DICKSON
Environmental Monitoring + Compliance Experts

TEMPERATURE MONITORING & VACCINE INTEGRITY

BY DICKSON

Environmental Monitoring
+ Compliance Experts

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VACCINES AND THE COLD CHAIN

Vaccines generally fall into two categories based on whether they need to be refrigerated (held between 2 and 8 °C) or frozen (-15 °C to -50 °C) during storage. Some vaccines may need to be stored at even lower temperatures, such as the Pfizer/BioNTech Covid-19 vaccine, which needed to be stored at -70°C when it was first released.

From manufacturing to administration in patients, the vaccine distribution process follows a refrigerated supply chain known as the "cold chain". For a vaccine to maintain its potency, the cold chain must be unbroken from start to finish.

Disruption in storage conditions during vaccine distribution can have serious consequences on patient health. Administering doses that were not stored under the proper conditions can not only result in medical complications for patients, but also expose them to risks of contamination, as they will incorrectly believe they have been immunized against the virus.

Furthermore, if a vaccine batch is compromised due to a faulty cold chain not being detected fast enough, the financial consequences can be high while also damaging to brand reputation if products need to be recalled.

To reduce these risks and ensure cold chain continuity, it is critical to monitor temperature throughout the entire vaccine distribution process. This effort concerns every step of the process, from manufacturing and shipping to storage at the vaccination center.

Widely accepted internationally, the most common method for monitoring vaccine temperature involves solutions using digital data loggers that are connected and controlled remotely via a web-based monitoring system hosted on a secure Cloud platform. There are many advantages to this type of system:

◻ Access to data in real-time via a platform that offers a clear overview of monitored equipment, even for networks with many measurement points

◻ Secure data traceability that ensures compliance with the most demanding industry recommendations, such as those of the Food and Drug Administration (FDA) 21 CFR part 11

◻ Advanced alert management that enables operators to act rapidly when problems are detected

◻ A high level of solution flexibility and versatility for adapting to customer needs

THE 5 BEST PRACTICES FOR EFFECTIVE AND WORRY-FREE VACCINE TEMPERATURE MONITORING

1.   UNDERSTAND YOUR ORGANIZATIONAL NEEDS

 When planning to implement a vaccine temperature monitoring system, a few broad areas should be considered. The first step is to ask yourself a series of questions to help you define project scope in the most detailed manner possible Here is a non-exhaustive list:

How many pieces of equipment do you need to monitor ?

How many measurement points ?

How many data loggers do you need ?

Where will they be placed ?

What types of sensors will be used ?

How often will sensor data be recorded ?

Do you need to simultaneously keep any eye on other parameters (light, CO2 levels, humidity) ?

Another important piece of the puzzle is to perform an audit of the equipment being used for storing and transporting vaccines. This means checking whether freezers and/or refrigerators are in good working order and without any particular issues that could potentially cause problems.

Lastly, an in-depth risk assessment process must be implemented in order to address all the questions that are sure to arise as you define your needs. Part of any robust monitoring system, this process enables you to identify all the risk factors related to vaccine integrity, notably those that may have an impact on the cold chain. The evaluation also gives you an opportunity to plan procedures to implement for handling problems. Identifying potential issues enables you to adapt the monitoring solution to optimize the effectiveness of implemented procedures.

2.   HAVE A CLEAR INSTALLATION PLAN IN 4 STEPS

Having a well thought out, simple to execute plan for installing your vaccine temperature monitoring system will help to avoid costly issues to correct installation mistakes later on. Here are a few areas to cover in your plan.

a.   Sensor placement

Based on risk assessment and temperature mapping, determine the number of sensors needed and where they should be placed to optimize product safety, and identify possible equipment problems as early as possible. Effective sensor placement boosts the monitoring system's ability to notify users in case a problem arises.

Another important factor is to decide how frequently sensors will be read. The risk assessment process will help you determine sensor reading and data storage frequency.

b.   Establish standard operating procedures

Standard operating procedures (SOPs) should be written that cover routine operation of the vaccine temperature monitoring system, as well as response procedures for emergency situations. Again, the results of the risk assessment can be used to identify likely emergency situations that could arise. In addition to step-by-step, clear, and complete procedures, the SOP should also identify specific responsibilities of individual personnel and their contact information.

c.   Installation Qualification (IQ) and Operational Qualification (OQ)

IQ/OQ processes are a key part of your quality management system. It is therefore important to audit the physical installation and operational compliance of your monitoring solution. Installation qualification involves thorough checks to ensure that equipment and software are configured correctly, that the manufacturer's instructions are followed, and that any relevant documentation is preserved. Operational qualification consists of making sure that the solution functions as defined in a detailed specifications document.

d.   Calibration

Sensor calibration is a critical aspect for ensuring effective and reliable vaccine temperature monitoring. The World Health Organization recommends calibrating sensors at least once a year, and the Center for Disease Control (CDC) recommends having sensors calibrated by a laboratory that is accredited to perform calibrations according to the ISO/IEC 17025 standard, or using a NIST-traceable standard.

Calibration is the only way to ensure that data collected in the temperature monitoring system is correct. Sensors transmitting imprecise measurements turn the solution into an inefficient resource and considerably increase the risk of damaging vaccine integrity.

3.   ESTABLISH THOROUGH TRAINING PROTOCOLS

The efficiency of a vaccine temperature monitoring solution relies on properly training staff members involved in vaccine handling, making sure they know how to use the tools at their disposal. A 2017 UNICEF review found that one of the main causes of low temperature excursions in vaccine handling is insufficient training.

Any staff members involved in vaccine handling should have a "thorough understanding" of their job functions, according to the FDA's 21 CFR Part 600 guidelines. Here are a few points to make sure to include in staff training for a vaccine temperature monitoring system:

TRAINING PLAN

- Knowledge of main data logger features

- Basic use and maintenance of data loggers

- Training on the software to be able to interpret readings uploaded to the platform and to detect anomalies

- How to respond to alarms triggered by the system

- Generate reports

4.   DEFINE AN EFFECTIVE AND ROBUST ALERT STRATEGY

Defining an alert strategy is a critical factor in setting up a vaccine temperature monitoring solution. In fact, a temperature monitoring system is only effective if it notifies the right people or groups in case a problem arises so that they can take prompt action to protect vaccine integrity.

Alert management offered by remote monitoring solutions generally includes the ability to choose how people should be notified, such as by e-mail, SMS/text message, or voice call), whether notifications should be sent to specific groups or individuals according to the type of problem, while also taking into account scheduling considerations for days off, holidays, weekends, working hours, etc.

An effective and relevant alert strategy involves setting up personalized alerts. Here are a few tips for setting up custom alerts in your temperature monitoring system:

o   Configure alerts to notify only the people authorized or most likely to resolve the problem as quickly as possible. For example, alerts about malfunctioning pieces of refrigeration equipment can be sent to local support staff. Wider scale issues that require organization-level reallocation of resources can be escalated to the management level.

o   Include a description of the problem in the alert. This will help the responding personnel to be prepared upon arrival.

o   Use historical data to determine the conditions where an alert should be triggered. For example, look back at past temperature excursions to see what warning signs were present before the excursion took place, and set up alerts to warn staff when those conditions are present.

o   Be mindful of "alarm fatigue", a situation where excessive false alarms lead to staff ignoring or disabling alarm systems. This can be addressed by fine-tuning the alert system to minimize false alarms, and by acknowledging and addressing alarm fatigue in staff training.

5.   PREVENTIVE AND/OR CORRECTIVE ACTION FOR EXCURSIONS

Continuous improvement should be an integral part of any vaccine temperature monitoring solution. In the context of vaccine temperature monitoring, this means regularly reviewing system-wide data, to identify trends and look for ways that the alert strategy, equipment management, and risk reduction can be improved.

The CDC and WHO recommend these types of reviews to document the root cause, consequences, and preventive and/or corrective actions related to temperature excursions with vaccine storage equipment. These reviews could be labor intensive without a centralized temperature monitoring system to collect data and automate regular reports.
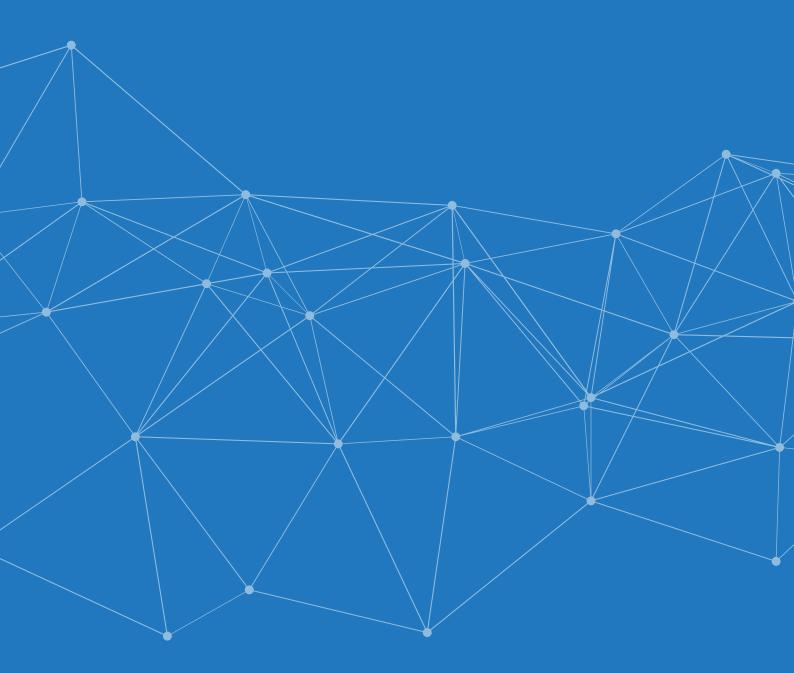
CONCLUSION

Maintaining a solid cold chain for vaccines is a major issue for all stakeholders involved with the vaccine supply chain, from manufacturing to administration in patients. The risks of unseen temperature excursions are real, potentially leading to significant consequences for the vaccine maker as well as individuals and community health in general.

Setting up a reliable and continuous vaccine temperature monitoring system is a critical component of maintaining a robust cold chain. Its optimization helps ensure vaccine integrity throughout the distribution process.

Today, health organizations and regulatory bodies recommend implementing a temperature monitoring solution based on digital data loggers that are connected and can be monitored remoted via a secure Cloud platform. Staff training and ongoing improvement must be integrated into any monitoring solution in order to optimize efficiency.

ABOUT DICKSON

Since 1923, Dickson has been changing the way organizations monitor their temperature, humidity, and pressure-controlled environments. By incorporating the best and newest innovations, Dickson enables organizations to manage compliance, asset protection, data analysis, and quality control with confidence.