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# How to overcome supply chain soft spots

Supply chain soft spots are the vulnerable points where temperature excursions and other logistical disruptions are most likely to occur.

Disruptions in the availability of safe and effective medicines not only pose serious health consequences for patients, but also pose significant risks to pharma companies, such as product loss, stock-outs, and increased financial and environmental costs.

This white paper outlines a strategy to identify, analyze, and address these soft spots by leveraging real-time monitoring devices, advanced analytics, geotagging technologies, and expert partnerships.

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# How to overcome supply chain soft spots

Pharma decision makers report that supply chain disruptions are among their top five concerns, alongside legal, regulatory and macroeconomic risk, and at least twice as pressing as other major concerns, such as competition, labor, and climate risks. (Source: GlobalData's *Company Filings Analytics* report for Q1 2024.)

Complex and highly regulated, the pharma industry faces significant challenges in addressing soft spots in the global drug product supply chain. To mitigate risks and improve supply chain resilience, ensuring the continuous availability of essential medications, pharmaceutical companies can take actions to increase visibility, diversify manufacturing, strengthen quality control, collaborate with third-party stakeholders, and invest in new technologies.

## Mitigating risk with digitalization

Complex and highly regulated, the pharmaceutical industry faces significant challenges in addressing soft spots in the global supply chain. To mitigate risks, pharmaceutical companies can take actions to increase visibility, diversify manufacturing, strengthen quality control, collaborate with third-party stakeholders, and invest in new technologies.

Digitalization is key to identifying and analyzing these soft spots. Traceability technologies, such as real-time monitoring, serialization, barcoding, and anti-counterfeiting packaging, can combat counterfeit products, enhance supply chain efficiency, secure the safety of products, and build patient trust. IoT solutions can provide real-time data, enhancing knowledge and ensuring compliance with regulatory standards and quality control measures.

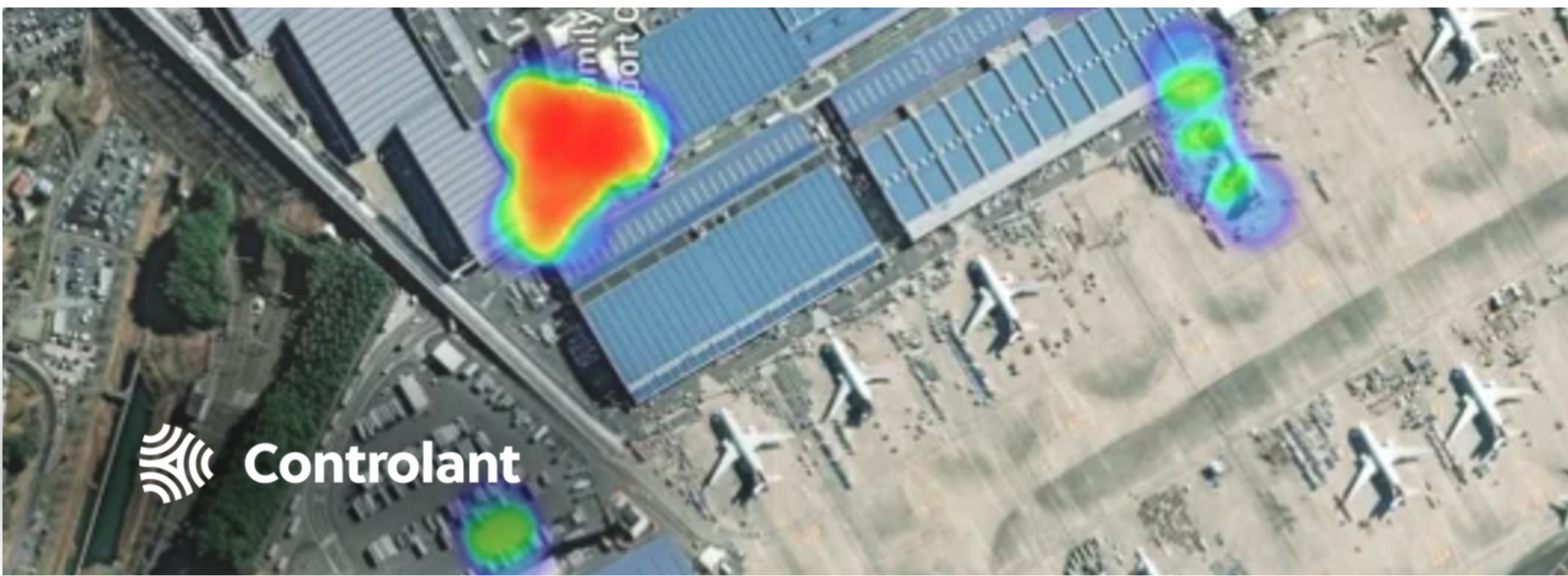
However, scaling traceability data and data-driven analysis remains a challenge, due to the huge amounts of data generated. The complex and highly regulated nature of the pharmaceutical industry is also a challenge, calling for a validated, GxP-compliant, real-time digital interface to the supply chain.

## Ongoing challenges

*The State of the Biopharmaceutical Industry* (2024 Edition, Mid-Year Update) from GlobalData's Thematic Intelligence Unit states that pharma supply chains continue to face ongoing challenges, including disruptions from geopolitical events, shortages of materials, drug demand fluctuations, logistical complexities, and regulatory compliance requirements.

Global drug shortages are getting worse due to supply chain woes and the difficulty faced by medical professionals in sourcing substitute therapies. Both anaesthetics and cancer medications are in especially high demand, and shortages of either of these drugs can have a devastating impact on patients.

Addressing these challenges requires close collaboration with industry players, as pharma supply chains involve multiple stakeholders. And while the use of AI is touted as a technology that can help streamline and enhance processes, the widespread implementation of such technology will take time.



# Global implications of the US BIOSECURE Act

With ongoing drug shortages in the US often linked to a reliance on foreign manufacturing, the Biden Administration in the US has been seeking to onshore manufacturing capacity and reduce reliance on foreign manufacturers. In January 2024, the US introduced [the BIOSECURE Act](#) to secure pharma supply against geopolitical threats.

The bill was passed in the House but is now (November 2024) in limbo with a Congress in post-election transition. If signed into law, it would prohibit companies contracting with Chinese biotechs, and prevent Chinese manufacturers from accessing US federal funding.

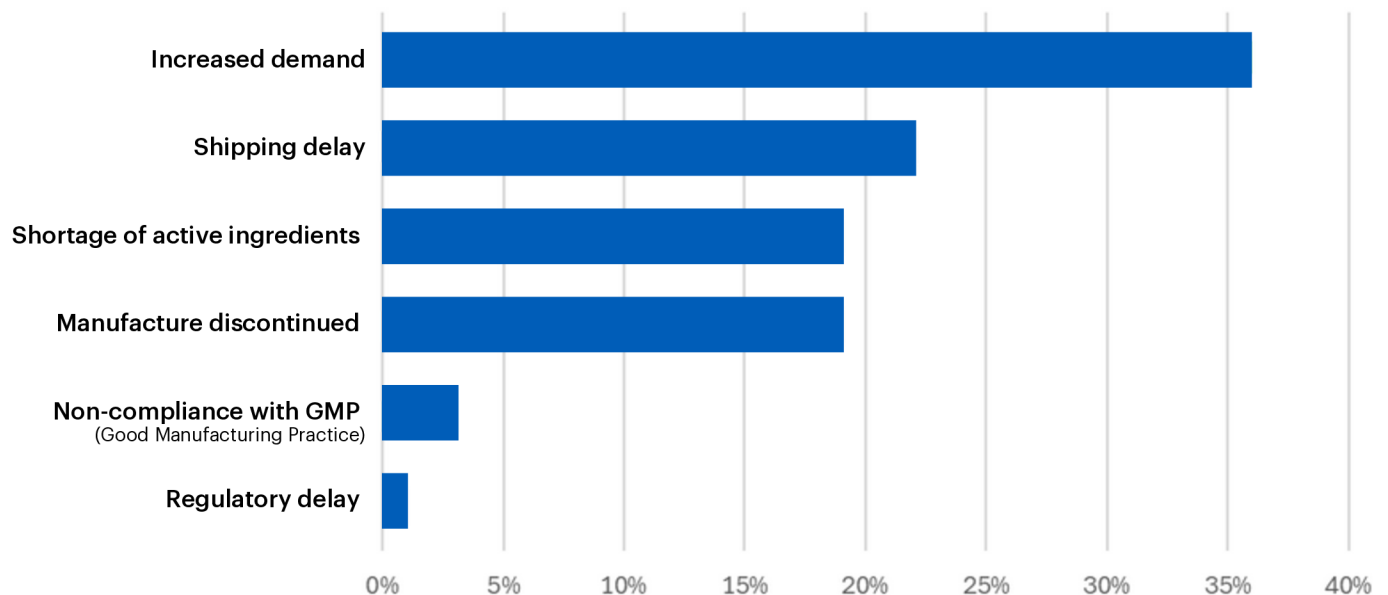
Predicted implications for US pharma companies include a dip in manufacturing capability until more manufacturing moves to the US or ally countries, and trade obstacles put forward by China in retaliation.

Given the anticipated need to replace Chinese counterparts in developing and producing therapeutics, it comes as no surprise that when asked about the wider implications of the BIOSECURE Act, the biggest proportion of respondents said they expect more manufacturing to move to US ally or neutral countries. (Source: GlobalData: *The State of the Biopharmaceutical Industry*, 2024 Edition (Mid-Year Update), p.91). But also among the top five implications identified, was that the supply chain will become less safe and less resilient.

## A range of logistical challenges

The BIOSECURE Act doesn't tackle some of the other issues that threaten supplies, such as damaged or lost shipments, and delays not linked to foreign manufacturing. Identifying the soft spots in the supply chain where temperature excursions and other logistical disruptions are occurring is the first step towards avoiding these delays and losses.

**Figure 1:** Reasons for current drug shortages in the US



In the US alone, shipping delays are responsible for 22% of drug shortages, excluding shortages with unknown/ other causes. Source: GlobalData: *The State of the Biopharmaceutical Industry*, 2024 Edition (Mid-Year Update), p.25

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# Common problem areas

Soft spots in the supply chain have a direct impact on the distribution of pharma products. When there are cracks in supply chain operations, such as a lack of visibility, limited manufacturing capacity, geographic concentration of manufacturing sites, or quality issues at sites, it can lead to shortages and disruptions.

In a worst-case scenario, these soft spots can result in life-saving medications becoming unavailable; and for clinical trials, delays in bringing life-saving drugs to market.

In the pharma cold chain, temperature excursions are concentrated at handover points, the most likely time for conditions to change. So common problem areas are airports and transportation routes. Any disruptions in these areas – from faulty refrigeration to natural disasters – can lead to delays or damage to the shipments, which can result in compromised product quality and safety.

A lack of visibility in the supply chain can make it difficult to identify soft spots and actively address them. For instance, greater visibility into the upstream supply chain can help identify potential risks and enable preventive measures, such as diversifying manufacturing locations or increasing the number of manufacturers for a particular drug.

Delays in pharma shipments can compromise drug products that are in transit, especially medicines that are temperature sensitive. Inappropriate storage conditions and shipment delays can cause products to be stored outside the required

temperature ranges, potentially damaging the integrity of the product. Without real-time visibility, it is difficult to manage products' stability budgets in order to mitigate this risk.

As well as the more obvious issues, such as patients not receiving their medications on time and potentially affecting their treatment plans and health outcomes, there are also issues around reduced availability of materials, such as excipients and packaging components, which are essential for the production of drugs and other treatments.

For clinical trials, inventory shortages, impacting the availability of drugs, may lead to requiring additional production runs or fill/finish work, leading to extended trial timelines or delays in product launches. This can pose serious health consequences for patients, and serious costs for pharma companies, as any delays reduce the period of market exclusivity of new drugs.

Given disruptions in the supply chain often have a material adverse effect on health and business outcomes, pharma companies take various measures to address soft spots in the supply chain and to improve the distribution of products. These measures include restructuring operations, enlisting third-party stakeholders, and investing in real-time supply chain visibility to identify vulnerabilities and mitigate risks. There is also growing recognition of the need for a more diversified supply chain to spread risk and ensure multiple avenues of supply.



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# To identify soft spots and mitigate risks posed by them, pharma can take measures such as:

## **Increase visibility**

Greater visibility into the upstream supply chain can help identify vulnerabilities and potential soft spots. This can include mapping the supply chain and understanding the characteristics of each drug's supply chain.

## **Strengthen quality control**

Quality issues at manufacturing sites are one of the identified risk factors for drug shortages. Implementing strict quality control measures and addressing any quality issues can help reduce the risk of supply chain disruptions.

## **Implement data-driven automation**

Digitalization is the only way to make effective use of all the data available. Pharma companies that automate key processes can streamline operations, integrate data, and gain real-time insights, enabling accurate and efficient data-driven decision-making.

## **Invest in new technologies**

Building resilience into the supply chain requires investment in capabilities, such as risk monitoring, performance tracking, and simulation modelling, to anticipate and mitigate potential disruptions. New IoT technologies make tracking and monitoring more efficient and cost-effective, in real time.

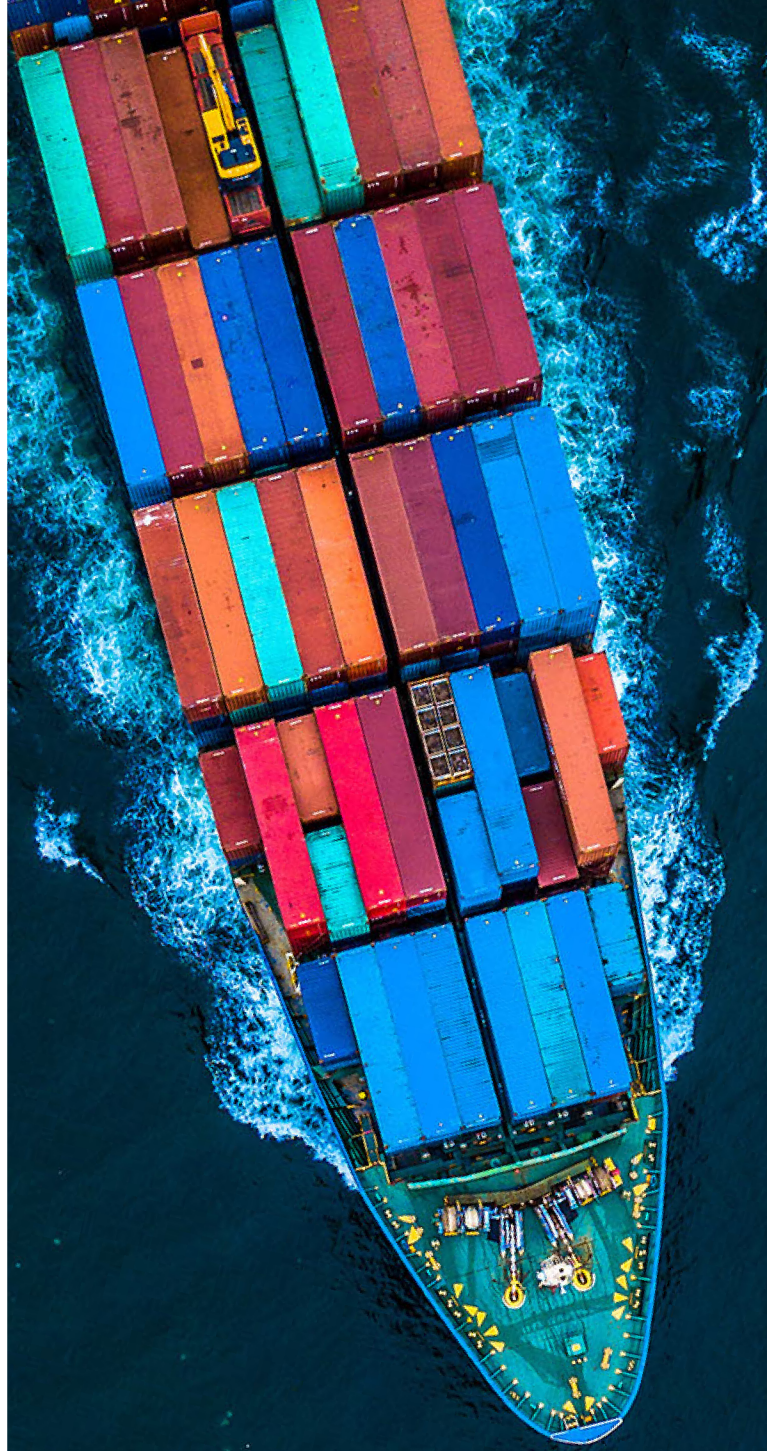
## **Collaborate with strategic partners**

In order to focus on your core business, engage with third-party stakeholders whose industry-specific expertise provides valuable insights and assistance in addressing supply chain vulnerabilities.

## **Diversify manufacturing**

If a particular drug is vulnerable due to being manufactured in a single location, diversifying the manufacturing sites can help mitigate the risk of shortages.

For more information:  
[controlant.com](https://www.controlant.com)



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# Leveraging technology to tackle soft spots

One of the biggest advancements in recent years is the use of GPS, geotagging and hierarchical spatial indexing, which, combined with data analytics, AI and IoT (Internet of Things), can help identify and address supply chain soft spots.

Geotagging is the technique of incorporating geographical information, such as latitude and longitude coordinates, into various types of media, such as photographs, videos, and text. Commonly used in travel and tourism, this information allows the media to be associated with a specific location on Earth.

Hierarchical spatial indexing is a technique used to organize and analyze spatial data in a hierarchical manner, with each level representing a different level of detail or granularity, allowing for efficient storage, retrieval, and analysis of such data.

By accurately tracking product locations and analyzing real-time data, using IoT sensors attached to shipments, manufacturers can monitor factors such as temperature, humidity, and light exposure, enabling real-time identification of suspicious events or deviations from desired conditions.

Some tracking and monitoring systems include alerts and notifications to stakeholders for immediate action when any irregularities or suspicious events are detected. Monitoring technology can provide valuable data insights that can be used to optimize logistics, improving overall supply chain efficiency. This includes better inventory management, demand forecasting, and route optimization.

For stakeholders, interactive business intelligence (BI) dashboards offer a visual representation of this real-time data, allowing users to easily monitor and track shipments and identify bottlenecks or delays in the supply chain. These dashboards can be invaluable for making informed decisions and allow the user to take immediate action when necessary.

By leveraging technologies like IoT, AI, and robotics, BI dashboards streamline and optimize monitoring and response processes, collecting and analyzing data to track the location, condition, and quality of pharma products in real time. By automating manual tasks and processes, these systems also help reduce human errors, increase efficiency, and ensure end-to-end traceability of pharma products, crucial for recalls and audits.



# Data-driven solutions from industry experts

Ensuring the seamless flow of goods from producers to consumers involves a complex interplay of logistics, technology, and human action for pharmaceutical firms. Picking the right partner can fast-track firms hoping to master it.

Controlant has industry-leading expertise in real-time monitoring solutions for the pharma supply chain, and its Supply Chain Soft Spots (SCSS) and Right First Time (RFT) solutions are revolutionizing the way pharma companies reduce critical temperature excursion rates and drive operational efficiency in their supply chain.

SCSS is an interactive map-based interface that heat maps the supply chain, providing the precise locations of soft spots, including details of specific facilities. By leveraging unique insights into where temperature excursions occur throughout all shipments, pharma companies are reducing critical temperature excursion rates in their supply chain.

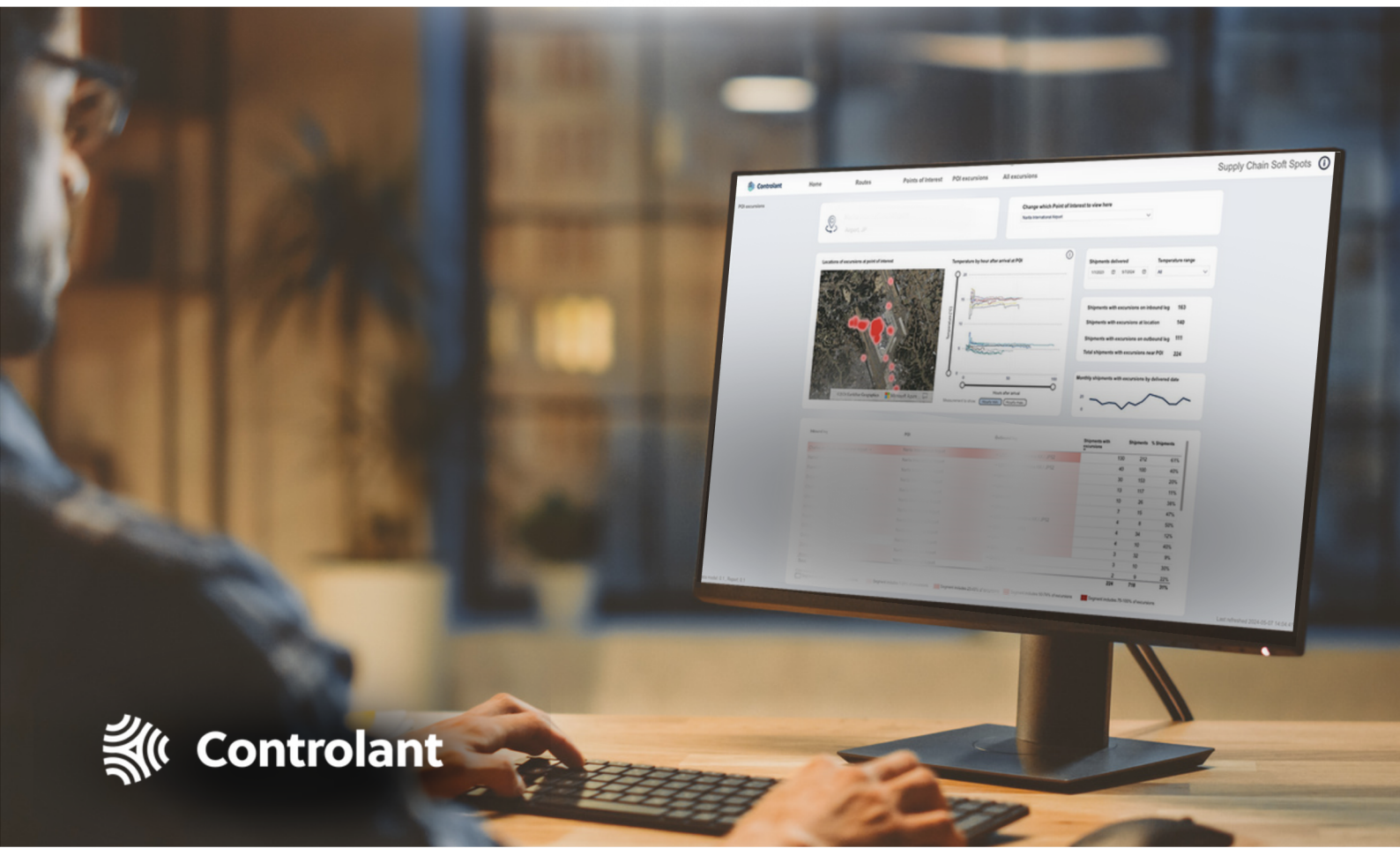
Any handover point comes with the risk that conditions will change, or the route will be disrupted. In 2023 alone, Controlant analysis shows one pharmaceutical company recorded temperature excursions at 102 airports and 10

harbors, highlighting how the potential for things to go wrong tends to be concentrated at supply chain checkpoints.

To enhance the efficiency and reliability of supply chains, Controlant's RFT solution centralizes relevant data and provides detailed analytical insights into why a shipment wasn't delivered right first time, identifying opportunities for automation or improvements.

A shipment is considered right first time if it is automatically delivered and closed on the Controlant platform without the need for manual intervention. The ratio of closed shipments that meet this criterion, tracked monthly, acts as a key performance indicator, giving businesses precise insights on where weaknesses may be creeping in.

These solutions are interactive dashboards created using data gathered from Controlant's devices, the Controlant Platform, and third-party data sources, to provide insights about customer shipments, root cause analysis for temperature excursions and operational inefficiencies, process performance by site or lane, insights into airports, harbors, customer locations, and so on.



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# Partnership is key to implementing new strategies that address soft spots

In an era of instability, tackling vulnerabilities and disruption in the supply chain is one area where pharma companies can now quickly toughen up and ensure resilience.

But finding the best solution involves finding the right strategic partner.

Controlant's solutions are tailor-made for pharma. Drawing on their capabilities in advanced analytics and automation, Controlant's experts work closely with pharmaceutical companies to bolster overall supply chain performance by addressing inefficiencies and enabling data-driven decision-making.

Contact us to learn more about how our cutting-edge technologies can help you address challenges posed by soft spots in your supply chain, and deliver a significant ROI.

[Contact us](#)

This white paper is an updated version of *Supply chain soft spots: How pharma firms can overcome them*, originally published on [pharmaceutical-technology.com](https://pharmaceutical-technology.com) in collaboration with Controlant.

