How to reap the benefits of a real-time supply chain monitoring solution

A look at three case studies covering air, road, and sea

Controlant

The pharmaceutical supply chain is increasing in complexity and creating a demand for digital transformation in order to gain total supply chain visibility and control. Adopting scalable and cost-effective solutions will be mission-critical moving forward to ensure public safety and protect the bottom line.

Real-time temperature monitoring and supply chain total visibility offers many benefits: proactive product waste reduction; exponential operational cost savings, including reduced time spent on quality review; faster release times; improved collaboration with logistics partners; shorter delivery times; and more accurate forecasting.

Collecting and leveraging the right supply chain data is paramount. Real-time data might potentially force businesses into reaction mode, responding to every alert that occurs, day or night. In practice, working with the right technology solution provider makes it possible to leverage the data through a services-based partnership. Alerts are managed and corrective responses facilitated on behalf of the pharmaceutical enterprise or logistics partner.

This white paper explores some of the major challenges faced today in the pharmaceutical supply chain. Three actual case studies demonstrate where a real-time temperature monitoring and visibility solution provides enhanced visibility for products travelling by air, road, and sea. The use cases explore how technology enables enterprises to better monitor, measure, and manage the supply chain, mitigate risk, drive continuous improvement, and generate substantial cost savings and ROI.

We provide clarity to the issues keeping pharma supply chain enterprises awake at night →

"I need to prevent lengthy quarantines and all lost shipments."

"I need to launch new products and quickly validate new lanes."

"I need an automated way to get time, temperature, and location data so I can prevent product waste and reduce my release decisions."

"I want to make real, long-term cost savings in the supply chain."

"I have good stability data. I only want to be notified for the critical issues."

"I need an unbiased source of data. We rely on third parties for critical information."

"I want to predict which lanes to ship through to avoid risk points and delays."

"I want to be able to analyze my lanes and determine how I can mitigate risks and focus efforts only where needed."

"I need to comply with the track-and-trace requirements. Temperature is an extension of this."

"With real-time data, I don't want to be in response mode all of the time."

Today's supply chain challenges

Real-time visibility is now mission-critical. The global supply chain has become increasingly more complex due to growing product demand, the introduction of pharma products to new markets, and shifts in regulations that require complete chain-of-custody tracking and control throughout the supply chain. While patient safety is the number one objective, a myriad of challenges forces the ensurance of product integrity through the last-mile. As handoff points increase so do the threats to the integrity of product quality.

Regulatory compliance

Pharmaceutical enterprises and logistics providers must comply with strict regulations for GDP (Good Distribution Practices) and GMP (Good Manufacturing Practices). Strict record-keeping, access to critical data, thorough review, and a close working relationship with partners are all integral parts of ensuring compliance. When it comes to the cold chain, the manufacturing, distribution, and storage of pharmaceutical products occur under strict temperature conditions, often between 2-8°C or 15-25°C.

Validation of supply chain tools is required in order to use the data to release products and provide information for audits. Over recent years, a shift toward digital tracking has occurred as enterprises move from PDF reports and paper trails that are generated at the end of a shipment, manually uploaded from data loggers, and sent for quality review and release. Today, real-time solutions that are validated and compliant for life sciences can automatically generate shipment reports and send them to the relevant stakeholders at the end of a shipment. Technology can help reduce manual entry and the potential for human error.

Fulfilling an auditor's request can now occur in a matter of minutes as opposed to tracking down required information needed, which might reside with someone on the other side of the world and in a completely different time zone. More recently, the introduction of new track and traceability regulations have impacted the pharmaceutical supply chain. In the EU, the Falsified Medicines Directive (FMD) and the US Drug Supply Chain Security Act (DSCSA). These new regulations protect consumers from exposure to counterfeit, stolen, contaminated or otherwise harmful drugs. The regulatory theme is compliance and prevention – the ability to maintain an accurate and documented chain of custody for products moving throughout the supply chain.

The need to maintain an accurate chain of custody and visibility to protect and control the end-to-end supply chain means these changes challenge the status quo of manual temperature data loggers and have deemed them insufficient.

Risk reduction

Risk mitigation, continuous improvement, and cost optimization often go hand in hand. Real-time monitoring solutions provide the ability to illuminate supply chain weak spots. They provide visibility — connecting time, temperature, and location data — and make that data available on demand. The data enables businesses to focus only on what matters most, rather than approaching each part of the supply chain equally. Pharma manufacturers and their logistics partners can identify problem areas and prioritize their response to them, thereby focusing resources only on what is most important.

Risk mitigation enables continuous improvement, which leads to supply chain optimization, an increase in efficiency, and greater cost savings. As businesses shed light on and mitigate risks, fewer temperature excursions occur, and less time is spent replacing the product and reviewing shipments. Over time, these improvements add up.

Machine learning and predictive analytics can improve the accuracy of supply chain forecasting. For instance, forecasting can identify various times of the year, customs issues or weather patterns that make shipping products by sea freight instead of by air more prudent. Businesses can gain these insights through the power of data.
Real-time monitoring automatically connects temperature, time, and location data and empower businesses to:

- Illuminate the dark spots in the supply chain
- Identify and prioritize risks
- Proactively reduce excursion rates and shipment review time
- Reduce product and operational waste
- Improve shipment release times
- Validate packaging and shipping lanes
- Release new products to market faster
- Predict lane performance and risk based on historical data
- Drive continuous improvement across the supply chain

Product and operational waste reduction

As global supply chains increase in complexity and products move through a greater number of touchpoints, product, and operational waste are major challenges today. With real-time data, organizations can proactively respond to temperature deviations in order to proactively prevent product waste. If a temperature range is set to 2°C to 8°C (35.6°F to 46.4°F), and temperatures start to deviate, instant notifications and alerts allow for immediate, proactive responses and actions.

Accurate and reliable data helps prevent product quality degradation and wastage, as well as the downstream effects of a stock outage in a particular market, which can impact public health and safety. Real-time temperature and location data help save time spent investigating the root cause of a temperature deviation. The data helps to segment the shipments requiring review so businesses need only focus on the problem shipments.

With real-time data, all of the risk elements from departure to arrival such as airports, freight forwarding sites, and shipping ports are visible. Users can identify exactly where an excursion happened without question. A standard USB logger always incorporates guesswork and requires assumptions based on where the product should have been at a certain time.

Patient safety

Patient safety is the number one reason why pharma companies and logistics partners need to maintain the most effective and risk-free supply chain. Pharma supply chain stakeholders work with products that can save or enhance lives in one way or another. Ensuring a controlled and secure supply chain is vital to achieving this goal.

Moving from supply chain differentiator to strategy

Digital transformation is happening. However, it is necessary but not sufficient to build an operationally efficient supply chain. The life sciences supply chain is moving toward real-time. In a 2019 LogiPharma Benchmark report, of the more than 100 heads of operations and supply chain surveyed, only 4% reported access to real-time as unimportant. Most regarded real-time visibility as important or very important, while 99% indicated that real-time monitoring and alerts would benefit their operations.

Most pharmaceutical and pharmaceutical logistics companies have already digitized their supply chains or are making it a priority. According to the LogiPharma Benchmark report, 97% of the leaders in the industry indicated that digitalization is a top priority for their company. The number one change expected to occur within the next 10 years was moving the supply chain from a cost center to a competitive differentiator.

While the pharmaceutical supply chain has shifted from analog to digitalization, digital transformation in the supply chain will enable businesses to identify new business opportunities and leverage them.

Controlant's advantage: Cold Chain as a Service

Controlant's solutions facilitate true digital transformation in a manner that is both cost-effective and scalable across the global supply chain. Our real-time visibility solution, Cold Chain as a Service (ChaaS), is threefold consisting of hardware, software, and services:

- Wireless and reusable IoT data loggers that collect time, temperature, and location, and light events in real-time, automatically sending data to a validated cloud software platform.

- Access to a centralized cloud software platform, where shipment for a single shipment or the entire supply chain is accessible on demand. Data is user-permissioned; when owned by the customer data is shareable with other supply chain stakeholders as desired.

Included services:

- **24/7 global support** - Around-the-clock access to our first-level support team.

- **Integration support** - Leverage our rest APIs to integrate with your favorite business systems.

Optional services:

- **24/7 global monitoring and response** - Our team of experts is available to proactively respond to temperature alerts and work with designated stakeholders to facilitate corrective action as needed.

- **IoT asset management and reverse logistics** - We manage your data logger pool, including reverse logistics and servicing (calibration and repair), on your behalf.

- **Customer success and program management** - A dedicated customer success manager will onboard and train internal and external stakeholders on the Controlant system.

- **Custom business intelligence dashboards** - We'll work with your team to set up custom BI dashboards to help you monitor and optimize your supply chain.

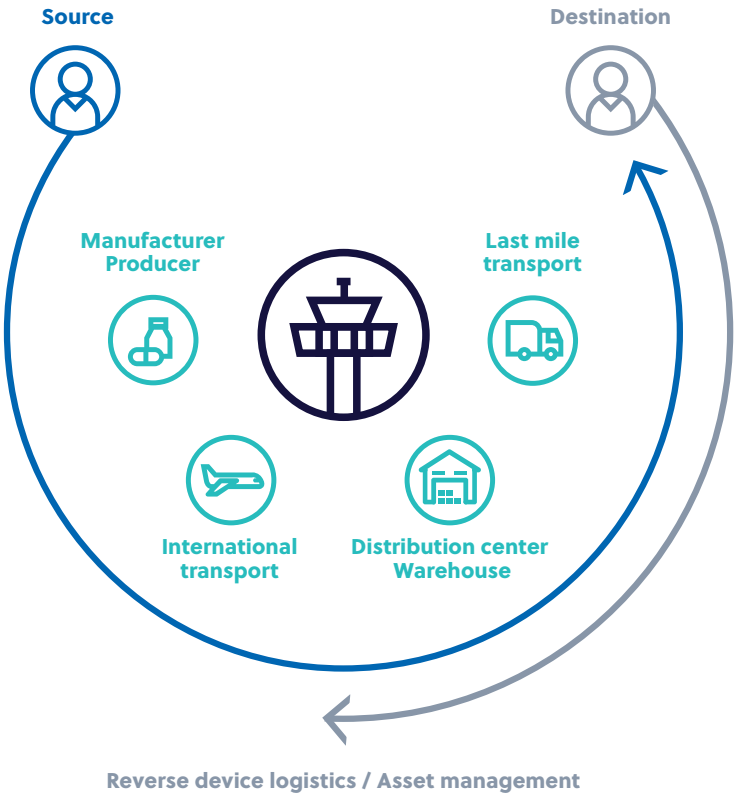
- **Consulting services** - Our team of experts provides temperature and mapping studies, lane and packaging validation, and change control support.

Rather than requiring upfront investments in thousands of data loggers that must be managed internally, our solution is offered as a subscription-based service. Pharma enterprises and logistics partners lease the IoT hardware and we manage the hardware logistics. Rather than a vendor-based model, our services respond to the need for a partnership-based model, where we work directly and closely with internal team members and logistics partners to ensure the program's success.

Real-time temperature monitoring provides a control tower-like visibility for the end-to-end supply chain.

Total visibility

- 24/7 real-time visibility
- Live notifications and alerts
- Automated alert handling
- 3PL/LSP/4PL outreach
- Root cause suggestions
- Mange by exception
- Analytics and insights
- Revers IoT logistics handling

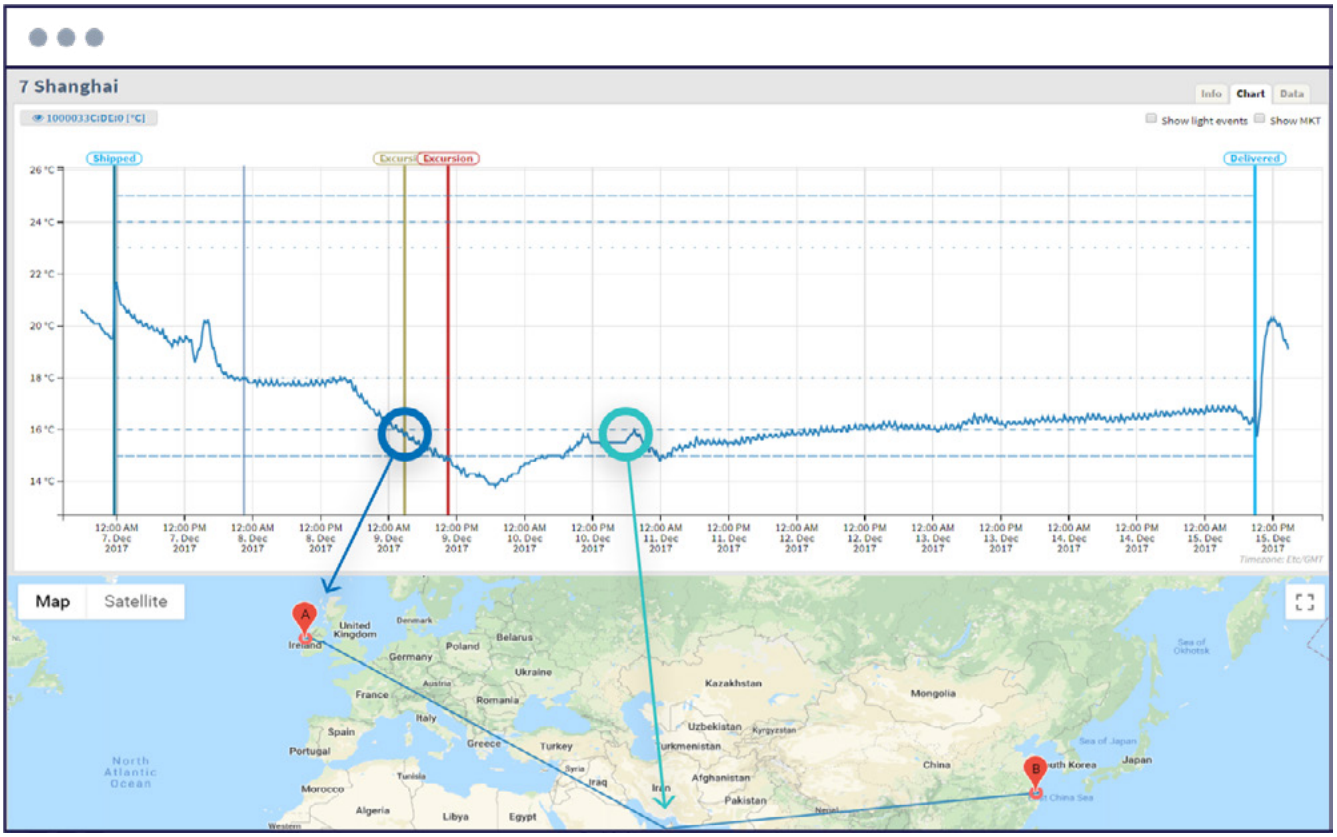


Real-time visibility in action

The following use cases demonstrate real-time visibility in action, and draw from actual examples where enterprises reduced excursions, optimized supply chain efficiency, and substantially reduced operational costs.

Case study 1

Air shipment



When shipping pharmaceutical products by air freight, real-time monitoring provides critical visibility of shipments while at the airports. Airlines cannot always guarantee storage within their temperature-controlled facilities, which are often treated on a first-come, first-served basis as storage space allows.

Tracking a shipment to China by air several benefits were realized. The customer started receiving alerts on day two while the goods were stored at the airport. Due to cold ambient temperatures at the originating airport, the temperature began to decrease. Upon contacting their freight forwarder, the customer learned that their shipment of pallets was at the airport handling facility and due to capacity issues was not held in temperature-controlled storage.

Contacting the airline in a timely fashion and explaining the severity of the issue, the onsite staff agreed to move the pallets into the temperature-controlled storage facility. Soon after, the temperature fell within the acceptable boundaries. Receiving alerts in real-time allowed

for immediate action to rectify the deviation from temperature standards. The products were exposed to a minor excursion for a short period of time. This resulted in the shipment, valued at several million dollars, passing the QA requirements and release of the products to the market upon their arrival.

Key takeaways

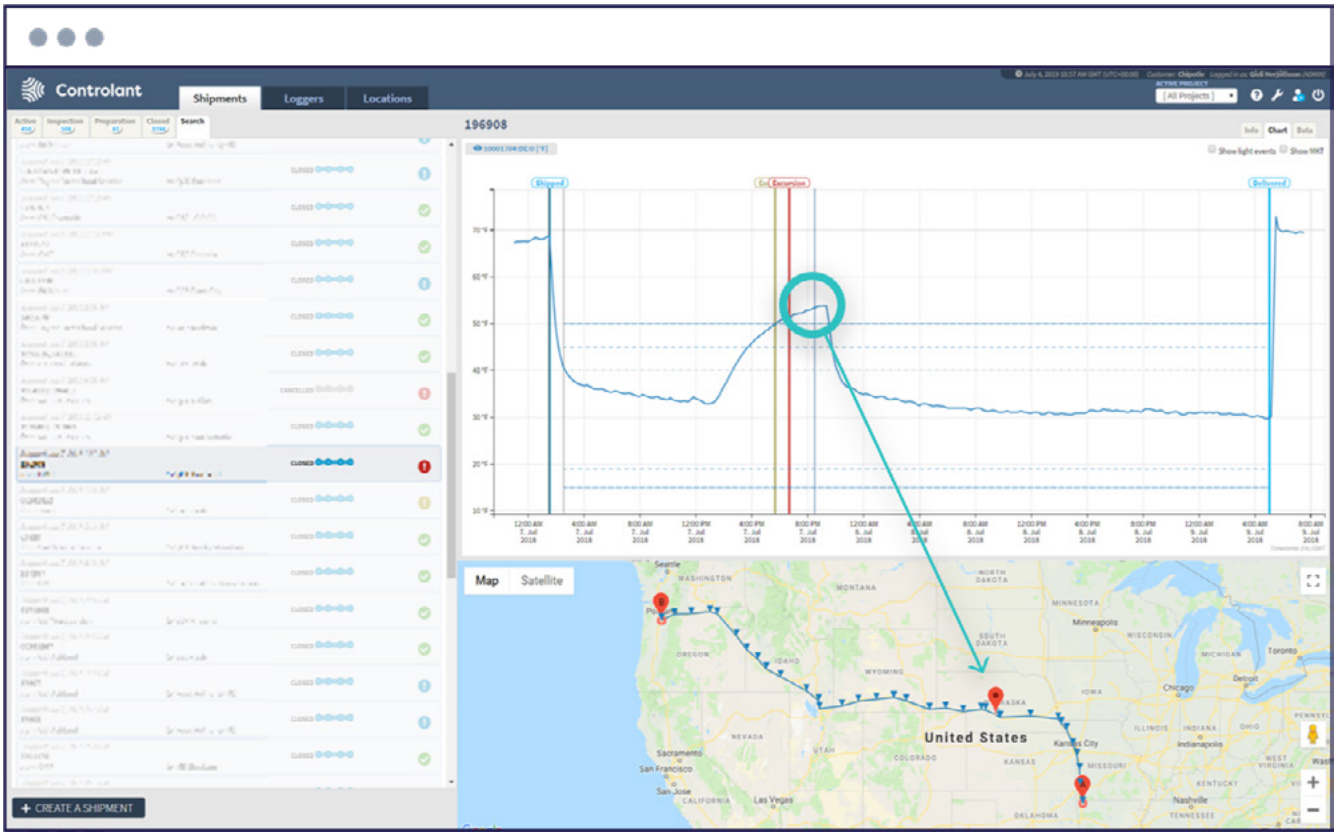
- Critical alerts received in real-time made it possible to respond and save the product.
- Collaboration with a freight forwarder was made possible through centralized access to shipment data, improving efficiency.

Case study 2

Ocean freight

With sea freight, connectivity may be a challenge while a ship is in the middle of the ocean, most excursions occur before a shipment leaves the dock or shortly after it arrives at the destination port. With a real-time temperature monitoring solution, environmental data is available centrally via a software platform as soon as connectivity is available. Alerts can immediately notify stakeholders of a temperature deviation as products are loaded or unloaded, or waiting at a seaport when an excursion is most likely to occur.

For example, sea freight was meant to travel from Brussels through Rotterdam's port and then travel on to Lewisville, Texas. The customer viewing the shipment location could see that it wasn't moving despite the passing of an already-scheduled departure. They traveled to a harbor that was not connected to a validated route. A problem with the vessel required re-routing of the shipment. Accessing real-time data, it was determined that the shipment could travel through the non-validated port to make on-time delivery possible. The real-time data facilitated in-time delivery and quality review, resulting in product released into the market.



Key takeaways

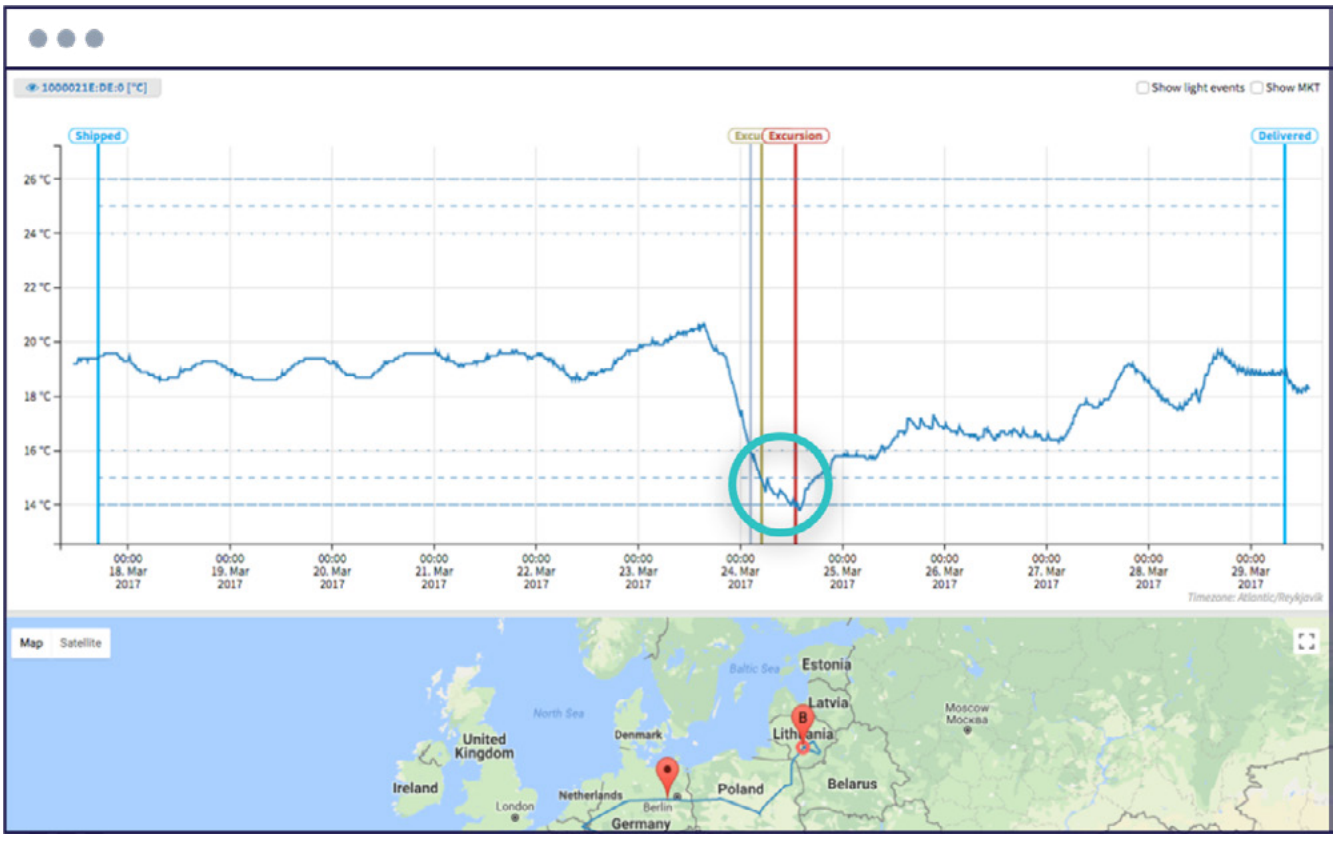
- The customer wouldn't have known their product wasn't moving without the real-time data.
- The customer wouldn't have been able to accept re-routing through a non-validated port.
- Data connecting time, temperature, and location supported and expedited the quality review and release process.

Case study 3

Truck shipment

Critical data sent at the right time can significantly reduce the time spent on investigation and enable quality teams to quickly review shipment data to get to the root cause of temperature deviations. While carriers may have their own tracking systems, they may only track ambient temperatures and may not provide a complete picture of what is happening on the product level.

The example below includes a truck shipment carrying pharmaceutical products shipped from Italy en route to Lithuania. Halfway through the shipment, temperature deviation triggered an alert, which was immediately sent to stakeholders by email and SMS via the Controlant software platform. The truck driver was contacted.



The truck maintained its own temperature monitoring system, which did not show that an excursion was occurring inside the truck. Upon closer inspection, it was discovered that a ventilation window located at the back of the truck had been left open, likely following a customs check.

Through real-time data, the customer quickly deduced the root cause of the excursion. Had the data not been available, it is possible they may not have known about the issue with the shipment until much later, if at all. The data enabled the customer to implement process improvements to prevent a similar event happening in the future.

Key takeaways

- Monitoring ambient truck temperatures only does not always provide a complete picture.
- Real-time visibility makes it possible to proactively respond to alarms and issues.
- Product was saved that would have been wasted.

Manage by exception process

The first thing real-time visibility over your data can bring is the ability to manage shipments by exception. Pharma companies often spend inordinate amounts of time examining shipments in order to release them as safe for the consumer. This is a tedious and time-consuming process. With the right tool, automatic shipment reports are easily producible with a range of alarm security levels sent to the right stakeholders. This allows for an examination of only the shipments in which something went wrong during transit. It offers peace of mind that the shipments that went smoothly without excursions are safe.

When an excursion does occur, accessibility to data accessible by all stakeholders saves precious investigation time. With real-time location traceability, there is no question as to a

shipment's location at the moment an excursion occurred, which immediately narrows down the possible options significantly. With root cause analytics it makes it even easier.

Big data fuels predictive insights

A variety of environmental factors can impact the fast-moving, constantly changing cold chain at any moment. The greatest risk to a therapeutic product in transit is the impact of weather on both temperature control and on-time delivery. A late or damaged load has downstream effects that can lead to medicines and vaccines not reaching patients.

Today, the pharma cold chain requires more than 100% visibility. The focus continues to center on late and off-schedule loads that threaten to disrupt operations, trigger a compliance event, and eventually challenge their regulatory reputation. A shift toward utilizing predictive analytics to drive proactive management practices leads to more informed decision making, ensuring efficiency, and productivity across the supply chain.

With the right analytics solution, data is available earlier in the shipment process. Quality teams receive an immediate alert if an issue arises. Shipments without any temperature deviations can be automatically closed, and problem shipments segmented for further review. This can translate to an annual reduction in up to tens of thousands of human hours that would otherwise be spent digging into shipment data to determine root cause and to piece together what happened during a shipment. Those operational cost savings can add up to millions of dollars.

One pharmaceutical manufacturer saw excursion rates reduced by 1/2 and investigation hours drop from 72,000 hours per year to 6,000, within the first 12 months after starting the roll-out of real-time temperature monitoring across the supply chain. It is estimated that the reduced excursions and resources spent on review saved the company $7 million within the first year.

When considering a supply chain environmental and product movement data visualization and decision support tool, data analytics are important, as are services that can support enterprises to effectively leverage the data. Supply chain intelligence data can provide granular level insights while still demonstrating how to run a cold chain broadly. It involves the analysis of past cold chain logistics patterns and tying them together with external data streams to define what actions to take in any given situation.

The right cold chain solution with advanced data analytics enables businesses to streamline operational efficiency, improve visibility and collaboration throughout the supply chain, optimize route performance, and manage by exception.

Monitor, measure, manage and improve

Real-time temperature monitoring and product movement traceability will be mission-critical as supply chains move to digitize. Any misstep in the supply chain can lead to product loss and jeopardize patient safety. Companies can identify and mitigate risk, drive continuous improvement, reduce product and operational waste, alleviate reliance on third-party data, and reduce costs by moving away from single-use temperature technology that requires a substantial upfront investment.

Businesses moving towards real-time solutions that are delivered on a pay per shipment basis:

- Visibility and control over all data, rather than limited visibility with a lot of guesswork.
- Complete reports that show exactly what happened, when, where, and why.
- Data consistency and compliance.
- A reduction in blind spots due to continuous visibility.
- Fewer disputes over who is responsible for issues that happen in the supply chain (the proof is in the data).
- More automation, less manual work, and error.
- Automated quality review and faster release times.
- Reduced product and operational waste.

Pharmaceutical industry leaders have started to embrace digital transformation to drive supply chain performance — shifting supply chain from a cost center to a competitive differentiator. Getting starting with a real-time temperature monitoring solution that is validated and compliant for pharma is easy today. Getting stakeholders together from the beginning to define program objectives and pilot the solution via a strategic lane is recommended. Our seasoned team of customer success directors and program managers are available to ensure a successful implementation of our real-time solution across all primary and secondary distribution lanes and facilities. Contact us to get started today.

About Controlant

Controlant is an ISO 9001:2015 company, headquartered in Reykjavik, Iceland with operations in San Francisco, US, and Dublin, Ireland. We deliver product quality, compliance, and stakeholder value through our real-time and prescriptive data and our unique services-based solution partnership. To learn more or get started with a pilot, please visit controlant.com or contact us at sales@controlant.com.

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