Supplement to:

BioPharm INTERNATIONAL

March 2011

The Science & Business of Biopharmaceuticals

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Supply-Chain Transformation: Strategic Necessity for the Life Sciences

New supply-chain challenges, including counterfeits, are forcing companies to act in different ways to secure product safety.

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Fueled by the discovery and commercialization of blockbuster drugs, life-sciences companies have for decades enjoyed profitability and growth. Seemingly immune to the challenges faced by other industries, including the clothing and apparel, electronics, and automotive industries, companies in the life sciences have enjoyed ongoing investment, enabling the formation of new entities in the evolving biotech sector.

These halcyon days for the life-sciences industry are over. The combination of the expiration of patents for high-revenue products, failure of products within the discovery pipeline, and the global economic decline has cast a cloud of doom. Mergers, acquisitions, and consolidation are symptomatic of these issues and have created challenges for stakeholders and constituents, not the least of which is the pressure to reduce cost, improve cash performance, and either consolidate facilities or outsource manufacturing and other functional areas. Emerging econ-

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omies in the BRIC nations (Brazil, Russia, India, and China) as well as their satellite "factory states," are harvesting the benefits of this shift in operational focus, with industrial areas mushrooming up seemingly overnight to provide factories and human resources to meet the growing demand for so-called offshore manufacturing. Recognition of the importance of mastering a global network of operations, many components of which are now run by external parties through an ongoing trend to outsource perceived noncore functions, has placed a spotlight on the teams and leaders responsible for delivering quality products and services.

New business models elevate supply chain

As sources of supply and demand change, so must business strategies for the manufacture and distribution of life-science products. Supply-chain management, once considered a mere support function, is a crucial component of today's outsourcing environment. Executive suites have opened their doors to the focus, and many leadership teams now focus on supply- chain issues.

During the past decade, leading global companies have recognized the importance of supply-chain management, creating cross-functional teams to integrate their supply and demand operations. There are many examples within the electronics industry of companies that have created collaborative supply-chain environments facilitated by the combination of industry best practices at the process level and powered by information technology. Building on the foundation of "inter-enterprise" collaboration, facilitated by the adoption of a single technology platform (e.g., large scale entreprise resource planning systems), this model has been extended to include external players, delivering on the promise of the extended virtual enterprise.

Until now, buffered from the economic necessity to take such actions, life-sciences companies have been slow to follow. The increased requirement to reduce cost, complexity, and risk, however, has created a compelling case for collaboration across the global network of suppliers and third-party logistics providers and customers. Many companies are taking advantage of the capabilities of new partners—contract manufacturing provides a good option as new products find their way to market—especially in emerging economies. Outsourced relationship models should build upon the regional knowledge of the contract manufacturing or logistics providers to create a sustainable supply-chain network to meet current and evolving needs.

The fine balance between supply and demand

In common with big pharmaceutical companies, biopharmaceutial companies are reevaluating their supply chains and looking at outsourcing and contract manufacturing as a growth strategy. However, unlike traditional pharmaceutical companies, who are currently focusing on reducing costs, biopharmaceutical companies are more concerned about managing the risk factors that have been introduced throughout their extended supply chains. This difference was evident during presentations and panel discussions at the Biotech Supply Chain Academy event held in San Francisco, in October 2010. Concerns related to supply disruptions, particularly for single- or sole-source suppliers, were common. The impact of a shortage, or worse, contamination, of a key ingredient that could prevent manufacture of crucial compounds was a major concern. Whether considered from the viewpoint of financial loss, reputational risk, or patient safety, supply disruptions are a major challenge for biopharmaceutical companies. As products move from discovery to commercialization, stabilizing supplier relationships is crucial, but complicated. Projecting demand for new compounds requires close communication between manufacturers and healthcare professionals.

Companies are creating cross-functional teams to integrate their supply and demand operations.

An additional factor for consideration is an increasing focus on the patient, in many cases requiring specialized supply-chain management and oversight from manufacturing location to the end user. Because some biotechnology products are designed and developed to address issues for small patient communities, the sector has facilitated an environment of patient intimacy, with close cooperation between companies, caregivers, and beneficiaries. This advantage should be incorporated into supply-chain strategies.

Additional risk factors for biotech companies

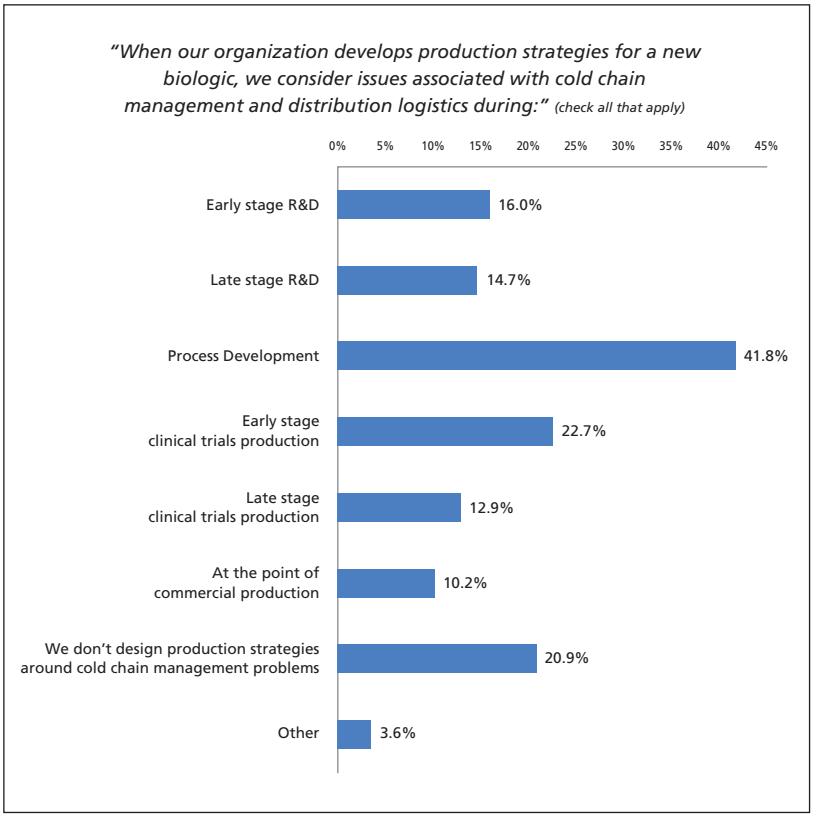
In the case of biotechnology products, the stability of the ingredients and components is a crucial element and one that needs to be managed across the product life cycle, from acquisition and transformation to distribution and consumption.

Cold-chain management is a key factor for nearly all biotechnology products. However, this challenge is not always taken into account during the transition from discovery and

product approval to the commercial-manufacturing stage. Figure 1 reflects responses on this topic from the Sixth Annual Report and Survey of Biopharmaceutical Manufacturing, conducted by BioPlan Associates in 2009.

According to Eric Langer, president of BioPlan Associates, "Cold chain management of biologics is becoming an increasingly important function in the overall marketing, manufacturing, and production of these products. If the infrastructure for delivering these products to end-users is not available, or is inadequately controlled, product quality and drug efficacy may be compromised. As global markets for biologicals expand, this has become an increasingly important issue."

Figure 1. Respondents indicate the phase of process development during which they first consider cold-chain management (Data reprinted with permission from the *Sixth Annual Report and Survey of Biopharmaceutical Manufacturing*, BioPlan Associates, 2009).



Counterfeiting and diversion

Counterfeit drugs are a growing global problem, one that the biotech industry shares with other sectors in the life sciences. While some of the most troublesome cases involving counterfeit drugs have flowed through traditional drug distribution channels, globalization of drug manufacturing techniques and direct-to-consumer product delivery *via* the Internet, mail, and direct-to-door carriers have formed new distribution channels for counterfeit drugs. Other issues include increased production of counterfeit pharmaceuticals and biotechnology products in locations that are sources of supply for legitimate products, such as China.

The introduction of counterfeit or diverted biotechnology products into legitimate channels is a real threat that requires oversight from brand owners and their supply chain partners. The impact of counterfeit drugs is felt across the whole supply chain—at times with fatal outcomes. There are a number of mechanisms and techniques either in use or in development and design to ensure that the biotech product is authentic and to combat counterfeiting. This includes a drug pedigree or, in conformance with pending California legislation, an ePedigree. (An ePedigree is an electronic record containing the information regarding each transaction resulting in the change of ownership of a prescription drug from the manufacturer through distribution to the dispensing of an individual unit of a drug by a pharmacy or hospital. Companies are required by FDA to maintain pedigree reports and must be prepared to have them audited.) With proper implementation and controls, the chain of custody for a pedigree document can be established, creating a high degree of confidence in the origins and authenticity of an item.

Forging the links across the chain of custody

Short product life cycles—that is, compounds and components that are susceptible to variations in temperature, vibration, and environmental factors—create challenges for all participants in the biotech supply-chain community. Visibility across the chain of custody in an increasingly global network has become a necessity.

When addressing the challenges of global logistics, with additional complexity of regulatory compliance, one should take into account both sources of demand and supply, providing additional oversight in the chain of custody. Product protection through specialized packaging and information technology components,

including temperature sensors, monitors, and auto-identification tools, should be introduced to ensure that delicate life-saving compounds are not compromised on the path from production to patient. Standards, policies, procedures, and processes to safeguard the security of the supply chain should be agreed to by all participants (no matter how small their role) and should be reinforced by clearly defined service level agreements and reporting mechanisms. With all company participants focused on the same goal of delivering a better quality of life to patients, true supply-chain transformation is possible. **BP**

Guiding principles for supply chain management.

1. **Educate the chain:**
   - It is crucial that all supply chain partners are aware of their role in ensuring safety and compliance
   - Service level agreements that are part of the legal terms and conditions of procurement and service contracts should be used to help ensure compliance
2. **Demand data collection excellence:**
   - In many cases, the technical capabilities of suppliers —or lack of it —can create constraints
   - Parties should understand and plan for data collection, capturing required data elements and required information through media in place and digitizing this as soon as possible
3. **Institute documentation and communication consistency:**
   - Documentation is crucial to ensure that the correct packaging, storage, and handling procedures are consistently applied
   - Communicate and share information with all participants in the chain of custody, taking into account language, literacy and other constraints
4. **Pay full attention to recall and destruction:**
   - It is all-important to ensure that members of the extended supply chain know what to do if the product has been compromised and spoiled
   - This should be clearly outlined in service level agreements between all players in the pharmaceutical supply chain
5. **Be obsessive in continuous monitoring:**
   - Take nothing for granted. Insist on timely and accurate records for product recall, processing, and destruction
   - Outsourcing is no excuse for negligence
   - Best practice companies put in place data analysis processes and human knowledge collection procedures to spot specific red flags in their end-to-end supply chains
   - Changes in cost elements, participants, trade lanes, and modes of transport should be investigated.