

Building Supply Chain Capabilities in the Pharmaceutical Industry

Part 2: Winning supply chain capabilities



UPS Supply Chain SolutionsSM

Our Insight.

A UPS Supply Chain Solutions
White Paper

In “Building Supply Chain Management Capabilities in the Pharmaceutical Industry Part 1: Trends Impacting the Supply Chain,” we explored the business implications of major trends impacting pharmaceutical supply chains.

Unless pharmaceutical companies begin taking action now to create more business-effective cost and process structures, survival will be at stake.

These trends are having the greatest impact on sales and marketing, channel management, and new product development and rollout. Ultimately, we believe these trends and implications are converging to create an environment in which price pressures are becoming so intense that a growing number of pharmaceutical companies will struggle to meet shareholder expectations.

Unless pharmaceutical companies begin taking action now to create more business-effective cost and process structures, survival will be at stake. We propose that the winning pharmaceutical companies will build differentiating capability in five supply chain areas:

- Production
- Fulfillment
- Customer Management
- Forecasting & Planning
- Procurement

Organizations that do so not only will be able to meet financial expectations despite falling margins, but also will be in a position of financial and operational strength. The prize? Attractive acquisition and in-licensing deals possible because pharmaceutical companies with suboptimal supply chains will be forced to divest or seek business suitors.

AS THE MEGA MERGER WAVE CALMS, THE VALUE CHAIN CONTINUES TO EXPERIENCE RESTRUCTURING

- Evolution of new channels as PBMs and disease management programs (e.g., cancer service centers) grow in popularity
- Disintermediation of wholesalers and distributors as 3PLs increase service levels and accommodate pharma regulations
- Growth in outsourcing extends into research and development and sales and marketing in addition to CRM/call center functions
- New genre of niche companies focused in biotech, bio and genetic engineering

MARKET SHARE AND MARGIN EROSION

- Shorter periods of exclusivity for new drugs
- Increased competition from generics: faster adoption of generics and faster product development
- Rising R&D costs due to increased sophistication and complexity of research and collaboration required to generate innovation
- Intense price pressure from employers, government entities and consumer advocacy groups (e.g., AARP)

DESPITE INCREASING CONSUMER KNOWLEDGE OF DRUGS, ACCESS TO NEW DRUGS IS SHRINKING

- Increased usage of closed formularies by managed care organizations
- Higher HMO adoption of therapeutic interchange and step-care therapy
- Potential shift in DUR (drug utilization review) from efficacy to cost efficiency

Winning pharmaceutical companies will recognize the need for competence in global siting and production network rationalization.

Production

The pharmaceutical industry traditionally has been constrained by rigid global manufacturing with specialized production equipment, long lead times for materials and extensive regulatory requirements. This has led to inflexibility and an inability to react quickly to changes and facilities that are either capacity constrained or underutilized.^{1,2} Additionally, competition and the race towards gene profiling for therapeutic drugs may well push big pharmaceutical companies into niche drugs and smaller-batch production. The sum total of these trends and characteristics makes the drug manufacturing environment ripe for significant improvement.

What will it take to turn production into a supply chain capability worthy of future success? We believe the following three practices will be the defining characteristics of tomorrow's winners:

- Rationalized global production networks
- Changeover competence and smaller batch production
- Compliance management

Global Network Rationalization

As pharmaceutical companies gained global reach, production capability and the subsequent network have become unwieldy. Questions that require immediate and accurate answers include: which sites to continue operating and which to divest, where to manufacture which products and how best to support long-term product strategy. Tactical factors such as compliance, profitability, labor skill and costs, and age of equipment are key factors in making strategic decisions. Agility in these decisions directly affects growth and acquisition return on investment. Winning pharmaceutical companies will recognize the need for competence in global siting and production network rationalization. Furthermore, growth by acquisition companies will seek to define a streamlined method to continuously evaluate the production network as part of postmerger integration.

Changeovers and Smaller Batch Production

Today's manufacturing plants were typically designed for a specific drug or therapeutic class. Therefore, asset utilization and fulfilling high-demand products are systemic problems. Additionally, future genomic innovation will allow pharmaceutical companies to develop profile-specific drugs, and some market analysts predict drug tailoring for custom batches of one. The pharmaceutical environment is necessitating faster changeovers and smaller production runs. Simplifying changeovers and gearing down batch sizes will likely require changes to plant layout as well as material and inventory storage. Similar to forecasting and planning, reconfiguring manufacturing processes and facilities to build changeover competence and to run smaller batches will take time. Manufacturers should begin addressing change overs and future shifts in demand since it could take two to three years to rampup to consistent, reliable changeover performance.

¹ Radjou, Navi. "The Pharma Apps Prescription" Forrester Report, 2001 Feb.

² Bhandari, Manish et al. "A Genetic Revolution in Healthcare" McKinsey Quarterly, 1999 Quarter 4.

Compliance Management

Compliance should be integrated into all manufacturing processes and touch points. Compliance involves communicating regulatory changes, documenting standard operating procedures, integrating into processes and on-going training. Manufacturing execution systems (MESs) allow plants to optimize production runs and changeovers in a complicated environment with stringent rules and regulations. Once a compliance strategy is put in place, an MES should be considered a technology enabler. Successful compliance management involves an oversight council and cross-functional teams that define an integration strategy, evaluate enabling technology and instill performance measures supported by periodic audits.

Fulfillment

High levels of inventory, low turns (industry average of 2.5) and late deliveries have plagued many pharmaceutical manufacturers over the years. This performance has been tolerated in the past on drugs with locked-in patents and where only one source is available. With increasing competition, shorter exclusivity periods and smaller batch production, pharmaceutical companies need to reposition fulfillment capability to generate more accurate performance and respond to changing customer demand.

Changing Customer Demand: From Pallets to Packages

As previously mentioned, two trends that will dramatically affect the future of pharmaceutical fulfillment are:

1. Smaller batch production driven by genomics and customer demand
2. The addition of retailer, provider and consumer direct to manufacturers' customer base

Both of these point toward an inevitable shift from distributing larger pallet quantities to wholesalers to distributing smaller package-to-pallet quantities across a more diverse customer base. Technology as well as demand has presented opportunities for drug makers to sell direct to these new segments – segments in search of lower cost, better service and better information. The benefits to drug makers are golden: access to real-time demand and access to actual consumers.

Creating the ability to meet this emerging demand is not so golden. The order and service needs of hospital systems, pharmacists and consumers are dramatically different from those of large-scale wholesalers and GPOs. The one thing they have in common is the need for accurate delivery. What they don't have in common are needs such as:

- More frequent delivery – perhaps daily or multiple times a week
- Smaller packaging/SKUs with lower quantities in each package
- Combinatory delivery – literature, complementary devices and/or complementary drugs to provide complete treatment kits
- Smaller size pick/pack and delivery – including quantities of one
- Exponential delivery destinations – the numbers will explode quickly

Technology as well as demand has presented opportunities for drug makers to sell direct to these new segments – segments in search of lower cost, better service and better information.

Building fulfillment capability to meet tomorrow's demand will require infrastructure investments in technology, packaging/SKU rationalization and design, network optimization/3PL assessment and customer service. Logistics capability will need to include merge-in-transit and management of noncompany products. Drug makers will need to determine whether the golden egg of real-time demand visibility is worth the investment. Even manufacturers that choose to stay the existing course may find they have to deliver on some of these demands as competition heightens and wholesalers begin demanding services.

Changing face of the customer:

- Change in decision-making power
- More diversified customer base beyond wholesalers

Supply Chain Event Management

Separate supply chains with disparate systems have been the biggest impact from the wave of M&A in the pharmaceutical industry. In most situations, two merging parties have two different ERP systems and associated bolt-on supply chain applications. Whether struggling with disparate systems in an M&A situation or not, Supply Chain Event Management (SCEM) can provide tremendous benefits to an enterprise and its partners.

The core elements of SCEM are gathering, monitoring, measuring, simulating, notifying and managing across supply chain processes, internal organizations and external trading communities. The objective is to create smooth-running operations by seamlessly notifying the right people at the right time when action or intervention may be necessary. For example, it is 5 p.m. on a Saturday and a certain manufacturing lot has been quarantined. Product is not available for order fulfillment of a critical order due at a hospital at 8 a.m. on Sunday. How do you recognize the pending issue? How are you notified? What are your options? How do you fulfill the order from another site? Which site? What are the modes and cost options for delivery? Who do you notify? How do you track the order from the new source? SCEM assists with all of these decisions and business processes.

Customer Management

The face of the customer is fundamentally changing for drug manufacturers. First, the focus of decision power will shift from that of primarily medical providers to a mix of medical providers, pharmacists, pharmacy benefits managers, managed care providers and consumers. The evolution towards this increasing mix of decision influencers and makers for pharmacological treatments will not be a linear path. Regulatory bodies, policies of pharmacies and managed care providers and the very stages of the product life cycle will affect who has the greatest influence and who ultimately makes the buying decision.

Secondly, the customer base for drug makers is changing. Customer base diversification from primarily wholesalers and GPOs to retailers, providers and consumers presents opportunities for manufacturers to lower overall supply chain costs and gain visibility to real-time demand.

UPS Consulting believes that these fundamental shifts in the customer base warrant a fundamental shift in sales and marketing along two fronts:

- A cost-management-based sales approach by disease/indication
- Segment-based marketing and sales channel management

In the last five years, pharmaceutical sales forces have grown 85%. In fact, behind R&D, sales representative costs are the second largest category of expense for drug makers.

Cost-management-based Approach

The current sales model for many drug manufacturers is to release product data and samples to sales forces that struggle to get a two-minute window of time with medical providers. In that window, a sales representative may be introducing several new drugs and/or reinforcing current products. Current sales efforts are becoming less effective and more costly as sales forces are expected to cover more and more products. In the last five years, pharmaceutical sales forces have grown 85 percent.¹ In fact, behind R&D, sales representative costs are the second largest category of expense for drug makers.

Just recently, the Department of Health and Human Services issued new standards to drug manufacturers' sales approach, stating that "drug makers could not offer incentive payments or other 'tangible benefits' to encourage or reward the prescribing or purchase of particular drugs by doctors, health plans or companies that manage drug benefits for employers and insurers."³ The government has informed the industry that many of its sales and marketing practices may violate federal fraud and abuse laws.

Given the new mix of influencers and decision makers, we anticipate that the traditional sales approach will not be effective in the future. Sales and marketing must change to discern the needs and expectations of each decision player and then respond to those needs. For example, managed care providers are taking stronger roles in approving acceptable treatments. Top of mind for managed care is total cost of treatment. A 1996 study that evaluated formulary efficacy found that HMOs with restrictive formularies experienced higher use of other medical services.⁴

From a consumer standpoint, however, insurance coverage or point-of-use cost may be primary in selecting or requesting a drug treatment and side effects and length of treatment secondary. Consumer needs are different from that of managed care.

Now consider the pharmacist. While a doctor can prescribe a brand, the pharmacist evaluates an insurance policy and often ultimately determines how a prescription is filled – generic, competitor product based on the formulary or prescribed brand.

Cost is playing an increasingly higher role for nearly all decision players, which indicates a need for a cost-efficacy approach to sales and marketing. The awareness and education that takes place through sales and marketing should take on a feasibility flavor rather than pure efficacy. The question of how a drug is more feasible than other treatments should be answered, requiring strong analytic capability and technology to support life-of-treatment analysis and modeling across a therapeutic class. In fact, such an approach has implications even for product development and life-cycle management.

FEASIBILITY EXAMPLES: PhRMA, 2001 Industry Profile

"A new drug is lowering the total cost of caring for patients with migraine headaches. Although drug expenditures increased, the total costs of treating migraines declined 41% as a result of treatment with the new drug."

"A recent study sponsored by NIH found that treating stroke patients promptly with a clot-busting drug not only reduces disability but also saves health-care costs. Use of the stroke treatment resulted in net savings to the health system of more than \$4 million for every 1,000 patients treated."

¹ Radjou, Navi. "The Pharma Apps Prescription" Forrester Report, 2001 Feb.

³ Pear, Robert. "Drug Industry is Told to Stop Gifts to Doctors" New York Times, 2002, October 1.

⁴ PhRMA, Pharmaceutical Research and Manufacturers of America. 2001 Industry Profile, PhRMA, Washington D.C., 2001.

Segment-based Marketing and Sales Channel Management

Most pharmaceutical companies segment markets or customers. We question the validity of how segmenting takes place and what is done with segments – essentially, what is the value of segmentation?

We believe that organizations should gain two benefits from segmentation:

1. The ability to measure segment and channel performance to provide value-based service levels

There are good customers and bad customers. Do you know who your most profitable customers are? Can you reliably provide differentiating service levels to your most valuable customers? How will you maintain their loyalty and how will you upgrade mediocre customers into more profitable customers? A segmentation and channel management strategy should allow you to identify, measure and manipulate customer profitability and cost to serve.

2. The ability to respond to specific segment needs to increase the effectiveness of sales and marketing

Earlier, we discussed the shifting roles of decision players. These decision players should be included in segmentation, based on information needs, expectations and decision power. The interplay will change depending on a product's life cycle. A patented, new product for an indication with few treatment alternatives may require less managed care marketing than an existing drug with branded and generic competition.

In 1996, a study that evaluated formulary efficacy found that HMOs with restrictive formularies experience higher use of other medical services.

Cost management and segment-based marketing and sales management may well challenge existing skills and capabilities in the commercialization process. Scenario modeling may be helpful in evaluating long-term treatments and combinations of drug and medical treatments. Additionally, resources may need to be shifted away from traditional sales channels to other channels, and new departments may need to be created to focus on certain segments or channels. Drug manufacturers that outsource commercialization will need to assess the ability of contractors to take an analytical/cost-based approach as well as sales and marketing approaches that anticipate and respond to shifts in decision power.

Forecasting and Planning

The longtime linchpin of meeting customer need has been inventory. In fact, in 2001 Forrester Research targeted pharmaceutical overproduction to be more than double actual market needs.¹ It is no secret that pharmaceutical companies have traditionally developed forecasts and replenishment plans to ensure ample stock throughout distribution channels. However, in today's environment of price and margin pressure, the linchpin suddenly becomes a barrier to acceptable financial performance. Yet, manufacturers still take pause at discussions of turning forecasting and planning into a meaningful capability. Why is this?

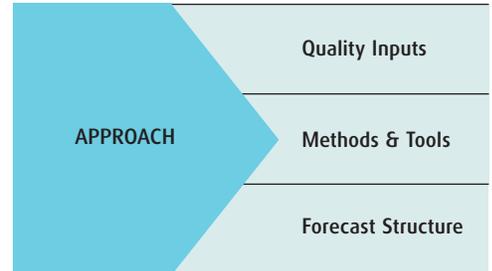
The hurdles to accurate forecasting are numerous, including lack of or delayed demand visibility, complex sales channels with established wholesalers, timely and accurate distribution inherently complicated by global operations and compliance with the FDA's Current Good Manufacturing Practices (CGMP). When the right forecasting methods are put into practice, it can be all for nothing if a wholesaler acts contrary to one's plans.

¹ Radjou, Navi. "The Pharma Apps Prescription" Forrester Report, 2001 Feb.

The objective of forecasting and planning is clear: to minimize inventory while meeting or exceeding customer needs. What isn't clear is how. Successfully achieving this objective requires consideration of four key components: Approach, Quality Inputs, Methods and Tools, and Structure.

Approach

Understanding the dynamics of the organization, how business functions work together, leadership philosophies and skill sets all factor into defining an appropriate approach. Components of the approach can be categorized as building proficiency, leadership support, rewards and incentives (business and personal) and execution.



Quality Inputs

“Junk in, junk out” applies to forecasting and planning. A significantly high level of input accuracy (a measure of precision) and reliability (a measure of consistency) is required to ensure quality output. Organizations should consider a mix of quantitative, qualitative, industry-specific and economic factors such as climate and market conditions.

Methods and Tools

Before technology assessments can begin, the level of sophistication an organization can reasonably and successfully execute should be determined. If the current method utilizes spreadsheets with internal data, the likelihood of a complex modeling tool being effective is low. This is not surprising. The speed at which forecasting capability develops depends on skill level, aptitude for advanced technology, readiness and availability of industry information such as distributor and point-of-sale data.

Structure

An effective structure allows for the highest levels of forecast accuracy and easy identification of dependencies among markets and products. Key components in defining a structure for forecasting and planning require organizational and tactical decisions like:

- Which business functions will be held accountable for forecast accuracy?
- Which business functions will be responsible for replenishment planning?
- Will planning time horizons need to change?
- At what levels will the organization generate forecasts?

No doubt you have seen the push by software vendors and independent market research firms touting the value of technology in forecasting and planning. Do not be swept away by the software bandwagon – there is no such thing as a quick fix when it comes to accurate, reliable forecasting. The initial primary focus must be on establishing the right process, organizational support and relevant proficiency before technology can be successfully leveraged.

In today's environment of price and margin pressure, (inventory) suddenly becomes a barrier to acceptable financial performance.

There is no such thing as a quick fix when it comes to accurate, reliable forecasting.

Procurement

Over the past decade, improving the purchasing function has become an important and strategic part of the goals of most organizations – primarily because of the recognition that increased profitability can be equally accomplished by spending less. A dollar saved in operating expense may have the same effect on profit as a \$10 gain in sales. In the pharmaceutical industry, e-procurement has been heavily embraced because of its association with lower transaction costs, lower unit price and a drive toward contract compliance. Often these concessions were achieved with little regard to quality, total cost and productivity and resulted in modest to minimal gains in cost savings.

There are significantly greater benefits to be gained in the area of procurement. We will focus on two:

- Strategic Sourcing
- Supplier Management

Both position an organization to more adeptly respond to changes in demand and to more strategically manage overall costs throughout the supply chain. While e-procurement may lower the costs within the four walls of procurement, it is most effective when led or supported by strategic sourcing or supplier management so that cost structures and productivity are also enhanced downstream.

Strategic Sourcing

Are you looking for ways to reduce working capital or lead times or make market-changing improvements to service levels? Strategic sourcing is the aggregating of goods and service needs to devise and execute a procurement strategy that optimizes and balances total cost of acquisition, working capital, productivity and service. Benefits often include reduced total costs for buyer and supplier, higher quality, ongoing reduction in working capital and lead times, and strategic supplier partnerships. The focus in supplier partnerships shifts from one of price reduction to relationship value and total cost management.

Strategic sourcing inherently focuses on both direct and indirect material items that make up the lion's share of costs and productivity problems. The more strategic aspects include in-sourcing/outsourcing and the management of contract manufacturing. Total cost management evaluates unit price, logistics and freight costs, import/export fees, taxes, service models and the cost of poor quality. A pharmaceutical manufacturer's approach to strategic sourcing and speed of adoption should be based on the organization complexity and current level of process standardization.

Supplier Management

Supplier management programs proactively manage supplier relationships and performance to ensure supply objectives are achieved. Proactive supplier management typically yields 10 to 15 percent savings for the purchasing categories addressed and then additional year-over-year savings of 3 to 5 percent. Moreover, the goals of a supplier management program may be critical to operations and sales. The pharmaceutical industry has been plagued with FDA penalties, fines and subsequent negative publicity – some of which could be resolved with a compliance-focused supplier management program.

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The focus in supplier partnerships shifts from one of price reduction to relationship value and total cost management.

The success of supplier management programs is highly dependent upon executive sponsorship, cross-functional input, measurable performance metrics and process enablement. Many of today's supply chain management and e-procurement applications offer supplier management functionality.

Organizations that effectively codify the FDA's CGMP will extend compliance and validation back into their supply base. By defining quality and performance criteria, segmenting suppliers into tiers through performance level or value to the organization, and establishing and measuring against metrics, suppliers can actually foster compliance and achieve other operational goals. Goals often include lowering overall costs, decreasing lead time and shortening product development cycles.

In Summary

Successful pharmaceutical companies will actively seek to position their organizations for future profitability by anticipating increased competition and the demise of high margins.

In this paper, we have highlighted five supply chain capabilities that winning pharmaceuticals should build to maintain competitive advantage:

- Production
- Fulfillment
- Customer management
- Forecasting and Planning
- Procurement

UPS Supply Chain Solutions believes that pharmaceutical companies that take action now to implement optimized cost and business infrastructure will be best positioned to continue strong financial performance. Each of these areas presents opportunities to generate real value and financial benefit in four to six months. Benefits will continue to be realized as proficiency and capability develop. Building competitive capability in some of these areas may take several years, but the earlier the start, the greater the lead against the competition.

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By aligning a client's business strategies with its operating processes, UPS Supply Chain Solutions can create high-performance supply chains that from inception to implementation generate real, hard-number values and quick benefit realization. This distinguishing capability, our experience in solving real-world challenges, and the resources of UPS enable us to set strategies, design and build solutions as well as implement, operate, manage and synchronize your world of commerce.