SUPPLY CHAIN MANAGEMENT AND THE IMPORTANCE OF SECURITY OF SUPPLY

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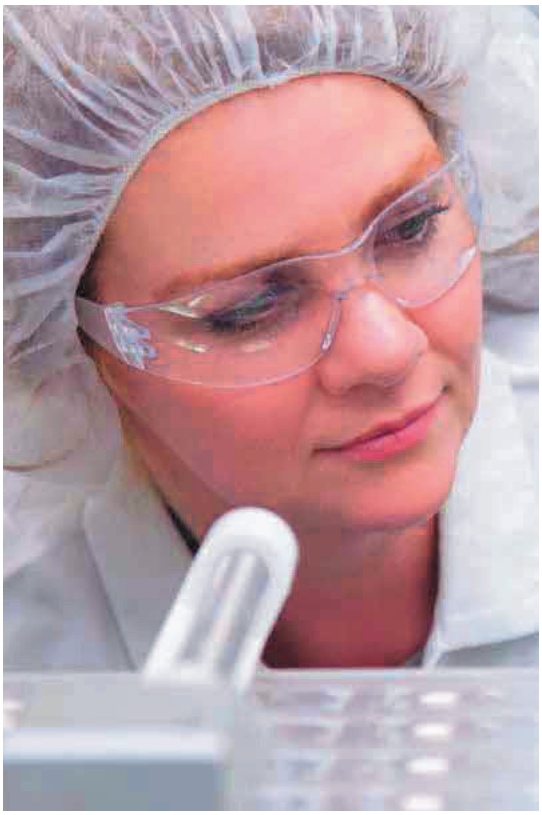

As global demands rise, supply chains are becomingly increasingly complex. Of course, with this increased complexity comes increased risk of error and, more significantly, increased risk of supply disruptions and drug shortages. In order to prepare for the possibility of unforeseen events affecting the supply chain, contingency plans are a priority. Alcami's innovative Protect Your Brand™ is a key example of this type of security service, offered through an outsourcing partner.

According to the FDA, 64% of all reported drug shortages are caused by quality issues (37% manufacturing, 27% delays/capacity) and another 27% are due to raw materials, so it's not surprising that the 2016 Nice Insight CDMO Outsourcing Survey showed quality as the most important factor when selecting a new outsourcing partner.[1,2] When a shortage occurs, companies face profit losses, damage to their reputation in the market and possible regulatory action, while patients – including those with chronic or life-threatening illnesses – are left without medication as healthcare providers scramble to find replacements when possible. In recognition of the risks associated with drug shortages and the importance of maintaining a sound supply network, many sponsors are actively pursuing contingency plans. Similarly, companies producing

drugs via reliable single-source supply networks are looking for zero-commitment, dual-supply protection options – a strong CDMO can become a valuable part of these strategies.

One such CDMO is Alcami, the alliance of AAIPharma Services and Cambridge Major Laboratories. Following the 2013 merger, Alcami became a leading provider of integrated chemistry, manufacturing and controls (CMC) services and, in October 2016, launched its new Protect Your Brand™ service to help pharmaceutical and biopharmaceutical companies alike establish a reliable dual-source supply chain. When dual supply is paired with innovative logistics solutions, the industry appears poised to continue minimizing the effects of drug shortages; however, risks in the supply chain continue to demand attention – management and partnership remain critical in the effort to keep operations moving.

CONTINGENCY PLANNING AND THE IMPORTANCE OF LOGISTICS

Contingency planning isn't new to the pharmaceutical or healthcare industry. In fact, according to the Eighth UPS® Pain in the Chain Survey, published in 2015 and focused specifically on the healthcare and life sciences industry, contingency planning was categorized as an area that needs attention, with the report noting that "unplanned events have impacted [6% of] healthcare supply chains in the last 3-5 years."[3] Regardless of this impact, only 60% of respondents to the survey viewed contingency planning as important. However, with global demands pressuring pharmaceutical companies to increase production volumes while continuing to speed development and drive costs down, contingency planning is only growing in importance. As production technologies become more advanced and sponsors continue to explore outsourcing options, including those in the emerging markets, many supply chains are becoming more complex than ever and the potential for both production and logistics issues is increasing.[4]

According to FedEx, "Finished pharmaceutical products represent about 4% of the total value of imported goods in the American import portfolio," and Ireland, Germany and Switzerland "[were] responsible for 46% of US pharmaceuticals import values in 2015."[5] With that volume relying so heavily on global logistics, it's critical for pharmaceutical manufacturers to understand how these goods are moving and, more than anything, what happens when shipments get stuck in customs or otherwise held up in transit. Just as many companies have found the value in establishing partnerships for outsourcing drug development and production, logistics partnerships are also beneficial.

Research from LogiPharma states, "66% of respondents indicated they currently outsource at least some part of their distribution and order fulfillment operations, and 67% outsource transportation management."[6] Logistics partners can help here by increasing supply chain visibility, offering import and export expertise, and providing specialized transportation and storage in the event of delays. FedEx, for example, recently opened a cold chain facility with approximately 1,000 square meters of temperature-controlled storage in Memphis, the largest port of entry in the US. However, logistics are only part of the problem facing the industry. Pharmaceutical and biopharmaceutical companies must also ensure that production proceeds as planned and, when it doesn't, that measures are in place to minimize downtime and, ideally, prevent shortages.

DUAL SUPPLY AND THE CONTINUED RISKS OF PARENTERAL DRUGS

Though drug shortages have decreased overall, to just 44 shortages reported to the FDA in 2014 – an admirable number following the spike in 2011 that brought 251 – the changing global supply chain and continued growth of biopharmaceuticals are keeping this risk relevant; of the 44 shortages reported in 2014, 68% were injectables, only a modest improvement since 2011.[2] Due to the comparatively shorter shelf life, specialized and costly storage

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requirements (e.g., temperature sensitivity) and sterile production requirements associated with biopharmaceuticals, quality problems frequently lead to shortages as many of these drugs are produced in an almost "as needed" manner. Further, in 2015 many existing biopharmaceutical companies were estimated to be operating at near capacity, while larger CDMOs were similarly estimated to be approaching capacity for both microbial fermentation (81%) and mammalian cell culture (71%).[8]

Though many pharmaceutical companies with legacy products may have significant inventory on hand or may be able to produce and store large quantities of the necessary API to weather production/supply chain issues, newer medications and biopharmaceuticals often cannot benefit from the same supply.[7] However, even the most minor excipients can change product characteristics and, as a result, require everything from preformulation analysis to regulatory-filing requirements, meaning that even those companies that might turn over inventory only twice a year are at risk if production delays occur.[9]

To make matters worse, supply chain preparedness issues typically span the entire chain, from sourcing to fill-finish, and these challenges are further magnified when dealing with biopharmaceuticals and parenteral medications in general. From 2002 to 2013, the demand for sterile injectables increased by 39% while the number of generic medications in this category increased by 57%.[8] With many legacy products likely to experience lower yields due to advanced technologies not being implemented on those lines and many generics manufacturers unlikely to feel any incentive to invest in manufacturing/infrastructure improvements due to smaller profit margins, the shortage risks in this area are still very relevant.[8]

Opening lines of communication along the entire supply chain — including suppliers, wholesalers, CDMOs and group purchasing organizations — can help by allowing companies to better forecast supply chain needs and possibly predict shortages in advance.[8] Contract development and manufacturing organizations are also uniquely positioned to help ensure the continued integrity of a supply chain. Engaging a CDMO partner can provide much-needed peace of mind, but selecting the right partner is key. More specifically, selecting a partner with capabilities that span both upstream and downstream processes for complex drug development and production — including sterile production and fill-finish operations — can allow companies to meet global demands and safeguard against the most likely shortages. Alcami has extensive capabilities and the capacity to provide analytical testing, development, prototyping and reformulation services for APIs with both oral-solid and parenteral- dose finished products.

PROTECT YOUR BRAND™

In addition to its industry-leading integrated offerings for both drug-substance and drug-product development, Alcami officially launched a service that can help ease the process of establishing a dual supply, at CPhI Worldwide in Barcelona in early October: Protect Your Brand™. Though Alcami strives to prevent production disruptions from occurring at any of its global facilities — three of which just completed FDA inspections with zero observations (Germantown, WI, Charleston, SC and Wilmington, NC) — the company also recognizes that unforeseen events can and have occurred across the globe and that all companies need backup. Protect Your Brand™ is a convenient, "no strings attached" — meaning no long-term contracts or commitment — dual-supply option that allows for the tech transfer and validation of drug substance and/or drug products in advance of potential production needs.

Even if drug shortages continue to become less frequent over the coming years, supply chain management and contingency planning will remain important. From unforeseen global disasters that can affect materials, supplies and shipments, to manufacturing challenges that halt production, a contingency plan can help reduce loss and ensure that operations return to normal as quickly as possible. When paired with its global presence and existing manufacturing expertise, Alcami and its new Protect Your Brand™ program combine to form a reliable partner capable of offering peace of mind in a supply chain with an increasing number of moving pieces. P

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Syed Husain, the commercial leader for Alcami, leverages in-depth experience in sales, business development, marketing and operations for the development and manufacture of small molecules, antibody drug conjugates, peptides and large molecules covering drug substance and drug product. Syed earned a BS in chemical engineering from New Jersey Institute of Technology in 2003 and an MBA from Cornell University in 2009.

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