

WhitePaper

Rx-360: All-Around Security for Pharmaceutical Supply Chains

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Introduction

“The tragedies related to economically motivated adulteration of glycerin in Haiti, Panama, and Nigeria, as well as heparin used in the United States and Europe, and melamine found in various products throughout the world, have taught us that unethical individuals and criminals have entered the pharmaceutical supply chain with tragic consequences,” said Martin Van Trieste, founding chair of Rx-360¹

Recent tragic events involving adulterated pharmaceutical and food products have focused the attention of pharmaceutical manufacturers, as well as the U.S. Food and Drug Administration, on supply chain processes.² The pharmaceutical industry is also increasing its focus on supply chain security because of concerns about deliberate tampering, counterfeiting, and theft, in addition to contamination.² Criminal enterprises have made counterfeit drugs and the theft of pharmaceutical chemicals into lucrative sources of illicit gain. Industry members are responding to these concerns by improving and increasing the level of cross-company collaboration, as well as by implementing company-specific initiatives.

The best way to enhance supply chain security is for manufacturers to have intimate knowledge of materials suppliers and their methods of manufacturing, storing, and transporting the materials. However, obtaining this information can be quite resource-intensive and challenging for individual companies. Collaborative ventures between pharmaceutical manufacturers to safeguard today’s extensive global supply chains are becoming more attractive to companies.

Purpose

The purpose of this white paper is to describe Best Practices that can be implemented by manufacturers to enhance global supply chain security. These Best Practices represent those implemented by members of Rx-360, a nonprofit consortium recently developed by volunteers from the pharmaceutical and biotech industries, including manufacturers and their suppliers. The Rx-360 mission is to enhance supply chain security and ensure the quality and authenticity of the materials moving through the supply chain.³ The organization works to enhance security and patient safety by auditing member organizations that supply materials to the pharmaceutical supply chain. Rx-360 then provides supplier audits to the organization’s pharmaceutical manufacturing members to facilitate information sharing. Keep in mind that although Rx-360 can provide manufacturers with valuable information, it is still the responsibility of each Rx-360 company to make its own decision about suppliers, based on its own company product requirements, policies, and procedures.²

General

A secure supply chain leads to open communication, problem prevention, constructive feedback and increased product safety—all of which results in consistent and reliable products that can promote health and improve patient lives.

Enhancing the safety and reliability of the pharmaceutical supply chain has become a critical component of manufacturing operations in an increasingly complex sourcing environment, with more at stake than ever. Suppliers are the critical link in the supply chain that

ultimately delivers value to the consumer, along with safe and effective products for clinicians and patients. Manufacturers should always collaborate with suppliers to enhance supply chain security.⁴

The Rx-360 consortium supports a number of Best Practices that help manufacturers enhance supply chain security.

Supply Chain Security Best Practices^{3,4,5,6}

1. Perform in-depth audits that identify carrier/shipping procedures and practices (based on thorough checklists, including evaluation of documentation systems), as well as manufacturing processes and details concerning the supplier's facilities.
2. Work with suppliers to develop an "e-pedigree" for all materials, in the form of an electronic record of each transaction that results in a change of ownership of a given raw material. This includes all transitions/transportation between owners or handling locations. While this is a complex task, the necessary technology itself (information systems, authentication methods, automation, RFID scanning, bar code encoding, etc.) is mature and available. But the technology has not yet been employed as the basis for solutions that encompass the entire supply chain back to the raw materials level. Some suppliers are currently working on solutions that, once identified, all suppliers should consider enacting. Additionally, a comprehensive e-pedigree system would require unique item identification or serialization of each product for easier tracking. Suppliers and manufacturers must work together to track raw materials through the supply chain.
3. Require tamper-evident seals that are uniquely identifiable (e.g., with supplier logo and/or name), multi-layer (e.g., both outer container seals and individual product seals inside), and globally standardized. The customer should be prepared to review and inspect the seals every time product is received.
4. Obtain advanced shipping notification of all details regarding every shipment (e.g., vendor/distributor name and part number, ship date, shipment number, quantity, PRO/bill of lading, lot number, and expiration date).

These details can then be checked against the actual shipment for irregularities that could be evidence of tampering, theft, or contamination.

5. Assemble photographic libraries of product labels, seals, watermarks, etc., for accurate records of raw material shipments. Incoming materials can then be checked against the photographic library to ensure accuracy. Photographic representation of all products can help inspectors/auditors recognize exactly what to look for and what types of tamper-evident seals are being used with each product packaging.
6. Perform right-size testing to match the stringency of the materials test (e.g., mass spectrometry/GC) and the need for specialized training and instrumentation with the perceived level of risk. For some products, it may be appropriate to streamline testing procedures to obtain greater throughput and cost-effectiveness. For others, sophisticated and specialized techniques, such as nuclear magnetic resonance (NMR) imaging, may be required. Additionally, suppliers and manufacturers should ensure categorization alignment—or a clear understanding of product grades, specifications and regulatory requirements—not only to ensure right-size testing, but also to secure the proper grade selection for a product's purpose.
7. Explore new technological options such as FedEx's in-flight, real-time GPS-based monitoring of shipments and FreightWatch's tracking and alarm systems to signal possible theft or hijacking. Technologies such as RFID should be integrated with an overall database for globally accessible tracking data.

All of these items should be built into an integrated quality system featuring consistent, well-developed procedures that are sustainable over time and across the complete variety of materials being shipped and received.

These practices can be highly effective in risk management and maximizing security. However, they require teamwork and close cooperation along each link in the supply chain, so that manufacturers have a solid understanding of everything that goes into their products.

References and Sources:

1. <http://pharmtech.findpharma.com/pharmtech/Ingredients/Sharing-Supply-Chain-Security/ArticleStandard/Article/detail/639209> Accessed April 28, 2011.
2. Presentation: "Ensuring Patient Safety Through Innovation, Collaboration, and Transparency in the Supply Chain," presented at DCAT, New York City, March 16, 2011 by Eric L. Berg, Amgen Inc. Director of Supplier Quality
3. <http://www.rx-360.com/Rx-360> web site. Accessed April 27, 2011.
4. Presentation: "Collaborating to Strengthen the Supply Chain: A Supplier's Perspective," presented at DCAT, New York City, March 16, 2011 by Joe Woodward, Avantor Global Director, Logistics & Planning
5. http://www.avantormaterials.com/Chemicals_Quality_and_Supply_Chain_Systems.aspx Avantor web site. Accessed April 27, 2011.
6. <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM178997.pdf>. Accessed April 28, 2011.



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