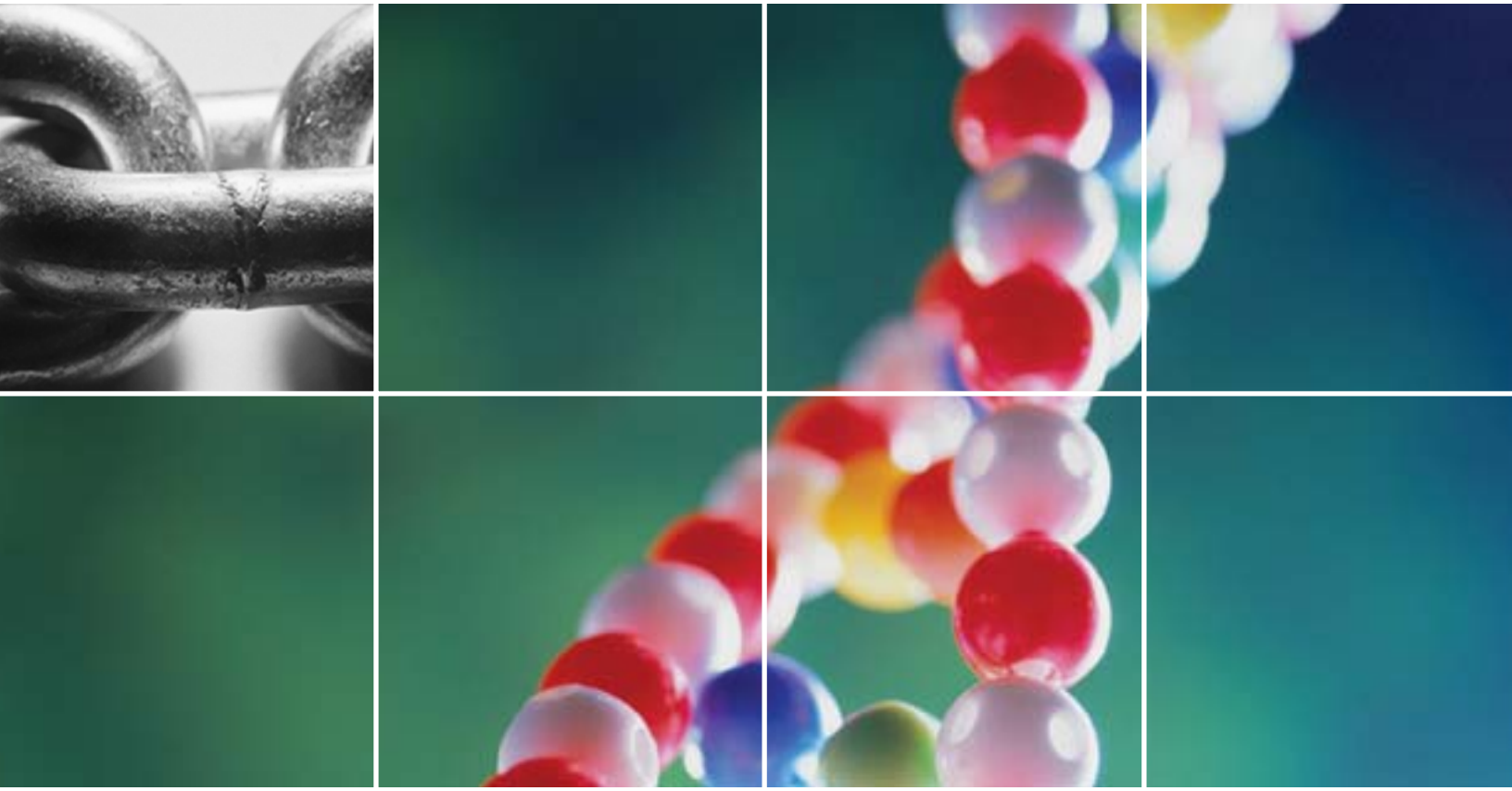
IBM Business Consulting Services

Pharma 2010: The value-creating supply chain



An IBM Institute for Business Value executive brief

The IBM Institute for Business Value develops fact-based strategic insights for senior business executives around critical industry-specific and cross-industry issues. This executive brief is based on an in-depth study created by the IBM Institute for Business Value. This research is a part of an ongoing commitment by IBM Business Consulting Services to provide analysis and viewpoints that help companies realize business value. You may contact the authors or send an e-mail to iibv@us.ibm.com for more information.

Contents

Introduction

At one time, the pharmaceutical supply chain only featured on the boardroom agenda when things went wrong. Today, it is subject to much greater scrutiny, as companies everywhere focus on how best to launch new drugs, assure the safety and supply of those drugs, and simultaneously cut costs. Manufacturing and distribution typically account for about 40 percent of the headcount and 60 percent of the capital employed in a large pharmaceutical firm, so they are obvious areas in which to look for savings and short-term productivity improvements in a time of declining growth.

But short-term cost and productivity measures are not enough to meet the fundamental challenges the pharmaceutical industry (Pharma) now faces. On the contrary, any company that wants to fend off the risks, and exploit the opportunities, that are currently emerging will need to submit its supply chain to a radical overhaul. The quality of a company's manufacturing and distribution can either impede its progress in getting products to market or accelerate that process and become a means of creating value. The supply chain of the future must be smart, efficient and agile.

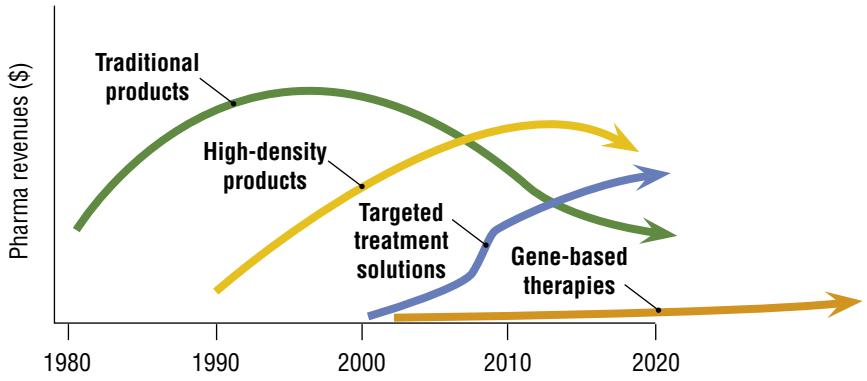
The challenges facing Pharma

After decades of growth, Pharma is under enormous pressure, especially in the U.S. – which accounts for 49 percent of the worldwide market. Intense competition, increasing use of generics, the might of the managed care providers and government measures to curb soaring healthcare budgets have all restricted its financial performance and driven shareholder returns down. Most companies are also struggling to replenish their pipelines and replace the revenues they are losing as numerous blockbusters come off patent. This veritable "sea of troubles" explains why the share prices of the industry leaders languish, despite the fact that global sales grew nine percent in 2003 – a rate companies in some other sectors might envy.[1]

The situation has been compounded by several recent changes in regulation. The Sarbanes-Oxley Act of 2002, the most far-reaching reform of the U.S. securities laws since the 1930s, imposes much stricter reporting requirements on all public companies. The U.S. Food and Drug Administration (FDA) has also issued an edict on current Good Manufacturing Practices (cGMP) for the 21st century, which has more immediate relevance for supply chain executives.[2]

Lastly, Pharma is on the brink of a scientific and technological revolution that will ultimately transform both the nature of the medicines it makes and how it makes them. In "Pharma 2010: The threshold of innovation," IBM predicted that a better understanding of the molecular sciences and massive advances in computing power would eventually enable the industry to develop targeted treatment solutions – or healthcare packages for patients with specific disease subtypes (see Figure 1).[3]

Figure 1. A scientific and technological revolution will result in the development of targeted treatment solutions.



Source: IBM Business Consulting Services.

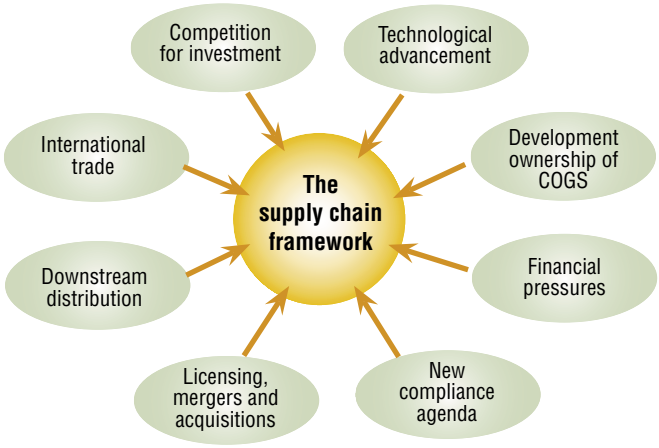
These targeted treatment solutions will be made using biological methods of discovery and development; they will be aimed at particular patient subpopulations; and they will measurably modify the diseases for which they are prescribed. They will also include biomarkers, devices, preventative medicines and a network of services for diagnosing, treating, monitoring and supporting patients, which will improve persistence and compliance.

In future, then, Pharma will not only make the white powders, creams and tablets it has traditionally produced, it will manufacture a complete mix of biopharmaceuticals, parenterals and diagnostics. Making targeted treatment solutions will generate greater revenues than conventional drugs and offset the increasing competition from generic producers. But it will also require the restructuring of the entire pharmaceutical value chain, including the fixed asset base and downstream distribution.

A supply framework creaking at the joints

The pharmaceutical supply chain is ill-placed to cope with this impending revolution because it is already creaking at the joints (see Figure 2). In the past, it could rely on receiving the capital it required, but internal competition for funds is now getting much greater, as research and development (R&D) costs soar and many companies react to the difficulties they are experiencing by pumping yet more cash into already huge sales teams, even though the evidence suggests that the primary-care market is saturated.[4]

Figure 2. The supply chain is under enormous strain.

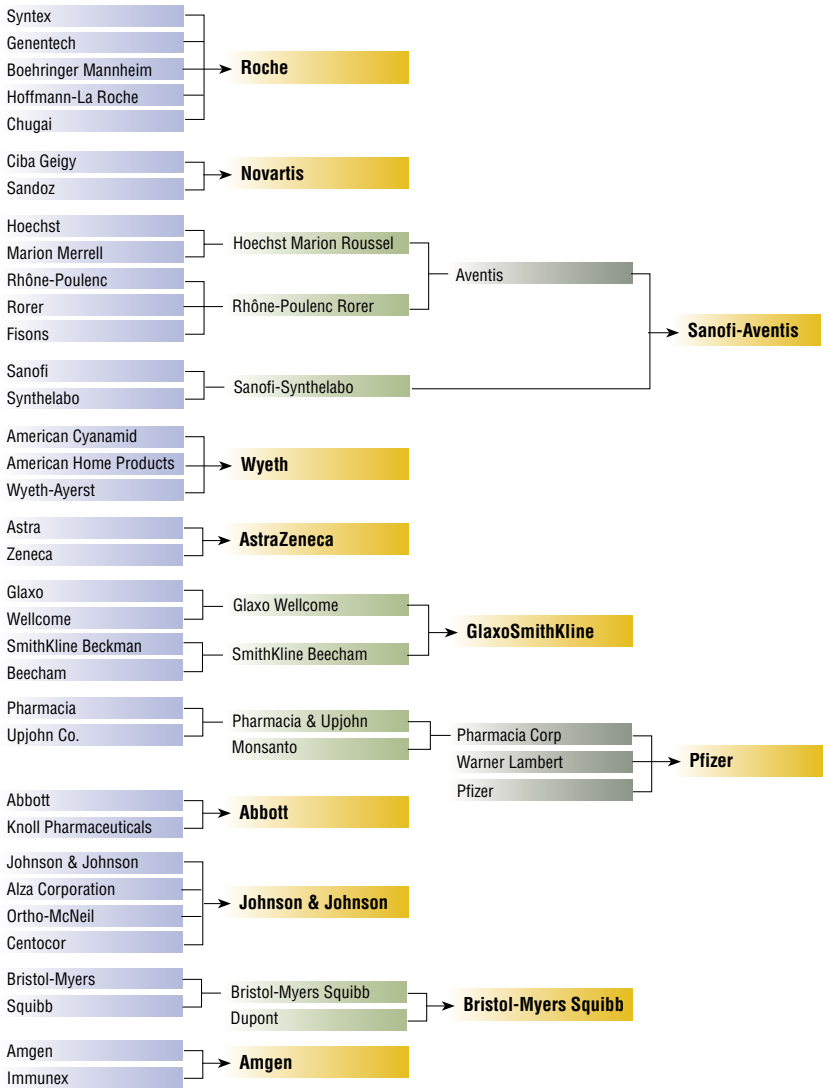


Source: IBM Business Consulting Services.

The spate of mergers and acquisitions that has reshaped the industry over the past two decades has also created problems, not least an infrastructure that is riddled with duplication and complexity (see Figure 3, p.4). At least 50 percent of all mergers fail to live up to expectations, and few produce the dynamic environment required for innovation.[5] In fact, they more often prove to be short-term

palliatives or mechanisms for squeezing out costs. As a result, many pharmaceutical companies have supply networks that are accidents of history rather than consciously designed to face the future.

Figure 3. Numerous mergers and acquisitions have reshaped Pharma over the past 20 years.



Source: IBM Business Consulting Services.

Worse still, the economies of scale the supply chain once enjoyed are gradually disappearing, with the expiry of the patents on a large number of blockbusters and a corresponding drop in product volumes. A substantial percentage of manufacturing costs are fixed and cannot be easily reduced, so shrinking volume throughput drives up the cost of goods sold (COGS) and erodes profit margins. In all, IBM's research shows there is now a marked upward trend in COGS, and that it could climb from the current average of 22 percent towards 30 percent over the next five years, unless the industry continues to consolidate – either through mergers or as a result of changes in national law (see sidebar on **Japanese affair**).

Japanese affair

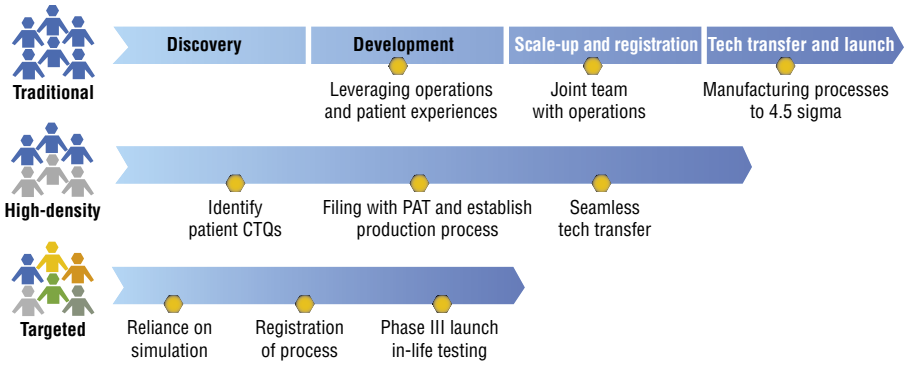
In Japan, the Ministry of Health, Labour and Welfare (MHLW) is revising the "Pharmaceutical Affairs Law," to initiate critical changes in the approval and licensing systems for the manufacturing and marketing of drugs – including deregulation for over-the-counter (OTC) drugs. The legislation is likely to alter the sales channels for OTC drugs entirely. In addition, it will allow manufacturing to be outsourced for the first time. These changes will probably bring about a reappraisal of manufacturing across Japan, and stimulate the consolidation of existing manufacturing capacity.

But the future holds even bigger challenges, as technological advances and greater product diversity increase the complexity of the manufacturing base. Biologics are more fragile and more difficult to scale up than small molecules, often involve novel drug delivery techniques and are more vulnerable to impurities in the manufacturing process. For all these reasons, it is far more difficult to produce biologics than it is to produce conventional chemical compounds. Demand for biomarkers and medicines targeted at patients with specific disease types will also be much lower than it is for mass-market drugs – and such products will have to be formulated and packaged more variously, with a corresponding increase in the number of stock-keeping units to be tracked.

Thus, with the development of targeted treatment solutions, Pharma will need new technology platforms that are capable of dealing with biopharmaceuticals, chemicals, diagnostics and electro-mechanical engineering. But the more complex a manufacturing process is, the more expensive it is and the greater the capital expenditure required to buy the equipment in the first place.

Moreover, much of the cost of manufacturing drugs is "designed" in during development and cannot be eliminated without returning to the regulators – a move at which companies understandably balk, given the effort that has gone into getting them approved. The shift to targeted treatment solutions will accelerate product development, locking in manufacturing costs at a much earlier point in the product lifecycle. At present, it typically takes about 10-12 years to discover and develop a drug. With biological techniques, simulation and in-life testing, that process could be reduced to as little as 3-5 years (see Figure 4, p.6).[6]

Figure 4. The shift to targeted treatment solutions will accelerate product development and time to market dramatically.



Source: IBM Business Consulting Services.

All these changes will intensify the financial risks involved. Product innovation of any kind increases a company's total capital at risk and the danger that it will not achieve its projected cash flows. But if it wants to make targeted treatment solutions, it will also have to invest that capital much sooner than before and avoid incurring additional running costs as a result of inappropriate product features.

The globalization of the supply chain might, perhaps, ameliorate some of the difficulties; countries like China and India are now becoming viable centers for pharmaceutical manufacturing. India has also signed up to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Accord with effect from 2005, which will increase its potential as a location for large-scale production to serve the global market. However, no company will want to make its most innovative medicines in any place where its intellectual property might be vulnerable.

And though the growing stability of some emerging economies is creating new opportunities for low-cost manufacturing, it is also increasing the risks in downstream distribution. With worldwide product sourcing, parallel trading becomes very much easier, threatening the industry's profit margins and the integrity of its products alike. It is no coincidence that the annual number of counterfeiting investigations conducted by the FDA has risen fourfold since 2000, or that the regulator is concerned by the prospect of drug reimportation into the U.S. (see sidebar on **Cross-border drugs**).[7]

Cross-border drugs

In June 2004, U.S. New Hampshire Senator Judd Gregg (R) introduced the latest in a series of bills to allow prescription drugs from Canada and other countries into the American market. Earlier bills have fallen by the wayside, not least because the FDA fears that drug reimportation could greatly increase the risk that consumers will be exposed to counterfeit drugs or products that have been contaminated. But Congress is now reported to be seriously considering such a move, and the Bush administration has set up a task force to investigate how drugs can be reimported safely.

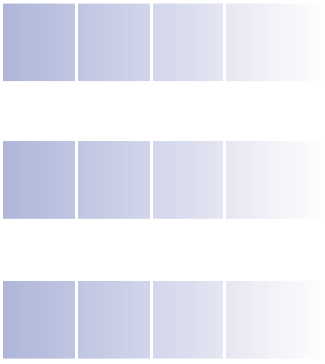
In short, the supply chain is already subject to considerable commercial and technological stresses – and about to come under yet more strain with a change in the manufacturing regulations. In August 2002, the FDA introduced the first fundamental shift in its policy for regulating drug manufacturing and product quality since the launch of paper-based GMPs 25 years ago. This new compliance agenda calls for the application of modern risk and quality management techniques; the replacement of product-based site inspections with GMP systems-based inspections; and demonstrable scientific understanding of the entire manufacturing process, from development through scale-up to production.

But very few, if any, pharmaceutical companies have physical assets and manufacturing, quality and compliance processes that are capable of meeting these requirements. Moreover, their quality systems focus on "testing quality in," and their manufacturing operations are not organized in a manner that facilitates systems-based inspections. They lack sufficient scientific understanding of the manufacturing processes they are using to adopt Process Analytical Technologies (PAT) for monitoring those processes continuously and avoiding the bottleneck created by end-product testing. And they could only acquire such an understanding by returning to development – a route that would be neither economically nor physically feasible for a complete product portfolio.

A strategic vision for the future

To put it simply, much of today's pharmaceutical supply chain is in poor shape for the 21st century. Over the years, the industry has sacrificed its leadership in manufacturing technology and its advanced process engineering know-how to regulatory fears and cost-cutting, leaving the supply chain ill-equipped to comply with the FDA's current requirements or produce the new treatments now beginning to emerge, as the molecular sciences and powerful computing tools transform the development of medicines.

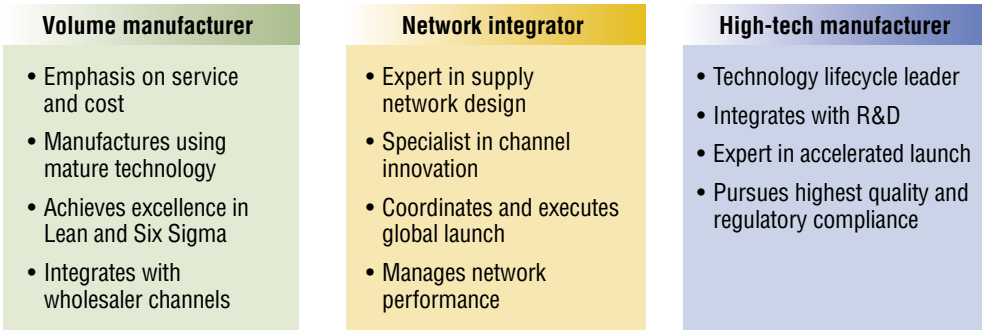
If the supply chain is not to become a barrier to drug commercialization, then, it must be completely redesigned. In the short term, pharmaceutical companies will have to optimize their supply chains and customer-facing processes to drive out costs, increase their capital efficiency and improve their productivity – a delicate balancing act that involves assuming greater risk without impairing performance. In the longer term, they will have to restructure their supply chains, and the savings they make in the short term will help finance that process.



But redefining and redesigning the supply chain is not an easy job. It requires accurate assessment of a company's existing and future product portfolio, the sources of value creation within the supply chain, and the fit of its people and sites. It also demands some difficult choices about the kind of business in which the company plans to engage. The industry giants have traditionally made "one-size-fits-all" drugs that share certain therapeutic and economic features, but, as totally new types of treatment emerge, they will have to specialize to a much greater extent.

Figure 5 shows various options, and the sort of supply chains they will need. Those companies that choose to make targeted treatment solutions, for example, will need to build high-tech manufacturing facilities that are closely allied with a strong R&D base, superb manufacturing skills and excellent scientific and analytical capabilities. Those that choose to become volume manufacturers will need to focus on mature and stable product technologies, using massive scale, low cost and high service to capture the value from increasing global volumes of off-patent drugs. And those that choose to become "network integrators," rather than manufacturers in their own right, will need to create integrated supply networks of different design and technology suppliers, specialist producers and distributors – much as Cisco Systems has done in the networking systems sector.

Figure 5. Here are three examples of the future roles the supply chain might fulfill.



Source: IBM Business Consulting Services.

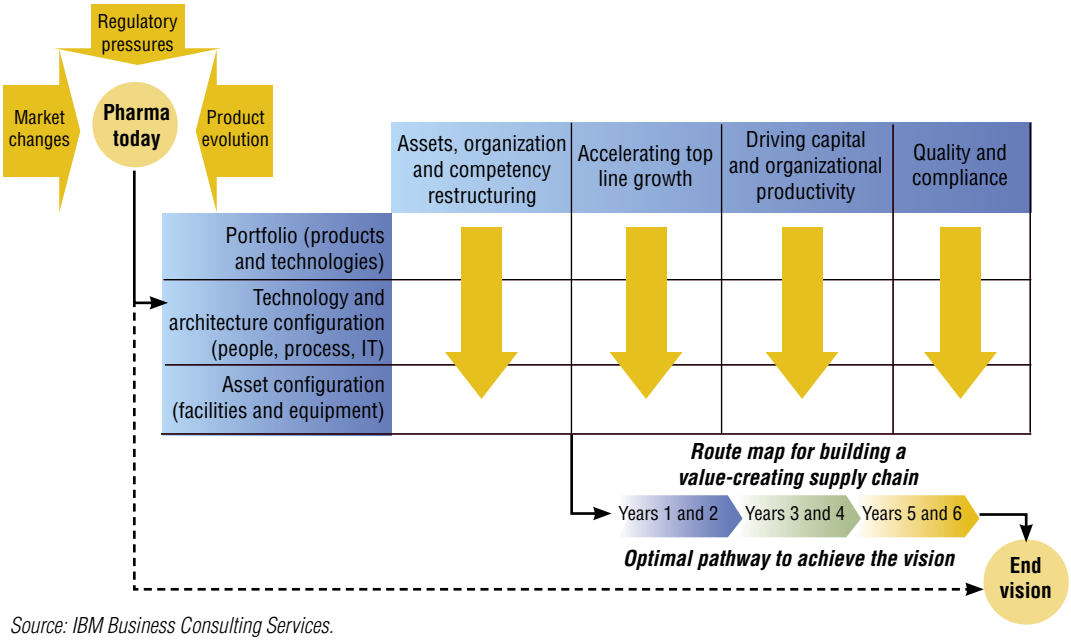
In fact, even if they decide to outsource both their high-tech and their volume manufacturing, all pharmaceutical companies will have to acquire new skills as network integrators, since they cannot afford to surrender control over the design, integration and orchestration of product flows through the factory and on to the patient. But the strategic choices they make about where, and how, to specialize will enable them to differentiate themselves much more effectively than before.

The following sections cover the five areas of manufacturing and distribution on which pharmaceutical companies will have to concentrate their efforts, if they are to create a supply chain that fulfills their future requirements:

- Demand synchronization and strategic sourcing
- Scientific manufacturing
- New product and process development
- Restructuring and asset rationalization; and
- Techniques for extending their reach to the customer.

The first task is to increase productivity and maximize the efficiency of a company's existing manufacturing facilities; the second, to ensure that its supply chain conforms to the FDA's new compliance agenda; and the third, to reorganize its plant, processes and people in readiness for the future (see figure 6).

Figure 6. The supply chain transformation agenda.



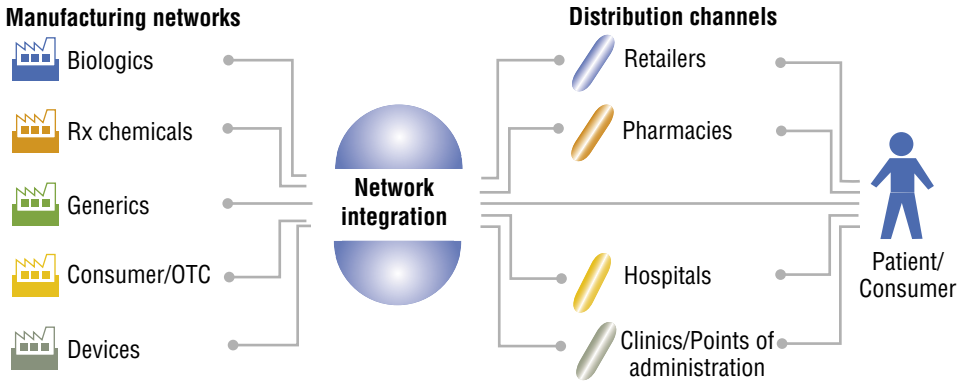
Source: IBM Business Consulting Services.

Demand synchronization and strategic sourcing

All pharmaceutical companies must improve the productivity of their manufacturing assets and capital efficiency over a sustained period of time. In other words, they must learn to make better use of their plant and people, and reduce their fixed costs. Three elements are essential here: a lean manufacturing culture; long-range modeling; and an integrated supply network.

Although six sigma, the methodology for measuring and reducing product variation, sets a target of six standard deviations between the mean and the nearest specification limit, most pharmaceutical companies still manufacture to standards of just two sigma. Adopting a six sigma culture helps a company increase its productivity and reduce cycle times by eliminating waste. It also saves money; moving from two to four sigma typically effects a 15 percent cut in costs. Creating a model of the economic and physical forces influencing the supply chain, and simulating the end-to-end process (including market demand, capacity and costs), enables it to identify which levers it should pull and what effect they will have. Lastly, building a network of trusted suppliers and integrating them in the supply chain ensures the model is comprehensive and makes it very much easier to coordinate responses to a change in demand, supply or production (See Figure 7).

Figure 7. An integrated worldwide network is essential for effective manufacturing and distribution.



Source: IBM Business Consulting Services.

Going lean around the globe

One of the world's top five pharmaceutical companies needed to improve the efficiency of the global supply chain for its biggest selling product. The active ingredient was manufactured in a highly complex chemical process executed in Europe, while production, packaging and distribution of the tablets took place in the U.S.

The company decided to adopt a "go-lean" approach that focused on improving productivity and reducing cycle times by eliminating waste; all directly reporting processes were synchronized to the manufacturing throughput rate. As a result, the company saw a productivity increase of over 30 percent in both chemical and pharmaceutical manufacturing. Cycle times were also reduced – by one-third in chemicals and almost four-fifths in pharmaceuticals – slashing the inventory by tens of millions of dollars. The company now plans to link its U.S. and European supply chains in a global supply chain that is expected to deliver significant benefits.

Synchronizing the manufacturing process involves sharing information on the design and movement of the products being manufactured, using track and trace technologies like radio-frequency identification (RFID) to provide realtime data on their progress along the production line. However, it can deliver substantial productivity gains, as well as reducing the amount of capital that is tied up in stock (see sidebar on **Going lean around the globe**).

Scientific manufacturing

The FDA's new compliance agenda will also force many companies to transform their supply chains. The regulator reasons that concentrating on GMP systems rather than products or profile classes will enable it to monitor companies more effectively with the limited resources it has at its disposal, because the systems are used to manufacture many different kinds of product. So, if it finds a problem with a particular system, it can shut down the whole plant.

But though this is a dark cloud, it comes with a large silver lining. The FDA recognizes that, in exercising its duty of care to the patient population – to ensure that only products which are safe and efficacious reach the marketplace – it has sometimes stifled innovation. Its new agenda accordingly signals that it is ready to help, with faster regulatory approvals for companies that use PAT to demonstrate their scientific knowledge of the products they are making and the processes they are using to make them.

Thus there is now an opportunity to improve the performance of the pharmaceutical manufacturing function substantially, by understanding and managing the quality criteria that are critical to patients; by acquiring a full scientific grasp of the processes that will be used to manufacture a drug while it is in development; by using PAT to measure and monitor key control points, and release productivity gains further down the production line; and by shifting from quality control to quality management throughout the supply chain. However, the structural and systemic changes required to ensure product quality and demonstrate scientific knowledge cannot be introduced all at once, so companies should start with their most important systems and products and cascade the changes gradually throughout the rest of their manufacturing facilities. They should also balance the remedial steps they take with an understanding of the root causes of failure in their systems and processes.

That said, those firms that can demonstrate their scientific mastery of the products and processes they are using will enjoy some considerable advantages. The FDA recently granted GlaxoSmithKline approval to use a rapid detection technology for controlling the manufacturing quality of a prescription nasal spray, for example, which will enable the company to release the spray to market within 24 hours, up to 80% faster than with traditional methods.[8] Similarly, such companies will have a head start in terms of getting their products to market. They will be able to obtain post-approval changes to the manufacturing process more easily and rapidly than their rivals. And they will be able to create barriers to generic competition with process patents. In short, they will be able to turn their manufacturing into a value-creating activity and set themselves apart from the crowd.

Food for thought

The global consumer products and food industry typically requires a fast innovation engine for its many products, most of which have short lifecycles. One major consumer products company recently succeeded in reducing its specification review and approval times by 70 percent, when it standardized more than 350,000 product specifications and linked them to preferred suppliers and formulae. It also improved its first-pass quality by over 10 percent and saved hundreds of millions of dollars on direct material costs. In all, innovative use of product lifecycle management to create new products and get them to market faster yielded a 15 percent increase in the company's earnings.

Over-the-counter culture

One of the world's fastest growing OTC healthcare companies – with products that are sold in over 130 countries – needed to accelerate its time-to-market to meet ambitious growth targets. It also needed to renovate a key brand.

The company accordingly embarked on a fast-track reengineering project to improve its new product development and introduction process. It adopted best-practice stage-gate techniques from the consumer goods industry (where product development is divided into distinct time-sequenced stages separated by management decision "gates"). It also introduced a new product lifecycle management system that allowed it to work on a global basis, and introduced organizational changes to clarify accountability at every stage from initial insight to product withdrawal. Its updated processes included earlier involvement of the supply chain and a new approach for addressing regulatory requirements.

As a result, the company identified ways to cut its development times by 25 percent. It now expects to generate many millions of dollars in additional revenue during the initial five years of each new product release.

New product and process development

Matching supply with demand and implementing PAT retrospectively in the parts of the manufacturing base to which it can be applied are relatively short-term measures. In the longer term, however, the pharmaceutical supply chain must also gear up for a new pipeline that includes many more – and more complex – products. If it is to do this successfully, it will have to play a much more active role in early development when a lot of the characteristics of a product that determine how it is subsequently manufactured are first defined.

Many companies in other sectors already integrate the design, development and production of their goods (see sidebar on **Food for thought**). But this approach – which is elsewhere known as product lifecycle management (PLM) – has equal potential in Pharma. It requires the construction of an integrated product and process data backbone spanning everything from early development to marketing and sales. Three areas are particularly important for manufacturing purposes: formulation and process development, utilizing design principles that support PAT; product and process data management; and the use of preferred technologies to support science-based development.

Creating a collaborative design-supply chain that straddles the entire product lifecycle has various benefits. It reduces the problems arising on the production line as a result of design features that make the manufacturing process unnecessarily difficult; it makes transferring a product from one manufacturing site to another much easier; and it accelerates new product introductions (see sidebar on **Over-the-counter culture**). Lastly, it provides an effective channel for communicating feedback from the marketplace to refine the development and manufacturing of future products.

The industry also needs to improve its quality management. At present, most pharmaceutical companies do not design new products for six sigma manufacturing. In future, however, they will have to introduce "quality by design" principles into new product and process development, and increase their manufacturing process capabilities with a concerted drive towards 4.5 sigma. That means they will have to integrate key design partners in the design chain, use predefined technology platforms wherever possible, and acquire new manufacturing and process engineering skills to support the production of totally different treatments. Collectively, these measures will enable Pharma to accelerate new product and process development, and hence new product introductions, dramatically.

Restructuring and asset rationalization

Redesigning the new product introduction process to prepare for the advent of targeted treatment solutions is vital, but it only covers a small part of product commercialization. All companies have limited resources, so it is imperative to direct those resources – be they capital, plant, skills or management time – to the areas of the business that create most value. Yet most pharmaceutical firms are currently looking backwards, not forwards.

They have supply chains that are engineered to manufacture the small molecules they have traditionally discovered and developed, rather than a much wider range of products, many of them biological rather than chemical in nature. They will ultimately therefore have to reorganize their manufacturing assets and, in doing so, take a zero-based view of the business, since a piecemeal or step-by-step approach to the restructuring of an organization and its assets does not work.

The six activities performed by the Pharma supply chain that have the greatest potential to add value – and are thus those that should be kept in-house, rather than outsourced – are:

- Control of product quality and patient risk exposure
- Intellectual property creation via new products and processes
- Strategic sourcing via tax-effective supply networks
- Use of innovative manufacturing process technologies, and expertise in working with such technologies
- Orchestration of the performance of the end-to-end supply chain; and
- Distribution and channel management.

The smart factory

A smart factory is one that draws on its technological design and capabilities to take complex products from development to the marketplace as fast as possible. It is modular in design – for rapid volume and process scale-up – and highly automated, with technologically advanced sense and response capabilities for built-in autonomic processes. It is located close to an R&D site and uses a combination of the best scientific and engineering skills to effect a seamless transfer from product development to full-scale manufacturing. Actual customer demand drives production, which can be ramped up or down as necessary. Information flows throughout the entire supply chain and pull-based demand signals enable the realtime adjustment of manufacturing and packaging schedules.

Most pharmaceutical companies manage all six core skills very well internally. They find it much more difficult to deal with external designers and suppliers, or to supervise their products once they pass out of the warehouse. But the ability to work with external organizations is becoming much more important. In future, they will therefore have to devote a greater share of their resources and management time to such activities.

They will also have to develop the infrastructure they need – whether they choose to become volume manufacturers, high-tech manufacturers or network integrators, or adopt any other supply chain model. So, for example, a company that wants to focus on targeted treatment solutions will need to concentrate its capital investment in a small number of sites and equip them with the most promising new manufacturing technologies – drawing on the concept of "smart factories" (see sidebar on **The smart factory**). It will likewise need to minimize its investment in mature technologies by selling off old plant and outsourcing the production of commodity drugs to contract manufacturers or joint venture partners.

Some of the industry leaders have a hundred or more manufacturing sites, as well as numerous regional and local warehouses. In practice, they probably only require about 10-15 high-tech sites around the world to support their future production needs. The rest of their manufacturing could potentially be outsourced. Again, however, it is crucial to keep control over strategic sourcing, supply integration and channel management; these are activities that should not be outsourced to a third party.

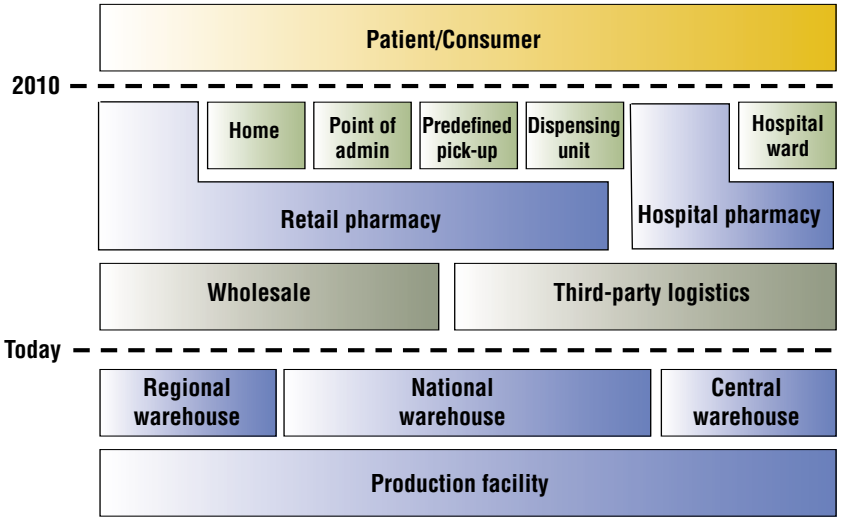
Techniques for extending Pharma's reach to the customer

So much for the manufacturing base, but Pharma also needs to extend its reach to its customers. The industry currently delegates distribution to wholesalers and third-party logistics (3PL) providers, and is weaker than most other sectors when it comes to channel management. This has several undesirable consequences. It limits the amount of information about patient demand and product flows that is passed back to the manufacturer; encourages parallel importing from cheaper into more expensive regimes; and prevents a company from being able to guarantee the integrity of its products beyond the warehouse door.

Parallel trading costs Pharma billions of dollars a year, but most of that money goes to the importers and pharmacy chains rather than healthcare payers and patients. IMS Health, the market research firm, estimates, for example, that although the level of parallel imports into Germany was about €1.3 billion in 2002, the saving to payers was just €126 million.[9] (This was a discount of US$132 million on parallel imports worth US$1.36 billion.) Moreover, most such imports are repackaged or relabeled, which increases the risk of errors (such as insertion of the wrong product or prescription guidelines) and makes it more difficult for pharmacists to distinguish counterfeit from genuine drugs.

Given these problems, it is important that pharmaceutical companies take control of their own downstream distribution, both to maximize the potential of the different channels they use and to protect patients from mistakes and fraud. They must reengineer their distribution models to push the boundaries of product supply from the warehouse to the point-of-dispensing (see Figure 8).

Figure 8. The supply chain will extend its reach to the customer.



Source: IBM Business Consulting Services.

Downstream savings

A multinational pharmaceutical company wanted to find out how it could restructure its supply chain to reduce its working capital, accelerate and increase its market penetration, and extend its reach to the customer. It established that it could maximize its profits if it focused on its downstream distribution strategy and assumed control of its channel management. The company recognized that it could not eliminate wholesalers from the distribution chain, but it could form partnerships with key wholesalers and exploit some alternative market channels by going direct to the point-of-dispensing. It now expects to achieve downstream savings of several million dollars per product and additional upstream savings in manufacturing through better planning and visibility in the supply chain.

The hidden blockbuster

Nearly 85 percent of all branded pharmaceuticals sold in the U.S. are bought by managed care organizations, pharmacy benefits managers or the government. Most pharmaceutical companies offer discounts and incentives to such big customers, but they generally base their prices and contractual terms on historical precedent because they lack accurate data. Now new regulations such as the Sarbanes-Oxley Act have highlighted the dangers of this approach, but they have also exposed the hidden potential for substantial savings for those companies that improve the accuracy and efficiency of their contracting and pricing processes.

One technique is to go direct – to deliver the most innovative and expensive products straight to retail pharmacies, hospitals and specialist clinics without using wholesalers (see sidebar on **Downstream savings**). In fact, with repeat prescriptions for some drugs, such as oral contraceptives, there is no reason why companies could not supply patients directly, too.

Wholesalers would still have a useful role to play in distributing mass-market drugs with high volumes; indeed, they could make a far larger and more valuable contribution than they are currently doing, by assuming responsibility for packaging such products and managing their distribution on a regional rather than a national basis. They are also in an ideal position to mass-customize certain products with different drug and packaging combinations for different customer segments, and to help in the battle against counterfeiting, using RFID to track products as they travel from the warehouse to the patient.[10]

A second, and complementary, approach is to manage the funds used to support pharmaceutical distribution and channel management more effectively. Carmakers have long relied on an extensive network of dealers to distribute their products, and used a mixture of incentives and bonus schemes to motivate them. Pharmaceutical companies can apply the same principles in managing the performance of their wholesalers and 3PL providers – and also in negotiating with important customers. There are significant opportunities, particularly in the U.S. market, for improving customer-facing processes such as contracting and pricing (see sidebar on **The hidden blockbuster**).

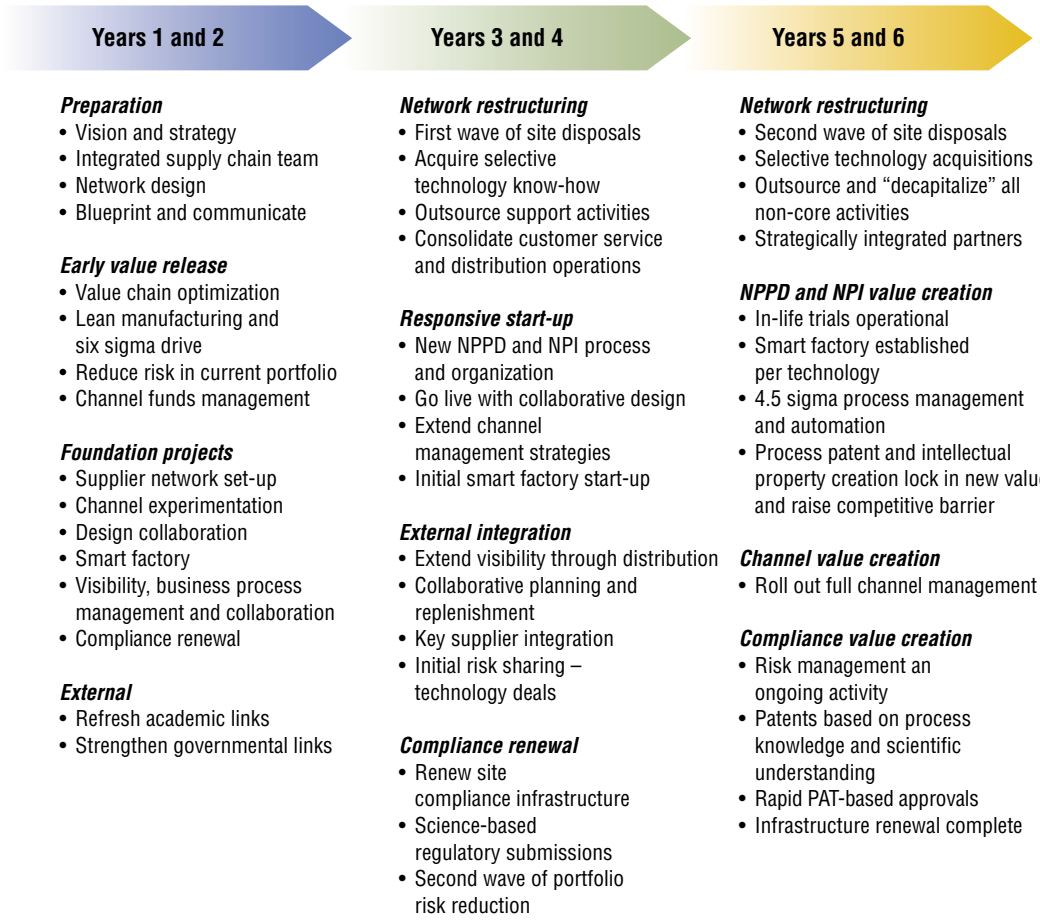
In all, pharmaceutical companies must create much stronger relationships with the retail pharmacies and hospitals that dispense their products, and focus much more clearly on the needs of patients through channel-to-market innovations. If they do these things, they can expect to see margins recover, to enjoy better market intelligence and channel control, to accelerate the point at which sales peak, to reduce planning inaccuracies and to be more effective in curbing counterfeiting.

The transformation of the supply chain

When it comes to building an excellent supply chain, there are no short cuts and there is no single solution. The scale of the change that is required depends on three factors: the depth and length of the R&D productivity gap, the pace of technological progress and the length of time it takes management to act. Some pharmaceutical companies recognized the challenge in the late 1990s and are now in the midst of making the transition; others have just begun the process; yet others, cushioned in some cases by strong product portfolios, remain in denial. But it is clear that the industry is undergoing a fundamental transformation – and that if the supply chain is not to inhibit that transformation, it must be reinvented. It must become smart, fast and efficient, without being expensive.

So how should companies respond? Figure 9 (see page 18) shows the sort of journey they must undertake. It is organized in three stages over a time span of five or six years. Stage 1 addresses the basics: strategy formation; the elimination of products and assets that are unlikely to comply with the FDA's new agenda; the introduction of six sigma manufacturing techniques; and the identification of key technologies and partners. Stage 2 focuses on asset rationalization, with the first wave of site disposals and commissioning of smart factories; the reengineering of new product processes; innovations in channel management; and the development of science-based submissions. Stage 3 covers the renewal of the remaining asset base; widespread use of channel management; and the embedding of risk management procedures.

Figure 9. How to build a value-creating supply chain.

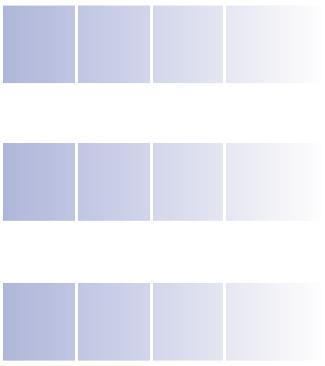


Source: IBM Business Consulting Services.

Conclusion

To sum up, a scientific and technological revolution is taking place. It will ultimately enable Pharma to make profitable new medicines both for conditions it cannot treat very well at present and for conditions that have previously resisted all treatment. But that same revolution is posing problems with which the supply chain has never had to contend before. As a greater volume and variety of new products – large and small molecules, biomarkers and devices – move into clinical development, the industry's pipeline will become wider and more complex, and the demands placed on manufacturing and distribution will become correspondingly heavier.

This much is obvious. The only question is how individual pharmaceutical companies respond. They can either concentrate on alleviating the short-term pressures they face or take the long view and, in doing so, recognize the *real* contribution the supply chain can make. Negotiating contracts, procuring materials, getting them to the people who manufacture the products and shipping the finished goods to customers is often seen as an unglamorous, albeit essential, part of the business – like the plumbing that is required to provide running water. But the supply chain can either obstruct or enable future growth. It can be used to help accelerate time to market and the maximizing of revenues from new products; to impede generic competition; to protect patients from taking counterfeit drugs; and to stem the financial leaks beyond the factory gate. Managed properly, it is a major source of value-creation.



About the authors

James Prendergast is the IBM Global Supply Chain Leader in Life Sciences/ Pharmaceuticals. He can be contacted at *james.prendergast@us.ibm.com*.

Richard Holmes is the IBM EMEA Supply Chain Leader in Life Sciences/ Pharmaceuticals. He can be contacted at *richard.holmes@uk.ibm.com*.

Mark Yeomans is a Supply Chain Partner in IBM EMEA Life Sciences/ Pharmaceuticals. He can be contacted at *mark.yeomans@uk.ibm.com*.

Heather E. Fraser is a Managing Consultant with the IBM Institute for Business Value Life Sciences/Pharmaceuticals team. She can be contacted at *hfraser@uk.ibm.com*.

Contributors

Dennis Bell, Associate Partner, IBM Business Consulting Services – Life Sciences/Pharmaceuticals

Frances Bruttin, Partner, IBM Business Consulting Services – Life Sciences/Pharmaceuticals

Fergus Byrne, Global Lead, IBM Business Consulting Services – Distribution

Doug Dean, Global Compliance Lead, IBM Business Consulting Services – Life Sciences/Pharmaceuticals

Marc Herlant, Partner, IBM Business Consulting Services – Life Sciences/Pharmaceuticals

Michele Pesanello, Partner, IBM Business Consulting Services – Life Sciences/Pharmaceuticals

Walter Van Dyck, Associate Partner, IBM Business Consulting Services – Life Sciences/Pharmaceuticals

Colm White, Associate Partner, IBM Business Consulting Services – Life Sciences/Pharmaceuticals

Editorial advisor

Dr. Helen Kay is a senior business writer. She provides editorial support for the IBM Life Sciences/Pharmaceuticals Practice and has worked on most of the reports in the Pharma 2005 and Pharma 2010 series.

About IBM Business Consulting Services

With consultants and professional staff in more than 160 countries globally, IBM Business Consulting Services is the world's largest consulting services organization. IBM Business Consulting Services provides clients with business process and industry expertise, a deep understanding of technology solutions that address specific industry issues, and the ability to design, build and run those solutions in a way that delivers bottom-line business value.

References

1 IMS Health, "IMS Reports 9 Percent Constant Dollar Growth in '03 Global Pharma Sales." http://www.imshealth.com/ims/portal/front/articleC/0,2777,6652_3665_45365325,00.html (accessed June 4, 2004).

2 U.S. Food and Drug Administration, "A Risk-Based Approach to Pharmaceutical Current Good Manufacturing Practices (cGMP) for the 21st Century." http://www.fda.gov/cder/gmp (accessed April 16, 2004).

3 IBM Business Consulting Services, "Pharma 2010: The threshold of innovation." 2003, p.11. Copies available at http://www1.ibm.com/industries/healthcare/doccontent/resource/thought/390030105.html

4 IBM, "Pharma 2010: The threshold of innovation," p.13.

5 PricewaterhouseCoopers, "Speed Makes the Difference: A Survey of Mergers and Acquisitions." 2000.

6 IBM, "Pharma 2010: The threshold of innovation," p.35.

7 U.S. Food and Drug Administration, "Combating Counterfeit Drugs." February 2004. http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html (accessed June 4, 2004).

8 Pall Corporation, "GlaxoSmithKline Process Using Pall Rapid Microbiological Test Is First Approved By FDA." May 27, 2004. http://www.pall.com/sls_27369.asp (accessed June 31, 2004).

9 IMS Health, "Parallel Trade in Europe - Assessing the Reality of Payer and Patient Savings." http://www.imshealth.com/ims/portal/front/articleC/0%2C2777%2C6652_41382706_43286344%2C00.html (accessed June 4, 2004).

10 IBM Business Consulting Services. "Thwarting counterfeiting in the pharmaceutical manufacturing industry: Protect your brand and increase operational efficiency using radio frequency identification." 2004.

IBM Global Services
Route 100
Somers, NY 10589
U.S.A.

Produced in the United States of America
08-04

G510-3611-01