BY DENISE MYSHKO

» SUPPLY CHAIN

SUPPLY CHAIN STRATEGIES

As with all other areas, **GLOBALIZATION WILL HAVE A TREMENDOUS IMPACT ON THE PHARMACEUTICAL SUPPLY CHAIN.** The industry will have to manage resources that are much more widely dispersed.

Globalization and multichannel distribution systems — coupled with the concern about counterfeiting and making distribution more efficient — are creating a more complex supply chain.

Mark Hassenplug, global life-sciences supply chain leader at Ernst & Young, says supply chains are now traversing multiple geographic regions with numerous import and export rules, regulations, customs, and duties, with fines and penalties increasing for noncompliance.

"With new global players entering the value chain, there can be increased vulnerability to counterfeiting and safety lapses, with important implications for patient health and a company's reputation," he says. "Ultimately, lapses in this area can also lead to increased scrutiny from government authorities."

Emerging markets are particularly challenging, says Ellen Reilly, managing director, pharmaceutical and life-sciences advisory services group, at PricewaterhouseCoopers.

"The focus will be on Asia, Africa, Australia, and Latin America, which will account for a much greater share of the industry's revenue," she says. "Organizations will need to define or redefine their operating model with an eye on a specific strategy. They can choose to fully outsource to trusted partners, become low-cost providers, become service innovators, or combine the latter two strategies to build supply chains that are profit, not cost centers."

Mr. Hassenplug says with the industry's revenue growth becoming more dependent on new and emerging markets and less on developed countries in North America and Europe, companies will need to develop and build more flexibility and agility into their supply chains to reach underserved markets.

"Beyond globalization, the current economic crisis will drive companies increasingly to rely on external vendors and suppliers as they work to confront the inherent supply chain inefficiencies and utilize working capital more effectively," he says.

Bob Silvers, managing director of SSA & Co., says as the pharmaceutical industry and its contract manufacturers continue to feel the strain of the economy, more and more companies will need to uncover untapped sources of cost reduction.

"In this effort, leaders must recognize that squeezing water from a stone will require new tools and approaches to achieve breakthrough levels of performance; traditional methods will not suffice," he says. "Only through a radical focus on process reforms and a break from traditional ways can companies achieve and maintain global leadership in quality and innovation."

Mr. Hassenplug says the current economic crisis, which has so constrained capital for companies of all kinds, has increased the need to evaluate the financial health and resilience of third parties.

"Companies can mitigate their vulnerability in this regard by performing detailed financial analyses and due diligence up front, as part of the ongoing relationship," he says. "Early identification of potential issues can allow for scenario planning to reduce vulnerability, which is critical for ensuring a robust and uninterrupted supply of product is available to patients who need it."

The global anti-counterfeit market for food and pharmaceuticals is expected to be valued at $79.3 billion by 2014, with an estimated CAGR of 8.6% from 2009 to 2014. The North American market is expected to account for almost 62% of the total revenue.

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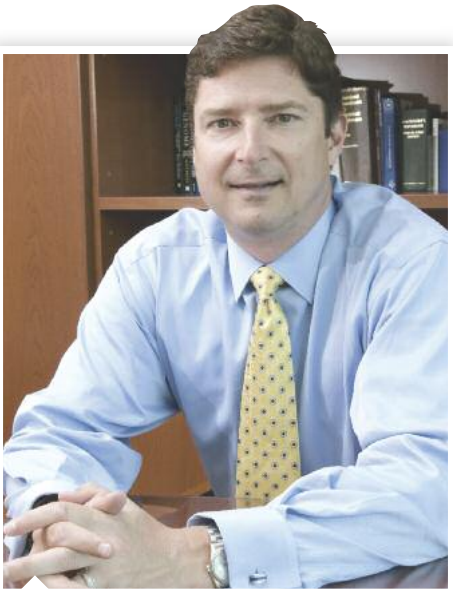

John Chiminski
Catalent Pharma Solutions

"Increased personalization or targeting of drugs for subpopulations will require increased manufacturing flexibility versus that currently in place. As a result, manufacturing will likely become outsourced by default."

GAPS IN SUPPLY CHAIN

Today, the biggest gaps in efficiency may stem from the failure to plan adequately and to work more closely with the clinical teams, says Astrid Frank, general manager at Fisher Clinical Services.

"Often the clinical supply teams are not part of the early discussions and by the time they receive information on a project, it is too late to offer insight into a better approach," she says. "With distribution taking on critical importance, the clinical supply chain partner needs to be involved at the time of protocol development to share practical knowledge for factors impacting timelines, regulatory requirements, customs considerations, and even assessing the role of patient compliance."

Ms. Frank says maintaining a stand-alone clinical trials management function is a capital- and labor-intensive process amid a heavily regulated portion of drug development.

Mark Hassenplug
Ernst & Young

"With the industry's revenue growth becoming more dependent on emerging markets and less on developed countries in North America and Europe, companies will need to ensure an even more agile supply chain capable of serving new and often disparate markets."

Astrid Frank
Fisher Clinical Services

"A best practice is to develop a customized plan for the supply chain that takes into account the variety of factors that are likely to impact the project timelines and handling. The focus should be on overall program success, not a line item discount structure."

"We are beginning to find that many companies are considering fully outsourcing this function to a partner and expect that this trend will continue," she says "But more effective outsourcing will come from a more intensive approach to understanding organizational and clinical goals and combining those with the clinical supply chain capabilities."

John Chiminski, president and CEO of Catalent Pharma Solutions, says outsourcing partners will likely be strategic partners in product success by assuming full responsibility for product supply.

"But to make this work, it will require seamless integration with in-house supply chain management functions," he says.

Bill Hook, VP of global strategy, healthcare logistics, at UPS Supply Chain Solutions, says the trend toward more integrated relationships between healthcare entities and their outsourced partners will continue.

"Outsourced partners will play a broader role overall in supply chain execution and will likely invest more heavily in creating technologies, infrastructures, and a broader set of services to create more shared environments for manufacturers," he says.

One key concern now and in the coming years is managing supply chain security. Experts say with a lack of decisive regulation and guidance, and with continued globalization, product diversion and counterfeiting will become more prevalent.

"As the distribution chain becomes more complex and products pass through more touch points, there are greater opportunities for introducing adulterated product into the chain," says Robert Finamore, director of validation services at QPharma. "Many promising technologies for anti-counterfeiting and anti-diversion exist or are emerging, but adoption rates are lacking. The coming years will see more widespread use of these technologies, coupled with better regulation, guidance, and enforcement to secure the supply chain."

Robert Finamore
QPharma

"The coming years will see more widespread use of anti-counterfeiting and anti-diversion technologies, coupled with better regulation, guidance, and enforcement to secure the supply chain."

Counterfeiting is one of the biggest risks facing the pharmaceutical industry today. According to the WHO, about 10% of the worldwide drug supply is counterfeit.

MANUFACTURING ISSUES

Mr. Silvers says while many leading companies are highly innovative in many aspects of their research and marketing, most still rely on the same manufacturing methods that have been in place for decades.

"Firms simply have not invested in developing the basic operational measures to really understand what drives their performance, an approach common in almost every other industry," he says. "In addition, most pharmaceutical companies look only within individual functional silos when identifying inefficiencies. We believe this to be a huge opportunity for the industry, as management must have the ability to truly understand how product flows through their manufacturing facilities if they are going to identify opportunities to improve."

Mr. Chiminski says increased personalization or targeting of drugs for subpopulations will require increased manufacturing flexibility versus that currently in place. As a result, manufacturing will more likely become outsourced by default — except where current outsourcers are not up to internal expectations. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

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BY DENISE MYSHKO

SUPPLY CHAIN

SUPPLY CHAIN BEST PRACTICES

Companies need to **EVALUATE THEIR BUSINESS THROUGH THEIR VALUE STREAMS** rather than by individual processes or components.

According to Bob Silvers, managing director, at SSA & Co., by applying the rigors of Lean Six Sigma to underperforming areas, pharmaceutical companies can completely transform their supply chain and operating performance and deliver substantial benefits to the bottom line.

Astrid Frank, general manager of Fisher Clinical Services, says one of the biggest mistakes the industry has made is adopting a one-size-fits-all approach to supply chain management.

"This is largely driven by the mentality of volume discount and does not take into account the nuances of product requirements, be they in packaging, storage, or shipping," she says. "As drug development has shifted to all parts of the world, the conditions in which drugs are transported can vary widely, as do the climates and local logistics."

Ms. Frank says a best practice is to develop a customized plan for supply chain performance that takes into account the variety of factors that are likely to impact the project timelines and handling.

"The focus should be on overall program success, not a line item discount structure," Ms. Frank says. "Savings will come through superior performance and reduction of overage."

Bill Hook, VP of global strategy, healthcare logistics, at UPS Supply Chain Solutions, says building flexibility into the supply chain is key so that companies can be nimble to meet changing customer demands.

"They also need to establish deeper collaboration among stakeholders in the supply chain; drive more synchronization in the supply chain through linking technologies and looking for ways to reduce handoffs in the system; and focus on resiliency to ensure that supply chains can anticipate, be flexible, and adapt to industry disruptions," he says.

Ellen Reilly, managing director, Pharmaceutical and Life Sciences Advisory Services Group, at PricewaterhouseCoopers, says best-in-class pharmaceutical companies are implementing supplier collaboration tools to share manufacturing instructions and recipes, batch records, inventory, critical quality factors, and fully integrate their partners in the supply chain.

> 88% of respondents (more than 20 industries and every major geographical segment of the world) have set objectives for purchasing to generate cost savings in the next 12 months.
>
> CSC

"These companies are defining metrics and managing to those metrics with a continual eye on cost optimization and the advantages offered by outsourcing," she says. "They are focusing on inventory turns and cash-to-cash cycle times to challenge the make-to-stock behaviors. They are doing simulation of their supply chain network and taking advantage of tax-based network designs to take out costs and moving to a configurable supply chain model."

According to Tom Russell, general manager of enterprise solutions, at SciQuest, some of the best practices and most exciting developments in the management of the supply chain can be found not in manufacturing, but in the indirect supply chain for goods and services used in R&D and other functions.

"With R&D pipelines increasingly dry, and the industry as a whole moving into emerging markets, manufacturing operations represent only one component of the supply chain," he says. "One can make a strong argument that the indirect supply chain and its governance of the purchases required to get new operations up and running not only is crucial, but in many cases will determine the pace of expansion in emerging markets. " ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

SUPPLY CHAIN A TOP CONCERN

Reducing the risk of counterfeit drugs and contaminated medications amid the complexity of global manufacturing are among the top concerns of the pharmaceutical and life-sciences industries today, according to a recent IBM study. More than 50% of executives polled say their companies fail to respond quickly enough to pandemics and other emergencies because of lapses in their supply chain.

The study surveyed executives at pharmaceutical, biotechnology, medical-device, and consumer healthcare industry companies who are responsible for planning, logistics, procurement, and coordination throughout the life of a drug or medical device.

Companies must work to improve their ability to keep wholesalers, hospitals, and pharmacies stocked with the products they need to meet patient demand. Tracking every step of how drugs are manufactured and distributed are key priorities for more than 70% of companies.

OTHER KEY FINDINGS:

- 64% reported rising customer demands such as requests for designer drugs or specialized packaging as a major challenge.
- Monitoring risk to prevent counterfeiting, drug and device recalls, or even the loss of intellectual property, is a priority for 75% of executives, as margins become slimmer and supply chain complexity rises. Three-quarters have risk and performance initiatives such as surveillance programs, anti-tamper devices, and specialized labeling, but with mixed results.
- 46% consider vendor-managed inventory for their customers extremely effective, but only 4% use it to ensure they are precisely meeting customer demands for products.
- 65% collaborate with suppliers on demand planning but only 31% do so with customers, often resulting in an overstock of supplies or missed sales targets.

Source: IBM

Sound Bites From The Field

PHARMAVOICE ASKED INDUSTRY EXPERTS TO IDENTIFY THE TOP FACTORS THEY BELIEVE ARE CURRENTLY IMPACTING THE SUPPLY CHAIN.

BOB CELESTE is Director, GS1 Healthcare US, a national healthcare industry user group that supports the adoption and implementation of global standards. For more information, visit gs1us.org.

"One area of compliance-enhancing packaging may be in the area of smart phone use. Personal medication management via smart phone applications may make use of the unique identifier that is part of the packaging (bar code or RFID) to prompt patients to take their medication in the recommended manner (with food, without food, etc.) and at the right time.

As smart phone technology advances and the population depends on these devices to simplify areas of their lives, it will be a natural progression for the smart phone to interact with the things in our lives. Already, in technologically advanced parts of the world, smart phones are used to pay for products and services and read bar codes and RFID tags on items to gain more information or access additional services. It is a natural progression that these devices will be expected to help in the complicated process of managing multiple prescribed medications and simplifying the various compliance regimens."

TERRY HISEY is Vice Chairman and U.S. Industry Leader, Deloitte LLP's Life Sciences Practice, an international consulting firm. For more information, visit deloitte.com/us.

"There is an increased need for an e-pedigree-like capability — not so much to assure compliance, but rather as a more holistic approach to risk mitigation and competitive differentiation.

Companies will need to undertake different tactics to deal with underutilized, nonflexible assets in the face of cost restructuring, end-of-life sales, generic competition, and enterprisewide cost reduction programs. If contract manufacturing is central to everyone's strategy, there is a risk that not all companies will be able to secure manufacturing resources to assure the quality and availability of safe product."

BILL HOOK is VP of Global Strategy, Healthcare Logistics, UPS Supply Chain Solutions, a package delivery company and a global provider of supply chain services. For more information, visit ups-scs.com.

"Companies today are much more focused on changing the game rather than just on driving efficiencies, and this has led to more integrated and more innovative supply chain solutions. For example, UPS is seeing companies do things they haven't considered in the past, such as fully outsourcing the management of their distribution facilities and changing the way they serve customers, such as moving to a direct-to-patient or direct-to-physician distribution model.

We are seeing more and more pharmaceutical companies embracing outsourcing as a way to leverage shared investments for meeting regulatory requirements and gain more flexibility in their supply chains. More companies are focused on risk mitigation, placing numerous demands on the supply chain for technology and security solutions and greater visibility across all areas of the supply chain."

TOM RUSSELL is General Manager of Enterprise Solutions, SciQuest Inc., which provides procurement automation and supplier enablement solutions. For more information, visit sciquest.com.

"The greatest factor impacting the supply chain currently is the rapid globalization of the industry and growth in emerging markets, a development that in many cases will necessitate the extension of the supply chain into areas where the role of governments and rules of commerce are completely different or prone to change rapidly.

Supplier risk will increasingly be a key issue in the supply chain, particularly in emerging markets where the availability of supplies is subject to widely varying and rapidly changing conditions. In the coming year, the ability of supply chain professionals to effectively address risk, will to a large degree, shape how successful expansion into emerging markets is for the industry as whole.

Quality control will be crucial in the supply chain next year, particularly as the globalization of the industry necessitates operations in regions with a poor track record of ensuring that quality or public safety needs are met. One only has to look at the experiences of contract manufacturers in China over the past year to know that quality control will be a top-of-mind issue for pharmaceutical leaders in 2010."

TE SMITH is VP of Communications at MarkMonitor, which provides enterprise brand protection, comprehensive solutions, and services that safeguard brands, reputation, and revenue from online risks. For more information, visit markmonitor.com.

"As consumers increasingly purchase drugs online and offshore manufacturers embrace B2B exchange sites to sell bulk quantities of branded prescription drugs, scammers are embracing the online trend, too. Some take advantage of demand-generation channels such as search advertising to divert traffic to illicit sites, including online pharmacies. Others take advantage of e-commerce channels, such as online B2B exchanges where they can sell bulk quantities of counterfeit goods.

For marketers to maintain positive brand equity, they must address online brand protection as part of their brand management strategy. Savvy marketers understand that as consumers move to the Internet for health-related information and to buy prescription drugs, preventing brand infection by scammers is crucial to the health of their brands."