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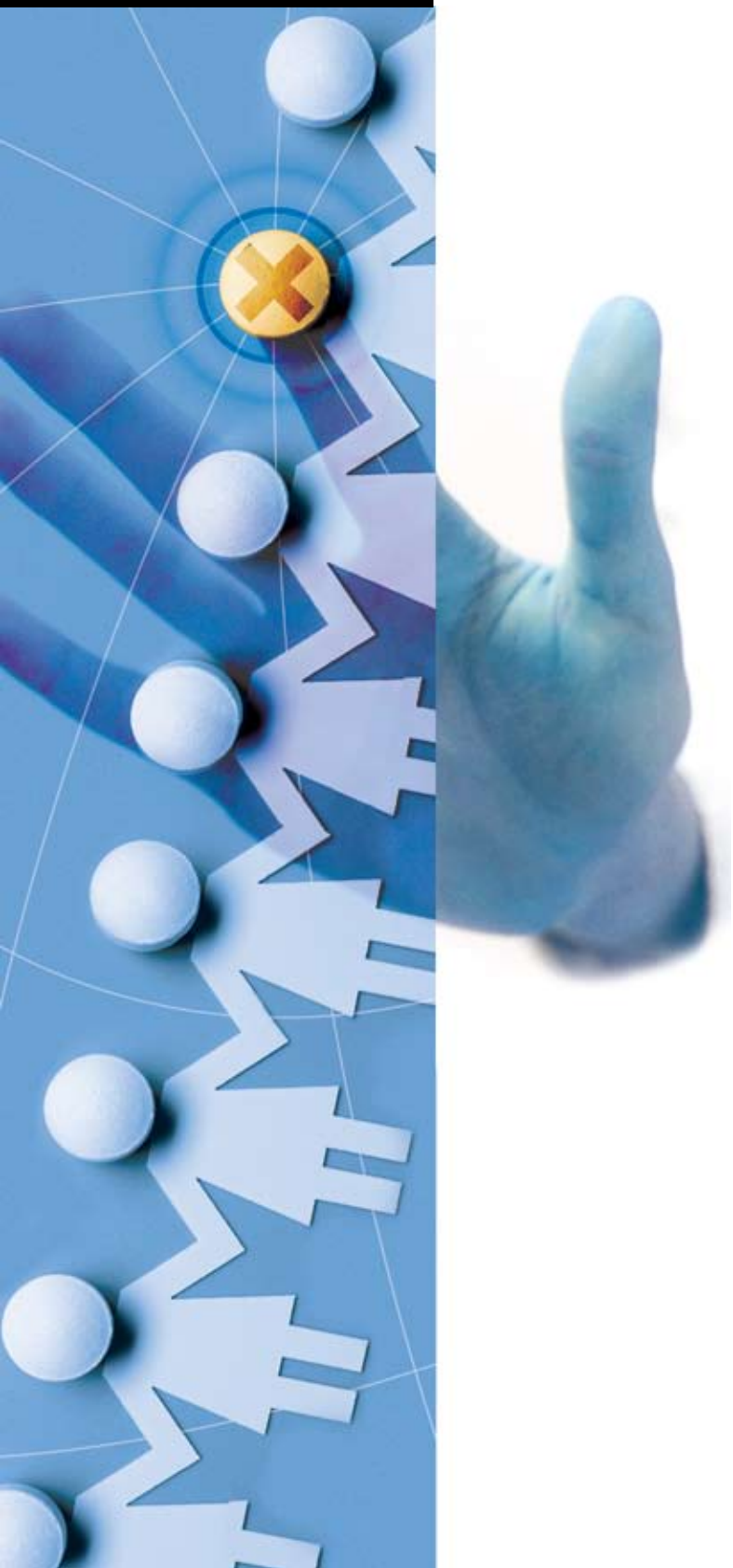
INSIGHTS

Trade versus Trust in the Pharmaceutical Industry



Introduction

Life sciences organizations invest a significant percentage of revenue into building brand awareness and company reputation. Like most manufacturing businesses, they know that losing control of their supply chain threatens the investment in their brand. It only takes one case of contamination, from any source, to cause loss of life and destroy the public's trust, along with your sales, brand image and shareholder's confidence.

Absent systems to protect the integrity of their product, from raw materials to point of dispensing, across multiple supply chain partners and under increasing public scrutiny, many companies find themselves at the mercy of trusting in their trading partners' security to protect their brand and reputation.

As companies seek to justify supply chain integrity projects, the lack of the very same systems they seek to employ makes it difficult to quantify the problem or to establish a return on investment. To make matters worse, the lack of globally accepted standards for traceability and chain of custody systems compound the problem. Those at the end of the supply chain must bear the burden of acquiring a multitude of systems to address various solutions. Questions such as how to track ingredients to finished goods in the supply chain, whether to use specific barcodes or radio frequency data carriers, how to numerically encode products or how to securely exchange chain of custody information all further confound the problem.

As various commercial systems emerge to address parts of the traceability equation, many companies find themselves mired in a confusing mix of domestic and global standards, technologies, business integration and supply chain relationship issues. Developing a strategy and roadmap for maturing your organization's supply chain is an important step in protecting brand and company reputations. This paper discusses the following:

- Summarize the current approaches to supply chain integrity.
- Review security approaches.
- Define a maturity model that companies can use to rank their supply chain.

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Current situation

Pharmaceutical counterfeiting is often likened to an iceberg, with detected counterfeiting representing only the exposed tip. The lack of systems to track pharmaceuticals in the supply chain makes it difficult to determine exactly how much of the problem is hidden beneath the surface. Nevertheless, the World Health Organization (WHO) estimates that counterfeit drugs range from less than 1% in developed countries to over 30% in some developing countries. Even if the US counterfeiting is only half the WHO estimate, or 0.5%, that would mean that approximately 17 million counterfeits were among the estimated 3.4 billion prescriptions filled in the US in 2007. Just imagine if the recipient of one of the counterfeits was a loved one.

The U.S. based Center for Medicines in the Public Interest predicts that counterfeit drug sales will reach $75 billion globally in 2010, an increase of more than 90% from 2005. The integrity of pharmaceuticals can be compromised at many points in the supply chain, from raw materials or ingredients, to packaged counterfeit products, legitimate products intentionally mislabeled with higher dosage or extended expirations, or to diverted shipments with a questionable chain of custody. The inability to track drugs in the same way we track automotive parts or high-end luxury goods means we must continue to guess and leaves pharmaceutical companies exposed and trusting in the security of others in the supply chain.

Counterfeit ingredients

Early 2008 saw dozens of news reports regarding deaths associated with Baxter's heparin blood thinner product. The problem was traced to a counterfeit active pharmaceutical ingredient (API) from China, where the API was replaced by a molecularly similar ingredient which passed tests for heparin but was deadly to humans. Tainted product was being found on pharmacy shelves even months after the January 25, 2008 recall announcement, and the lack of tracking systems complicated recall efforts. Aside from the horrendous loss of life, Baxter's reputation was damaged and is now often referred to when discussing counterfeiting. In fact, if anyone does question the extent of the problem, searching for information on counterfeit drug deaths on most search engines will yield hundreds of articles, and these may be only the tip of the iceberg.

Counterfeit packaging

Many counterfeiters have become adept at producing very authentic looking packaging, including overt methods such as holograms, government stickers, barcodes with correct numeric encoding and even bogus serial numbers. Counterfeiters can encode radio frequency tags or complex barcodes. This has made it more difficult to rely on the appearance of packaging or specific data carriers as a form of counterfeit detection.

In fact, serial numbers alone do little to thwart counterfeiting. However, when combined with other information, such as secondary authentication codes, the serial numbers of containers and chain of custody data systems such as advanced shipping notices (ASN) or pedigree documents, the serial number becomes an important component in the foundation of an anti-counterfeiting and anti-diversion strategy.

Uplabeling

The widely used example of epoetin alfa (Epogen) vials manufactured to contain 2,000 units/mL being relabeled as 40,000 units/mL resulting in the near death of a 16 year old in Long Island, NY illustrates the tragic results of label tampering, where information such as dose or expiration are altered. After sale by the manufacturer, the supply chain included two primary wholesalers, a pharmacy, a physician "go between," a counterfeiter who relabeled the vials, several distribution centers and the community pharmacy that dispensed the counterfeit drug leading to near death. The subsequent investigation revealed that approximately 100,000 vials of epoetin alfa may have been "uplabeled" with a potential profit in excess of $42 million.

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Human error

Pharmaceutical manufacturing processes are carefully planned, validated and verified. Often, at many steps in the process a review or second signature is required to confirm an action. Documentation and automation help to further attenuate the likelihood of human error. Nevertheless, errors caused by humans do occur and may lead to mislabeling, incorrect ingredients or even incorrect or contaminated product. Most organizations employ an overlapping set of processes to catch human errors before they enter the distribution phase of the supply chain. Wholesalers and distributors often sample items to test for purity and ensure the product is correctly labeled or not counterfeit. Often lacking the ability to pinpoint specific recipients downstream in the supply chain, when an error is detected it may result in a public recall which erodes public confidence in the brand and company reputation.

Malicious intent

The necessity for control of pharmaceutical supply chain integrity may also extend beyond protecting patient safety or brand integrity. In the light of recent reports regarding cyber-terrorism, the lack of systems to authenticate pharmaceuticals may expose an opportunity for life threatening bioterrorism. Moreover, increasing evidence from the international front also suggests that the sale of counterfeit goods, including drugs, is being used to finance terrorists.

Internet purchases

Obtaining prescription drugs from Canada and other countries via the Internet is an appealing option for U.S. citizens. Boards of pharmacy in several states have inspected and licensed several Canadian pharmacies that provide pharmacist/patient consultation and have approved specific Internet sites from which state residents may order FDA-approved prescription drugs. By contrast, U.S. citizens may also submit a legal prescription to a storefront pharmacy that arranges for signature of a Canadian physician who never saw or examined the patient and processes the order to an Internet pharmacy that may provide no pharmacist consultation with the patient. The results of the FDA's "Operation Bait and Switch" inspection of drugs ordered from Internet sites claiming to be of Canadian origin indicated that 85% of the drugs were manufactured in 27 different countries, and many parcels contained counterfeit drugs. The absence of systems to help authenticate items may mask the problem with Internet sales and may further erode confidence in a legitimate pharmaceutical company's brand or reputation.

In addition to taking regulatory action against operators of several Internet sites, the FDA has issued a consumer safety guide and several warnings to educate consumers of the risks associated with the purchase of prescription drugs via the Internet. Nevertheless, the absence of systems to authenticate drugs purchased from the Internet leaves legitimate pharmaceutical manufacturers exposed.

Building patient trust

Supply chain integrity is at the heart of ensuring patients' trust in the medicines designed to help them. Many supply chain integrity solutions fail to track raw materials or ingredients through to specific packaged items or points along the supply chain distribution. Likewise, many systems designed to track and authenticate drugs fail to include the patient. The problem of patient authentication is further complicated by bulk drugs being dispensed by pharmacies into smaller pill containers. The absence of a complete end-to-end solution greatly reduces the effectiveness of the investment in improving supply chain integrity and protecting brand and company reputations through patient safety.

The approach to security is different for each product and point in the supply chain. As with most security systems, an end-to-end solution should include an overlapping set of systems.

As demonstrated by the Baxter heparin case, simply testing active pharmaceutical ingredients (API) is not enough to ensure patient safety. Counterfeit APIs pose a potential health hazard because their original manufacturer is often unknown to the brand owner. The fact that the manufacturer is unknown means that there is no product history. Therefore, the safety and efficacy of the product cannot be assured, the impurity profile is unknown and the age, storage, manufacturing environment, and/or the synthesis of the product cannot be determined. Moreover, the failure to have a product history means that the results of research and development and the clinical trials done by the brand owner are negated.

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Trusting ingredients

Companies seeking to protect their brand and ensure patient trust must begin by certifying all sources of ingredients and documenting the sourcing back through preprocessors, suppliers, bulk distributors, and to the original chemical manufacturer. This often poses a challenge for pharmaceutical manufacturers due to unwillingness by some suppliers to release what they may feel is proprietary or competitive information. Pharmaceutical companies also often represent a relatively small portion of the overall sales for many chemical companies and therefore have little negotiating leverage. Nevertheless, the cost of ensuring safety may be in requiring this information. To combat concerns, some have suggested independent 3rd party certification to preserve confidentiality while confirming good practices and testing back to the original source of ingredients.

Trusting the chain

Another area of potential risk is the change in custody as finished packaged goods travel from manufacturer through wholesalers, distributors and into hospitals or pharmacies. Seeking to address this risk, in 2006 the FDA sought to enforce existing regulations under the Prescription Drug Marketing Act (PDMA) of 1989. Under the PDMA, manufacturers were required to uniquely identify their products and to start a chain of custody document, known as a pedigree. The pedigree was to be signed at each change of custody in the supply chain. This documented each handler and provides traceability for authentication back to the manufacturer.

However, lacking specific guidance for uniquely identifying products or for managing pedigree, those at the end of the supply chain were burdened with obtaining multiple systems to comply with the regulations. A lawsuit was won in the District Court of New York enjoining the FDA from enforcing the pedigree provision of the PDMA. In another attempt toward pharmaceutical traceability, the Food and Drug Administration Act of 2007 requires the Secretary of Health and Human Services, using the FDA, to develop industry guidance for uniquely serializing pharmaceuticals by March 2010. At the time of this writing several states have issued regulations requiring chain of custody certification based on manufacturing batches or lots and not individual items. A law passed in 2008 in California will require unit serialization and an electronic pedigree beginning in 2015. Also at the time of this writing there are multiple bills introduced into the US federal legislature requiring serialization and chain of custody certification such as pedigree.

Some standards organizations, such as GS1 in the US and the European Federation of Pharmaceutical Industries and Associations (EFPIA) in Europe, are promoting systems to harmonize the approach toward tracking pharmaceuticals. The general approach is to leverage widely used standards for Global Trade Item Numbers (GTIN), containing a company code and item number or the FDA National Drug Code (NDC), a serial number and using standard barcode data carriers. Items and containers of items, such as cases and pallets, are each uniquely identified and the GTIN, serial numbers and their relationship to their serialized containers is exchanged in an electronic document, digitally signed by each participant in the chain of custody. Information is then exchanged using the GS1's EPCglobal published standards for electronic product code information services (EPCIS). A future registry known as the Global Data Synchronization Network (GDSN) may be used as a central repository. The GDSN will store GTIN and product information. A Discovery Services database will link product information from the GDSN with serial number data sources or data pools, chain of custody information and locations (using the GS1 Global Location Number or GLN).. In an effort to reduce the cost of scanning products using line-of-sight technology such as barcodes, some pilots are exploring the future use of radio frequency identification tags to transmit the GTIN and serial number without requiring a scan of the package.

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Examples of public e-pedigree solutions include the following:

- Since 2004, Purdue Pharma has incorporated RFID technology into unit level packaging of Schedule II drugs.
- Pfizer included RFID and 2D barcode tags on all cases and individual item level packaging of sildenafil.
- In 2006, Cephalon Pharmaceuticals initiated a pilot program involving shipment of RFID-tagged pallets and cases to multiple RFID-enabled facilities.
- Also in 2006, GlaxoSmithKline began shipping RFID-tagged bottles of abacavir/lamivudine/zidovudine (Trizivir) and planned to evaluate applying RFID technology to other products.
- Wal-Mart has required RFID tags on Schedule II drugs distributed within their network.
- In 2004, FIT Enterprises initiated a nationwide e-pedigree system to track distribution of vaccines and human plasma products.
- Since 2005, McKesson, Cardinal Health and AmerisourceBergen have initiated pilot RFID programs to track movement of selected products through portions of their distribution system.

Technology

Since the FDA announcement to begin to enforce the serialization and pedigree requirements of the PDMA, various technologies and solutions have been announced to support the requirements. The following is an explanation of some of the solutions.

Radio waves

Radio frequency identification (RFID) tags have been around for many years and have been used in many situations, including detecting shoplifting, paying roadway tolls, passport documents and identifying large shipping containers. In the pharmaceutical industry they are being considered to reduce the cost associated with individually scanning each serialized item or for scanning containers such as cases or pallets.

The passive RFID being considered require power from a reader to power the tag. The tags contain a small integrated circuit and antenna. The integrated circuit stores the electronic product code (EPC) made up of company code, an item code and a numeric serial number. A common RFID tag used in the pharmaceutical industry is the second generation ultra high frequency tag capable of storing 96 bits of data, commonly referred to as EPC-96 Gen2. This tag will store a company identifier registered with the GS1 organization, a company assigned item number to identify the specific product and an 11-12 digit numeric serial number to uniquely identify the specific item.

Wholesalers and large distribution organizations are encouraging the use of RFID by manufacturers to reduce their cost of handling goods and for ensuring accurate shipments. The use of RFID on unit level pharmaceuticals is also gaining interest from patient safety advocates for ensuring that the correct drug is being administered to a specific patient and reduce human errors. Strategies for traceability should consider the future use of RFID as the price decreases and additional value is recognized.

Packaging holograms

In an effort to overtly authenticate a product, some manufacturers use holograms or color shifting ink on the packaging. The use of these techniques helps the pharmacist to visually detect products likely to be authentic. As counterfeiters have become more sophisticated they too may include the same visual indicators.

Two-dimensional bar codes

The use of rectangular barcodes is growing in popularity as a method of encoding more information in a small area of a package. These barcodes, sometimes referred to as 2-D, datamatrix or databars, can contain much more information in the space previously used by their linear barcode predecessors. By extending the information normally found in a standard linear barcode, usually only a company code and item number, the packager can provide a method for recipients to move more information into their business systems. These barcodes can contain the manufacturer's company code, an item number, a unique item serial number, expiration date, batch or lot, and even a secondary authentication number. This allows business systems to detect expired products or automatically confirm a product's authenticity. The use of two-dimensional barcodes does require a more sophisticated reader than traditional linear codes and are only now growing in use. Many labels contain both linear and 2-D barcodes to avoid concerns from supply chain partners unable to scan 2-D codes.

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Chemical fingerprints

One method of covertly authenticating products is the use of special inert chemical combinations. As the sophistication of counterfeit packaging grows, many manufacturers are using covert techniques that can help them determine if a product is counterfeit. This technique allows suspect products to be detected through chemical analysis, usually a destructive test and not widely used for mass testing. The emergence of nondestructive x-ray techniques such as Energy Dispersive X-Ray Diffraction (EDXRD) may extend the usefulness of chemical fingerprints.

Specialty printing systems on each tablet

Another method of covertly authenticating products is the use of micro or specialty printing on each tablet or capsule. These systems print information too small for human readability and often too difficult for most counterfeiters to mimic. The special printing may be used to help determine if a product is counterfeit.

Silicon based ink

The use of covert packaging technologies such as conductive ink is being explored as methods for detecting counterfeit packaging from sophisticated counterfeiters. These techniques allow packagers to form small circuits that may be checked with inexpensive handheld devices.

Detection methods

To automate the detection of the various techniques above, wholesalers and distributors have turned to technology to aid in their battle to maintain the integrity of the supply chain.

Machine vision

Automated vision systems use sophisticated cameras and computers to review information on a package label. These systems can verify text, decode barcodes, and check colors or precise placement of information on the label. Machine vision systems are also used during the packaging process to detect incorrectly or mislabeled products and for controlling automated rejection systems in an effort to reduce human or machine errors. Machine vision systems are also used during packaging to confirm serial numbers in barcodes and to commission or record the serial numbers for future tracking.

X-ray

The use of Energy Dispersive X-Ray Diffraction (EDXRD) and Raman spectroscopy can be used to discover counterfeit drugs while still inside their packaging. These techniques scan through sealed packages to analyze the chemical makeup of the contents. The brief few minute analysis compares the findings against expected results. The expense of these systems may be prohibitive for widespread usage but may offer a non-destructive way of combating sophisticated counterfeit packaging. The use of EDXRD may also provide a relatively rapid method of analyzing ingredients in the manufacturing process.

Radio

When radio frequency identification (RFID) tags are used on both items and cases, wholesalers and distributors can scan a pallet or individual case and detect all of the serial numbers of its contents. By electronically comparing the serial numbers of a case and its contents against records such as serialized advanced shipping notices (ASN) or pedigree documents, the company can determine if the relationship between the serialized container and contents has been altered. This container to content or parent to child relationship may be used to detect potential counterfeits or diverted shipments.

Criminal activity

Despite efforts to authenticate raw ingredients and packaged goods, numerous criminal activities threaten to undermine those efforts and create doubt in the brand owner's ability to protect the integrity of their product.

Active undercover work and overlapping security systems are needed to thwart criminals bent on counterfeiting pharmaceutical products. Brand owners who simply trust their contractors and trading partners are relinquishing their brand and company reputations, their shareholder and investor confidence and the safety of the patients they serve, to others.

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Third shift operations

Unauthorized manufacturing and packaging during off hours allow criminals to produce seemingly real product using the very same systems designed to thwart counterfeiters. These products may be the ingredients sold to the manufacturer or the packaged goods shipped to distributors. As the pharmaceutical industry sheds manufacturing and distribution logistics operations, contract organizations will take on more and more of the work associated with manufacturing, packaging and distribution. Without tight controls over contractors, the brand owners must trust in their partners to protect their product's image and patient trust.

Because many contract manufacturers, packagers and third party logistics (3PL) firms perform operations for multiple brand owners they may be reluctant to disclose information about their full operations. This may hinder audits and opens the door to unscrupulous use of their facilities during so called third shift operations. For example, a contract packager's facility could be used to package fake product in authentic packages. A 3PL's systems could be used during a third shift to create authentic shipping notices or pedigree.

Shadow plants

Because of the lucrative nature of pharmaceutical counterfeiting, "shadow plants" have cropped up to fill demand for active pharmaceutical ingredients (API) and packaged goods. In the case of APIs, these plants produce ingredients using low cost practices without the safeguards or testing found in legitimate manufacturing. These organizations often produce bogus records and procedure documents to mask their true operations. In the case of packaging, these facilities often use sophisticated packaging systems that precisely mimic the packaging found on authentic products. These well packaged products pass most tests, including barcodes with serial numbers, but often contain fake or dangerous contents.

Falsifying documents

Effective anti-counterfeiting and supply chain control systems require more than documents or serial numbers. Counterfeiters can easily create false documents such as pedigree and packaged products with holograms, barcodes with serial numbers or RFID tags. Electronic systems which authenticate both the distributor and recipient using technologies found in ecommerce are often used to augment documents to confirm they are authentic. Electronic data interchange (EDI) systems are often used to transmit an electronic advanced shipping notice (ASN) and confirm receipt of the information by the expected recipient. Since EDI systems must be configured between trading partners they help to inhibit counterfeiters using false documents by requiring both parties in the exchange to authenticate the other.

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The physical integrity of the supply chain

One area that needs additional attention today is the physical integrity of the supply chain. While life sciences companies have been investigating systems to provide greater physical control over the supply chain, many have been reluctant to implement solutions until regulations emerge to define minimum requirements. This regulatory-driven approach leaves the companies exposed to trusting their trading partners to protect their brand name and company reputation.

Manufacturers seeking to take greater control of their supply chain may wish to develop agile or adaptable systems based on lessons learned in other areas of commerce. Many high end consumer goods, electronics and automotive parts include solutions that improve the physical integrity of their supply chain.

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Track and trace technology

Track and trace systems allow participants in the supply chain to review the chain of custody of a specific item. The foundation of these systems is uniquely identifying each unit with a serial number. These systems then collect events relating to the serial number and store the information in systems that are accessible to other trading partners. Many track and trace solutions also use the relationship between serialized items and the serial number of their containers, such as cases and pallets, to authenticate the shipment. This parent to child relationship is often difficult to reproduce in mass.

Difficulty arises when there are no standards for serializing or exchanging information or when there is distrust in the supply chain. Without standards, those at the end of the supply chain must implement multiple systems to handle a multitude of track and trace solutions. Unscrupulous trading partners might also use these systems to obtain shipping information on their competitors.

An emerging track and trace process in the pharmaceutical industry is to leverage widely used standards for Global Trade Item Numbers (GTIN), containing a company code and item number, or in the US only the FDA National Drug Code (NDC) and a serial number, to uniquely identify each saleable unit and container. This information is then encoded on the package using standard barcode data carriers. Serialized information about the units and their containers is then exchanged in an electronic document, digitally signed using technology found in ecommerce by each participant in the chain of custody. Information is then exchanged using the GS1's EPCglobal organization's published standards for electronic product code information services (EPCIS). A future registry known as the Global Data Synchronization Network (GDSN) may be used as a central repository. The GDSN will store the serialized GTIN, the Global Location Number (GLN) for the shipper and receiver and other information about each shipping event.

In an effort to reduce the cost of scanning products using line-of-sight technology such as barcodes, some organizations are considering the future use of radio frequency identification tags to transmit the GTIN and serial number without requiring a scan of the package. The use of non-line-of-sight technologies such as RFID is especially important to avoid the need to trust or infer the contents of a sealed case and not open each case and scan every item.

As track and trace systems emerge in the pharmaceutical industry, manufacturers may use information on their products in the supply chain to mature their operations and develop just in time demand driven operations. The use of EPCIS or equivalent technology will allow manufacturers to query information about the status of their products from trading partners. The use of data pools such as the GDSN, or equivalent systems hosted by regulatory bodies like the FDA, could be used by manufacturers to gain important business intelligence about goods in the supply chain, such as when they have been consumed or soon to expire products. Using this information, manufacturers can refine their production and move the business up the supply chain maturity model.

Temperature control and cold-chain

Absent systems to track the chain of custody of an item in the supply chain, downstream trading partners cannot be assured that an item has been maintained under its required conditions. This may mean that some authentic drugs diverted from normal distribution may have been exposed to conditions that affect the efficacy of the product. The use of techniques and technologies for anti-counterfeiting and anti-diversion may also provide traceability of those handling the product.

Some organizations are linking traceability information such as serial numbers with environmental control systems shipped with cold-chain products. This ensures that environmental information can be traced to a specific item should a recipient question whether the item has been properly maintained.

Tamper evident seals

Tamper seals are often used to detect physical access to the contents of the container. Many tamper systems are also designed to aid in anti-counterfeiting. Some seals contain a number sequence unique to a specific packaging batch, printed during packaging, as an overt method of increasing the difficulty for counterfeiters. The package or package insert document may include a notice to confirm the number on the seal with a number on the outer package, such as a batch number.

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Picture books

One method used to aid in the authentication of a packaged product is a picture book showing the correct labeling and providing information on detecting counterfeits. The picture book may contain photographs of the various packages and measurements or other markers unique to the real product.

Container and trailer seals

The sealing of trailers and containers is also an important aspect of physical security. Without physical seals the contents of the container may be diverted or replaced with counterfeit goods. In many other industries seals are required and must meet or exceed the current ISO 17712 standards for high security seals. Written procedures must stipulate how seals are to be controlled and affixed to loaded containers and trailers and include procedures for recognizing and reporting compromised seals for downstream trading partners. Many manufacturers fail to include the contractual obligation to control access to their brand while in the supply chain.

Physical access controls

Another often overlooked aspect of physical security is the control and recording of personnel access with batch records for manufacturing and packaging. Access controls prevent unauthorized entry to facilities and maintains a record of employees and visitors. Often access information is not linked to tracking systems and manufacturers cannot track errors or suspicious discoveries back to personnel.

Maturity model

In addition to the examples above, the pharmaceutical supply chain is under pressure on multiple fronts. Changing regulatory requirements, the shift from acute to chronic lifelong medications, continued pressure on margins, aggressive global competition as patent periods end, shorter product lifecycles and increased reliance on partnerships are among the concerns. Today's global supply chain challenges are driving the need to manage these concerns. This includes synchronizing supply and demand, multi-source orders for ingredients, competing trading partner requirements and unexpected demand fluctuations.

Companies have traditionally focused their supply chain initiatives on increasing internal operational excellence in specific functional areas. These activities have included narrow solutions to solve a single need, using off-the-shelf systems, or increasing outsourcing of non-core functions. The renewed focus on traceability has led some organizations to focus on the supply chain to transform their business. Legislative and regulatory pressure to ensure the purity of pharmaceutical products is also causing companies to reevaluate their supply chain operations. This includes looking at the end-to-end processes horizontally rather than in silos, and changing the way the entire business views the supply chain.

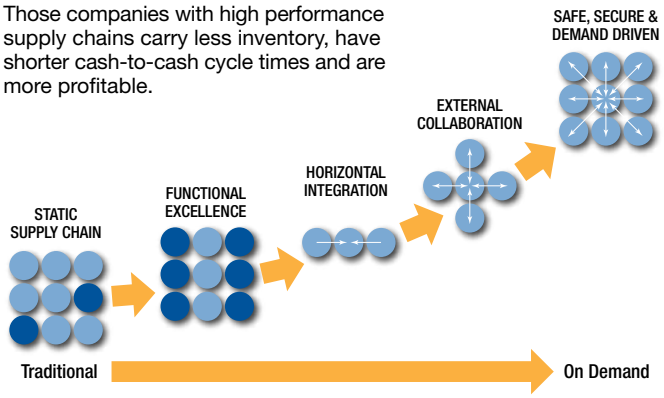
To build a competitive advantage and mature their supply chain, organizations are moving from static initiatives in specific business areas to externally collaborative and on demand supply chain models. According to AMR Research, companies with high performance supply chains carry less inventory, have shorter cash-to-cash cycle times and are more profitable.

Lessons learned from recent regulatory driven traceability projects include the need for a strategy that addresses the requirements of manufacturing, packaging, distribution, finance and trading partners. Many companies found that initiatives focused on only a specific area, such as packaging or distribution, created complex integration challenges and did not fully address all of the issues associated with supply chain integrity.

The mature pharmaceutical supply chain manages the process from raw materials to the point of dispensing, leveraging collaborative systems to drive demand and ensure patient safety.

Supply Chain Maturity Model

Those companies with high performance supply chains carry less inventory, have shorter cash-to-cash cycle times and are more profitable.



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Conclusion

Growing regulatory pressure from around the world to improve confidence in the purity of pharmaceutical products is spawning a renewed interest in supply chain operations. Highly publicized drug recalls, coupled with numerous food product recalls, are increasing public awareness of the issues. As pharmaceutical companies continue to invest a significant percentage of revenues into building brand awareness and company reputation they can no longer neglect the effect of an insecure supply chain on those efforts.

The absence of the systems needed to track and trace pharmaceuticals makes it difficult to determine the full extent of the problem and to justify the expenditures during difficult economic times. The opportunity to uncover additional cases by "data mining" is further hampered by a lack of coding for injuries associated with suspected counterfeit drug products by injury databases such as those operated by numerous government entities.

Efforts from organizations such as Rx-360, GS1, HDMA and the EFPIA are helping to drive standards and reduce the complexity and cost associated with improving supply chain integrity. These efforts will further interoperability and collaboration and allow companies to mature their supply chain initiatives in the areas of traceability and product authentication.

The need for pharmaceutical authentication may also extend beyond simply ensuring the purity of a drug and play an important role in reducing human errors. The systems used to uniquely identify the item, such as barcode data carriers, may also be used in the pharmacy or at the point of dispensing to confirm the specific drug and dosage. These systems can further be linked with other patient safety systems to identify prescription errors and contraindications. Also, as packaging or vials become smaller to save on storage and distribution costs, emerging technologies such as radio frequency identification tags or two-dimensional barcodes containing more information may be used to aid in the confirmation of the product.

Trust alone is not enough in today's world. Companies seeking to protect their brand name, company reputation, shareholder confidence and patient safety should develop a flexible, agile strategy to leverage emerging standards and comply with global regulatory requirements. To gain from the business advantages of a mature supply chain operation, companies may wish to develop their strategy independent of existing commercial products, free from confusing sales positioning, and then map products back into their requirements. Clarkston Consulting has experience providing unbiased strategy, roadmaps and planning in the area of supply chain, traceability and anti-counterfeiting.

Founded in 1991, Clarkston continues to strengthen our industry depth working with senior executives in the world's foremost companies managing the best of brands. As the market shifts in both life sciences and consumer products from bottom-line cost cutting to driving top-line growth, we are helping our clients focus on every aspect of their business from innovation and new product development to manufacturing and supply chain execution and out to the field working to maximize customer relationships and pricing strategies.

About the author

Mr. William (Bill) Fletcher is principal consultant for Clarkston Consulting's life sciences vertical. Mr. Fletcher's background spans over 27 years in pharmaceutical, enterprise software and healthcare systems. As a principal consultant, Mr. Fletcher leverages his deep subject matter and project management experience to help solve complex business problems. His experience in life sciences spans from packaging/labeling automation and inspection systems, serialization, barcoding, RFID, distribution systems, e-Pedigree/RxASN and supply chain track and trace to drug discovery and R&D, clinical trials, brand marketing and physician education. Mr. Fletcher has spoken and published numerous times on pharmaceutical industry issues, and, as a member of several industry advisory groups, has had an impact on guiding the way organizations navigate the issues driving business strategy. Mr. Fletcher has managed teams of technology professionals and projects throughout the pharmaceutical lifecycle, and is currently focused on pharmaceutical serialization, track and trace and anti-counterfeiting.

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About Clarkston Consulting

Clarkston Consulting is a different kind of management and technology consulting firm. We deliver a unique experience for market leaders within the Consumer Products and Life Sciences industries. Considering professionalism, expertise, and value as prerequisites, we take service a step further through our unyielding commitment to the success of people as individuals, both our clients and our employees. By combining integrity, adaptability, and a whatever-it-takes attitude, we have achieved an extremely high rate of referral and repeat business and a 7-year average client satisfaction rating of 97%.