

[SNAPSHOT] PHARMACEUTICALS



[OVERVIEW]

Pharma Logistics: Prognosis Positive

Pharmaceutical manufacturers, drug distributors, and health care providers are taking a double dose of technology and business process improvement to keep consumers safe and competition one step behind. BY LISA TERRY

Transformation in the pharmaceutical marketplace is challenging traditional approaches to manufacturing and distribution.

"Pharmaceutical, medical, and medical device margins are collapsing quickly," says Daniel Carbery, senior vice president of operations and generics for Endo Pharmaceuticals, a Chadds Ford, Pa., pain medication manufacturer. Greater price transparency means products are increasingly sold below cost, with others marked up to compensate.

"Pharma has staggeringly high inventory levels. As margins shrink, inefficiency becomes a problem. Entire segments of this industry are built around

holding a lot of product," he adds.

As pharmaceutical companies outsource production globally, product moves through even more layers of distribution before landing at a pharmacy or health care facility. Expanding market and clinical trial activities offshore also present infrastructure and regulatory challenges.

Financial and business model changes aside, compliance requirements, industry consolidation, competition, and rising costs are forcing pharma companies to address pipeline velocity, visibility, and demand-driven value networks to become more responsive to shifting market conditions.

[HOT TOPICS] Pharma Feels the Pain



Standardizing Safety One of every 100 doses of pharmaceutical and biotechnology products manufactured in developed countries is counterfeit, according to World Health

Organization estimates. Every pharma company benefits from securing its supply chain and proactively eliminating counterfeit drugs before they enter the system. At the same time, the industry is being tested to determine how much security supply chains can afford without impacting service and budget constraints.

At the center of this struggle is e-pedigree—the use of

electronic data to track and trace pharmaceutical products through the supply chain; and serialization requirements that assign individual codes to each item. Where the Food and Drug Administration (FDA) hesitates to tread in establishing e-pedigree regulations, states have stepped in to fill the void. The most aggressive, California, continues to modify its requirements and deadline schedule for e-pedigree compliance.

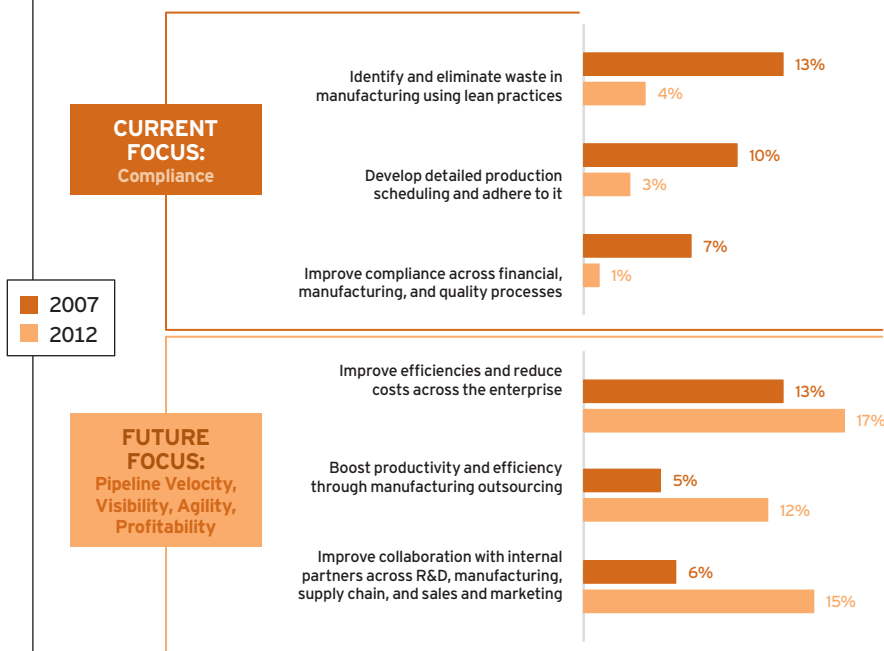
Many manufacturers, distributors, and pharmacists have objected to aggressive regulatory mandate deadlines and high compliance costs, while acknowledging the ultimate benefits. Pharma giant Pfizer, for example, has been a leader in e-pedigree use for its Viagra product line, but told the California Board of Pharmacy that it would take five to seven years to implement serialization for all its products.

“Regulations aren’t in alignment with standards,” notes Mike Crawford, vice president of integrated supply chain for AstraZeneca, Wilmington, Del., a top-10 pharmaceutical manufacturer. “In response to the call from legislators, we’re out ahead by ourselves.”

Radio-frequency identification (RFID) is regarded as an excellent would-be enabler to capture and deliver chain of custody data through the

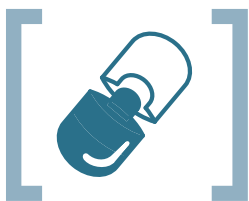
Compliance Today, Profitability Tomorrow

While their primary product supply business strategies focused on compliance during the past few years, life sciences supply chain executives responding to a recent AMR survey plan to shift their attention to pipeline velocity, visibility, agility, and profitability in the coming years.



Source: AMR Research, Life Sciences Survey, November 2007

pharmacy supply chain—if it works for every product. Among adoption issues is the difficulty in getting good RFID reads on item-level packages, particularly for liquids and semi-solids. In one pilot, OxyContin maker Purdue Pharma is adding a customized antenna to Gen2 tags so that it can use both high-frequency and ultra high-frequency bands. But the cost of equipment to read these tags is still prohibitive. As an alternative, many companies are using 2-D symbologies for e-pedigree data to avoid interference issues.



Integrating Integrity
An increasing number of pharmaceutical products are temperature-sensitive—particularly in the biologics category—a factor that introduces additional safety requirements in a lengthening supply chain.

[CASE STUDY] Endo Pharmaceuticals: Collaboration Cures Inefficiency

For Endo Pharmaceuticals, the smart route to an effective, efficient, and secure supply chain is close collaboration with its partners.

Perhaps surprisingly, one of these partners is the U.S. government. As a manufacturer specializing in pain medication, many of Endo's products are controlled substances. For years, it had to endure cumbersome, paper-intensive processes for tracking orders to the end customer, then reporting to the Drug Enforcement Administration (DEA), which archived the paperwork. Delays led to excess inventory and the process was burdened by high costs and lack of visibility and control.

In January, Endo will publish the results of a five-year collaboration with the DEA and other pharma companies to replace those multi-part forms and processes with the Controlled Substance Ordering System (CSOS). CSOS swaps paperwork for public key infrastructure (PKI), digital certificates, and e-commerce to speed orders and give companies and the DEA more visibility into the location and movement of controlled substance drugs, and significantly boosting security and enabling less inventory.

"In theory, the DEA can track quantities by ZIP code for every opiate," says Daniel Carbery, senior vice president of operations and generics for Endo Pharmaceuticals.

It's a voluntary program, but "is becoming a defacto requirement because the current system is so painful," Carbery says. CSOS is a great example of successful industry-government collaboration, he adds.

UPS Supply Chain Solutions, Endo's fourth-party logistics partner (4PL), is also party to CSOS' successful implementation. UPS SCS monitors the movement of orders to detect micro patterns in shipments: complaints, damages, or changes in ordering habits. If a micro pattern develops over two to three months, the routing is changed to avoid the possibility that a diversion or other problem is occurring, even though in most cases this step is merely precautionary.

When Endo Pharmaceuticals formed in 1997, executives made a strategic decision to outsource the bulk of its logistics and distribution to avoid costly investment in internal infrastructure. UPS operates a semi-fixed system for Endo—the manufacturer rents dedicated space and UPS picks, packs, and ships its orders. The 4PL provides domestic and international transportation services, as well as customer service and security. Endo employees are tasked with quality control.

The two companies work closely together, and this flexible partnership allows Endo to scale its operations quickly. Carbery provides one example: "In 30 days, we acquired a drug. On the day the deal closed, we moved products from the previous owner's warehouse to ours and started to ship under the new name, a pace rarely achieved in the pharma industry."

The arrangement provides a competitive advantage for Endo that exceeds questions of lowest cost. "Using a 4PL can be incredibly expensive without the right internal talent," observes Carbery.

Endo's approach, he adds, is an effective strategy in an industry where margins are no longer enough to compensate for supply chain inefficiencies.

"My goal is for product to move from the factory, through the UPS DC, to the store," says Carbery, minimizing additional touches that increase cost, time, and risk.



“Manufacturing used to happen closer to market, but now there are more international cold chain requirements,” says Bill Hook, vice president, global strategy, healthcare logistics, for UPS Supply Chain Solutions, a third-party/fourth-party logistics provider. Regulations dictate how and at what temperatures product must be transported.

“Distribution outsourcing is more widely accepted by big pharma to address such challenges,” Hook adds.

Advances in passive and active handling/packaging processes also help contain the higher cost of storing and moving goods with stringent temperature parameters.

U.S. Special Forces, for example, equips medics with a specialized thermal container that maintains its payload temperature for several days. It uses this to transport emergency doses of Coagulation Factor VIIa, an injectable clotting drug, to seriously wounded soldiers in the field without benefit of active refrigeration.

Some companies use RFID tags imbedded with sensors, particularly in international lanes, to maintain temperatures throughout the supply chain. These sensors are programmed to “sleep” on planes so their signals don’t interfere with flight controls.

Other companies employ 24/7 monitoring services for temperature-sensitive shipments, with intervention and

contingency plans to prevent product spoilage.



Ensuring Compliance

Pharma has long been a heavily regulated industry, with compliance costs a key focus for executives. “We’re really keeping an eye on legislation,” says AstraZeneca’s Crawford. “It has great potential to change how we do business.”

However, “leaders are no longer looking at compliance for the sake of compliance,” reports Hussain Mooraj, research director, healthcare and life sciences, for research analyst firm AMR Research. “They’re looking at incorporating compliance into excellence initiatives—how to improve processes and develop operational effectiveness. Compliance comes along for the ride.”

While there will always be areas where compliance seems to add little value, in a surprising number of cases it can be part of overall business process improvement



Introducing New

Products Pharma companies invest heavily in research and development, then must attain FDA sanctions before releasing a product to market. The time required for approvals, a highly competitive sales environment, and a substantial tier of generic drug companies poised to jump into the market upon patent expiration, all combine to magnify speed-to-market demands.

The *Wall Street Journal* reports that generic competition will likely eliminate \$67 billion in U.S. pharma sales each year between 2007 and 2012, as more than three dozen drugs lose patent protection. So as new drugs near market-readiness, pharma companies must hit on all cylinders to market and deliver those products quickly.

Companies are increasingly using contract manufacturing sites across the globe to quickly and economically meet market expectations—but globalization adds complexity. Consequently, pharma manufacturing executives’ number-one future concern is leveraging contract manufacturers to facilitate new product launches and agile response to demand, according to AMR Research’s 2007 Life Sciences survey.

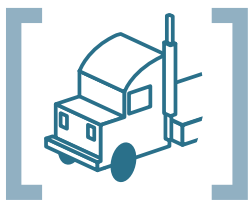
“It takes a cross-functional team to be successful in introducing new products,” says Vincent Colicchio, manufacturing and product supply chain manager at dermatological



pharma manufacturer Stiefel Laboratories, Coral Gables, Fla.

Enterprises must tap operations, distribution, manufacturing, quality control, financial, regulatory, and sales functions to execute new product introductions quickly.

“You’ve got to be nimble and flexible to meet all the product requirements,” he says.



Optimizing Transportation and Distribution

Periodically re-evaluating logistics networks is a best practice in any economy, but rapidly rising fuel and materials costs make now a smart time to rethink transportation and distribution.

For example, AstraZeneca once moved most of its inbound pharma products by air, but has shifted one-third of that volume to ocean to satisfy economical and environmental concerns. Accordingly, the company expects to reduce freight costs by at least \$20 million in 2008.

“We manage transportation closely to keep lead times in line with demand,” says AstraZeneca’s Crawford. “We’re trying to adjust at both ends to keep inventory at the right levels. You can’t recapture time, but you can accelerate in other

areas to compensate.”

As a result of a network optimization initiative, Stiefel Laboratories will shave close to \$250,000 a year in fuel costs. The company closed a distribution facility in Duluth, Ga., and consolidated U.S. distribution in its Oak Hill, N.Y., operation.

Stiefel is also working with its carriers to reassess and prioritize routes, thereby shortening lead times to customers for both in-house and contract-manufactured goods. “We expect to see improvement in finished goods inventory, freight costs, speed to market, and efficiency,” says Colicchio.



Prescribing Supply Chain

Success The pharmaceutical industry is just beginning to embrace the supply chain as a competitive differentiator.

“Supply chain teams at leading companies are focused on synchronizing demand and designing the most profitable response, which means focusing holistically on each interaction,” reports AMR Research.

“This is a significant shift from existing thinking. Imbuing this point of view within the business and inspiring the traditional life sciences supply chain organization is a

Pharma 3PLs: Curing Supply Chain Ills

AIT Worldwide Logistics

Itasca, IL
www.aitworldwide.com

Aspen Alliance Group

Temecula, CA
www.aspenlogistics.com

CLS

Winston-Salem, NC
www.cls.inmar.com

Kuehne + Nagel

Jersey City, NJ
www.kn-portal.com

McKesson Logistics

Oakville, ON, Canada
www.logistics.ca

NLM

Detroit, MI
www.nlm.com

Priority Solutions

International
Swedesboro, NJ
www.prioritysolutions.com

SQS

Puerto Rico
www.sqswarehouse.com

TMSI

Fernandina Beach, FL
www.tmsilog.com

Tucker Company

Cherry Hill, NJ
www.tuckerco.com

UPS Supply Chain Solutions

Alpharetta, GA
www.ups-scs.com

UTI

Los Angeles, CA
www.us.go2uti.com

major challenge and needs to be led from the top down to be successful,” the report notes.

With healthcare in the national spotlight, pharma companies are under pressure to refocus processes around the patient. Supply chain executives play a role in delivering efficiencies that contain costs while enabling their companies to be innovative and profitable.