Pharmaceutical Supply Chains Require New Operational and Technology Models to Enable Collaboration and Efficiency

To combat slowed growth and industry pressures, pharmaceutical companies must embrace demand-chain thinking and cloud-enabled solutions to become more agile, flexible and able to share data in real-time with partners, from contract manufacturers and CMOs, through 3PLs and retailers.
Executive Summary
The pharmaceuticals industry is facing an era of transformation, from the supply chain to the distribution channel. Supply chains are stressed by SKU proliferation, demand variability and lower margins. Meanwhile, expiring patents and heightened competition from generics have curbed the top-line potential of branded pharmaceutical business units. And finally, pharmaceutical distribution channels must address the increased use of online ordering and direct-to-customer delivery processes.

All of these factors, coupled with looming regulatory mandates, are compelling pharma businesses to rethink their supply chains and IT strategies and develop more collaborative models that enable them to be more agile, flexible and compliant.

In many ways, pharmaceutical operations and IT have traditionally been self-contained within the enterprise. When they reached out to external stakeholders, such as suppliers, customers and distributors, it was mainly for transactional purposes. It is only recently that the industry has begun to build collaborative networks that connect partners across the value chain, as seen in other industries. These networks will help the industry better manage drug supplies in the face of increasingly unpredictable demand, gain better visibility into inventory across the value chain and service diverse markets.

In this paper, we explore the business and IT imperatives of trying to refocus supply chain strategies along these lines. We also explain how communication among stakeholders in the pharmaceuticals value chain can become more proactive, and we describe how cloud-enabled platforms can provide a common platform to connect and share data. Companies that follow these guidelines can engender trust and align incentives through greater transparency and accountability.

Symptoms of Declining Health
Industry experts acknowledge that the pharmaceuticals industry will continue to experience reduced profit margins as a result of the dwindling pipeline of branded products and growing competition from generics. In fact, revenue growth of the top 100 pharma companies has fallen to 2%-4% during 2011-12, from 11%-14% during 2003-2007.

While growth is slowing, product pricing is increasingly restrained by payer organizations. The average operating margin for large pharmaceuticals companies is forecast at around 20% in 2013 compared with over 24% from 2003 to 2009. This is a sharper decline than seen in the early 2000s, when there were fewer pharmaceutical products, more stable demand and comfortable margins.

While growth and operating margins are being squeezed, supply chains are stretched to reduce costs in the face of increasing regulatory scrutiny, M&A activity and expansion into emerging markets.

As top-line growth slows and operating margins narrow, companies must address their operational inefficiencies. The pharmaceuticals supply chain lags behind other industries in multiple ways, but by addressing manufacturing and equipment lead times, obsolescence and inventories, these firms could expect to boost profit margins 9% to 11%.

While pharmaceuticals firms can increase operational efficiencies in multiple ways, such as implementing more efficient and high-throughput manufacturing and packaging techniques, there are also some relatively low-hanging fruits. Enterprises can readily leverage the following opportunities to boost their operating margins in the short (one to three years) and medium terms (four to six years):

- **Optimizing inventory throughout the supply chain:** Due in part to inadequate incentives in the supply chain, the pharmaceuticals industry maintains higher inventory levels than most other industries. This issue is compounded by the rapid SKU proliferation generated by the emergence of generics. The expensive returns and destruction process of expired products raise the cost of obsolescence and overage inventory beyond that of comparable industries.

- **Improving inventory visibility across the supply chain:** Serialization and track/trace initiatives not only facilitate regulatory compliance, but they can also prevent costly product recalls and limit the risk of revenue loss through product diversion and counterfeiting. They also contribute to inventory reduction by providing data on inventory from downstream supply chain partners, which can be leveraged to model demand and regulate drug supply. This can result in supply chain
efficiencies both within the four walls and across the extended supply chain.

- **Customizing supply chains for regional products and markets:** A one-size-fits-all supply chain can efficiently manage only one product category. By increasing supply chain diversity and moving products between supply chains according to market conditions, organizations can reduce product, overhead and inventory costs while providing better service for customers.

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**Taking Action**

Historically, comfortable returns from blockbuster and branded drugs have resulted in complacency among pharmaceuticals firms in terms of instituting supply chain improvement measures or collaboration with external stakeholders. Typically, pharmaceuticals enterprises have closely guarded sales forecasts and manufacturing pipeline information. They have also tended to deploy largely independent ERP systems that serve their core operations very well but do little to help them interact with stakeholders beyond purchases and sales orders. However, there is much to be gained from gathering and making use of data from supply chain partners.

We perceive the need for shifting the conventional mindset from a traditional, compartmentalized enterprise to an extended “virtual enterprise” that entails a more collaborative model. The result: Proactive sharing of demand and inventory data across the value chain. In practice, this cannot be achieved without two key prerequisites:

- **Business trust among value chain stakeholders.** This includes suppliers (especially those deemed strategic and part of the “virtual supply chain”), manufacturers, 3PLs, retailers, etc. Trust is built over time by aligning the incentives of each stakeholder, leveraging risk-sharing approaches.

- **Scalable and secure IT platforms** that facilitate real-time or near real-time visibility of data across the extended supply chain.

Most ERP systems in use today were designed for a stand-alone enterprise. Managing collaborative networks that span various partners across the value chain is next to impossible using such systems. Therefore, we foresee a two-tier system

### Pharma’s Lagging Supply Chain

Operational metrics suggest huge opportunities.

<table>
<thead>
<tr>
<th></th>
<th>Pharmaceuticals</th>
<th>Medical Devices</th>
<th>Fast-Moving Consumer Goods</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inventory</strong></td>
<td>258 days</td>
<td>153 days</td>
<td>72 days</td>
</tr>
<tr>
<td><strong>Obsolescence</strong> (% of sales)</td>
<td>3.1%</td>
<td>2.8%</td>
<td>0.5%</td>
</tr>
<tr>
<td><strong>Manufacturing Lead Time</strong></td>
<td>120-180 days</td>
<td>120-180 days</td>
<td>3-7 days</td>
</tr>
</tbody>
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Figure 1
composed of traditional on-premises ERP systems, coupled with cloud-enabled collaboration platforms. Connected systems can engender trust, ensure transparency and increase accountability by providing a single version of the truth.

Beyond technology, pharmaceuticals organizations need to invest in building trust and ensuring that vendors and customers also receive benefits from cooperation. This will ensure both real and virtual collaboration across the value chain and yield mutually positive outcomes.

Collaborative Forecasting
The nagging issue of inordinately high inventory can be addressed, at least in part, by collaborative demand forecasting. When faced with similar, if not greater, challenges of SKU proliferation and product obsolescence, the fast-moving consumer goods (FMCG) industry partnered with the retail industry to successfully implement collaborative forecasting and reduce inventory. Today, collaborative forecasting enables the FMCG industry to operate with 25% to 50% of the inventory of pharmaceutical companies (see Figure 1, previous page).

The pharmaceuticals industry can achieve similar results if it similarly leverages distributor and retailer data for sales and operations planning (S&OP). However, this ideal state is a far cry from the current practice, in which pharmaceuticals companies mostly plan in silos to meet financial targets. Common complaints across the pharmaceuticals supply chain include:

- Distributors and retailers accuse manufacturers of “channel-stuffing,” wherein distribution channels are loaded with too much inventory toward the end of fiscal periods to meet financial targets. This hurts

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Quick Take

**Technology Enabler #1: Enveloping Core ERP with Cloud**

While most stakeholders appreciate the benefits of demand-driven supply, a key impediment to implementing this model is the lack of tools that can facilitate collaborative forecasting and planning based on consensus. Although such tools and systems are common in other industries like FMCG and retail, the pharmaceuticals industry has been slow to adopt them because of its skepticism of cloud solutions in particular and the security of shared data in general.

However, pioneers of software as a service (SaaS) and cloud infrastructure have made significant progress in data encryption, and supply chain leaders should re-evaluate the merits of creating a cloud-based planning layer over their core ERP. A cloud-based planning layer can enable the sharing of S&OP data with key stakeholders: contract manufacturers, branded and generic business units, distributors and retailers.

This planning layer would enable collaborative and iterative simulation planning that takes into consideration pertinent factors such as current demand, projected sales scenarios and supply constraints like lead time and capacity.

Once a forecast and the corresponding supply planning version have been agreed to by all concerned stakeholders (for example, the brand owner and its contract manufacturers), the plan can be adopted by the respective ERP systems to dictate lower-level planning like MPS or MRP. Needless to say, this requires the evolution of new data models that can be easily rolled out to multiple sites within the enterprise and also adopted by new suppliers and customers.

Leading pharmaceuticals manufacturers are already starting to realize that when they have close to 100 contract manufacturers in different regions, integrating these manufacturers into their core ERP would take several years. They are looking to cloud offerings to provide almost instant connectivity and the ability to maintain a complex and scalable network, regardless of the number of interfaces involved.
logistics providers directly and manufacturers in the long run because of the costly and often complicated processing of unsold and expired inventory returns.

- **Manufacturers complain that distributor inventory data is not readily available** and that delays in receiving their demand projections at the SKU level adversely affect their master production schedule (MPS) and material requirements planning (MRP).
- **Companies managing external suppliers or contract manufacturers** with relatively smaller contracts often find them to be inflexible in switching the supply of SKUs if needed.

While vaccine and sterile operations manufacturers are adopting a collaborative S&OP model, most pharmaceutical manufacturers are still struggling to instantiate this model, especially when it comes to sharing forecasts outside their four walls.

In summary, the pharmaceuticals industry is not very responsive to changes in demand. This is due to both structural problems (a long supply chain network with multiple nodes and long manufacturing lead times involving multiple quality checks), the absence of information sharing on inventory disposition and the rate of depletion of inventory at each node of the supply chain network on a real-time or near real-time basis.

**Visibility**

The global population’s rapidly growing healthcare needs present a mission-critical purpose for pharmaceutical manufacturers. Pharmaceuticals product manufacturing and replenishment must be tightly managed to avoid stockouts, because unlike stockouts in other industries, they sometimes entail a life-or-death situation.

Product visibility is an important component of agile supply chains. Visibility enables organizations to adapt to demand variability, enhance supply chain security and meet regulatory compliance needs. Analyzing product data at an aggregated level, rather than at the sellable unit level, is insufficient for pharmaceutical supply chains, as they deal with tremendous challenges in product diversion and product recalls, product counterfeiting and adulteration, and evolving global regulatory requirements.

In addition to frequency and speed of replenishment, compliance requirements such as serialization, e-pedigree and traceability reporting are emerging in the U.S. (in California and at the federal level), China, India, Argentina, Brazil, Turkey, the European Union and elsewhere. These regulations – expected to cover nearly 70% of global drug production and distribution by 2017 – demand that every sellable unit has the following characteristics:

- **Trackability in the supply chain.** The organization needs to be certain of the unit’s location, whether it faces the risk of imminent expiry or spoilage and if it is still progressing through legitimate channels.
- **Traceability to its upstream supply chain events,** such as packaging and the commissioning and decommissioning of pallets.

The vision is to generate an improved level of transparency for inventory, warehouse and logistics data, which will ultimately enable a more responsive and secure supply chain. However, to achieve visibility at this level across distribution networks and up to the patient’s bedside, global solutions need to be implemented through a partnership of key supply chain players. Collaboration is key because the supply chain is only as strong as its weakest link. Unless all stakeholders – manufacturers, distributors, 3PL providers and retailers – are onboard, end-to-end visibility will be difficult, if not impossible, to realize.

The previously mentioned regulatory mandates have already forced industry leaders – regardless of the role they play in the pharmaceutical supply chain – to collaborate on developing and adopting universal technology and infrastructure standards (e.g., 2-D barcode, RFID and GS1 interface standards).

**Adaptive Supply Chains**

The majority of pharmaceutical products are managed by a uniform supply chain with little to no adaptation for the specific product or market that it serves. This forces high inventory and service levels for all products, regardless of need. As margins decline and competition increases,
the pharmaceuticals industry and its products — particularly generics — will begin to resemble the consumer goods industry.

As this occurs, the most competitive pharmaceuticals companies, like consumer goods companies, will require several supply chains, each adapted to serve a particular market, product type or product lifecycle stage.

While the supply chain for a new high-margin drug under patent protection may resemble the current one — with production located in the innovating company’s facilities and a highly complex supply chain — the supply chain for an older drug or one competing with generics must look very different and be focused on cost competition. Such a supply chain will utilize global networks of contract manufacturers positioned close to suppliers and customers to provide products tailored for unique local requirements. The new model will more closely resemble today’s consumer goods supply chains, which are able to supply low-margin products at low prices almost without interruption.

The traditional pharmaceutical supply chain requires, on average, 75 days for pharmaceutical products to reach distribution centers from manufacturing plants. However, several leading companies have reduced lead times to 30 days by adapting their supply chains to be more like consumer goods supply chains, which are able to supply low-margin products at low prices almost without interruption.

Quick Take

Technology Enabler #2: Cloud-based Master Data for Tracking, Tracing

Managing collaborative networks through existing on-premise ERP systems is difficult. A growing consensus agrees this is best done through an independent cloud-based supply platform that allows each player in the supply chain to connect to the central system regardless of its own IT infrastructure. The network approach followed by the cloud platform enables customers to more quickly and cost-effectively build scalable master data platforms (GTIN, UPC, e-pedigree, etc.) and transactional data (commissioning events, repackaging, delivery, etc.). Costs are lower partly because of the decreased total cost of IT and partly because of the lower cost of integration using standard data models, plug-ins/APIs, etc.

Independent cloud solutions for serialization and track-and-trace will also mitigate challenges typically faced when implementing serialization initiatives, such as long equipment lead times, a limited talent pool, uncertainty around how data will be shared, whether the mandate’s timeline will change, change management risks from an operational standpoint, and layering in new systems and validating them. We see organizations migrating toward cloud-based service providers to address their track-and-trace needs and build a single source of truth for all aligned players.

Areas where we see progress include hosting and data exchange management to achieve track-and-trace reporting, event acquisition, storage and reporting, product authentication, and reporting and sharing requisite data with supply chain partners. Such solutions are provided by mobile and cloud-based serialization products, service providers and systems integrators that are able to host collected data on- or off-premise and then share required data with partners and regulatory agencies.

Many of these providers are now even offering serialization solutions such as SaaS hosted on the cloud. This approach is being embraced by leading pharmaceuticals manufacturers to not only comply with mandates around serialization, but to also extend compliance to contract manufacturing partners and truly leverage efficiencies across the extended supply chain.
chains to align with product characteristics and customer requirements (see Figure 2). This segmentation is only possible through collaboration among suppliers, manufacturers and 3PLs because no single party may possess all necessary data points.

A more adaptable network of manufacturing facilities enables organizations to source drugs from production facilities appropriate to the manufacturing process’s infrastructure and environmental requirements. Highly complex or new drugs require expensive facilities to produce. However, low-complexity drugs are often also produced at these facilities to offset the site’s overhead, requiring the facility to be larger and more costly than needed.

The average pharmaceutical manufacturing facility operates well below capacity, due to factors such as over-design, the use of numerous setups to accommodate a multitude of products and the difficulties of maintaining up-time in highly complex systems. Efficiency can be improved by segmenting the production of low-complexity drugs (which often involves little more than formulation) to more cost-efficient, low-sophistication contract manufacturers, as well as consolidating the production of complex drugs to fewer sophisticated plants.

Likewise, warehouse and logistics capacities are also inefficiently utilized. This is particularly the case for cold chain products, whose distribution is growing twice as quickly as the biopharmaceuticals industry as a whole.

In the next decade, a pharmaceuticals’ manufacturing network will become a source of competitive advantage. To enable segmentation, flexible global networks of manufacturers with different capabilities are required. And to improve processes, manufacturers need to be offered incentives, such as a share of the benefits they generate. For this to occur, both pharmaceutical and contract manufacturers will need to provide levels of transparency not found in relationships today. A trusting, long-term relationship based on benefits-sharing will boost confidence in the contract manufacturer’s ability to deliver consistent, compliant products and greater flexibility. When a manufacturer is confident that it will be treated fairly, changes to production schedules and volume can be made more rapidly than would be possible through contract amendment.

Both pharmaceutical and contract manufacturers will need to provide levels of transparency not found in relationships today.

### Segmented Supply Chains Improve Service Levels, Reduce Supply Chain Planning Costs

![Graph showing improved service levels and reduced planning costs](image)

**Source:** “Building New Strength in the Healthcare Supply Chain,” McKinsey & Co., January 2013. Figure 2
Looking Ahead
The pharmaceuticals supply chain has been challenged to reduce costs to counter dramatic changes in the business environment. To succeed, pharmaceuticals companies that have traditionally focused inwardly must redefine the boundaries of their enterprise. Suppliers typically regarded as outside the four walls, including CMOs, 3PLs and retailers, will become partners in a “virtual supply chain” and function more as captive suppliers. In some cases, they will function as an extension of the company itself and not be viewed as mere transactional partners.

We recommend three short- to medium-term initiatives to improve supply chain performance through enhanced collaboration:

• **Reduce inventory levels and product obsolescence costs** by implementing cloud-based ERP interfaces, collaborative forecasting and production planning.

• **Leverage track-and-trace requirements** to build systems that not only meet compliance requirements but also provide SKU-level inventory, replenishment and demand data directly from downstream partners to get ahead of demand shifts and facilitate an agile supply chain.

• **Reduce manufacturing and logistics costs** by adapting supply chains to serve specific products and markets.

The success of these initiatives depends on a supply chain organization that is both supported and driven by executive leadership who embrace the concept of true collaboration enabled by cloud-based and other pertinent technologies. Pharmaceuticals firms will need partners who can share and apply best practices from industries that have undergone similar changes to help with their organizational and technology transformations.

Footnotes
1 S&P CapitalIQ
Acknowledgments
The authors would like to acknowledge the contributions of Eric Laager, Senior Consultant in Cognizant Business Consulting's Life Sciences Practice, and Anirban Ghosh, Senior Consultant in Cognizant Business Consulting's Life Sciences, to this white paper.

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