SPECIAL REPORT

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Managing a Safe, Secure, Global Supply Chain That Includes Contract Partners

RESOURCES AND BEST PRACTICE FOR MEETING THE DAUNTING COMPLEXITY THAT IS TODAY'S PHARMACEUTICAL SUPPLY CHAIN.

NEXT

CONTENTS

INTRODUCTION

Supply Chain Management:
What You Need to Know to Optimize Efficiency

Supply chain management has become increasingly complex, especially with increased globalization. This eBook outlines four challenging aspects and offers solutions to ensure success while minimizing interruptions, unexpected expenses and quality control issues.

The first article discusses potential problems of the controlled substance supply chain for companies lacking in-house capabilities and resources. Controlled substances are highly regulated and must be vigilantly monitored from the laboratory to the marketplace. In addition to abundant federal and state regulations, globalization — with its stringent import and export restrictions — has made compliance even more challenging.

Managing the sourcing of materials has also become extremely challenging. Reducing time and costs are important goals, but increased regulations and more rigorous enforcement make these goals difficult to achieve. These trends have forced companies to optimize sourcing activities for raw materials, intermediates, active pharmaceutical ingredients (APIs) and other material components for clinical supplies and commercial manufacturing.

Connecting key information systems ensures suppliers all pull in the right direction. Consider the benefits pharma manufacturers can reap by enabling the sharing of critical information about product quality and manufacturing efficiency. Meshing quality, manufacturing, laboratory and other business information systems can help accelerate understanding of potential quality problems and support a faster resolution of plant floor issues.

The last article discusses harmonizing the Quality Management System to extend to CMOs and suppliers. It details four reasons why you should do it and three reasons why you're not. The idea of harmonization involves creating a standard process for all quality and compliance, regardless of the location and operational area. Many organizations have trouble seeing their data if the processes are disjointed from one area to the next.

Effective Controlled Substances Supply Chain management

What you need to know to ensure compliance and optimize efficiency

AT A TIME when supply chain management has become increasingly complex, managing the unique challenges of the controlled substance supply chain can seem daunting for companies lacking in-house capabilities and resources. Controlled substances are highly regulated and must be vigilantly monitored from the laboratory to the marketplace to prevent theft and illicit sale in the black market, a growing trend. In addition to abundant federal and state regulations, increased globalization — with its stringent import and export restrictions, permits and declarations required for controlled substances — has made compliance even more challenging.

Effective management of the controlled substance supply chain and navigation of the regulatory process with minimal costs and delays requires considerable time, effort and expertise. For a drug company and/or its contract development and manufacturing organization (CDMO), management calls for rigorous attention to compliance, thorough planning, robust risk-management capabilities and the skills for effective implementation. Understanding and complying with federal, local and, if applicable, global regulatory requirements of your supply chain destinations is critical to prevent delays and penalties. With supply chains growing faster than resources today, many companies producing controlled substances are outsourcing to gain the needed expertise, efficiency and

flexibility. Partnering with a CDMO experienced in supply chain management of controlled substances can prevent costly delays, steep penalties for noncompliance, and the potential postponement of a clinical trial.

CONTROLLED SUBSTANCES: SCHEDULED DRUGS AND LISTED CHEMICALS

A controlled substance is a drug or chemical substance that is highly regulated under the Controlled Substance Act (CSA). The foundation of the CSA is a five tier "schedule," a classification system for drugs based on their abuse potential, with Schedule I having the highest potential. The schedule generally dictates the degree of precaution used with the substance in the clinical supply chain. Products or actives can move up or down in the schedules as determined by the Drug Enforcement Administration (DEA), or be added to or deleted from the schedules, and an active can be in a different schedule than the finished product.

SCHEDULE I

- High potential for abuse and no accepted medical use in treatment in the U.S.
- Lacks accepted safety for use under medical supervision
- Investigational drugs for actives not currently approved for use in the U.S.
- Examples: dronabinol, marijuana, heroin, crystal methamphetamine

SCHEDULE II

- High potential for abuse
- Currently accepted medical use in treatment in the U.S., or accepted with severe restrictions
- Abuse may lead to severe psychological or physical dependence.
- Examples: fentanyl, hydrocodone, hydromorphone, methamphetamines, methylphenidate, morphine

SCHEDULE III

- Abuse potential less than Schedules I and II
- Currently accepted medical use in treatment in the U.S.
- Abuse may lead to moderate or low physical dependence or high psychological dependence
- Examples: buprenorphine, dronabinol (marinol), ketamine, testosterone

SCHEDULE IV

- Low potential for abuse relative to Schedule III
- Accepted medical use in treatment in the U.S.
- Abuse may lead to limited physical or psychological dependence relative to Schedule III.
- Examples: diazepam, clonazepam, midazolam

SCHEDULE V

- Low potential for abuse
- Accepted medical use in treatment in the U.S.
- Abuse may lead to limited physical or physiological dependence
- Examples: codeine-containing cough medications, diphenoxylate (Lomotil)

LISTED CHEMICALS

Listed chemicals (List I and II) are specifically designated chemicals and precursor chemicals that, in addition to their legitimate use, are used in the illicit manufacture of a controlled substance in violation of the CSA .

For example, pseudoephedrine HCl is referred to as a scheduled List I chemical because it can be converted to methamphetamine. Acetone is a List II chemical.

REGULATION OF CONTROLLED SUBSTANCES
Three treaties establish the framework for an international drug control system and the statutory basis of the Controlled Substance Act of 1970, as well as most of U.S. drug control policy. Their purpose is to limit the use of narcotic drugs and psychotropic substances and their precursors to legitimate medical and scientific purposes. The role of the DEA is to assure the U.S. meets the treaty commitments by enforcing the provisions of the CSA and regulations of the U.S., including the manufacture, distribution and dispensing of controlled substances.

The DEA has decentralized the enforcement of diversion control operations. Each local office has significant autonomy, with local interpretation and enforcement of regulations.

There are also separate state regulations of controlled substances, which frequently change. For example, a state may have more stringent requirements for substances with the highest abuse in their state. It is important for the manufacturer or its service provider to know the regulatory nuances of each state and DEA office along its supply chain route.

Navigating the maze of regulations and managing the required paperwork demands considerable skill, time and expertise, as well as meticulous planning.

Registration, Records and Reports

A CLOSED DISTRIBUTION SYSTEM
The CSA created closed system of distribution for controlled substances. Every person and company authorized to handle controlled substances along the supply chain must be registered with the DEA and keep records with respect to all transfers.

In addition to substantial registrations, two other requirements contribute to the complexity of the controlled substance supply chain. First, to prevent diversion, it is essential to account for and report the location of all drug supply as it moves from one DEA-registered activity to another — such as distribution to a wholesaler, any lost in manufacturing or testing, and the remainder from clinical trial.

Second, the manufacturer/distributor must also report suspicious orders to the DEA. The DEA expects the distributor to know its customers, and be able to flag unusual orders

— such as orders of unusual size or frequency, and those deviating substantially from a normal pattern.

REGISTRATIONS

Manufacturers/distributors must obtain a DEA registration to handle controlled substances. A controlled substance registrant can also be registered to handle listed chemicals.

In some cases, multiple registrations may be required, depending on the type of activity and location. Beyond the basic security and record-keeping requirements for all schedules, Schedule I, II and III (narcotics) have additional documentation requirements. For the clinical supply chain, multiple registrations are typically required. Clinical trial research protocols for Schedules I and II must be submitted to the DEA for prior approval before the materials can be shipped.

Most states require a separate registration for controlled substances. The DEA will ask for proof of registration with the state before approving and upon each renewal application. Registrations may also be required for each state to where the product is being shipped — this can often be a major challenge and cause shipping delays.

Importing or exporting a listed chemical requires a separate registration. In certain circumstances, a registration can be amended to add a new controlled substance in the schedule — and in some cases, it is not required.

Registrations can have a narrow or wide scope. For example, an exporter may only export, whereas an importer may distribute what it imports. A manufacturer may test material it manufactured or ship the material to another location within the U.S. However, it may not import, export, or receive samples for testing from another registration. Normally each physical location requires a separate registration, but not always. Often one location will have multiple registrations such as export, import, listed chemical import, manufacturer, distributor, and analytical.

RECORDS AND REPORTS

All DEA-related records must be retained for a minimum of two years. These include documentation of purchases, shipments, material consumed in testing, batch and waste disposition.

Quarterly reports must be submitted to the DEA regarding the movement of all Schedule I and Schedule II raw materials, standards and finished goods, and raw materials and standards of Schedule III narcotics. Annual reports must be submitted to DEA regarding movement and inventory for Schedules I and II materials and Schedule III narcotics as well as selected psychotropic agents as required by international treaty. Inventory must be conducted at least biennially and records documenting receipt and disposition are required.

Exporting and Importing Challenges

Exporting controlled substances demands careful planning, allowing adequate time for each step. The number of countries to which a controlled substance is being exported, and each country's regulations, determine the complexity of exporting. Applicants who can submit the required paperwork must be registered with and authorized by the DEA to export controlled substances.

Adding a drug to a DEA Export Registration requires a written request to the local DEA office requesting an amendment to the registration. The response time from the DEA can range from one to more than six weeks. If you are outsourcing this function, be sure to provide all needed information to your CDMO in a timely manner, including ports of entry/export, mode/name of transport/transporter, and dates of departure/entry, as well as the addresses for each destination and re-export recipient, or the letter of no re-export.

Ensuring an Efficient Supply Chain

The starting point for successful, compliant supply chain management of controlled substances is a project management team that includes participants with demonstrated expertise in the regulatory requirements,

transportation, logistics and storage of these materials. Whether you are working with a service provider or managing the supply chain internally, here are considerations for maximizing efficiency and accuracy while reducing delays and potential penalties.

PLANNING

Begin planning with the DEA as early as possible. If you are working with a CDMO, provide detailed information in a timely manner. The sooner the supply chain manager knows what is required and when, the better the chances of effectively navigating shipping, regulatory, and storage requirements. If importing and exporting are considered well in advance, they should not impact time to market.

Start by developing a definitive plan for production and sharing the plan with your CDMO. Determine drug strengths, package sizes, batch sizes, number of batches, and targeted production date. Include:

- What are the intended primary and secondary package sizes?
- Where do you plan to market the product?
- When do you plan to submit the application to the FDA?
- Who will be your distributor and where are they located?
- Are DEA List I chemicals required to manufacture the product?
- What is the plan for handling unused clinical materials?
- What is the controlled substance/impurity-related substance reference standard? Will it cause a delay in testing raw materials or products before they can be released for distribution?

The supply chain manager will then develop a detailed plan with targeted dates for movement of materials.

MANUFACTURING AND DISTRIBUTION

When determining the shipping schedule, the sooner the CDMO knows what is to be shipped and to whom, the less likely the chance of a DEA-related issue. The CDMO should coordinate with the recipient to assure receipt of any required documentation well in advance of shipping, and must first obtain confirmation of each recipient's DEA registration.

Schedules I and II substances require DEA Form 222, and in some instances a Certification of Available Quota from the recipient. All Schedule I and II substances and pseudoephedrine require a quota from the DEA, which can take 8 to 12 weeks to obtain and is one of the most significant barriers to beginning distribution. Your service provider needs a letter of intent from your company stating the number of batches planned to include with the quota application.

Depending on the schedule, adding a new active or finished product may require an amendment to the registration. In some cases, a DEA inspection may be required prior to approval, usually involving a storage issue. The schedule can also impact the type of storage space required for raw material, finished goods pending shipment, samples and waste.

Occasionally a reference standard has a different controlled substance schedule than the active ingredient. This may require amending a registration and possibly applying for quota to purchase the standard if purchased under the manufacturing registration.

CLINICAL TRIALS

Timing and compliance are critical to ensure materials reach clinical trial sites on time. Failure to follow all regulations can lead to costly delays and regulatory audits or investigations. If the recipient/investigator and a third party responsible for clinical labeling do not have the appropriate DEA registration, the trial can be delayed.

The procedure for unused trial material is particularly important for controlled substance products that require a quota. The best approach is for the site to arrange a transfer to a reverse distributor. In some cases, the manufacturer may not have sufficient quota to buy back unused clinical trial materials.

STORAGE

DEA regulations have specific storage requirements for controlled substances. Schedule I and II material must be stored in a vault or other structure approved by the local DEA office, depending on the type of registration. Schedule III to V material may be stored in a caged area built to the specifications provided in the regulations. The local DEA office makes the final call as to what is appropriate.

COMMON ISSUES: AVOIDING REGULATORY PURGATORY

One of the most common reasons companies receive fines or noncompliance warnings from the DEA is failure to identify and report suspicious orders both for controlled substances and listed chemical sales. It is important to vigilantly monitor sales and flag any unusual orders of commonly abused substances.

Another reason is incomplete or inadequate documentation, resulting in lack of traceability. A qualified service provider will ensure that all required documentation is accurately completed and efficiently submitted.

CONCLUSION

Maintaining the supply chain of controlled substances from development to the final destination is more challenging than ever. As supply chain dynamics grow in complexity, life science companies responsible for controlled substances are recognizing the need for considerable expertise, vigilant oversight of processes and movement of materials, and substantial attention to regulatory requirements.

Increasingly, they are realizing the value of strategically partnering with a highly competent CDMO to gain needed efficiencies and a competitive edge.

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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.

In this article, DPT discusses ways to overcome regulatory hurdles, avoid supply chain disruptions, ensure quality, gain price and scheduling advantages, and improve inventory management. The article 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. The company 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
- 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

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.

CAPITALIZING ON THE OUTSOURCING OPTION

This document explains how and why a contract development and manufacturing organization (CDMO) can help your business thrive under changing market conditions. It also provides tips for initiating, building and maintaining a service provider relationship that benefits both parties.

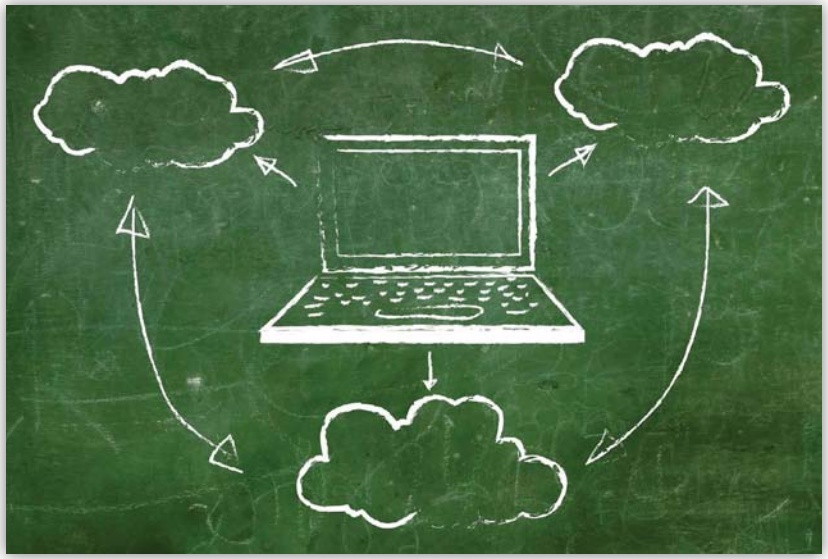
CLICK HERE

Harnessing IT to Strengthen Relationships

Connecting key information systems assures your suppliers all pull in the right direction

BY DOUG BARTHOLOMEW

IT'S 2013. Do you know where your drugs are on that other guy's plant floor? You should. Unfortunately, pharmaceutical companies often lack the visibility they need to carefully manage their contract manufacturers and contract development organizations' performance.



That's surprising, considering the benefits pharma manufacturers can reap by connecting key IT systems enabling the sharing of critical information about product quality and manufacturing efficiency. First and foremost, meshing quality, manufacturing, laboratory, and other business information systems can help accelerate understanding of potential quality problems and support a faster resolution of plant floor issues. In other words, by expanding the flow of information between pharmaceutical companies and their contract drug manufacturers, both entities stand to gain. The payoff is greater visibility into operations, better information on which to make business decisions and easier tracking of manufacturing exceptions.

As pharmaceutical firms' dependence on contract manufacturers has increased, the need to expand and speed up connections with suppliers has intensified. While many of the most prominent pharmaceutical companies have connected business systems such as enterprise resource planning systems (ERP) with those of their outsourcing partners for supply-chain purposes, those that have connected other pharma-related IT systems — CAPA, LIMS, QMS, MES and enotebook systems — tend to be far fewer.

MINORITY REPORT

Of the 173 pharma industry professionals who responded to a *Pharmaceutical Manufacturing* magazine survey last year, only a minority reported that their firms had connected their various internal quality systems with those of their outsourced manufacturers.

For example, about one-fourth (24%) said they had integrated their corrective and preventive action (CAPA) systems with those of their suppliers. Only a limited number of respondents (13%) said they were using technology to connect their quality management systems (QMS) or similar IT platforms with those of their contract suppliers. Finally, one-fifth indicated that they had set up dashboards to electronically monitor key performance indicators (KPIs) for their contract partners.

Clearly, by strengthening connections with their contract suppliers through better, more extensive integration and application of various IT systems, pharmaceutical manufacturers stand to reap a host of benefits. One of the most obvious places to start is automating the workflows supporting various processes.

Another factor driving the increased use of technology for information sharing is the need to provide serialization.

"The more you use technology, the better off you are in terms of efficiencies," says Tee Noland, chairman of Pharma-Tech Industries, a pharmaceutical contract manufacturer in Royston, Ga. "Connecting our ERP system with our customer Johnson & Johnson saves a lot of time for them, because we do a lot of the supply planning for them. For instance, with Johnson & Johnson, we manage our inventory in their distribution centers," Noland says. "It saves a lot of time for them, because we do a lot of the planning. And of course, if they have a promotion, we have to boost our inventory to meet the increased demand."

Pharma-Tech, which uses an ERP system from Syspro, depends on it for a variety of information essential to the company's successful providing of services to its customers. "Our ERP system gives us information on inventory, scheduling, production, production efficiencies, and materials ordering, as well as financial information," Noland explains. "We also have our own homegrown databases to track quality issues and any non-conformances."

Each shipment from Pharma-Tech to Johnson & Johnson is accompanied by an electronic notification that the shipment is en route. In a similar fashion, once each week, Johnson & Johnson sends Pharma-Tech an XML-formatted file containing a forecast for the products the contract firm needs to provide. "I take their forecast and import it into our system, and we use that to schedule our production," says Kristin Brown, customer service and planning manager at Pharma-Tech. In the next step, Brown uses the electronic forecast to do the materials planning for the customer. "We receive the forecast file and then go in and do the planning for them," she says. She connects with the Johnson & Johnson SAP system through the pharmaceutical company's SAP portal. "We see their inventory and sales, and then we do the planning and supply chain work for them," Brown adds.

Still, many of Pharma-Tech's customers are smaller drug makers that continue to use purchase orders, sales forecasts, and other non-electronic means of communicating with the contract firm. For quality-related issues, Pharma-Tech's quality department sends the appropriate forms to the customer's website or portal.

“For the most part, with our smaller customers,” Brown says, “they email us their purchase orders, and we manually type them into our system. For a broad supply chain view, it’s better to have all the information imported directly into our system.

“Overall,” she adds, “If we had more electronic connections with our customers, it would bring improvements, including better planning, better decision making — for our own company and for the customers as well — greater visibility, and the ability to order in bigger chunks. And it gives us better flexibility in scheduling the workload.”

Pharma-Tech also is able to share certain financial information with customers. For instance, the company shares pricing data for raw materials used to manufacture their products. If the cost of raw materials goes up during the year, Pharma-Tech is able to recover the variance in the purchase price by pulling the purchase information out of its database into a spreadsheet that displays the variances. “If there are price changes during the year, we want to get the money back if the cost of goods went up, or we may have to reimburse them if the costs were lower,” Brown explains.

Another factor driving the increased use of technology for information sharing between pharma companies and contract manufacturers is the need to provide serialization of products to facilitate tracking and tracing. For instance, some larger pharma companies are using their ERP systems to provide the serial numbers to be used by CMOs, which in turn, communicate back to the pharma OEM a status report.

“The CMO will provide an overall ‘statusing’ of which codes were used, which were not used, and which were for products that were pulled for quality sampling, or where the labels did not come out right and the product was scrapped,” says John Danese, Senior Director of Life Sciences at Oracle Corp., one of the leading ERP vendors.

Despite the apparent benefits, many pharmaceutical companies have been somewhat slow on the uptake to embrace the sharing of various kinds of information with contract suppliers. “I think the bus is about half full, with some pharmaceutical companies yet to get on board,” Danese observes. “For some CMOs, their idea of advanced communications is a fax. There is a broad spectrum of maturity among companies in the way they deal with their partners.”

Looking ahead, Danese believes that in the next few years, the industry will more fully embrace the electronic sharing of product quality information between pharma companies and their outsourcing partners. “The exchanging of quality information electronically is a bit down the road,” he says. “I think we’ll see a larger uptake in the next three to five years.”

In fact, the sharing of quality data has historically been an area where pharma firms have lagged. While most pharmaceutical firms have a CAPA system in place, those systems’ lack of connectedness or integration to larger systems such as ERP has been a serious stumbling block to information-sharing between drug manufacturers and outsourcers. One reason is that CAPA systems often are not connected with other plants or with systems that can measure overall process effectiveness.

Nonetheless, connecting CAPA with ERP promises huge potential benefits. The chief goal is to ensure that everyone who needs to know about — or act upon — production miscue or quality problems, has easy and immediate access to the necessary data. The ability to both trace a batch of material to the source as well as to access all documents associated with it through the production journey can be very helpful in correcting and preventing future occurrences of similar problems.

Compared to the pharmaceutical industry, the high-tech industry is light years ahead in terms of information sharing with contract partners. Of course, outsourcing has long been a way of life for electronics firms, which often have little or no manufacturing of their own, but instead depend on an entire ecosystem of semiconductor foundries, assembly makers, and test providers to handle production. Many high-tech companies outsource logistics and warehousing as well, and some even outsource every aspect of their business.

But in a highly regulated industry like pharmaceuticals, there is an even greater need for information sharing and stronger ties between manufacturer and CMO. “We see pharmaceutical companies sharing quality data both ways, manually and electronically,” says Elaine Schroeder, vice president of sales at Pilgrim Software, a provider of quality and compliance management systems.

From a quality standpoint, OEMs must first certify the supplier through an audit to determine that the contract firm adheres to standard operating procedures and GMPs. For instance, if a packaging non-conformity has been identified at the CMO, the pharmaceutical company may require the outsourcer to report on the problem electronically. “Pharma companies that have a quality management system may require the packager to respond through their supplier portal,” Schroeder says. “But some respond through faxes or other means,” she adds.

“Usually if the pharma company issues a change in supplier materials, they will communicate this through a supplier portal,” Schroeder points out. On the sharing of CAPA data, Schroeder says, “It’s not all that complex to have one CAPA system feed another CAPA system.”

Yet another challenge facing many pharmaceutical firms is, ironically, an internal one — too many versions of the same ERP system that have yet to be consolidated into one. This

lack of consistency within an organization inhibits the smooth sharing of data with outsourcers. “We have a well-known medical device company with three versions of SAP that don’t communicate with each other,” Schroeder says. “Another client has more than 60 versions of their call-center software, so they are not even treating their customer complaints in any homogenous way.”

Companies that have a manufacturing execution system (MES) in place have a leg up when it comes to collaborating with contract suppliers, Schroeder explains, because they have more detailed production data already on tap. Certainly in the high-tech industry the use of an MES with web-based access at both the electronics manufacturer and the contract outsourcer provides:

- Demand signs to the contract partner
- A view of current production status at key points
- Quality data
- Data for measuring supplier performance

Much of the impetus to adopt these technologies in the pharmaceutical business can be attributed to action on the part of regulatory agencies. “I think the regulatory bodies are providing the push in certain sectors of the industry, such as in the medical device area,” Schroeder says. Device makers are required to do electronic submission of product deficiencies or non-conformances to a regulatory agency, she adds.

“There is a great deal of interest in expanding connections between pharma companies and their contract manufacturers,” Schroeder adds. “But the contract manufacturers look at it as a way to get a competitive advantage by having a QMS in place.”

Still another stumbling block preventing the industry from fully embracing more IT systems for collaborative purposes is a widespread concern among pharma companies over exposing their proprietary information to others. “The pharma industry still has a real fear of exposing their quality systems to suppliers,” says KR Karu, pharmaceutical industry solution director at Sparta Systems, a provider of quality management systems.

“When it comes to the business systems, there is a back-and-forth of data sharing between systems,” he says. He cites just-in-time ordering data utilizing shared inventory information, shared purchasing information and other supply-chain data that is routinely provided by pharma companies to their outsourcers, and vice-versa. Not so, however, with product quality data, which often is kept within the manufacturer’s systems.

By contrast, Karu points out, “In the high-tech world, the electronics firms’ partners are in their systems as if they work there.” Although most pharma companies adopted quality management systems years ago for use inside their own firms, few were willing to share that data with their contract suppliers. The result has been that many drug companies now find themselves handling quality issues the old-fashioned way. “Now that the industry is moving to more of a real supplier base, pharma companies are dealing with quality problems through phone calls, faxes and emails,” he says. “There are quality issues falling between the cracks, I am sure, as a result.”

The gains to be had by sharing quality data, however, far outweigh any concerns over data security, asserts Sparta’s Karu. “For example, when you have a manufacturing deviation,

you are not sure what the cause is, and having all hands on deck throughout the supply chain is important," he says. "You need visibility and transparency across the organization. If you have a supplier that fails, you need to know right away, so you can find another supplier somewhere in the world who can provide this service."

Standardization of data is another key area for collaboration between the pharma firm and the contract provider. "One of the top life sciences companies is working with us to take standard procedures and standardized data so that everyone is doing things the same way," explains Ken Rapp, managing director and senior vice president at Accelrys, a provider of lab execution and management systems. "As a result, we are now getting real transfer of process data between systems."

This kind of connectivity between systems at different partner companies has been extremely difficult up until now, Rapp asserts. "It's been nearly impossible to get the job done in the past, but I think there is change afoot," he says. "Today we have tremendous pull between the supply side and the partner side to get this done."

As an example, Rapp cites a pharmaceutical client that depends on Accelrys to keep close tabs on what's happening at its suppliers' labs. "We have a customer with three contract suppliers that they monitor closely. They run a dashboard every day to see what's going on with the manufacturing process at their three partners," he says.

"It's become a critical need for our customers to know what's going on," Rapp adds. "They want systems that include process informatics, and they want them faster, easier to deploy, and with shorter times to get to the benefit. We need to broaden the number of companies that can take advantage of these systems."

ABOUT THE AUTHOR

Doug Bartholomew is a journalist specializing in manufacturing, technology and finance. His articles have appeared in New York Magazine and Los Angeles Times Magazine, and he is a former senior technology editor for IndustryWeek and senior writer at InformationWeek.

Harmonizing the Quality Management System to Extend to Contract Manufacturers and Suppliers

Four reasons why you should do it, and three reasons why you're not

BY TIM LOZIER, ETQ, INC.

THE WORLD has gotten smaller. There are scarcely any constraints any more to confine our businesses. When looking at Life Science organizations — specifically those who strive to achieve GMP Compliance — many still tend to think within their four walls. They concern themselves with their processes and quality management, yet fail to consider the organizations that affect them outside their four walls.

Over the past few years, Quality Management and Compliance Management practices have sought to create a truly harmonized system. The idea of harmonization involves creating a standard process for all Quality and Compliance, regardless of the location and operational area. The concept has grown in interest since many organizations have trouble seeing their data if the processes, such as Corrective and Preventive Action (CAPA), are disjointed from one area to the next. As a result, one CAPA governs all areas within the organization — a common process for all.

This idea of "being common" has become a valuable tool in corporate Quality within organizations today. Many companies have taken this a step further and adopted technology to help drive this commonality — creating multi-tiers of functionality into their Quality Processes, so that the site-level process can remain "unique" while adhering to the corporate harmonized process.

Why harmonize, you ask? Harmonization gives you a single picture of the system; a common thread to measure Quality and Compliance from throughout the entire organization. This is what corporate needs to make better decisions, ensure Quality and Compliance are met throughout the organization, and continue to drive operational excellence.

But, we're missing a component here. As I said, the world is smaller, and we no longer can operate within our four walls. Many organizations are extending manufacturing to a supply chain, with contract manufacturers, preferred vendors and a full host of suppliers within the product lifecycle. So, it would make sense that if we want to standardize and harmonize our Quality systems, we would want to harmonize and standardize our supply chain!

With all the compliance initiatives to increase visibility into the supply chain, and the stringent regulations that companies must adhere to, it would make sense to provide a system that spans enterprises in addition to your facilities, plants, or divisions. Here's why:

Visibility: Having a contract manufacturer work in your QMS provides you with the real-time visibility into their own Quality operations. With this level of visibility, you can maintain control over the state of Quality outside of your four walls.

Real-time Collaboration Cuts Cycle Time: If there is a defect or noncompliance, then the collaboration to resolve the issue can happen much more quickly. Unlike in current disparate systems, you do not have the "lag time" while the supplier works on their end to resolve the issue — Quality and compliance events now become a collaborative effort, all working toward the same goal and cutting the overall cycle time.

Compliance Right, First Time: Certainly, the time taken to resolve any of these supplier quality events causes a loss in time, and the time taken to re-work and re-produce becomes a factor against demand. With clear visibility and control in the contract manufacturer's process, you can now help to get the product right the first time, reducing the time to market.

Technology Helps to Create a Secure Platform: Of course the first concern is, "no way are they getting into my data." Technology has caught up with this — you can place security on every aspect of the software, fields, keywords, etc. — so that external enterprises only see the content that is relevant to them. You still control your data; they are now just able to operate in your environment—unable to see anything but their required information.

Ok, so objectively speaking — this isn't something that is done right now. And, why isn't this being done today? Here's some insight:

Fear, Uncertainty and Doubt (FUD): There's always going to be FUD. Certainly in the regulated space, companies protect their intellectual property very carefully. The concept of allowing contract manufacturers access to their data — even if protected — poses a certain degree of fear.

Technology Is Still Leading Edge: Not many software solutions offer this level of security, so it's not been widely accepted as a practice. But there are a few vendors in this area leading the charge on this multi-tier security concept.

Knowing "Too Much": Sometimes, ignorance is bliss — even in this world we live in today. Some companies do not want this level of visibility and/or control. This may be due to liability issues, this may be due to "plausible deniability," or it could

just be that they don't have the bandwidth to engage the contract manufacturers at this level. But think of this — if there is a serious event related to your product as a brand owner, who is liable for the repercussions? The answer is the brand owner, not the contract manufacturer. So the pain of knowing too much may bite back at you in the long-run.

The world is smaller, and more and more companies are collaborating on new levels. The key to success, especially in the regulated environment, is incorporating more layers of visibility into the various areas that help to make your products. This not only includes standardized compliance between divisions, it will also mean standardization across enterprises.

ABOUT THE AUTHOR

Tim Lozier is Product Strategy Manager for EtQ, Inc. Tim has an extensive background in software technology and has been involved in the creation of leading-edge technologies in user-interface design and development. Tim is responsible for fostering the development of leading quality management software solutions, and has helped shape EtQ's strategic vision. He provides strategic leadership for EtQ, the leading Enterprise Quality and Compliance Management Software for identifying, mitigating and preventing high risk events through integration, automation and collaboration.

Serialization and Supply Chain Security

Regulatory compliance should be the byproduct, not the goal

BY JOHN DIPALO, CHIEF TECHNOLOGY OFFICER, ACSIS, INC.

A year after adulterated heparin caused deaths in the United States and Europe, inspectors in California were still finding contaminated product in hospitals throughout the state, even though the manufacturer had sent out multiple recall notices, and the issue with the product was well known. As the pharmaceutical industry responds to regulatory mandates to address such weakness in the supply chain, it's important to ask, "Could this same thing happen in a 'serialized' world?" The answer depends on how companies choose to architect their serialization solutions and to what level companies integrate serialization into their business systems. Manufacturers and packagers who let compliance drive their serialization implementation strategies may be missing the opportunity to drive significant business benefits by implementing an enterprise resource planning (ERP) driven solution.

SILOED SERIALIZATION IS A LIMITED SOLUTION

Without a way to pinpoint the locations that received tainted product, manufacturers must recall all items shipped within a particular timeframe. Serialization can help with that. However, organizations that focus their serialization efforts on recall management will experience some benefits, but they will lack the granular end details that can support more effective solutions, more precise recalls, tighter inventory control and better identification of fraudulent activity. Regulatory compliance should be the byproduct, not the goal, of serialization.

Ideally, organizations should look for enterprise-wide solutions that will ultimately support sharing serialization information across the internal supply chain as well as among trading partners. This requires integrating serialization data with the

ERP system and adding context or business data, ultimately tying it all to the serial number.

This end-to-end approach not only enables timely track-and-trace capabilities, but it also expands advantages throughout the entire supply chain as it enables synergistic benefits from the business data in the ERP system. This connection between the serialization system and the ERP system makes it possible gain visibility of product from the point of manufacturer to the patient.

END-TO-END IS THE END GOAL

It is the ability to use the business information stored with each serial number that makes product serialization valuable. A serialization strategy that ties into ERP systems and provides real-time visibility throughout the entire supply chain offers significant benefits for the entire organization:

- Brand Protection — During the first six months of 2011, the federal Food and Drug Administration issued more than 40 Class-1 recalls. Automated tracking throughout the supply chain is critical for efficient response to such events, and an end-to-end serialization solution supports more effective recalls. Companies that can promise recall integrity increase patient safety. This may help differentiate their product, boost their brand image in the eyes of customers and end users, and help protect the reputation from negative consequences.

- Supply Chain Efficiency — Inefficiency costs money. According to the Healthcare Distribution Management Association, the pharmaceutical industry loses some $2 billion annually on returns and lost product and spends the same amount processing returns, expirations and recalls. An enterprise-wide serialization strategy could provide the necessary level of visibility to allow companies to control these costs by ensuring that returned product is credited at the cost at which it was sold. An enterprise-wide serialization solution could also integrate the information in warehousing, order fulfillment, etc., providing a level of granularity that increases shipping accuracy and reduces the likelihood of taking back ineligible returns. Extending information capture to trading partners enhances the benefits. Drawing a real-time picture of where product is at any point in the supply chain enables tighter inventory control, especially in short-supply situations, and drives better understanding of the impact of disruptions or process changes, ultimately supporting better decision making.

- Greater Control — An end-to-end system can capture key information and metrics as the product moves through production, associate it with the serial number and make appropriate information available to trading partners. This information could include anything from quality assurance data to special handling requirements to business data. For example, manufacturers could share information to help ensure that specifications — such as required storage temperature — are met as the product moves through the supply chain. This benefit becomes increasingly important as the industry increasingly moves toward specialty drugs, many of which have high degrees of control requirements. By 2020, most of the top 10 most prescribed drugs are expected to be specialty medications.

- Reduced Risk — Each year an estimated $45 billion in counterfeit drugs enters the supply chain. In April the FDA reported a new batch of counterfeit Avastin in the United States, packaged as Altuzan, the brand name for Avastin in Turkey. The fake product did not contain a key ingredient in Avastin, an injectable cancer drug. The agency had reported a previous counterfeit batch in February. A serialization strategy that provides the infrastructure to allow transparency across trading partners enables the timely track-and-trace capabilities that can help reduce this type of counterfeit risk, fraud and diversion.

- Pricing Accuracy — A serialization strategy that extends to trading partners also addresses issues with special pricing, controlling who gets the price and how those chargebacks are executed and also preventing the problem of duplicate chargebacks. Manufacturers save the costs associated with manually investigating discrepancies in chargeback requests and resolve disputes more quickly.

THREE STAGES TO SUCCESS

A successful move to serialization should begin with a vision of how much the organization intends to leverage the technology and then move toward modular implementation.

At the simplest level, companies need to serialize items, manage the codes and share that data with downstream partners to ensure product authenticity and chain of custody. At this point, the solution primarily involves packaging, ERP and a central serialization repository with ePedigree capability. Although this level may satisfy current regulations, it merely provides a foundation.

At the next level, the company integrates serialization information with additional business transactions and processes. This may include its internal warehousing, inventory control, order fulfillment, quality assurance, returns, pricing, contracts, etc., to increase the business benefits across the enterprise. This stage allows the organization to gain experience with this granularity of information and deriving benefits from its use.

Ultimately, sharing serialized information with trading partners across the entire product lifecycle produces the broadest range of benefits discussed above. This is where true track-and-trace, or ePedigree, becomes viable.

Eventually, cloud-based event registries could provide automated authentication and other benefits. Some of this must be driven by the market environment, but companies that have early experience will have a strategic advantage.

GET AHEAD OF THE CURVE

Although some companies have implemented small serialization pilots, in the United States, many manufacturers and packagers seem to be waiting to see whether regulatory mandates — specifically those in California — are going take effect in 2015, whether there will be another delay. This "wait and see" serialization strategy can cause a number of problems. Companies that hesitate to develop and implement a forward-looking serialization strategy do themselves a disservice. Unless they are proactive, they are likely to get behind the learning curve and lose the ability to change their business processes and leverage serialization data to take full advantage of the benefits of serialization.

As compliance deadlines approach, they may also find that their vendors of choice may have limited availability due to high demand for their services. Keeping in mind the time frames necessary for implementation, companies that start putting serialization in place now can select best-in-class vendors and start realizing benefits like better recall management, managing pricing and returns, and more accurate order fulfillment sooner rather than later. When compliance becomes an issue, they will already have the building blocks in place to achieve it and, in the meantime, they will reap the benefits of this powerful business technology.

ABOUT THE AUTHOR

John DiPalo, Chief Technology Officer at Acsis, Inc. (Marlton, NJ) has more than 25 years of experience in process and systems analysis and design, and he has implemented many manufacturing and warehousing systems across multiple ERP, mid-range and client-server environments. At industry events, he frequently speaks on serialization, RFID and barcode technology, and shop floor automation, and he has authored many white papers on serialization and supply chain optimization.

ABOUT DPT

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