logger into a computer's USB port, and then using the associated software to download the data from the data logger, or by using a data logger that automatically transfer data on a regular basis wirelessly to an online system.

It is worth considering how easy it is to export data from the sensor you are planning use.

Psst.. Did we mention that our specialized temperature mapping kit contains data loggers that automatically transfer data to specialized validation software through Wi-Fi?

[Learn more in our solution catalog](#)



5. Document and evaluate results

When you are done, it is time to draw some conclusions based on the data.

Typically, the hottest and coldest areas of the equipment will be of interest since the risk of temperature deviations during normal use are high in these areas.

If you have located areas unsuitable for temperature sensitive items, it may be a good idea to mark those with tape to notify staff members. At the same time, note which areas are within the temperature limits and thus can be used for storing critical goods.

The data from the mapping study can also be visualized in 3D, which can help improve the understanding of where a potential issue is, or where it is safe or not safe to store valuable goods.

Sometimes the results of the mapping study can show that the cooling equipment have to be adjusted. A new mapping study is thus needed afterwards.

The data gathered from the temperature mapping can also be used to locate where it is useful to place temperature monitoring devices during normal operation. If the cooling equipment has a zone where large fluctuations occur, this location can be used for temperature monitoring since it will provide an early warning if the equipment malfunctions.

It is especially advantageous to use a **temperature monitoring system** with an alarm function, that notifies you if the equipment fails or does not work properly. This way deviations can be discovered immediately, which will save valuable goods.

Lastly, it is critical that a consistent justification for decisions is established and that these are documented as part of the validation procedure. The reasoning should be scientifically based, applicable to facilities and products and suitable for the intended use of the area being mapped.

Warehouse temperature mapping

In the case of warehouse temperature mapping, the goals of the mapping are the same as if mapping smaller pieces of equipment, but in practice, the mapping studies can vary.

When mapping a warehouse, one of the important things that the mapping should investigate is possible airflow issues. Especially at large warehouses there can be issues with airflows, which result in cold or hot zones, either due to the high flow of cold air in some areas, or the lack of airflow in other areas.

A temperature mapping should take possible airflow issues into account and can provide guidance on where to place sensitive assets and where not to. **Next to air vents, doors, and packing areas**, etc., temperature variations can be expected, and therefore these areas are often of special interest.

Another important factor is external influences. This could be from walls that are connected to areas of substantially different temperatures, or outer walls that will experience great temperature differences due to seasonal changes. Therefore, a temperature mapping of a warehouse is often performed at the **coldest and hottest time of the year**.

By conducting a proper mapping study, these variations can be measured, analyzed, and adjusted throughout the entire system to ensure a more efficient and effective operation of managed warehouses.

Another point of interest is the amount of sensors used to perform the thermal mapping of a warehouse. When a large area is being mapped, a **larger amount of sensors is often needed**. Care should be given when choosing the amount and position of sensors, to properly allow the detection of variations in temperature in different areas of the warehouse.

Temperature mapping can help understand the temperature dynamics of the warehouse and ensure that the most sensitive areas are controlled.





Validating storage areas with temperature mapping

Storage areas can both be small rooms with medicine or huge storage buildings with robotic placement machinery. Validation and mapping could in theory follow the same protocol but that is not always the case. In both cases it is necessary to thoroughly consider where to place the sensors.

When storage areas are being thermally validated using a thermal mapping, airflow issues are one of the major points of interest. As there are often storage racks with goods stored on them, the airflow can be obstructed, and thus creating large variations in temperature and humidity.

Therefore, it is often required to perform mapping with and without goods on shelves, which can confirm that the storage area can still maintain temperatures or humidity levels within specifications, even though goods obstruct airflows.

Cold room temperature mapping

When mapping cold rooms, it is important to understand the implication loading of goods has on the temperature in different areas of the cold room.

Also distribution of air, or airflow, can have a big influence on the performance of the cold room. If there is no airflow, or if the airflow is obstructed, the risk of having areas with a lower or higher temperature is high. When air is not being circulated properly, areas which are in close proximity to a hot surface, e.g. an outer wall, will be at risk of becoming non-compliant.

Frequently asked questions about temperature mapping

Below you can see specific details for things to be aware of when you perform a temperature mapping study in cold rooms, freezers, fridges, warehouses and storage areas.

As well as pointers on which zones that are most often non-compliant.



Where can I get help to perform a temperature mapping?

Funny you should ask. At Eupry, we work to optimize how we handle temperature compliance within pharma, biotech, and logistics. We do this through automation, digitalization, and rethinking processes.

A part of this is consulting on, conducting, and supplying solutions for mapping. Among other things, we offer an easy-to-use mapping kit with accredited DANAK ISO 17025 calibration and 21 CFR Part 11 compliance that contains:

- Practical mobile box with the number of data loggers (temperature sensors) you need
- A wireless base station and extra batteries
- All data loggers are START calibrated, and an END calibration is performed

[Read more here](#) or [contact us](#) to get more information.

What limits should I use as an acceptable temperature range?

This depends on multiple factors, one being the type of products that are stored. For pharmaceutical companies it is crucial to maintain temperatures at the right levels, which for medication, in most cases, are between 2° C and 8° C in refrigerators and between -50° C and -15° C in freezers dependent on use.

Another factor which should be accounted for is the uncertainty of the sensors or data loggers used for the mapping. The uncertainty of the measurement equipment should be taken into account by decreasing the span of acceptable temperature or humidity fluctuations.

What kinds of sensors should I use?

The sensors for performing a mapping of any kind of equipment or facility should be chosen based on the task at hand.

Some specifications to look for are:

- Resolution: The resolution should normally be at least 0.05°C so that even small temperature variations can be detected.
- Accuracy: Dependent on the acceptable span for different mapping exercises, the required accuracy can vary from $\pm 0.1^{\circ}\text{C}$ to $\pm 0.5^{\circ}\text{C}$ for either small acceptable spans to larger spans. For humidity a normal acceptable accuracy is $\pm 3\%$.

Furthermore, it can be beneficial to look at how data is handled, both during and after mapping, as time used for gathering data can be higher than expected if wired systems are used rather than wireless systems.

If you use software requiring tools to collect and download data or produce reports, you will need to document that the software has been tested and complies with qualification requirements.

How many sensors do I need and where should I position them?

When mapping cooling equipment such as freezers, refrigerators and fridges we recommend using between 8-12 sensors per unit as a rule of thumb.

Size differences of the equipment can affect the number of sensors needed though. Look in the sections above on temperature mapping of specific equipment for information on where to place the sensors.

When mapping storage rooms you must analyze the room and classify possible causes of humidity and temperature variations such as doors and windows. Include these observations in your reasoning so that reviewers of the thermal validation can understand and assess your choices.

These are called the rationals and are an important part of the mapping exercise.

What kind of calibration is needed for my sensors?

All sensors used for a mapping exercise must be calibrated, either traceable or accredited based on quality requirements.

Based on quality requirements, it should be decided whether the sensors should also be calibrated after the mapping exercise.

In less regulated areas, a start calibration is sufficient, while more rigorous standards of quality require an end calibration to be performed to ensure that the sensor is also accurate at the end of the mapping exercises.

What is the duration of a mapping study?

The duration of your mapping study should be long enough to ensure that you have accurately captured the environmental dynamics of the area being mapped.

The larger the area or the more activity is ongoing during the study, the longer the estimated time of the mapping study.

It is worth considering seasonal changes. It can therefore be necessary to perform a mapping study in the hottest and the coldest time of the year to get the most accurate picture of the temperature fluctuations in your equipment or warehouse.



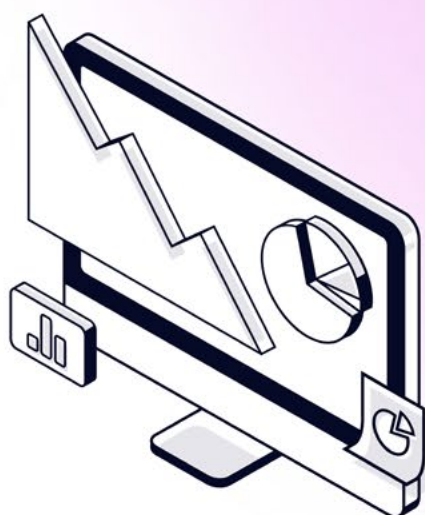
Gain full confidence in your temperature mappings with Eupry

Go hands-on with a leased GxP-compliant mapping kit designed to perform quick and reliable studies in highly regulated industries like pharma, biotech, and logistics.

- Easy digital reporting
- GxP-compliant mapping kit
- Validation experts on call
- Calibration included
- All the data you need in one platform



How the mapping kit works



Automated temperature compliance in one place – no gaps, no mess.

Eupry is more than mapping.

Be in full control of your temperature compliance at all times. Collect temperature and humidity monitoring, mapping, and calibration in one GxP-compliant solution

[See how the solution works](#)

[Get a free solution catalog](#)