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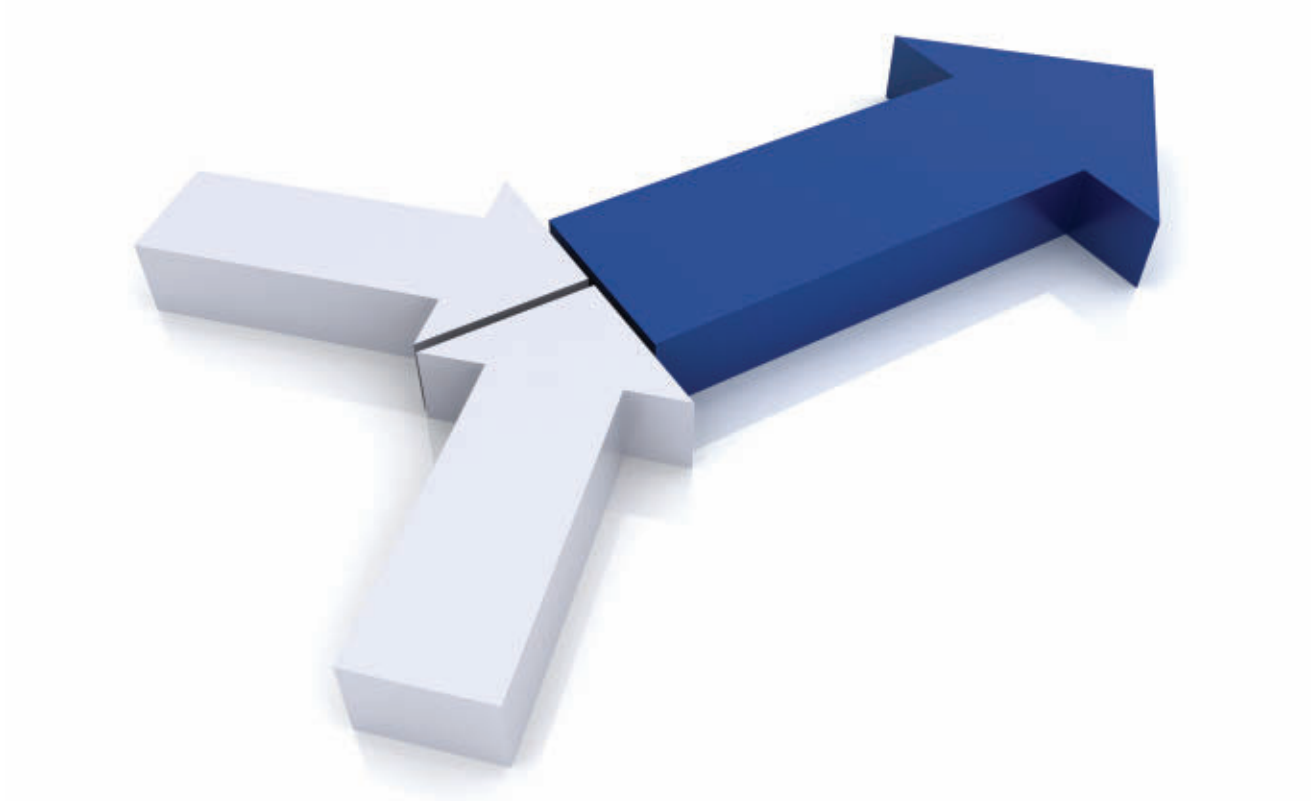
The Changing Dynamics of the Pharmaceutical Supply Chain

With the fabric of healthcare distribution in flux, the challenge for pharmaceutical distribution executives is focused on how to leverage distribution infrastructure to reduce costs, but maintain the flexibility needed to mitigate risk across the supply chain.



Pharmaceutical distribution, like with any other industry, has its peculiarities that require specialized applications to keep products moving through the supply chain efficiently and shipped to the intended destinations on time. With pharmaceutical distribution, however, the requirements are extreme. For patients who are critically ill, receiving their medicines and antibiotics a day or two late at the pharmacies, hospitals and critical care centers can literally mean a life and death matter. Timely delivery is absolutely critical, but just as important as on-time delivery, the order has to be accurate, as there is no margin for error in the distribution of pharmaceuticals. The bulk of pharmaceutical orders, both prescription (RX) and over-the-counter (OTC) products, are in small quantities, and packaged and delivered for individual drug stores, hospitals and healthcare centers. Some of the products are controlled substances requiring strict handling under FDA and DEA compliance. In this case, the systems for handling the products through every part of a distribution center, from receiving to inventory to shipping, must be done under tight security regulations. Many of the products are refrigerated or frozen, and need to be handled in temperature-controlled environments requiring same-day or next-day delivery, or require a combination of special handling activities. Such constraints are endemic to the pharmaceutical distribution cycle.

Distributors typically distribute to independent retail pharmacies, national and regional chains, hospitals, clinics, pharmacy benefit managers, prescription mail order facilities, physician offices and long-term care facilities. But, an increasing number of distributors are focusing on specialty pharmaceutical products for physicians and patients, handling such drugs as rheumatology and nephrology products, vaccines and biopharmaceuticals, oncology drugs, and plasma derivatives including albumin, immunologic products, hyper-immune globulins and antihemophilic factors, and other critical specialty products such as surgical items. More than 30,000 different pharmaceutical, and associated

products such as milk formula, nutritional items, beauty products and paper products, are distributed within the supply chain. In large distribution centers, 90% of this inventory is stored by the case or individual units, and 10% by pallet-load.

Servicing both pharmaceutical manufacturers and healthcare providers in the supply channel, pharmaceutical distributors strive to provide drug distribution and related services designed to reduce distribution costs and improve patient outcomes. Such service solutions extend into pharmacy automation, product packaging and consulting services.

MARKET SHIFTS IMPACTING PHARMACEUTICAL DISTRIBUTION

Already a challenging distribution environment, a combination of demographic trends, healthcare legislation, new drug introductions and other factors are elevating the visibility and importance of healthcare logistics and distribution activities. Pharmaceutical logistics executives are required to navigate through one of the most complex of business environments. With all of the changes occurring in the marketplace, this complexity continues to increase.

The Patient Protection and Affordable Care Act (PPACA) includes measures that significantly impact the U.S. healthcare system, including product distribution.

Many hospitals, physician groups and insurers are assembling into accountable care organizations (ACOs), attempting to realize savings generated by improved and better coordinated care. This shift impacts consumer services and distribution methods.

The aging of Americans places further demands on an already taxed healthcare system. Aging baby boomers increase overall demand for healthcare products and services. Increasing life expectancies, due to prevention and medical advancements, compound demand growth, and technological advancements increase demand for services. How this change is affecting distribution models is still in evolution.

More drugs are expiring from patent protection than are gaining regulatory approval. In the past, high gross margins overshadowed supply chain inefficiencies. With fewer high margin drugs in the channel, pharmaceutical companies are finding new ways to achieve efficiencies and maintain profitability, taking a closer look at distribution models.

The increased focus on specialty drugs—biologics, proteins and other complex solutions—has brought distribution procedures to the forefront. These pharmaceutical products often cannot withstand exposure to high temperatures for extended periods of time without degradation of their active components, making conventional ambient-temperature distribution methods unacceptable for these products. 2010 was the first year that FDA-approved specialty drugs were higher than traditional drug approvals. This trend continued in 2011 and 2012, and is expected to continue.

The Drug Supply Chain Security Act, enacted in November 2013, will transform how the domestic supply chain operates. The new regulations from the FDA are designed to ensure product safety and stringent supply chain track and trace requirements. This places greater requirements for real-time data capture of SKU lot codes, and soon, full serialization traceability of product movement across the entire supply chain. These new mandates for the distribution of pharmaceutical pallet, mixed-case and split-case product serialization will require changes to current product labeling and barcode requirements. High-volume distributors will require high-speed camera-based scanning, integrated with automated labeling to efficiently track and trace the shipments.

Pharmaceutical wholesalers have one of the most difficult industry positions across the healthcare supply chain, since they must respond to not only the changing macro situation, but also the needs of their suppliers and end customers.

OPTIMIZING DISTRIBUTION PROCESSES

Supply chain distribution optimization is increasingly being viewed as a means to contain costs while improving patient outcomes.

As is exemplified in the 2013 Executive Survey on Supply Chain Management, sponsored by the Association for Healthcare Resource & Materials Management (AHRMM), the study results show that 78% of C-Level executives in healthcare agreed that supply chain optimization will be one of the top three expense reduction strategies used to meet the challenges of healthcare reform. Further, the study shows that 86 percent of C-Level executives agreed that supply chain management must become a core competency. And 92% of C-Level executives agreed that supply

chain management has a direct critical relationship with, and impact on, quality outcomes.

The Healthcare Industry Distributors Association (HIDA) reports, "Provider organizations expect reimbursement cuts to force reductions in operating margins of up to 30% through 2015. While all costs are on the table, the supply chain is universally considered the top priority."

Healthcare providers are ready to look beyond product cost and examine end-to-end supply chain costs, and are looking to manufacturers and distributors to help them become leaner and more effective. Assessing waste in the supply chain from the manufacturer all the way to the patient is critical (e.g., logistics, inventory management, data management, and customer demand management).

The need for productivity in reducing costs is very apparent when you look at the healthcare distribution industry as a whole, which has very thin margins. Typically, pharmaceutical wholesaling, with a flawlessly-run network, will profit about one percent of sales, so there is very little margin for error.

Pursuing business model transformations to aggressively reduce overall supply chain costs and distributor operating costs is vital. Central to facilitating this efficiency is the employment of warehousing technology solutions to the problem. Such automated systems will maintain consistent high levels of throughput, while achieving high order accuracy rates.

But supply chain executives should not make the fundamental mistake of thinking that technology should be the basis and starting point of their distribution solution. Instead, thorough conceptual design aimed at process improvement should be the central aspect of any automated solution, rather than focusing on the material handling equipment.

Approaching system design from a process perspective does not necessitate the implementation of any specific automated technology, but leaves the door open to any options to achieve the objectives of the DC's supply chain executives.

According to Dr. Hui Zhao, assistant professor of supply chain management, Department of Supply Chain and Information Systems, Smeal College of Business, The Pennsylvania State University, "To adapt to this changing healthcare market, system flexibility would also be a critical feature in the distribution solution, including warehouse automation."

Historically, the more you automate the less flexible your process. That is, unless your automation is highly flexible, as well. "With the increased number of biologic drugs," continued Zhao, "the need exists for more careful handling of these types of products in the distribution processes and transportation." Astute attention to the selection of material handling automation is critical here.

"It is well understood that pharmaceutical distribution is fraught with risk," explained Zhao. "Product sterility, the handling of controlled substances, potential breakage of fragile glass containers, strict temperature controls for biologics, shelf life and regulatory compliance—most of these risks also need to be assessed against the material handling systems under consideration. Automated systems that were installed in distribution facilities eight or ten years ago may not be the most efficient systems today for handling the increased volumes of sensitive biologics and other special drugs.

"The first step when considering a material handling build-out would be to have a full conceptual design prepared to define the distribution center's needs and parameters," said Zhao. "A thorough conceptual design ensures that the right amount of technology will be implemented for current and future growth needs. Too much equipment is capital absorbing. Too little equipment will necessitate higher operating costs by increasing labor."

DISTRIBUTION NETWORK ASSESSMENT

With the industry-wide changes occurring within the healthcare supply chain, many pharmaceutical manufacturers and distributors are reassessing their distribution network models. The million-dollar question then becomes, "How many distribution facilities are needed to optimize our customer service at the lowest total cost, factoring transportation, facility, labor, equipment and inventory?", and "Where should these DCs be located?"

Most pharmaceutical manufacturers have a large manufacturing location, or multiple locations, with a distribution center on-site where finished inventory is held until it is needed to be distributed downstream into the supply chain. Or, finished prod-

uct may be held in multiple off-site distribution centers. That network model has proved workable for dry formulation products, providing a good level of inventory security. But, with the escalating presence of biologics, from a temperature control perspective, that might not be the best place to be housing that inventory. It might be better warehoused closer to the end user, so that it does not have to go through a longer and expensive transportation process to get to that end user, especially considering such products have a shorter shelf life.

Fundamentally, because large inventories of biologics cannot be warehoused for long time periods, in essence, this inventory is being taken out of the system, and inventory redundancy is a historical way to mitigate risk. So, the strategy becomes how to design flexibility into a distribution network to mitigate this risk.

The challenge here is assessing the best distribution network model for handling both types of diverse product lines. Developing a successful distribution network optimization plan poses significant challenges, even for the most seasoned supply chain executives.

The components comprising a comprehensive distribution network optimization are organized into five primary functions:

1. Data Discovery. Precise detailing of a company's distribution network should be the initial step. Both business and facility discovery identifies assets, capacities, facilities, operational processes and performance.
2. Predictive Analysis. Used to determine future infrastructure requirements. What-if analysis is used to show the tradeoffs of various demand levels with different network configurations.
3. Baseline Model. Utilizing information gained from Data Recovery and Predictive Analysis, a baseline model is built of the existing distribution network, to which alternative scenarios can be compared.
4. Modeling. Given fixed or variable inputs, modeling will process events and calculations to produce scenarios for expected throughputs.
5. Strategic Plan. Once the supply chain model is defined then a distribution strategic plan is developed that aligns the company's business, technology, operations, vendors and customers.

Assuming that the above steps are conducted comprehensively, the resultant strategic plan provides a comprehensive roadmap for achieving an optimal network configuration, and permits tactical implementation plans for moving forward.

LEVERAGING A BROADER PERSPECTIVE

The changing healthcare scenario is driving distribution executives to look for better distribution options. Evaluating the tremendous volumes of information required, and making the correct decisions throughout every step of the healthcare distribution process can be a risky and daunting task for any logistics team. Every company's distribution needs are different, and healthcare distribution executives have a broad palate of options for fulfillment. The best strategic, tactical and operational solutions will be highly specialized to fit the needs of a company's distribution operations.

With the changing dynamics in the healthcare environment, managing supply chain risk takes on a different complexion. Gone are the days when financial investments in redundant facilities, significant inventories or super-premium transportation can be easily justified on a daily basis. Designing supply chains to competently manage risks is becoming more and more important. As such, common approaches to understand and evaluate risks, and develop contingency plans are moving from an ad hoc longer-range event to a more rigorous process with annual, monthly and even weekly review periods and resolution activity. Not only do these approaches help manage risk, they also help organizations make their supply chains more efficient overall. Supply chain risk management is moving from a cost of doing business to a competitive advantage. **CP**

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