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The Digital Cold Chain Reimagined



Leveraging Supply Chain Visibility in the Pharmaceutical Industry to Improve Operations

One of the biggest challenges that the pharmaceutical industry has ever faced is unfolding right now as the world focuses on developing and distributing new COVID-19 vaccines globally. Under normal circumstances, managing and monitoring the many suppliers that produce the ingredients that are part of drug production on a global scale is a challenge. With this vaccine, global demand is truly global. With supply chains disrupted, it is essential to address the blind spots within the supply chain to mitigate losses from missed handoffs, theft, product spoilage, re-testing and compliance issues. In fact, the pharmaceutical industry loses approximately $35B annually as a result of failures in temperature-controlled logistics.

"Going forward, supply chain visibility will be crucial, and it should be the number one priority for chief supply chain officers."

Dr. Hau Lee, *Professor at Stanford University Graduate School of Business and Co-Director of the Value Chain Initiative*

Today's cold chain supply chains are complex logistics networks with a large ecosystem of suppliers and transportation modalities. This includes bulk drug producers, brand manufacturers, cold chain container & packaging companies, fill & finish companies, multi-modal transportation, carriers, warehouses, distribution centers and hospitals. The product needs to be kept in high integrity and compliance across this entire network. The challenges for all organizations include data silos within the organization, across suppliers and partners, data accuracy, timely data, dark spots or lack of data during transport and lack of contextual data. The predominant method of collecting data when products are in movement has been through passive data loggers which store data and must be uploaded to the enterprise systems at the end of the product journey. Learning about issues or damage after the journey makes it impossible to prevent issues and difficult to remediate issues.

Continuous, real-time visibility delivers insights to make timely decisions; this is a game-changer for pharmaceutical supply chains, as it produces demand-driven value networks. This change in operating model enables companies to be dramatically more responsive to market and customer variability and drive significant value for each business in the connected supply chain.

Fortunately, achieving 80-90% visibility is no longer aspirational, but both a reality and a requirement—near-optimal visibility is the foundation for agility, resiliency and the Next Generation Supply Chain. Higher visibility leads to better business outcomes that make operations more efficient, resulting in higher profitability, less waste, better product quality and less diversion.

"Technologies that enable you to get real-time, granular data providing complete visibility into your supply chain, along with smart contingency planning, are now required to deal with managing day-to-day business."

Maria Nieradka, *pharmaceutical supply chain executive*

Importance of Supply Chain Visibility in the Pharmaceutical Industry

One of the key challenges in the pharmaceutical supply chain has been the lack of visibility that leads to inaccurate predictions, poor planning, delayed decision making, higher risks and loss of product. In fact, visibility has several value dimensions:

- Prompt actions and responses to events that have deviated from the plan, helping in course correction
- Fully informed responses, enriched with data and context of the supply chain beyond the event we are addressing
- Predictive insights to signal issues with leading indicators before problems occur
- Accurate and timely reporting of performance measures, which are necessary for incentive alignment

Visibility helps in understanding the tradeoffs in various alternative decisions, leading to the optimal choice mitigating business risks.

Turning visibility into actionable insight demands a fundamental shift from traditional functional, efficiency-focused supply chains to demand-driven value networks. To make this shift, technology that provides point-in-time status of product flow from EDI and barcode scans must be augmented or replaced with continuous real-time Internet of Things (IoT) signals at the product level. This shift drives 100% visibility from delivery to customers back through integrated business planning, into operations and back to the supplier network.

Continuous visibility provides real-time data versus aged, static data, making analysis and actionable insights available in time to trigger systems to alert or notify of possible exceptions and remediate the situation.

Gaps in Visibility

Increasing visibility is critical to digital transformation, performance improvement and attaining higher stages of supply chain maturity. Yet pharma companies find that gaps in visibility inside manufacturing facilities, distribution centers, patient care facilities and between locations constrain their strategic or digital transformation. Many of the business and operating processes that tie locations together in the ecosystem today fail to capture critical multi-dimensional data. This includes edge data such as location, temperature, humidity, shock and other contextual information, such as weather, flight and traffic data that is crucial for advanced planning and execution.

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Vaccine Distribution Challenges

Fixing gaps in visibility is critical during the COVID-19 global pandemic. There are several challenges specific to optimizing cold chains for the delivery of a vaccine such as COVID-19. The vaccine supply chain requires properly functioning storage/packaging, cold chain transit, shipping and storage solutions. To distribute the manufactured vaccine globally, billions of doses will have to be monitored, transported and delivered through an elaborate logistics distribution system in the most efficient manner and under the conditions required for a new vaccine. To remain viable, a COVID-19 vaccine will sometimes need to be transported at cryo-temperatures such as -80 to -90 degrees Celsius and, according to CDC, always maintained at 2-8 degree Celsius. Any kind of temperature excursion from this range could result in an entire shipment of spoiled vaccines.

The successful immunization of at least 70% of the world's population with a COVID-19 vaccine requires a sophisticated network of properly refrigerated transport that must work perfectly at every point along the supply chain. This success depends on the ability to achieve end-to-end visibility throughout the first, second and third-tier suppliers across the vaccine supply chain. In addition, track and trace technology as well as sensors can be leveraged to provide real-time visibility into temperature excursions.

Framework for Supply Chain Visibility

There are many parameters that need to be tracked for improving supply chain visibility in pharmaceutical, biotech and life sciences companies. Some argue that the key to higher productivity is tracking progress in business processes, leading to the identification of exceptions in a timely manner and orchestrating operations based on that visibility. These are referred to as soft attributes. On the other hand, some argue that tracking the location and condition of goods and supplies in real time as they move through the supply chain, involving different stakeholders across organizational boundaries, is the basis for smarter decision-making. These are referred to as hard attributes. Both viewpoints (figure 1) point out bottlenecks in the supply chain in their own way and identify the points of intervention for overcoming them.

The linking of hard attributes to values and consequences is clear and recognized; however, the same is true for soft attributes, as they could fundamentally change the values and consequences of a product or an object.

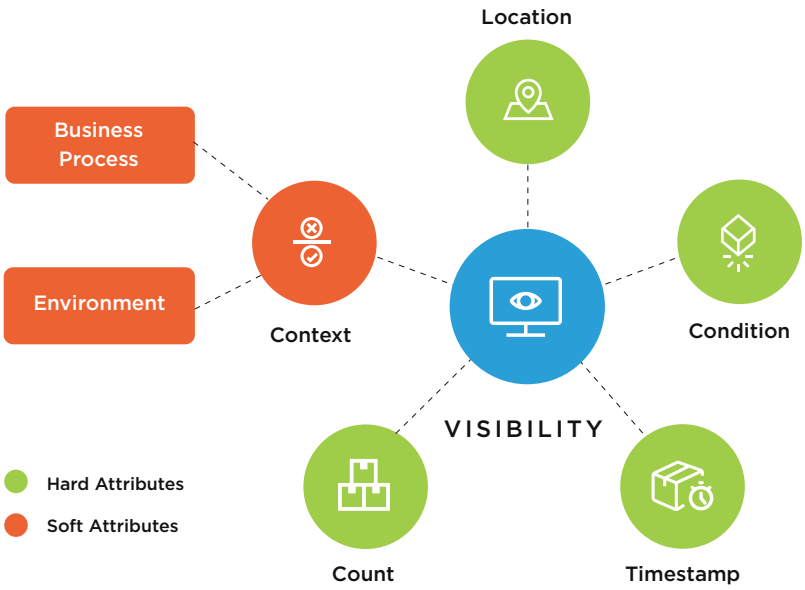


Figure 1: Framework for Supply Chain Visibility

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Visibility is the foundation of good supply chain management; without visibility into all dimensions of your supply chain, you will not be fully informed nor agile enough to take immediate action based on your data.

Visibility of the hard and soft attributes removes the blind spots so that we can see the true values over time. The "blind spots" can be eliminated in the supply chain and progress in Value can be observed clearly if both the hard and soft attributes are tracked (see Figure 2). When soft attributes are tracked and complemented with the tracking of hard attributes, the movement of Value can be clearly observed as it changes progressively from point to point along the axis.

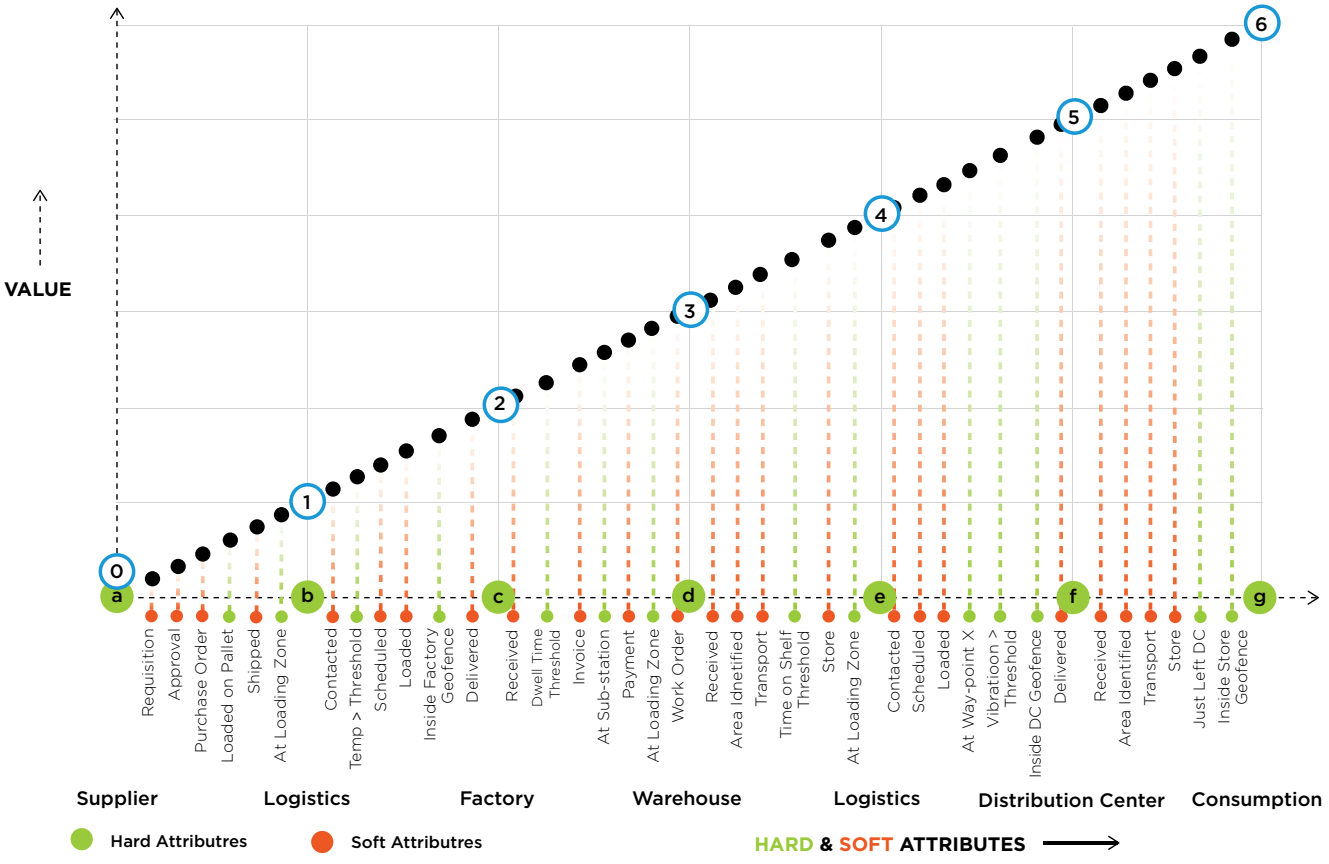


Figure 2: Value Diagram when both Hard and Soft Attributes are tracked

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Power of Hard Attribute Tracking

Hard attribute-based tracking provides the ground truth as the sensors gather the information from the raw materials/components and finished goods in real time. The ground truth consists of a variety of real-time data that help answer important business questions like:

- Is the component in transit kept under the desired ambient condition or has it experienced temperature excursions?
- Is the component at rest (in a warehouse or factory) in good condition or damaged?
- Has the component in the receiving bay been lying for a long time without being picked up?

Tracking of soft attributes enables faster detection of the problem, quicker identification of the cause and faster resolution of the problem.

Power of Soft Attribute Tracking

Visibility of soft attributes provides additional granularity to visibility and helps the stakeholders become more agile in their decision-making. For example, materials could be visibly present at the Supplier as indicated by the location sensors but not yet handed over to Logistics who loads the delivery truck.

Soft attribute tracking enables insight into the business processes — is there a paperwork issue keeping the handoff from happening or is it something else? A fuller picture results in quicker identification of the cause and faster problem resolution leads to higher efficiency, improved throughput and fewer delays.

Most companies have a lot of data sitting in “silos” or “islands” within their own organization and across their suppliers, 3PLs, warehouse WMSs and ERP systems. Bringing these islands together in a data lake enables visibility across their disparate systems. Fortunately, this is where a lot of the soft attribute data sits today; combining soft attribute data with hard attribute data from sensors and contextual data from external APIs will provide a comprehensive picture into their product flows.

Modern digital visibility platforms built with state-of-the-art cloud, IOT, sensor and AI/ML technologies enable these capabilities, with hyper scale and security, while being agnostic to hardware, unstructured data sources and rapid technology evolution. Modern digital visibility platforms are easy and economical to deploy, without large-scale IT spending.

Having a complete system to accurately monitor location, dwell times, condition and movement history will enable companies to increase FDA compliance and reduce spoilage and waste.

By deploying a digital visibility solution, you can identify and rectify weak links in your supply chain. With Cloudleaf, pharmaceutical companies can shine the light on supply chain gaps and turn this powerful end-to-end visibility into insight for better decision-making and a smoother delivery of life-saving products.

Using a digital visibility platform enables you to control the chaos and get the critical information you need to identify and maintain the integrity of your pharmaceutical products. With Cloudleaf, you can optimize your cold chain for successful product storage and packaging, seamless cold chain transit, accurate and shipping all while staying in regulatory compliance. Contact our team at cloudleaf.com/learn-more.

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