DPT Thought Leadership
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MANAGING THE COMPLEXITIES OF GLOBAL PHARMACEUTICAL SOURCING

With the increased globalization and complexity of the pharmaceutical supply chain, managing the sourcing of materials has become extremely challenging. Reducing time and costs are important goals of sourcing, but increased regulations and more rigorous enforcement make these goals difficult to achieve. These trends have forced life science industry companies to optimize sourcing activities for raw materials, intermediates, active pharmaceutical ingredients (APIs) and other material components for clinical supplies and commercial manufacturing. If the sourcing function is not rigorously managed, these challenges can result in supply chain interruptions, unexpected expenses and quality control issues. In this challenging environment, companies are increasingly relying on highly qualified contract development and manufacturing organizations (CDMOs) to effectively manage the sourcing role.

This risky supply chain environment has pharmaceutical and life sciences executives concerned about supply safety, legal and regulatory compliance, and the timeliness of receiving materials. A report co-sponsored by Price Waterhouse Coopers,* based on a survey of 112 industry executives worldwide, found that 50 percent see raw materials sourced outside of the U.S. as the greatest vulnerability to the supply chain and 61 percent view contaminated or nonconforming raw materials as the top threat, although 78 percent believe global sourcing will be increasing. Only 25 percent stated they share common practices and information with suppliers, and nearly 60 percent said they are concerned about the willingness of suppliers to provide information to address regulatory requirements.

With appropriate resources and systems in place to manage these issues, CDMOs such as DPT Laboratories offer a turnkey approach to control costs, avoid disruptions and ensure quality across the supply chain. DPT has decades of experience in materials sourcing. Its purchasing department, in conjunction with its regulatory and quality assurance experts, has the resources, tools and expertise to provide clients with reliable, efficient sourcing.

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In this white paper, DPT discusses ways to overcome regulatory hurdles, avoid supply chain disruptions, ensure quality, gain price and scheduling advantages, and improve inventory management. The paper also includes a checklist of qualifications your outsource partner should have to ensure effective sourcing.

Navigating Increased Legal and Regulatory Hurdles

A growing number of U.S. agencies have become involved in the legal and regulatory processes for pharmaceutical material imports. In addition to the U.S. Food and Drug Administration (FDA) and Drug Enforcement Agency (DEA), the U.S. Customs Service and Department of Homeland Security play an increasing role. Homeland Security, for example, has added a significant number of regulations. A CDMO helps sponsor companies navigate the nuances and requirements of all legal and regulatory entities, including foreign government agencies and distributors, and U.S. distributors, certification agencies and regulatory authorities at the federal, state and local levels.

In many situations, advance notification of a shipment as well as supporting documentation such as end user (sponsor) letters, bill of lading, and packing slips are required before the export of a shipment can leave the port of origin. Understanding the documentation and timing requirements for importation is critical. When a shipment arrives at Customs, the importer of record, generally the sponsor company or its contract partner is responsible for ensuring the goods comply with local laws, filing required documents, and paying import duties. With an API import, the FDA follows certain procedures to ensure that it was manufactured by a drug facility that is in compliance with FDA drug establishment registration regulation and is an appropriate source for the API.

Managing these complex situations often requires direct communication with the regulating port agency as well as a thorough understanding of regulations. FDA compliance officers and import entry reviewers check for valid FDA registration at all ports of entry. Imports that are not in compliance with all FDA regulations or are from unregistered drug facilities are subject to FDA import detention, import alerts and refusal of admission. Lack of awareness of required regulations and noncompliance can result in long, unexpected delays and significant additional costs.

In most cases, these problems are avoidable, especially if companies work with a CDMO that provides the right regulatory help and guidance. On occasion, DPT has intervened to support a customer's attempts to have a delayed shipment released in a timely manner and with minimal financial risk, often resulting in transferring the sourcing function to DPT. DPT also provides regulatory submission support such as Chemistry, Manufacturing and Controls (CMC) preparatory services for IND applications to ensure fast, accurate submission.

While U.S. laws and regulations governing imports have not changed significantly in recent years, imported materials and ingredients have been undergoing more rigorous FDA scrutiny. Information about imports must be readily available even before imports reach the U.S. The FDA is increasingly using its import database to verify the status of an API, its manufacturer and whether it is referenced in a valid NDA or has a valid IND. The IND must be in effect before importing the API into the U.S. Advanced planning and working with a knowledgeable Customs broker and experienced quality and regulatory professionals are recommended.

DPT manages the entire import process, providing documentation and details to regulating agencies, which require a thorough understanding of the regulatory requirements. DPT also assumes responsibilities for each shipment until delivery to the U.S. destination, so clients are not faced with this often daunting job. DPT's staff, along with support from an established Customs broker firm, ensures the timely delivery of imported goods with a minimum of delays from import regulatory issues.

Avoiding Supply Chain Delays

Avoiding disruptions in the global supply chain typically requires more than just managing internal inventories, supplier lead times, delivery delays and having all the proper documentation in order. It also requires advanced planning to minimize environmental impacts and prevent delays. In advance of a shipment, companies must be aware of global geopolitical events and understand how they could impact the supply chain. To prevent a disruption, they must conduct a risk assessment of the supply chain and prepare a contingency plan to activate if the supply timeline is interrupted. The plan may include keeping a safety stock of materials or finished goods, or identifying and qualifying a secondary source, which help secure the supply chain while minimizing risks and cost.

Vigilance is not limited to political issues, and should include situations such as unpredictable weather and changing market trends. In recent years, DPT has experienced supply chain interruptions from extreme weather -- such as hurricanes, the 2010 tsunami in Japan, flooding in Southeast Asia and droughts in New Zealand -- but an effective contingency plan helped minimize damages.

The decline in market demand of one commodity can directly impact the supply of another. Chemicals produced as a by-product of other manufacturing processes are highly susceptible to supply chain interruptions. For example, DPT experienced a situation where the decline in the automobile industry affected the supply of a chemical commonly used in pharmaceutical laboratories. Had DPT been unaware of the manufacturing process and associated risk, they might have encountered a shortage. Because DPT had a close relationship with the supplier and knowledge of the risk, they were adequately prepared for the supply chain constraints, while many other industry companies suffered setbacks.

DPT analyzes risk in the supply chain for anomalies that might disrupt the supply chain, and has management systems in place to rectify problems. Delays resulting in a lost shipment or spoiled product can cost millions. If an emergency occurs, the CDMO must communicate with the sponsor, supplier, regulatory agency, or other entity involved to ensure swift corrective actions are taken.

Ensuring Quality

Mitigating risk is an important consideration in purchasing decisions. In addition to having contingency plans for unexpected issues, ensuring supply security involves strategies such as using market intelligence, procuring from multiple sources, quality audits, effective communication, and long-term supply agreements with the most highly qualified, reliable suppliers. Weighing the cost advantages of imports against quality and supply continuity is a critical consideration in the choice of suppliers.

Maintaining careful oversight of the supply chain, the CDMO should understand the inherent vulnerabilities and risks of each product, the methods by which it is packed, transported, stored, imported and distributed, and ensure the ingredients are authentic. At DPT, the specifications for each material purchased -- from chemicals and APIs to packaging components -- are maintained in a quality information system. When an order arrives, Quality Assurance checks the materials against the specifications and conducts a rigorous inspection. Samplings of all materials are performed following American National Standards Institute guidelines.

Whether sponsors require sourcing from their qualified suppliers or rely on their CDMO to choose suppliers, spending extra effort on due diligence to qualify sources can make a big difference in ensuring the supply quality. If required to use the sponsor's suppliers, DPT audits each supplier. If there is any indication the supplier is not suited, the sponsor is encouraged to reconsider.

An experienced CDMO will have long-established, flexible relationships with reliable, reasonably priced suppliers who have a good track record, have demonstrated their loyalty, and make every effort to provide safe, high-quality materials in a timely manner. With hundreds of suppliers in its network, DPT has forged strong relationships with a few who go the extra mile to secure each shipment. DPT offers its customers a selection of appropriate suppliers and commodities that have qualified through its rigorous audit and evaluation program. Key suppliers are monitored quarterly through an evaluation program based on quality, on-time delivery, lead times, price and service. DPT maintains a scorecard system throughout the year and reviews results with each supplier to ensure continuous improvement. Failure to exhibit progress removes the supplier from the program. DPT also conducts an initial audit to qualify suppliers followed by periodic audits.

Another essential element to mitigate risk is effective communication. Beyond the initial negotiations, purchasers should clearly communicate to key suppliers their global supply chain objectives and their importance. Sponsors, CDMOs and suppliers should be able to determine the status of shipments in real time, and should agree on corrective actions and communication plans to implement if issues arise.

Optimizing Costs, Timing and Inventory Management

Pharmaceutical companies can benefit from the economies of scale provided by a CDMO, which leverage the combined volumes of many customers and commodities to keep escalating material costs to a minimum. This enables both pricing and scheduling advantages, which may not be available to a pharmaceutical company that sources internally. CDMOs also leverage their relationship with key suppliers to gain customer benefits by considering all special customer arrangements with the supplier, including contract pricing, minimum order quantities and reduced lead times.

When deciding whether to outsource purchasing services to a CDMO, be sure to factor in all costs not directly associated with the piece price of the item. Consider the costs of qualifying and auditing each supplier, required resources and technology, and additional material costs.

A CDMO's purchasing service should include inventory management systems that ensure efficiencies throughout each step of the procurement process. DPT introduces an item into its enterprise resource planning (ERP) system after a thorough review of the supplier's qualification credentials and receipt of material specifications. Before committing to place the order, the procurement manager assesses the request, and prepares for any special handling, testing and storage conditions the material may require and any identified potential supply chain issues. Procurement of the item can only occur after all requirements are met, minimizing regulatory and financial risks. DPT also uses its ERP and quality systems to develop customized reports that facilitate retrieval of historical information. Records of ordering patterns, lead times, volumes, on-time deliveries, price and forecast fluctuations, and quality data are extremely valuable when attempting to secure the supply chain and negotiate pricing.

How Qualified is Your Outsource Partner?

Use the following checklist to determine whether your outsource partner has the appropriate qualifications to effectively manage your materials sourcing.

- A strong knowledge of global regulatory requirements and industry standards for importing pharmaceutical materials
- Expertise, considerable experience, resources, and strong project management skills in global sourcing
- Resources and technologies to efficiently manage the global supply chain
- Broad supplier base, including several established, high-quality, reliable suppliers

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- Effective collaboration between CDMO and sponsor, suppliers, shippers, etc.
  - How well and frequently do they communicate and provide data in real time?
  - Does the CDMO share information and common practices with suppliers?
  - Does the outsource partner understand your objectives and requirements?
- A risk-based approach utilizing:
  - A formal, robust quality agreement with suppliers
  - Initial supplier review, checking nonconformance and on-time delivery data
  - Continuous supplier/project oversight with periodic audits and frequent analysis
  - Reliable communication
  - Effective responses to deviations: i.e., swift corrective action when material or documentation does not comply with U.S. requirements
- Reasonable costs and solid record of on-time delivery

CONCLUSION

Increased globalization and more stringent enforcement of increasingly complex import laws and regulations have made pharmaceutical sourcing extremely challenging. Partnering with a CDMO that has considerable experience and a strong track record of effective supply chain management can prevent costly delays and steep penalties. Forward-thinking CDMO purchasing managers practice vigilance by thoroughly assessing suppliers, understanding and accurately fulfilling current regulatory requirements, establishing preventive and corrective action plans, and effectively communicating with all parties involved. DPT Laboratories has the established people, knowledge, processes and tools to efficiently and reliably manage a supply chain immersed in an extremely complicated and dynamic regulatory/compliance environment.

*Global Supply Chain Visibility, Control and Collaboration: Business Imperative, Regulatory Necessity. Research report co-sponsored by Price Waterhouse Coopers and published by Axendia. Pharmaceutical Executive. December 2010. http://blog.pharmexec.com/2010/12/06/what-happens-when-the-pharmaceutical-supply-chain-goes-global-how-to-let-it-not-be-more-counterfeiting-intellectual-property-theft-and-contamination/

ABOUT DPT LABORATORIES:

DPT is a contract development and manufacturing organization (CDMO) providing companies the best solutions to their sterile and non-sterile pharmaceutical development and manufacturing needs through innovation, technology, and service. Specializing in semi-solid and liquid dosage forms, DPT has a reputation for quality, unmatched technical expertise, extensive manufacturing capabilities, and an exemplary regulatory compliance record. With five cGMP facilities in San Antonio, Texas, and Lakewood, New Jersey, DPT offers full-service outsourcing solutions, including stand-alone development, site transfers, state-of-the-art manufacturing, packaging, and worldwide distribution.

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