Protecting Product Integrity in Transit: A Guide for Large Pharma & Biotech Firms

Why Protecting Product Integrity is Important to the Pharmaceutical Industry

Pharmaceutical and biotechnology supply chain leaders focus on protecting product integrity to comply with regulations that ensure patient safety, to save on costs associated with lost or damaged products and to protect the brand reputation of their companies.

Where Is the Greatest Risk to Product Integrity?

Product integrity can be degraded anywhere from the source of raw materials to the final delivery of medication to the patient. As such, pharma companies and distributors have extensive quality assurance programs and tools to:

- Control the quality of raw materials
- Ensure proper manufacturing control
- Use explicit packaging processes
- Maintain environmental controls for storage at warehouses/distribution centers

But the place where firms tend to have the least control is when supplies and partially or fully finished pharmaceuticals are transported between suppliers, plants, and storage and distribution points. In-transit products moving between these controlled 'safe havens' are most at risk for theft, damage and diversion.

What Is the Magnitude of the Risk to In-Transit Products?

In-transit product integrity problems drive both direct and indirect costs. There are the obvious direct costs of having to replace the materials that are damaged or lost while being transported.

There are many indirect costs of losing a shipment of expensive finished medicines or critical ingredients. Temperature-controlled materials may need to be tested if there are excursions outside of the regulated, safe temperature window. Key ingredients that do not arrive in time for a manufacturing batch may cause a plant shutdown. Medications that are stolen can be adulterated and sold on the gray market, harming patients and damaging the brand reputation of the product and company. There is also the risk of failing to meet customer expectations if an expected shipment does not arrive on time – or at all.

Using IoT and in-transit visibility technologies to protect product integrity yields both direct and indirect ROI. Companies can dramatically reduce manual monitoring of end-to-end ETA and delivery confirmation, freeing up human capital for more strategic work and improving record accuracy.

What Biotech & Pharma Firms Can Do to Preserve In-Transit Product Integrity

Pharma and biotech companies and distributors often use specialty third-party logistics providers (3PLs) that are licensed under the Drug Supply Chain Security Act (DSCSA) to store and carry their products to distribution points. Using specialty 3PLs offloads the logistics burden but does so at the cost of real-time responsiveness and data to improve supply chain operations.

While these carriers will have their own quality assurance systems, they generally do not provide real-time visibility of the physical location and condition of products to shippers. Without real-time in-transit visibility, shippers cannot respond to prevent delay, damage, loss or theft.

Further, there is no ability to capture data on in-transit performance. Having that information would enable pharma and biotech companies and distributors to diagnose repeated problems, identify corrective actions and prevent future occurrences.

The data latency of carrier or 3PL reporting on shipment progress and delivery has a negative impact on supply chains, especially the ability to proactively minimize delays.

Lacking real-time visibility for shipments forces companies to overstock materials to mitigate disruptions and delays.

Three Ways In-Transit Visibility Provides the Transparency Necessary to Protect Product Integrity

With in-transit visibility, biotech and pharma firms can track the location and condition of their shipments in real time. There are three key ways in-transit visibility technology empowers these companies to protect product integrity:

1. Demonstrate control from ingredient sourcing to customer delivery.

With in-transit visibility, companies add critical information monitoring products from suppliers to plant and from plant to distribution, controlling the entire manufacturing process from raw material sourcing to final delivery.

It provides companies with the means to track the location and condition of products like clinical trial materials. Organizations can gain detailed information about what is happening to their shipments with a record of all stops and where container doors were opened.

Additionally, firms get a sampling to diagnose areas where damage occurs and can monitor or avoid known risk areas where theft or diversion may occur.

2. Provide critical information for Corrective and Preventative Actions (CAPA)

The CAPA system is critical for quality improvements at pharma and biotech firms, allowing companies to improve processes, procedures, organization and business in a structured, well-documented and actionable way.

Real-time, in-transit visibility tools provide immediate exception alerting for timely correction. That alerting can be for unexpected stops or dwells – which could allow theft or diversion. It can also be for temperature excursions allowing a replacement shipment to be ordered as soon as a problem occurs.

3. Enable management review

It's not enough to have exceptions. You also need analytics to review exceptions, identify trends and develop action plans to improve over the short and long term.

In-Transit Visibility Supports Good Distribution Practices (GDP)

Proper storage and shipping for pharmaceutical supplies is a critical piece of Good Distribution Practices (GDP). Every pharma and biotech firm must set and control appropriate facilities for receiving, storing and transferring its products. To meet those GDP requirements, companies have to monitor products and materials continuously.

Multi-enterprise tools provide shared in-transit visibility for pharma and biotech companies and their supply chain partners including contract manufacturers, fulfillment centers, and distribution centers and dispensaries.

Two-way automated feeds between in-transit visibility tools and current systems of record support GDP.

An in-transit visibility tool is an electronic historical record for CAPA and carrier performance audits to compare against contractual service level agreements (SLAs) and key performance indicators (KPIs).

Real-time exception alerting mitigates or prevents supply and distribution disruptions. This includes temperature excursions or dwelling in known risk areas so supply chain managers can respond to save at-risk shipments or change shipping plans for future deliveries to prevent a recurrence.

Companies can balance how much buffer stock they actually need with actual historical requirements and monitor changes in delivery times.

Other GDP goals that in-transit shipment visibility can enable include faster Quality Release Process (QRP) with verification that medicines have stayed within the organization's control and at safe temperatures throughout the shipping process.

The Bottom Line: Embrace Technology to Protect Product Integrity

In today's digitizing world, pharma and biotech firms can't continue with a "business as usual" mindset. As medications become increasingly specialized and expensive, it will become ever more important to know the exact location and condition of each shipment.

The pressing question is, "Can I afford uncertainty about where my ingredients, clinical trial materials or medicines are – or if I can still use them?" If the answer is no, start building the business case for selecting and implementing a real-time, in-transit visibility tool.

In-Transit Visibility and Machine Learning ETAs Help Protect Product Integrity

We can help. Our in-transit visibility solution, **Savi Visibility™**, provides real-time visibility to the location and condition of goods in motion.

Savi Insight™ provides analytics to identify opportunities to avoid degradation or loss of in-transit product integrity using historical and real-time supply chain data and machine intelligence.

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