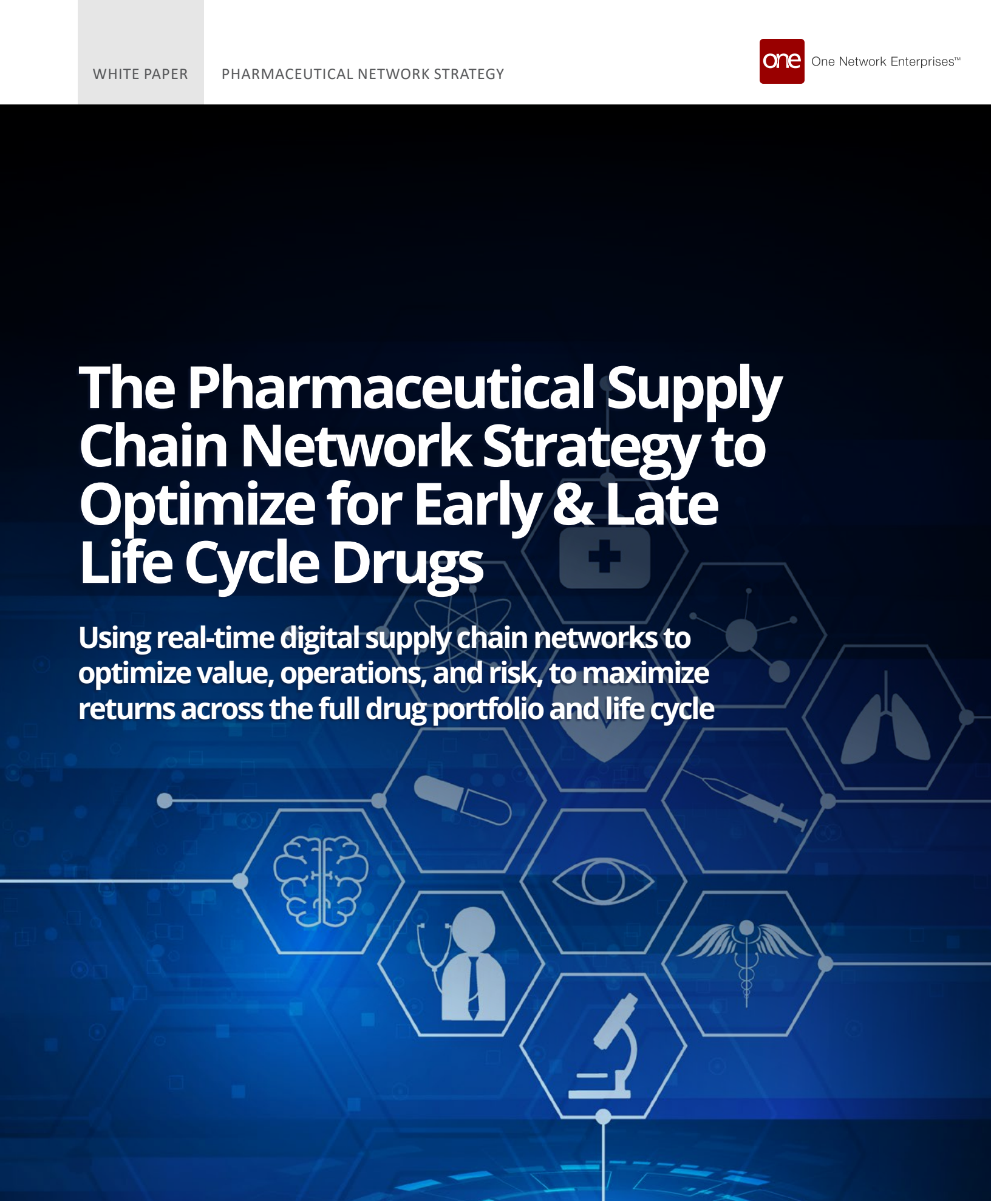
One Network Enterprises™

# The Pharmaceutical Supply Chain Network Strategy to Optimize for Early & Late Life Cycle Drugs

## Using real-time digital supply chain networks to optimize value, operations, and risk, to maximize returns across the full drug portfolio and life cycle



## STRATEGY

The pharmaceutical life cycle, which spans many years, is comprised of development, commercialization, and generic competition. Supply chain network strategies applied to the pharmaceutical life cycle have the ability to maximize exclusivity, gain a competitive edge, and improve patient outcomes. Once development is complete, the key is to deploy strategies to maximize the product's value and maintain market dominance before its patent expires and subsequently to maximize profitability post-patent expiration.

Effective commercialization is critical during the market exclusivity period to generate a return on the development investment which can span 10 to 15 years. This early life cycle stage covers the years between the launch of a new drug and the planning horizon for the market launch of its first generic competitor.

Early life cycle commercialization has many dependent variables to consider, each of which must work in concert to maximize both returns and patient outcomes. During this cycle focus is placed on the planning and logistics of bringing the product to market without detracting from product quality. The process must be correctly designed across plan, source, make and deliver, span both planning and execution, and include packaging and labeling, inventory management, transportation, product distribution, and product track and trace.

**Demand-driven network management leveraging digital supply chain network technologies will deliver against all these dependencies, optimizing outcomes through real-time analytics and improved decision making.**

As part of the early life cycle, post-launch success requires constant campaign tweaking and optimization across multiple trading partners. KPI monitoring across the network, for both quantitative and qualitative variables on a single version of the truth is core to making the best decisions possible at the right time with the right documentation shared across CMO's and their suppliers in real time.

The supply chain for early life cycle products must be designed with increased agility and flexibility given potential demand is uncertain and approval times can accelerate dramatically. CMO's will gravitate toward brands with these capabilities due to these market uncertainties. The risk is high given insufficient product supply upon launch could be devastating and would almost certainly affect patient health.

Late life cycle kicks in as we enter the planning horizon that includes generic entries into the market and requires that pharmaceutical companies leverage the knowledge they have gained during the early life cycle to streamline all processes related to drug sourcing, production and delivery. The "drug patent cliff" is when the exclusivity for the pharmaceutical product is nearing its end or has already expired. However late life cycle process design must start prior to the patent cliff given the generic competitors will have started their planning the moment commercialization of the new drug began. Generic competition will inevitably eat away at market share and profits with average price dropping as well as the branded drug's market share.

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During late life cycle supply chain networks can be leveraged to extend the product line by releasing a next-generation version of the drug product, or to seamlessly transition existing clients from the older drug to the newly patented product. Once a patent expires, pharmaceutical companies can leverage many of the same network capabilities that have been used successfully by CPG companies in terms of offering rebates or vouchers to maintain market share.

The shifting landscape in biopharmaceutical supply chains must be considered when designing future networks. The shift away from primary care to specialty products and personalized medicine, and from large-scale production of low-value small molecules to low-volume, high-value biologics must be considered as part of any future network design configurations. Currently a high percentage of pharmaceutical revenues are derived from small-molecule products, so many of today's networks are designed for small-molecule with biologics as a tangential process. However, looking forward about half of the research and development pipeline is devoted to biologics and we need to do a much better job in supply chain network designs for both large molecule as well as vaccines.

The shift in API production from internal manufacturing to CMO's has created the potential for an increasing number of issues upstream in the supply chain network. Because products can have many synthesis steps, it's good to have redundancy in sourcing. However, visibility to that redundancy and the ability to leverage decision making related to that flexibility can be challenging. A supply chain network for a product may look dual-sourced, but if a single step in those dual routes relies on a single producer, then you have a sole-source supply chain. Problems and issues related to variations in supply and demand across these networks as well as product quality should be presented in real time on a multi-party dashboard for resolution and decision execution to avoid product supply and quality problems.

CMO-based API production can also be subject to local market risks. Today companies have significant portions of their drug substance supply, in some cases more than 60 percent, located in emerging markets. When API production is no longer internal, the network data can be leveraged to ensure that contract manufacturing organizations maintain the targeted level of commitment to both quality metrics and standards.

## OPERATIONS – EARLY AND LATE PRODUCT LIFE CYCLE

Network operations for pharmaceutical companies are primarily composed of five capability centers including supply chain network collaboration, customer demand, drug product, supply, and quality collaboration. These capabilities have dependencies related to each other that must be well understood in terms of decision making.

## EARLY LIFE CYCLE

### Supply Chain Network Collaboration

Solves for today's weaker or non-existent collaboration capabilities across demand, supply, production, packaging and labeling, inventory management, transportation, and distribution. What-if scenario analysis across demand, supply, logistics, and cost will be served up on a graphical display with the ability to execute prescriptions designed to solve for any issues.

### Customer Demand

High forecast error is causing potential volume upside from being fully realized. Real-time collaboration and delivery date and time commitments across trading partners can be enabled to capture the upside demand or protect against any downside problems. Dependent constraints across the network can be considered so that planning and execution can deliver acceptable results based on demand priorities and supply constraints. Network issues causing order availability and customer delivery problems resulting in revenue shortfalls or cost overruns will be resolved within the financial period rather than after it is too late to react.

### Drug Product

Ongoing challenges with forecasting and planning requires an optimized execution capability across business functions and trading partners including materials, assets, orders, warehousing and logistics. With combined planning and execution track and trace data can be leveraged into better decision making and execution.

### Supply

Capacity and material constraints are impacting the business upstream in the network driving the need for increased visibility and collaboration as well as quality coordination for batch release. Chronic material availability, allocation, and production issues are symptomatic of silo-based IT system and related information latency and delays. These issues drive up costs and impact availability, affecting throughput and sales.

### Quality Collaboration

Campaign management demand synchronization with full visibility to qualitative as well as quantitative CMO batch failure and approval updates must be enabled as core capabilities. Quality yield adjustment data capture and impact analysis must be provided across multiple parties in real time.

## LATE LIFE CYCLE

### Supply Chain Network Collaboration

Maturity phase price drops require the automation of repetitive process steps to reduce network costs and maintain margins. Autonomous and interactive decision making through digitization must be made available at the network level to drive higher service levels at lower costs.

### Customer Demand

Promotional activities, patient rebates, vouchers, and adherence programs will drive demand variability. Real-time collaboration and delivery date and time

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commitments must be enabled similar to processes in the consumer goods sector to maintain on-time and in-full performance metrics. Forecasting analytics must adjust correctly for additional variables as patent cliff approaches.

### Drug Product

Streamlining of inventory and capital employed leveraging knowledge of stock levels, allocation rules, manufacturing data, batch failures and inventory expiration must be enabled through the network.

The ability to predict the probability of a batch failure across a multi-stage manufacturing network and take preventive and corrective action becomes part of the operating fabric. Optimized execution of supply and logistics ensures product availability and a lower cost to serve. The ability to drive asset leverage or “sweat the asset” as it is referred to in multiple sectors will drive significant benefits.

### Supply

Lack of upstream visibility and collaboration limits the ability to reduce late life cycle costs. Automating process and setting KPI guardrails where needed will solve for the fact that there are just too many people involved in decision making for a stable marketplace product. Proper controls need to be configured to leverage potential volume reductions or expansions beyond the forecast.

### Quality Collaboration

Batch failure, approval alerts, and general visibility from CMOs to quality data, rather than just quantitative data, must become a continuous part of the decision-making process rather than something that is event based. Access to critical process parameters and critical quality attributes needs to be enables as part of the network.

## RISK MANAGEMENT

Tracking product across the trading partner ecosystem with its interconnected network of hubs is a complex endeavor. Dependencies mean that variation in processing or movement in one part of the network affects the product many steps later. Scenarios are leveraged across the network to determine the risk that a failure will occur along with its impact and severity.

Brands can’t rely solely on their CMO’s to manage upstream supply risk or to define clear deadlines and milestones for deliverables. This is unrealistic given the unpredictability and complexities associated with manufacturing a biologic. From the brand perspective, CMOs are hesitant to provide potential worst-case scenarios for fear of losing the business. As a result, there are gaps in expectations on both sides. Collaboration can catch worst-case scenario variables early, which can then be addressed, both in today’s execution as well as in tomorrow’s plans.

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## VALUE POTENTIAL

Increased collaboration generates inputs that will improve planning and execution across the supply base and distribution centers. Collaboration enables pharma companies to access timely and accurate information for improving manufacturing as well as provides a foundation to reinforce supply chain security. Permission-based data sharing across sites including all stages of development and manufacturing allows for greater process understanding and predictability.

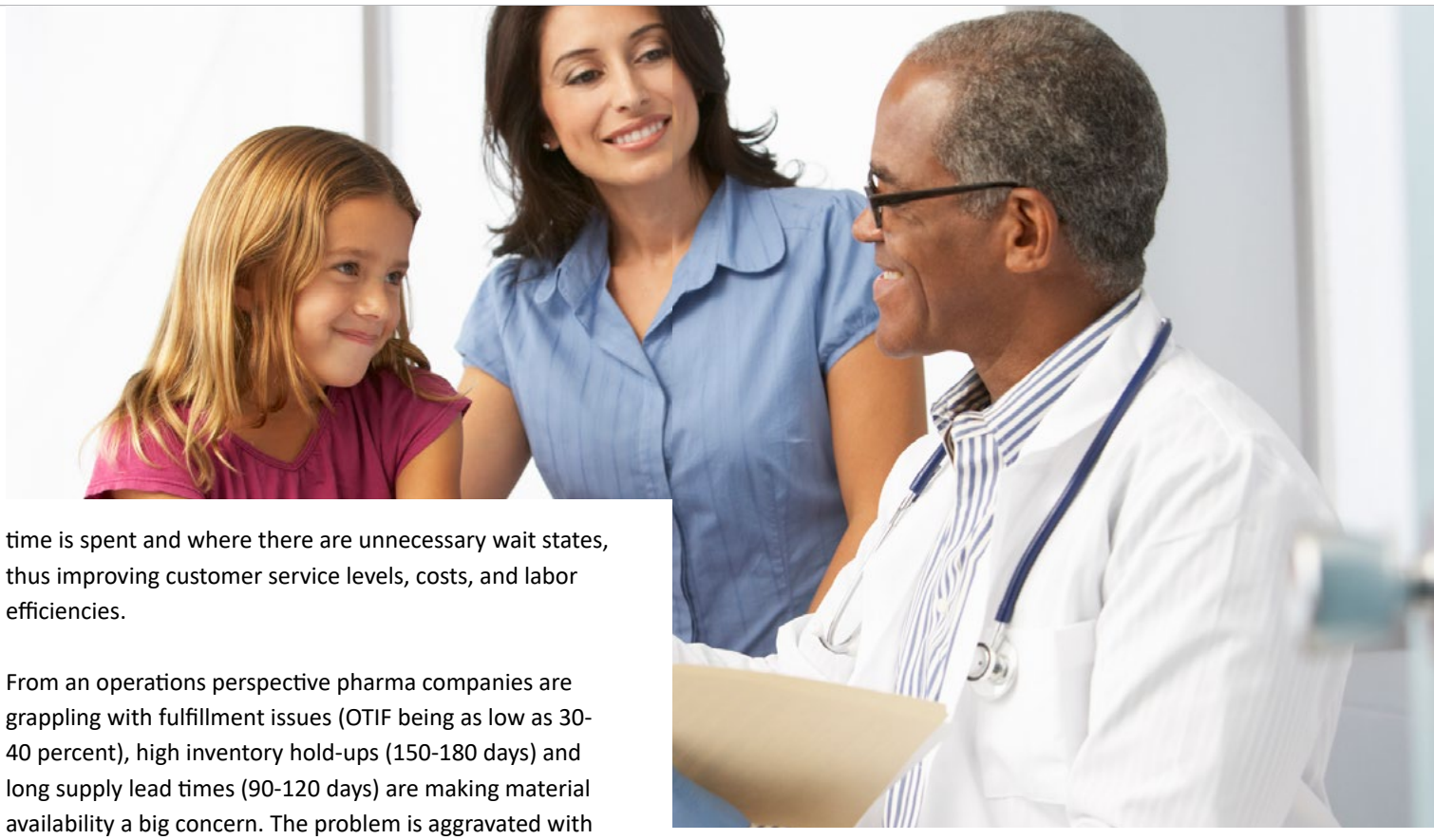
Visibility can be extended upstream from the pharmaceutical manufacturer and into multiple tiers on the supply side, reducing lead times, lowering premium transportation costs, and reducing stock-outs. This network effect generates an overall reduction in waste with less working capital tied up for shorter periods of time.

Providing accurate inventory balances for API and raw material levels and different classes of finished goods inventory can help pharma companies improve performance as well as financial reconciliations. Quality teams from both sides are looking beyond phone and email (which are estimated to take an average of 28 percent of the day) towards collaborative workspaces that provide a complete communication trail, from quality review initiation to final product release. This helps ensure quality expectations are met on both sides and provides new visibility into the quality process workflow and highlights opportunities to decrease delays in the review cycle.

Communication and collaboration are value accelerators when companies share process and manufacturing data in real time. Quality can vary from site to site and batch to batch, so the ability to identify and compare critical process parameters (CPPs) and key performance indicators (KPIs) in real time is extremely valuable, changing the process from reactive to proactive. Brands can increase the predictability of quality and yield by identifying root causes of process variability and atypical batches. Report preparation and distribution time are reduced as well as communication and information-sharing problems due to disparate data and systems.

Systems must be dynamic in nature to drive value over time given KPI's will shift, for example, during product life cycles. In early product life cycle, yield is often a critical factor as the API is scarce and lost production batches could impact the overall time to market. In late life cycle, yield continues to be an important metric, however, it may not have the same potential impact as a focus on OTIF and least landed cost.

Pharma company and CMO collaboration across the quality process has been shown to generate a decrease in batch record and deviation event review cycle time of 20-25 percent, due to better information flow and coordination. Virtual quality team members can see current review status in a concise dashboard, look at an integrated audit trail of all documents and communications for a specific review, and get notified immediately when information has been viewed or modified. With these state-based workflow capabilities, team members can diagnose where in the review cycle value-added



time is spent and where there are unnecessary wait states, thus improving customer service levels, costs, and labor efficiencies.

From an operations perspective pharma companies are grappling with fulfillment issues (OTIF being as low as 30-40 percent), high inventory hold-ups (150-180 days) and long supply lead times (90-120 days) are making material availability a big concern. The problem is aggravated with shifting disease areas, new product introductions (NPI), and mergers and acquisitions common in this sector. Supply assurance becomes especially critical to support successful product launches as new supply chains and networks are being designed. Variables to track with reference benchmarks based on full deployments are as follows:

- Labor efficiency improvements of up to 30%
- Sales increase 1 to 2%
- COGS improvement of 2 to 3%
- OTIF impacts of up to 15%
- Inventory holds reduced by up to 10%
- Batch record and deviant event review cycle time improvements of up to 25%
- Financial reconciliation cycle time of up to 30%
- Information lead time reductions of up to 40%
- Inventory improvement of 10 to 20 days (depending on life cycle and internal vs external assets)
- Premium freight and expediting cost improvements of up to 50%
- Improved customer service and productivity through an automatic 4-way match

## SUMMARY

One Network has deployed the capabilities described in this paper with great success over the past 10 years. These capabilities are deployed in its Digital Supply Chain Network™as cloud services and interoperate with existing legacy software systems. Time to value is short given there is no requirement to “rip and replace.” The services can be deployed in any sequence, thus allowing projects to focus on those outcomes most important to the business.

## ABOUT ONE NETWORK ENTERPRISES

One Network Enterprises (ONE) is the leader in supply chain autonomous planning, control towers, and provider of the Digital Supply Chain Network™. It is the only solution that gives supply chain managers and executives end-to-end visibility and control with one data model and one truth, from raw material to last mile delivery. Powered by NEO, One Network's machine learning and intelligent agent technology, it enables seamless planning and execution, across inbound supply, outbound order fulfillment, and logistics, matching demand with available supply in real-time. Lead your industry by providing the highest service levels and product quality at the lowest possible cost. Visit: www.onenetwork.com.

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