



End-to-End Supply Chain Visibility

Whitepaper



FOREWORD

Visibility provides a number of returns for pharma firms. Henrik Fröjdh, Associate Director of Supply Chain Management at Merck said that inventory reduction was one of the biggest drivers for Merck's business case for supply chain visibility. With a better understanding of the supply chain, shippers can manage risks proactively. The tracking required in serialization projects greatly enhances supply chain visibility levels. Embedded sensors right down to the individual product gives live location and safety information. This refined clarity places more control and actionable information at the hands of supply chain stakeholders for forecasting to enhance the network's efficiency. This can lead to reduced risk, increased quality and lower wastage. These benefits should lead to savings, but also an improvement to service, as the firm is enabled to make the right decisions at earlier points. Also, higher visibility allows for a complex supply chain to be managed at a lower headcount.

Ahead of the 16th Annual Global Forum for Temperature Controlled Life Science Supply Chains, Pharma Logistics IQ takes a look at end-to-end supply chain visibility in pharma.



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LOGISTICS

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Forecasting Inventory In Clinical Phases

Pharma firms should build their forecasting methods at the earliest opportunity, so in the clinical stages scale should be determined on how inventory will be managed once commercialized.

To forecast sufficiently, it is critical to have an understanding of the end user's demand, especially at pharmacies and hospitals. Collaboration initiatives will be needed to obtain visibility into distribution center's inventory levels and capacities. This information can guide the pharma firm's decisions on scale and distribution techniques once the product is commercialized.

The suppliers needed in the supply chain should also be considered at this point, which is a very integrated process. Marla

Phillips, Director at Xavier Health Xavier University noted: "Looking at today's common supply chain development model, [initially] there are cross-functional hand offs that happen leading to supplier selection and once the product gets onto the market a lot of resources are focused on supplier performance and corrective action. It becomes an unending cycle and resource sink for both sides." Her team of FDA officials and international industry members maintain that the supply chain development process should start with a cross functional alignment approach involving agreement on standardized criteria in the interests of quality, which is then followed by supplier engagement, supplier selection and then an ongoing resource efforts on improvement ideas and preventative action.



Supply Chain Blind Spots

Stakeholder engagement has a strong influence on the success of distribution. When stakeholder collaboration is fractured, supply chain visibility is weakened, especially with pharmacies and hospitals. Dan Mirica, former Head of Global Logistics at Lonza Biologics states that this has the power catch pharma firms off-guard and even throw off an entire manufacturing process. In our 2016 Temperature Controlled Logistics Future Trend Report, supply chain professionals marked managing partnerships and stakeholder efficiency in the supply chain as their third biggest pain point.

Another supply chain blind spot is avoiding the shortage of raw materials for example - active pharmaceutical ingredients. Enhanced visibility strategies allow manufacturers to spot any approaching issues in capacity or stock so they can best react to situations.

Real-time data provides more control to wipe out inefficiencies in the supply chain for example with smarter inventory management. Instant data notifications empower supply chain professionals to make the right decisions swiftly and improve packaging line speeds. The fast mitigation of problems at a lower cost is a major benefit of a supply chain visibility project. Event based alerts will significantly reduce the labour/costs (e.g call centers, service desks) required to identify the problems that can affect supply chain performance. For instance, if a cold truck arrives at a distribution center and is made to wait two hours

to be loaded this causes a significant impact downstream on planned delivery schedules. An instant alert can allow for a change in strategy to minimize inefficiencies. Supply chain visibility also enables more precision with cold chain operations to prevent temperature excursions as well as when handling equipment returns.

Emerging markets tend to attract planning complications. These markets tend to be very volatile and require bespoke business models. Fröjd said that it is hard to ensure a supply chain in an emerging market is as efficient as possible due to visibility limitations in regards to what the true demand is from local distributors in the markets.

The rise of biologics has caused a shift from volume manufacturing to more specialized and temperature sensitive production. Not only are these products harder to manufacture, but they intensify the classic challenges in the supply chain.



Supply Chain Risk Hotspots

Biologics are of high risk in the supply chain. The delicate stability of the products, which have tight turnaround times, in addition to their expensive price points mean that supply chain mistakes cannot be afforded. In order to preserve their effectiveness, the live materials in these medicines must be transported quickly, safely and within the correct temperature range. Everything from the weather to traffic jams and customs regulations can jeopardize this goal with these high volume and high value shipments.

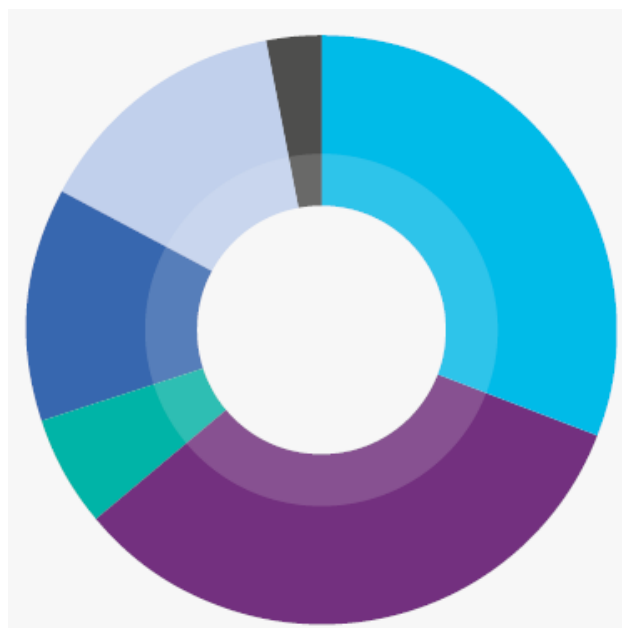
There is an increase of risk in the supply chain where a product is handed over to another party. Therefore, reducing links and handling involved in the supply chain is critical when reducing the likelihood of mistakes.

Track and trace systems are instrumental to the security of the supply chain. Serialization projects empower pharma firms to proactively combat counterfeit medicines themselves. Instead of waiting for national authorities to respond to a suspicion of counterfeiting, pharma firms can internally initiate spot checks through the supply chain process, via market sampling or the verification of databases.

When risk assessing a new lane through challenging territories Patrick Pichler, Head of Distribution Quality at Merck Group maintains that the most important step is to have a professional local to that territory to conduct the examination.

Name A Key Supply Chain Trend To Capitalize On Over The Next Few Years?

- Added visibility from serialization and track and trace programmes - 31.4%
- Unlocking emerging markets via innovative strategies - 32.9%
- Performance-based financing - 5.7%
- Driving toward greener solutions - 12.9%
- Cutting costs - 14.3%
- Other - 2.9%



He continued: “You need local people either from your subsidiary, affiliate or agent, that you invite to participate in this risk assessment and give insight on what is going on. Make sure this person is reliable. For example, if you look at some Arabic countries, they never have issues, but if you then go there you see that they [do] have issues. So you need to tell them that [there] is something they need to address.

“The second part of the risk assessment: You take your conclusion on the validation steps and involve the local players. What we did for recent validations in emerging markets, is we included the agents of our customs clearance, the forwarders that we use from the airport to the final destination and so on. They all read the validation plan and they all signed [it] besides customs, because the authorities [felt that they didn't have to sign it]. On the other hand, they were quite happy to receive this [plan] because they then said ‘We [now] know what we need to do.’ This was very enlightening for us because if customs

does not know how to handle the goods, then we [will] always face issues.”

He concluded it was crucial that all parties contacting the goods were included in the validation approach. Even though it took time until the validation protocol was ready, it was useful and Pichler notes that it is still functioning quite well in the lane [in question].



International Collaboration

With a global supply chain, visibility hinges on the ability for all sites to communicate, have interoperable technologies and function via the same standards. The pharma industry has always struggled with visibility problems due to platform complications and network changes. Also, traditional MRP systems require heavy duty, multiple year installation projects to get everybody on the same platform.

Now new technology is starting to breakdown these nightmares, simple connections to cloud technologies allow firms to scale up and look across a network.



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How can your stakeholders enhance the performance of your cold chain?

Val Petursson, Senior Director,
Logistics Europe & PTC/PP Teva:

“In general, we need to align with the information from quality clarifying the product in question. It’s information and stability data, the sensitivity of our product [being] grouped in the right risk segment and [having] good working procedures for excursions. Quality is the prime stakeholder here and the crossfunctional partner that is most important to us.

“Manufacturing is an [important] stakeholder as well as planning. For instance, with the loading procedures, the packing and pre-cooling of the equipment and the awareness of risks that can occur on the sites.

“In our experience we had high-value shipments opened by customs in Romania, which is fine. However, the market had not communicated to them what kind of value was in the truck,

so they left the truck open. [Therefore], during investigation they had contaminated the goods. There are all kinds of windows for miscommunication, like this, and these usually cause the worst excursions.”

Rubén Velázquez Treviño, Change Manager –
Transport Services, Bayer:

“Enhanced communication lines and relationships between production planning, demand management, and warehousing and logistics are key for the transportation process. You cannot have reliable planning and stable transportation lanes and transit times if you do not have planning visibility.

“The interactions between SCM departments and Quality have to be aligned and properly documented to avoid delays and ensure a seamless cold-chain process.”

The Last Mile

The challenge that is the last mile requires control and visibility through digital collaboration with pharmacies, hospitals and distribution centers. Whatever the region, Mirica notes that it is critical to be able to sense the demand to guide decision making.

Fröjd points out that FMCG and retail companies have an advanced understanding of their end customer's status in terms of stock and inventory. Pharma tends to have visibility to a distribution center, but then struggles to see what is occurring beyond that point.

The industry should strive to have visibility all the way to a local pharmacy to see how demand is moving. This should be communicated back up the supply chain to assist with efficiency. For this to happen pharma wholesalers will need to give visibility to manufacturers - a logical move since the accountability rests with them. This access could allow manufacturers to progress to conducting quality audits to verify their products are being handled appropriately. This transparency from wholesalers may need to be initiated by the State Boards of Pharmacy.

Serialization data has the power to lower recall size by increasing the accuracy of retrieval. Shipments could be decommissioned in bulk from the cloud system and reports can be sent to national systems to deactivate sales of the product in question.

Dr. Roland Klüber of Theron Management Advisors stresses the importance of smooth integration and interoperability in a serialization project when it comes to targeted recalls. For instance, "...if a recall happens a manufacturer needs to trace each single unit consistently and have demonstrated complete supply chain integrity. If that information is not fully linked into the supply chain then this can only be demonstrated via manual work at a high cost and time pressure."

To refine your supply chain visibility strategy and learn more on the subject attend the 16th Annual Global Forum for Temperature Controlled Life Science Supply Chains.

Resources

1. <http://www.pharma-iq.com/regulatorylegal/columns/packaging-labelling-thetechnology->