

White Paper: Controlling Temperature in Pharmaceutical Supply Chains



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A comprehensive analysis of temperature control processes as essential components of an efficient quality control process in pharmaceutical supply chains.

Introduction

Successfully transporting commodities across the world involves efficient and cost-effective storage and distribution processes. However, another element of successful supply chains requires that environmental specifications for every product are managed and monitored throughout the storage and distribution lifecycle.

This is especially important for sensitive pharmaceutical supply chains, which can be fundamentally compromised when exposed to incorrect temperatures. The effects of this decomposition can vary from lack of therapeutic effect to toxicity and even death.

Despite the dangers, some logistics companies incorrectly view temperature control as a customer requirement with a modicum of flexibility. To defy this mentality, MD Logistics' commitment to temperature control is based on the patients who are relying on the medications to enrich their lives.

After an initial discussion on the dangers of environmental excursions in pharmaceutical supply chains, this white paper will investigate temperature control in the warehouse and transportation components of pharmaceutical supply chains. It will also analyze the traits of an efficient and effective temperature monitoring process.

Defining Temperature Control

The hot-button topic in temperature control is building, monitoring and maintaining cold chains. These specific supply chains, in which pharmaceuticals must continuously remain between 2 and 8 degrees Celsius, present a myriad of unique challenges. Extreme cold chains, which maintain temperatures below -20 degrees Celsius, are extensions of this complexity.

Beyond cold chains, continuous oversight is also needed to maintain controlled room temperature (CRT) environments between 15 and 25 degrees Celsius.

Whether a logistics company is working in CRT or extreme cold chain environments, it's essential that they dedicate resources for establishing, maintaining, and refining temperature control processes. Too often, it can be the difference between an effective medication that works and one that doesn't and results in harmful side effects.

Defining Patient Safety Concerns

Logistics professionals versed on the intricacies of temperature control are tasked with maintaining necessary environmental standards that ensure a medication's efficacy. Without

this oversight, pharmaceuticals can be exposed to extreme temperatures and become dangerous.

If a biologic medication freezes, the drug precipitates – much like milk would curdle – and becomes chemically ineffective. On the other hand, a biologic medication will decompose if it becomes too warm. This chemical breakdown deactivates active ingredients and renders the medication ineffective.

Pharmaceuticals can be compromised at any point in the supply chain if temperature varies outside the required range. This is especially dangerous because it is difficult to discern when a pharmaceutical has degraded beyond effectiveness. In fact, this decomposition is often impossible to detect with the naked eye. This means temperature control is important not only to prevent problems but also identify when environmental excursions may have rendered a pharmaceutical ineffective.

So, how can pharmaceutical manufacturers, third-party logistics (3PL) providers and retailers remain cognizant of possible environmental excursions and product degradation? MD Logistics answers this question with a comprehensive quality control process that includes proactive and reactive planning during storage and transportation.

Temperature Control in the Warehouse

MD Logistics maintains the temperature monitoring systems necessary to safely store and distribute pharmaceuticals through systematic qualification and validation process.

Qualification

To ensure a warehouse, cooler, or trailer is compliant, it is qualified with a mapping study that uncovers areas prone to fluctuations outside approved temperature ranges. To determine realistic performance, this qualification test is done first when empty and again when stocked with product.

Monitoring

Warehouse space must also be continuously validated with regular temperature monitoring. Monitoring takes two forms: proactive and reactive measures. Proactive measures, such as guard band monitoring systems with alarms that sound when temperatures approach a specific benchmark and consistent data reporting, help identify potential problems. Reactive measures involve an ability to react quickly to unexpected crises, such as equipment failures or extreme weather events. Creating reciprocal contingency plans with area partners and establishing internal procedures for moving product before it's compromised are examples of reactive measures in a warehouse setting.

Temperature Control in Transportation

Once products are packaged and shipped, they enter a dynamic environment that is inherently unpredictable. To ensure temperature control and product efficacy, MD Logistics utilizes the same qualification and monitoring mindset during this part of pharmaceutical supply chains.

Parcel shipments

To date, MD Logistics utilizes 18 different types of qualified containers for parcel shipments. Before use, these containers are sent across the United States with tags that track whether internal temperatures fluctuate in various weather scenarios. Once qualified for a specific temperature range, MD Logistics approves the containers and continues to validate them with temperature tags.

Pallet shipments

MD Logistics' transportation department, MD Express, requires carriers to undergo a strict qualification process to ensure that individual contractors meet quality requirements. MD Logistics' quality department audits each carrier to assure compliance with this requirement.

The first step is empty load qualification. In this part, dozens of temperature mapping devices are placed in empty trucks left running for 24 hours. This allows the quality control team to determine whether the truck can maintain a consistent temperature.

The next step is live load temperature testing, in which the carrier is sent across the country stocked with real product and monitored for temperature fluctuations. This real-world qualification process is done in both summer and winter months to ensure a thorough understanding of the truck's capabilities.

Every year, MD Express requires carriers to be revalidated with live-load temperature testing to ensure they remain compliant. Between validation tests, real-time monitoring systems equipped with alarms are used to monitor carriers that transport extremely sensitive pharmaceuticals.

Attributes that Separate the Best

When considering a 3PL partner, companies always consider the provider's dedication to temperature control. Often, they find leading 3PLs like MD Logistics tend to have the following attributes:

Extensive qualification and validation systems

Qualification and validation programs that exceed FDA requirements are few and far between. However, MD Logistics' comprehensive system allows the company to stay on top of potential problems before they impact operations- or a customer's bottom line.

Frequent warehouse environment monitoring

The industry standard for measuring warehouse temperature is once every quarter. To remain proactive and aware of potential problems, MD Logistics' quality control team generates detailed reports on warehouse temperatures every week. This means quality control personnel are

constantly analyzing data, spotting trends and isolating fluctuations in the warehouse environment.

Robust quality control programs

Leading 3PL providers have experienced quality control personnel operating within a robust program geared towards proactive and reactive solutions. The best programs integrate these solutions into a complex system where elements complement each other and achieve synergies to make sure the program is functioning properly.

Conclusion

Temperature monitoring and control is an essential part of any quality control program, especially when sensitive pharmaceuticals and biologic products are involved. With their access to industry-leading technology and professionals dedicated to mastering innovative ideas, 3PL providers can help companies master the intricacies of temperature control in pharmaceutical supply chains.