Pharmaceutical Supply Chain Risk Management

CURRENT AND FUTURE STRATEGIES IN PHARMACEUTICAL SUPPLY CHAIN

Logistics accounts for 45–55% share of the value chain of a drug. Tied in with associated complexities around sourcing and manufacturing, supply chain management (effective or otherwise) clearly has a strong bearing on the total cost of a drug. Players in the pharmaceutical space are, therefore, undertaking a range of strategic initiatives to reduce cost across all phases of the pharmaceutical supply chain:

Raw Material Sourcing 'Outside Home Country'

Historically, the US pharmaceutical industry has relied on locally manufactured and sourced ingredients. According to a PwC survey (2011), 75% of life sciences supply chain executives indicated they were sourcing material from Western markets. This trend, though, is set to reverse over the next three years as 60% plan to decrease sourcing from Western Europe and 45% plan to source a lower quantity from North America. Conversely, 8 out of 10 executives plan to increase the percentage of material sourced from Asia Pacific, and 38% plan to source more from Eastern Europe.

Outsourcing

Pharmaceutical companies have traditionally preferred conducting R&D and drug manufacturing in-house. However, over the last decade, companies increasingly outsourced these functions to Contract Manufacturing Organisations (CMOs) and Contract Research Organisations (CROs). Contract manufacturing of bulk and dosage form drugs worldwide reached $49 billion in 2010, an increase from $26.2 billion in 2004. Global pharmaceutical CMO and CRO revenues reached $196 billion in 2010, up from $100 billion in 2004.

Going forward, outsourcing of drug manufacturing and R&D is expected to grow at a rapid pace. Contract manufacturing of bulk and dosage form drugs worldwide is expected to grow to $53 billion in 2011, up from $49 billion in 2010. Further, the figure is touted to touch $86 billion by 2016 at a CAGR of 10%. Revenue of CROs and CMOs is expected to grow to $218 billion in 2011, up from $196 billion in 2010. The figure is projected to reach $361 billion by 2016, increasing at a CAGR of 11%.

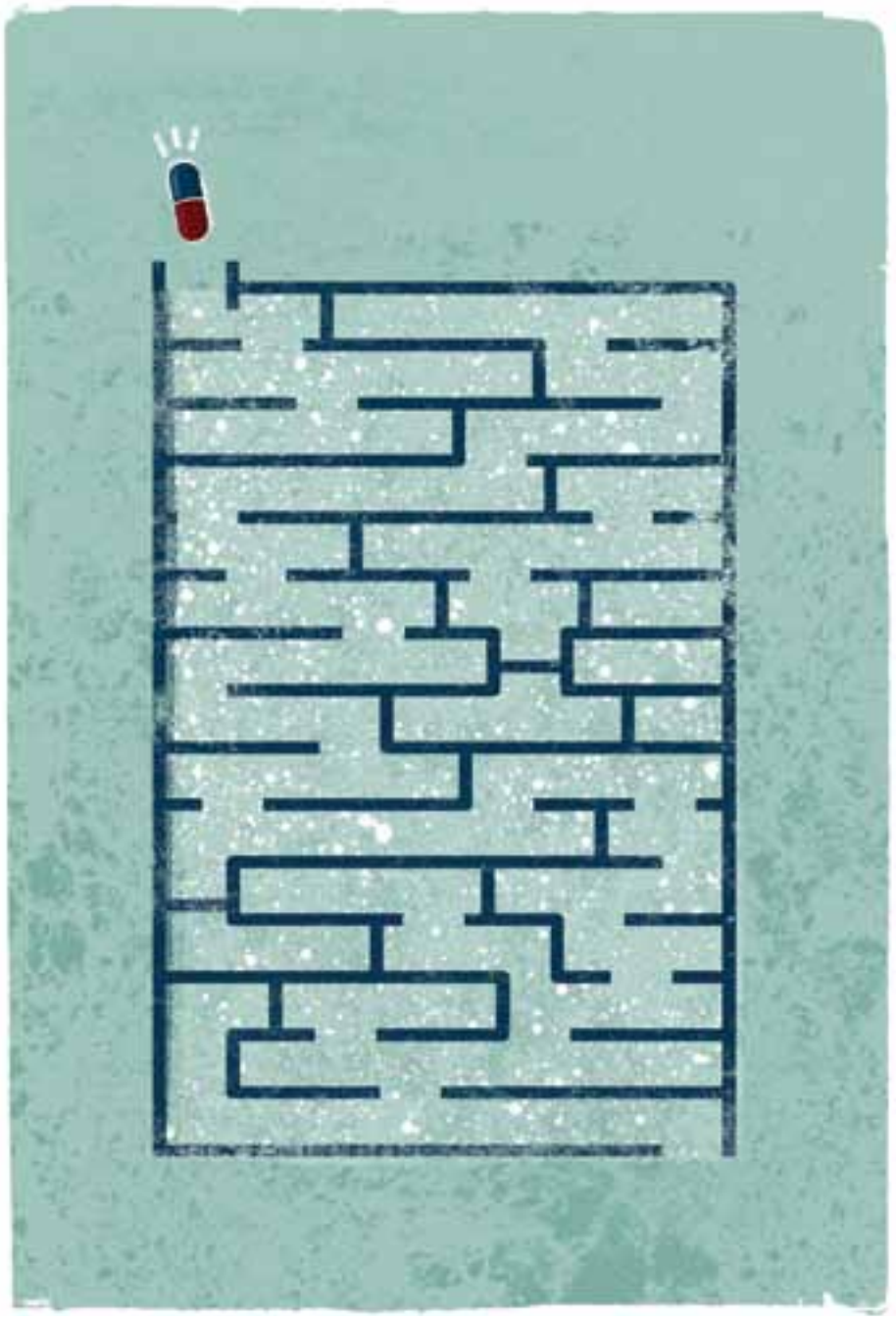
Catering To Diverse End-Users and International Markets/Customers

Globalisation is propelling pharmaceutical companies to develop strategies for serving a diverse base of end users, including wholesalers, governments, hospitals and retail pharmacies, as well as new geographies, each of which have unique requirements and expectations. Further, companies are globally sourcing raw material and supplying finished goods to end users across geographies. This is shifting pharmaceutical companies' focus to managing a global, dispersed and diverse supply chains from running a local, managed supply chains.

The rapid growth of sourcing and manufacturing in low-cost countries has further stretched supply chains, increasing the chances of disruption and making tight control more challenging. In addition, globalisation has created extended opportunities for pharmaceutical companies to sell their products and services in new markets and regions, calling for the management of a global supply chain.

Joint Ventures and Partnerships

Further integrating and adding complexity



to existing supply chains, pharmaceutical companies are entering into joint ventures and partnerships with organisations across industry domains such as telecom and technology. This trend is expected to continue going forward. **(Fig. 1)**

Integrating Supply Chains

To cope with emerging challenges such as patent protection (*Pfizer's Lipitor, Astra Zeneca's Crestor and Seroquel, Sanofi Aventis' Plavi* and *Merck's Singulair* are losing their patents in the near future) and technology transformation, pharmaceutical companies and healthcare players need to collaborate and realign their strategies for developing a value chain that caters to both the segments, such as looking for new end-markets, moving towards fuller service offerings in the healthcare sector, or reducing dependence on key revenue-earning drugs. For example, J&J's offers a fully diversified portfolio including generics, diagnostics and devices, consumer health, prescription and OTC drugs. Similarly, other pharmaceutical companies are expected to integrate their supply chain. **(Fig. 2)**

In the light of such expected strategies, the pharmaceutical supply chain is likely to undergo a number of changes. In adapting to these changing industry dynamics, pharmaceutical companies are expected to enter into more outsourcing partnerships, collaborations and joint ventures. This will require pharmaceutical players to strive for greater visibility, supervision and control over the entire supply chain.

EMERGING SUPPLY CHAIN RISKS: WHY MUST THIS ISSUE BE ADDRESSED?

Counterfeiting

"Approximately 10% of the worldwide drug supply is counterfeit" —*World Bank*

Counterfeiting is one of the most serious threats faced by the life sciences and healthcare sectors worldwide. A Pharmaceutical Security Institute (2010) survey estimated that drug counterfeiting has increased worldwide by more than 9% over the previous year. The survey identified 808 types of counterfeit pharmaceutical products in 2009, increasing by over 36% from 2008 (detected in 118 countries in 2008). Recently, Pfizer reported a case where it was necessary to recall 200,000 bottles of their cholesterol drug Lipitor from outside the US (total market value of about US$ 55 million) as these contained fake pills.

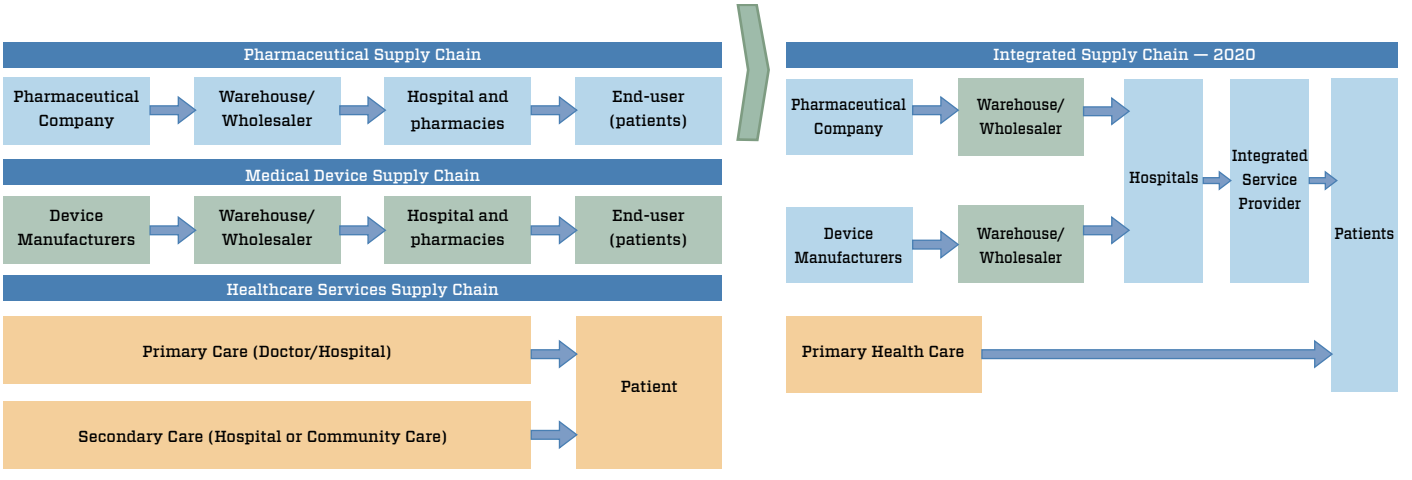
Outsourcing Risks: Product Diversion and Negligence in Regulatory Compliance

Healthcare and pharmaceutical companies

FIG. 1: KEY SUPPLY CHAIN INITIATIVES

Organisations	Supply Chain Initiatives	Implications in Supply Chain
Mental Health Research Institute Astra Zeneca	Collaboration in R&D to identify early stages in Alzheimer's disease	Detection of diseases in early stages results in an overall reduction in related costs and simplification of the supply chain
Pfizer Protalix	Partnership to develop and commercialise the treatment of Gaucher disease	New R&D approaches to enter the rare disease markets
J&J Apple	Ventured into health-care business by partnering with Apple to create health-related iPhone applications for monitoring blood glucose levels and check weight	Increased responsiveness with regard to testing blood glucose levels
Novartis Vodafone IBM	Novartis launched an initiative enabling health workers to send reports on supply and demand of medications, especially anti-malarial drugs, through mobile phones	Accuracy in forecasting supply and demand parameters and improved supply chain operation
Novartis Proteus	Ventured into health-care services by licensing with Proteus to develop a sensing technology for organ transplantation	Accurate monitoring of heart beat rate and blood pressure levels of patients and improved facilitation of data management

FIG. 2: EVOLVING PHARMA SUPPLY CHAIN



come under strict regulations and guidelines of their respective regulatory authorities. Across the entire supply chain (ranging from R&D phase to drug commercialisation), companies need to maintain strict quality adherence mechanisms, diversion from which could result in heavy losses and regulatory sanctions. While globalisation and outsourcing of manufacturing and R&D to CROs and CMOs have been on the rise, visibility and supervision over supply chain are concern areas. Outsourcing entails various risks such as dependence on outsourcing partners and negligence in ensuring regulatory compliance. Based on a PwC survey (2011), most life sciences supply chain executives believed that risks associated with outsourcing are second only to *counterfeiting* in terms of their magnitude and impact.

Delay In Distribution and Extreme Inventory Levels

Pharmaceutical players need to maintain optimum inventory levels and efficient distribution networks to meet patient demand on time and prevent excessive inventory (as perishable pharmaceutical drugs go to waste if not kept under strictly controlled environments). Forrester Research estimates that a one-day delivery delay of $1 billion worth of drugs costs a manufacturer $2.74 million in *lost sales*. Further, as per a survey by IBM (Global Chief Supply Chain Officer Study – 2009) conducted across 25 countries and 29 different industries, the life sciences industry had a median inventory turnover of 3.4X, which is significantly less compared with an average median of 5.5X for other industries combined.

Risks Associated with Inaccurate Assessment of Complex Consumer Demand

As pharmaceutical companies increasingly cater to diverse end-users and new international markets, their supply chains need greater customer insight and planning for assessing the *what, when, and how much* of supply. Inaccurate assessment of these parameters could lead to excessive inventory levels of perishable drugs, which imply potential huge losses for a company if they go to waste.

Integration and Partnership Risks

Increasing strategic diversification of pharmaceutical companies into the healthcare sector is expected to result in greater collaboration and partnerships within the industry. Any lapse in effective coordination may result in risks such as regulatory compliance-related risks and delays in distribution timelines.

Counterfeiting risks, regulatory compliance-related risks and delay in distribution timelines are the most critical risks associated with the pharmaceutical supply chain. These need to be addressed by coming up with accurate supply chain configuration and adaptability.

PROPOSED SOLUTIONS

Pharmaceutical players need to map out the entire supply chain to identify and prioritise risks at various stages/phases. The impact of the high-priority risks can be reduced by adopting appropriate risk mitigation strategies, as detailed in this section.

Outsourcing Risk Mitigation: Greater Collaboration

Greater collaboration and harmonisation among brand owners, suppliers, packaging and contract manufacturers, shippers, distributors and industry regulators help in achieving greater transparency, cost-control, sharing of information, and development of common standards and indicators, which in turn is likely to result in safer and higher-quality products. Industry groups such as the *Pharmaceutical Supply Chain Initiative*, the *Experimental Physics and Industrial Control System* and the *Rx-360 Consortium* have a critical role to play in fostering these collaborations.

> "The trade-off between partner collaboration and risk management is one of our largest challenges." —*Supply Chain Executive, medical solution provider, Europe*

Implication: Identify and pursue opportunities to join, partner and/or create cross-organization collaboration.

Outsourcing Risk Mitigation: Better Integration

The overall medical industry has become extremely complex in terms of the number and type of players involved, and the nature of the relationships amongst them. Integration of divisions from OTC, pharmaceutical, animal health, bio-tech and medical device will enable easier market entry and better leveraging of facilities and partners; further, it will eliminate duplicate supply chain execution efforts and costs. For example, pharmaceutical drug research outsourcing as well medical device research outsourcing could be done using the same supply chain partners, instead of employing individual supply chains.

Implication: Identify integration opportunities within the life sciences sector to eliminate duplicate supply chain efforts and costs.

Counterfeiting Risk Mitigation: Technological Enhancements

"Global supply chains face fundamental discontinuity around the world—we still do not have a global standard for RFID and customer sophistication, and adoption of advanced technologies still vary widely." *—President of Supply Chain, healthcare services provider, North America*

Pharmaceutical players need to address the threat of counterfeiting by establishing efficient mechanisms that address this problem. Pharmaceutical companies should investigate and develop intelligent products. For example, Barcodes and RFID tags are some of the tools that provide real-time visibility to prevent diversion and theft, and enable authentication to stem the flow of counterfeit drugs.

Implication: Identify and invest in countermeasures, such as traceability and authentication technologies, to minimize the impact of counterfeit drugs.

Counterfeiting Risk Mitigation: Packaging Solutions

Pharmaceutical companies should develop innovative packaging solutions to uncover fake (counterfeit) products easily as well as in a short time-frame. Using holograms (Dot Matrix, E beam technology, etc.), application of serialised codes, bar codes and other security codes on primary packaging, as well as subsequent packaging levels, are effective methods in tackling the threat.

Implication: Develop secure packaging solutions to mitigate counterfeiting risks that arise due to non-secure packaging of pharmaceutical drugs.

CASE STUDY: BILCARE RESEARCH

Context

Bilcare Research, through its research and technology division, Bilcare Technologies, developed a solution aimed at safeguarding the drug supply against the risk of counterfeiting.

Solution

Each package or product flowing through its supply chain had a tamper-evident, non-clonable tag, which was made using nanotechnology. The tag's "fingerprint" safeguarded the drug from being duplicated because of the random manner in which it was generated. To confirm authenticity, the end-users, such as retail pharmacies, hospitals and patients themselves, could simply swipe the packet across a scanner. On one hand, the nanotechnology tags safeguard the drugs against cloning risks, and on the other, it is cheaper than solutions involving electronic components. In addition, these tags were leveraged throughout the supply chain to provide track-and-trace capabilities, and helped save the US $1 billion lost each year to theft and diversion.

'Outside Home Country' Sourcing Risk Mitigation: Balancing the Trade-Off Between Low-Cost and Low-Risk

Large pharmaceutical companies have initiated well-defined programs in India and China to source raw materials. As these markets have matured, companies are now sourcing from new low-cost sources located in Eastern Europe and other Asian countries. Outsourcing, combined with low-cost country sourcing, significantly increases supply chain risks, such as *product quality diversion*. Therefore, it is imperative for these companies to evaluate their sourcing strategies in the light of cost-versus-risk proposition for different low-cost destinations, and implement better controls, policies and processes to mitigate the risks associated with low-cost country sourcing. For instance, in 2008, the US Food and Drug Administration recalled Heparin due to contamination in the lots produced in China—the drug was oversulfated as Chinese Heparin manufacturers were unethically cutting the medication with chondroitin sulfate to cut down on manufacturing costs. Another strategy that can be adopted to reduce these risks is highlighted in the next section.

Implication: Identify the risks associated with low-cost country sourcing and put into place better controls, policies and processes to mitigate these risks.

Supplier Risk Management: Strategic-Sourcing and Supplier Relationship Management

An organisation's procurement department has the ability to significantly reduce the risk associated with *'outside home country'* sourcing, by conducting collaborative strategic-sourcing initiatives and entering into supplier relationships that ensure safeguarding against myriad potential risks, such as quality risks, related to suppliers. Strategic-sourcing helps in reducing the total number of suppliers, thereby, reducing the

overall risk exposure to suppliers. Similarly, the Supplier Relationships Management (SRM) initiatives ensure consistent product quality and greater flexibility in the supply chain, which is essential in the highly regulated pharmaceutical industry.

Implication: Utilise strategic-sourcing opportunities in raw material procurement and enter into SRM programs with the suppliers to ensure greater regulatory compliance.

Meeting Complex Customer Demands: Flexible/Adaptable Supply Chains

Along with the prevalence of global pharmaceutical supply chains, is the increasing complexity and sophistication of consumer demands. Risks associated with these demands are typically region-specific and need to be managed/mitigated at the regional level. To facilitate this process of risk mitigation across different regions, it is imperative for regional supply chains to be flexible and quick in adapting to regional conditions.

> "One of our biggest challenges is developing the ability to work together with supply chain partners, sharing access to our organisations. All have their own agendas." —*Vice President of Supply Chain, pharmaceutical company, Europe*

Implication: Ensure flexibility and adaptability of the supply chain to meet complex customer demands in different regions across the globe.

The adaptability factor in a pharmaceutical supply chain is critical to determine the success of any risk mitigation solution/ strategy. Increased outsourcing trends and sales to international markets have made it imperative for pharmaceutical companies to adopt country-specific or region-specific supply chain risk mitigation solutions. If careful assessment and planning is done before entering into outsourcing relationships, it can turn out to be an effective risk mitigation strategy. In cases where companies are sourcing from outside of the home country, it is imperative to evaluate their sourcing strategies in the light of cost-versus-risk proposition for different low-cost destinations.

CONCLUSION

Outsourcing and globalisation are two key factors that have had a tremendous impact on supply chain risk levels in the pharmaceutical industry. However, the industry has shown

CASE STUDY: LEADING US-BASED DIVERSIFIED PHARMACEUTICAL AND LIFE SCIENCES COMPANY

Challenge

- Developing a comprehensive Supplier Relationship Management (SRM) program, to be implemented across direct material supplier base
- Understanding key gaps, challenges and opportunities in current SRM practices
- Aligning stakeholders in support of a formal SRM program and developing a customised SRM model incorporating processes, tools and templates

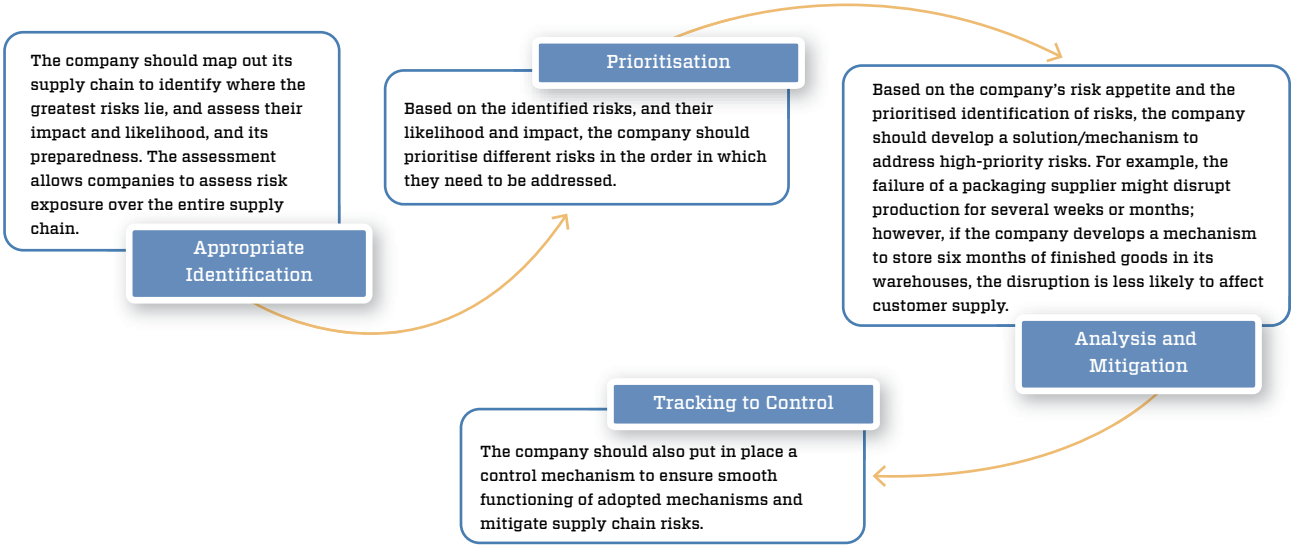
Solution

For addressing these issues, the company, with the help of a consulting company, developed an SRM programme. Under the programme, the consulting company reviewed supplier feedback, stakeholder requirements and existing resources to help define the stratification process and to strategically refocus resources. The approach also included designing governance processes and supplier development program, assessing training requirements and developing a communication plan to support implementation.

Results

- The SRM program was implemented across key raw material suppliers
- Under this new process, the client was able to improve risk management results with a key strategic contract manufacturer; the client successfully identified and resolved a potential quality issue
- The number of raw material suppliers was reduced 30%

FIG. 3: RISK MANAGEMENT PROCESS



that it can manage the risks associated with the process of globalisation (in production as well as sales), by altering the supply chain and by adopting different manufacturing routes and distribution channels, determined by the geography and the drug involved. Pharmaceutical companies will have to identify and implement new strategies and processes, supported by new technologies, to aggressively reduce and manage the new challenges it may face. With a proactive approach, the industry can reap the benefits of globalisation and, at the same time, efficiently manage its supply chain risks. **(Fig. 3)**

Going forward, supply chains will play a major role in their ability to adapt, consolidate or refocus their core business segments. Pharmaceutical companies will need to put in place the right supply chain configuration and adaptability, by using internal, external and country-specific resources to create best practice-based supply chains, and to overcome supply chain obstacles in a constantly changing global environment. ■

GLOBAL SUPPLY CHAIN MANAGEMENT
CASE STUDY: PFIZER

Challenge

Over the past decade, Pfizer experienced high growth through both market development and acquisitions. The company expanded rapidly and the production network grew to include over 100 facilities worldwide. The widespread network added supply chain and operations complexity. Each new acquisition brought different products, processes and technologies that needed to be integrated in order to deliver value.

Solution

Pfizer Global Manufacturing (PGM) launched a focused strategy aimed at reducing both cost and complexity. The plan included simplifying the manufacturing network and standardising processes and technologies globally. Instead of requiring all products and materials to be produced internally, Pfizer outsourced drug manufacturing to contract manufacturers. This initiative helped the organisation to reduce costs 25% and standardise the manufacturing phase of its supply chain.

Marshall Mathias, *Client Engagement Team*
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