Meeting Global Compliance with Reliable Temperature Monitoring

Case Study: A Medical Device Manufacturer's Perspective

SENSITECH

A Carrier Company

Case Study Highlights

Company Overview

Industry: Manufacturer and distributor of in vitro diagnostic devices and test kits, including ones for COVID-19 test kits.

Headquarters: Europe

Employees: 50,000

Business Challenges

- Increased global compliance regulations
- Non-compliant product packaging
- Rising distribution expenses
- Costly product disposition

Solution

Temperature-monitoring program with IoT devices and comprehensive cloud-based data management tools.

Beneficiary Outcomes

- Compliant storage and shipping globally
- Improved product efficacy
- Reduced product losses
- More effective shipping lanes
- Higher customer satisfaction

Introduction

Several years ago, regulatory compliance agencies around the globe began issuing strict storage and shipping regulations for in vitro devices (IVDs), a medical tool that diagnoses diseases, such as COVID-19. For IVD manufacturers, these new regulations led to many operational and logistics changes in order to achieve and prove compliance.

This case study describes the journey of a European IVD manufacturer and distributor as it faced new IVD compliance regulations for shipping product around the world. Thanks to a comprehensive temperature-monitoring solution from Sensitech, this company can meet the regulations of any country where its products are shipped and distributed with demonstrable and documented compliance data.

> We can now implement a temperature-monitoring program in any country that requires it, and be confident that we are compliant.
>
> **Director of Transportation**
> **European Medical Device Manufacturer**

Managing Compliance Around the Globe

This international medical technology organization is a manufacturer and distributor of clinical imaging, diagnostics, advanced therapies and related services.

One focus within the company's laboratory diagnostics is blood testing instruments, reagents and consumables that are used in public or private laboratories and hospitals.

These diagnostics include in vitro devices (IVDs), which are non-invasive test kits used to collect biological samples such as blood, urine or tissues to diagnose or exclude a disease. IVDs play a major role in the early diagnosis and management of diseases such as COVID-19. In fact, this company began producing SARS-CoV-2 test kits soon after the COVID-19 virus became a pandemic.

IVDs typically include temperature-sensitive reagents, which are now governed by strict regulatory guidance, much like prescribed drugs in the pharmaceutical industry.

THE MARKET CHALLENGE:

Ever-Increasing Pressure for Compliance

While government compliance regulations are common in the pharmaceutical industry, they are relatively new to the medical device market, under which IVDs are regulated. Compliance for IVDs is still in flux and evolving, with countries around the globe adopting and enforcing more stringent requirements to ensure greater efficacy and patient safety. This is a complex issue, as IVD regulations vary from country to country as well as from product to product.

One commonly required regulation that is now beginning to be frequently enforced is temperature control and management. Most countries require that manufacturers publish label claims that show the temperature that the products must be stored and shipped, which is typically 2-8° Celsius for IVDs. It's the responsibility of the manufacturer to assure this range is observed at every point in the product's journey, from point of origin to final destination.

As manufacturers began to comply with these global regulations, many discovered that their existing operations and logistics processes and procedures did not ensure their products' compliance. Consequently, they had to update product packaging, develop stricter standard operating procedures, and execute more stringent oversight on service-level agreements with third-party shippers.

THE BUSINESS RISK:

Costly Product Dispositions—and More

Like other IVD manufacturers, the company in this case study was suddenly facing increasingly stricter regulations as it distributed its products. For instance, the National Medical Products Administration (NMPA) in China began to require proof of temperature compliance for IVDs coming into the country. Similar pressure for more regulated temperature monitoring and documentation was occurring in the European Union, as well as Saudi Arabia and the United States.

Because of this increased need for documented compliance, the company wanted to implement changes in its operations and logistics departments to conform with the increasingly rigorous regulations. "We have a substantial volume of temperature-sensitive products in our portfolio," says the company's director of transportation. "There were strict demands to prove in-transit temperatures were kept within the limits of the product label."

"All of a sudden, we needed to demonstrate with verified data that we did everything possible to keep within the prescribed limits and the product was not harmed," notes the director. "If we didn't have the data to prove that we performed within the guidelines, we would have to dispose of products, which is, of course, something we don't want to do."

The company also recognized that its product packaging needed to be improved. “We knew that product packaging improvements would help us to adhere to the regulations, as well as help us better protect our products throughout the entire distribution cycle,” says the director.

The consequences of temperature excursions are costly for this company, not only financially, but in other ways as well. “If we had to dispose of products, it’s one thing as far as costs,” says the director, “but the bigger impact is that we would not be able to supply our customers with what they needed when they needed it.”

Many of the company’s products have a short shelf life, so it manufactures on demand and maintains low inventory levels. If a large order is compromised, it can be challenging to have sufficient available product to expedite a replacement order. “The impact on sales is much larger than a product loss,” adds the director. “It affects our reputation, which opens the door for a competitor to step in.”

THE SOLUTION:

A Reliable, Compliant and Data-Driven Monitoring Program

Before the increased regulatory pressure, this manufacturer was using a limited number of temperature-sensitive devices from Sensitech, initially focusing on passive dataloggers that reported time and temperature at the final destination.

With the increased pressure from regulatory boards, the company did a thorough review of competitive temperature monitoring devices in the market, and realized that to meet its objectives, Sensitech’s devices were some of the best in the industry. Sensitech’s wireless devices are hands-free, real-time dataloggers that communicate via cellular connectivity and deliver in-the-moment information that helps companies gain significant visibility into their cargo while in transit.

The other plus for expanding its existing monitoring program with Sensitech was the invaluable insight the company provided in helping the manufacturer understand the complex evolving regulations, including the requirements as they varied from country to country. “We have two distribution centers—one in North America and one in Europe—and we ship globally,” says the director. “Sensitech helped us understand the overall compliance requirements and what was needed to assure temperature accuracy, number of specimen points, the collection of temperature data and its management, along with what devices were a best fit. Regulatory compliance was new to us. It was a learning journey and Sensitech helped us each step of the way.”

Recently, the company also started using ColdStream® Select, an end-to-end cloud solution for validated data. “For shipments to China, we added loggers inside the cartons, as well as outside on the pallets so we could measure ambient temperatures,” says the transportation manager. “Monitoring the cargo in this way generates a lot of data, so using ColdStream helps us understand how to properly and effectively interpret the data. The fact that the data is in real time allows us to make decisions faster and resolve issues quickly.”

THE RESULTS:

Compliance, Improved Efficacy—and Surprising Discoveries

This company has now been using Sensitech devices for over five years to not only achieve compliance, but also to improve the quality of its operations and logistics. Here is a quick overview of some of the benefits the company is realizing.

Meeting global compliance regulations. The company now has a comprehensive data collection program that it can confidently roll out to meet the regulations of each individual ship-to country that keeps current with evolving and changing requirements. “We can now implement a temperature-monitoring program in any country that requires it,” says the director, “and be confident that we are compliant.”

Improved packaging for product efficacy. It was through the use of real-time dataloggers that alerted the company to the fact that its product packaging was not compliant. The manufacturer then made the appropriate improvements to increase efficiency and help ensure temperatures are kept within the acceptable range for reagent efficacy.

Identified excursions and SLA shortcomings. When the company started using real-time data loggers for shipments to China, it experienced several unexpected temperature excursions. “We had to dive in and find where the excursion was occurring,” says the director, “and what we found surprised us.” The company discovered that most excursions actually happened in the first leg of the journey between its distribution center in Europe and the local airport. The manufacturer had a service level agreement (SLA) for its cargo to travel and be stored in temperature-controlled environments on this leg, but uncovered its freight forwarder violated those terms. The third-party company improperly used environments that were not temperature controlled. “This was a systemic, reoccurring issue which we quickly corrected, thanks to the temperature and location data provided by the Sensitech devices,” notes the director.

Better lane management. With the data that is collected, the manufacturer can now drill down into deeper details and start exploring better ways to manage its shipping lanes, reduce costs and improve logistics.

"We have to qualify every lane and mode of transportation," says the director, "and we start by examining the data to find out what is not working. For instance, we are looking at our lanes in several countries and doing multiple analyses to see whether it is better to ship ocean or rail." With this initiative comes a comparison of the benefits of real-time devices used on rail, where there is continuous access to data versus the passive ones used over the ocean, where the data is available at the end of the journey.

"With the real-time data available for a rail shipment across Europe into China via Russia, I was surprised to see that there were hardly any connectivity interruptions, so I could get temperature and location data every hour of the day if I wanted," says the director. "As long as there is a signal, we can react faster to any issues that happen. That's easier and more effective."

THE CONCLUSION:

Compliance-Driven Devices, Expertise—and Quality Service

"With Sensitech's dataloggers, we are confident that our products are safe from both a packaging point of view as well as the distribution perspective," says the director. "The temperature data immediately tells us what's going on and it has directed us to process and packaging improvements to meet compliance requirements."

The director added that the company is now more aware of the impact of conditions such as shipping in summer versus winter, and whether products are shipped through airports in countries with hot weather, or direct to a destination. "These things may seem like minor details but we now understand they can have a huge impact on the temperature of our products and their safety," notes the director.

The company is getting faster, better information than it ever had before, with data that helps people make more informed decisions on lanes, transportation modes, excursions, average temperatures and product disposition.

As for the manufacturer's relationship with Sensitech, the director says he is pleased, and feels that Sensitech is top notch in the industry. "The organization provides fantastic service and support, no matter what our needs. It's a big company with a lot of resources as compared to others in the market that either don't have the maturity or the background. We rely on that experience, service and support to help us deliver complaint products to our customers."

About Sensitech

Sensitech Inc. is a global leader in delivering supply chain visibility solutions. Our innovative monitoring products and services help to maintain the quality, integrity and security of our customers' valuable products at every step in their journey, all around the world. For 30 years, leading companies in the food, pharmaceutical, industrial, consumer goods and other industries have relied on Sensitech to help protect their products—and their bottom lines.

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