



Leveraging Track & Trace in the Pharmaceutical Industry

An industry whitepaper

Topics

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The counterfeit drug problem

The counterfeit drug market, recognized by the Food and Drug Administration as a real and expensive problem, is responsible for the loss of billions of dollars every year. Counterfeit drugs are manufactured by using inactive (ineffective) or toxic (harmful) ingredients and are packaged to resemble genuine (brand-name or generic) drugs.

The World Health Organization estimates counterfeit drug sales to range between \$35 and 40 billion per year. Between 8 and 10% of the worldwide drug supply is estimated to be counterfeit, which means that by the year 2010, more than \$75 billion of sales will be lost per year.

Counterfeit products damage consumer confidence in the drug brand and in the supply chain. To counteract the counterfeit drug supply, manufacturers are forced to increase their inventory stock by up to 10%. Hospitals and retail pharmacies are spending, on average, between \$700,000 and \$800,000 per year on excess inventory.

An inefficient supply chain

According to Interactive Data Corporation (IDC), the pharmaceutical industry loses 4.5% of revenue because of supply-chain inefficiencies. Contributing to these inefficiencies is the complexity of the pharmaceutical supply chain, where drugs can change ownership up to 10 times before reaching the customer. Alternate distribution channels for drug products often ignore distribution rules, which can undermine the manufacturers' ability to authenticate some of the drug supply.

High supply-chain costs result from diversion, lack of visibility into product inventory, and inefficient processes for conducting recalls and returns processing. Collectively, these inefficiencies result in billions of lost dollars per year and create the need for technology that provides visibility of product movement across the total supply chain.

Recognizing business benefits

Customers can collaborate with IBM to solve the problems of counterfeit drugs and supply-chain inefficiency.

In addition to supporting government compliance mandates, IBM's InfoSphere Traceability Server offers business applications that improve overall supply chain performance and can allow customers to see a positive return on their investment. Through the ePedigree application, customers are able to automate compliance—and thereby increase the accuracy of—the process of tracking their products throughout the supply chain. This automation saves money and increases consumer confidence in the brand, in the manufacturer, and in the industry.

Once customers have established a compliance infrastructure based on InfoSphere Traceability Server and the ePedigree application, customers can easily take advantage of the data captured to solve additional business use cases such as Cold Chain Management and Targeted Recall to realize ROI and improved supply-chain efficiencies.

The pharmaceutical industry can leverage IBM traceability technology to solve challenges in multiple use cases beyond pedigree compliance such as supply-chain visibility, reverse logistics, and supply-chain integrity.

Reduce costs with Supply-Chain Visibility Cold-chain management

Traceability technology provides temperature and shelf-life data about cold chain products. According to a recent report by IMS Health, worldwide sales of biologic medications, which require temperature-controlled storage and shipping conditions, increased by 12.5% in 2007 to \$75 billion, nearly double the 6.4% increase in sales of traditional pharmaceuticals. With Traceability technology, customers can track temperature information and parameters to effectively monitor and manage cold-chain products. This enhanced visibility can increase product safety and reduce waste by generating alerts when a product is not located in the appropriate temperature-controlled location within

a specified timeframe. In addition, increased government oversight on environmental conditions requires manufacturers and distributors to track cold-chain products. Customers can add temperature information and parameters to pedigree data to effectively monitor and manage cold-chain products.

***Maintain brand image with Supply-Chain Integrity
Diversion detection and ePedigree***

Traceability technology helps solve the problem of lost revenue due to sales outside the normal supply chain by minimizing the risk of counterfeit or tampered products. Electronic pedigrees abide by governmental drug requirements, ensure patient safety, and minimize incidents of counterfeit and diverted drugs to create a safer supply chain and ensure brand image and consumer confidence.

Product authentication

With traceability and ePedigree technologies, members of the supply chain can confirm the authenticity of the products that they are handling. For example, a retail pharmacy that receives a shipment of serialized drugs can authenticate the product. This technology prevents counterfeit or imitative products from entering the supply chain, which prevents brand erosion.

***Improve supply-chain efficiency through enhanced
Reverse Logistics***

Targeted recall

Traceability technology helps manufacturers issue targeted recalls of individual packages of products that might be contaminated. For example, if a portion of a lot of a drug had been stored at a temperature that compromised the chemical composition of the drug, the manufacturer could issue a recall for only the affected items—based on the visibility of the status and movement of each individual unit’s unique serial number. Targeted recalls enable manufacturers to recall specific units of a product instead of a broad, excessive amount.



IBM Smarter Planet initiative

IBM introduced its Smarter Planet initiative, available at www.ibm.com/smarterplanet, to foster global collaboration based on the availability of “smart” and affordable technology. IBM’s Smarter Planet initiative recognizes that

the problems facing all people—a financial crisis, climate disruption, energy geopolitics, food-supply hazards—speak to the inter-connectedness of economic, social, and technical considerations across the world.

As the world is becoming more instrumented, interconnected, and intelligent, new monitoring and tracking technology can help countries and the globally connected pharmaceutical supply chain to realize smarter, safer outcomes that protect patient safety and improve supply chain efficiency.



Around the Smarter Planet initiative, IBM is championing solutions for New Intelligence—solutions designed to help organizations take advantage of the wealth of information available in real time and make more intelligent choices. By putting this New Intelligence into action, InfoSphere Traceability Server is in a position to help companies save millions of dollars in lost revenue resulting from counterfeit drugs and supply chain inefficiencies. More importantly, InfoSphere Traceability Server is helping companies reduce a major threat to the public health system and a constant risk for patients.

The IBM solution

Traceability is an emerging technology arena and provides a foundation for a variety of tools and operations. InfoSphere Traceability Server is part of IBM's Solution for Pharmaceutical Track & Trace which also leverages WebSphere Premises Server for data capture through sensors. As the thought-leader in the market, IBM advances its past success in traceability technology by enabling multiple business use cases through applications and business intelligence.

Built on InfoSphere Traceability Server, the ePedigree application enables pharmaceutical companies to create an electronic certificate of authenticity (known as an *electronic pedigree* or *ePedigree*) for every drug that passes through the

supply chain. All participants in the supply chain—manufacturers, distributors, pharmacies and hospitals—can access historical data on individual bottles or packages of medicine. This electronic pedigree guarantees authenticity and protects the drug from counterfeit imitations when the drug enters the market, thereby instilling consumer confidence in the safety of the drug.

The ePedigree application enables brand owners to automate and thus increase the accuracy of authenticity-checking processes while also complying with global serialization and pedigree regulations. Automation leads to lower costs, increased accuracy, and enhanced patient safety. This application builds a foundation for relationships built on confidence, trust, and reliability between IBM and brand owners, and it offers customers the ability to leverage the data captured for ePedigree to address other key business challenges:

- Authenticate pharmaceutical products through direct data exchange with trading partners
- Comply with federal regulatory drug mandates
- Develop, maintain, and ensure brand image and product authenticity
- Enhance sales revenue
- Improve the integrity of the entire drug supply chain
- Increase product, patient, and consumer safety
- Instill trust in the safety and security of a drug
- Help issue targeted recalls
- Minimize cost of excess waste



In addition to being certified with GS1/EPCglobal's Electronic Product Code Information Services (EPCIS) and Drug Pedigree standards, InfoSphere Traceability Server also integrates with customer master data systems to provide additional business context with product, location, and supplier information.

InfoSphere Traceability Server's customizability and multi-solution benefits provide the foundation upon which customers can build all of their track-and-trace operations.

The possibilities for track-and-trace operations extend beyond the pharmaceutical industry: the technology has great potential to solve similar supply chain problems in the automotive, food and beverage, and manufacturing segments.

Electronic Product Code Information Services

The pharmaceutical industry benefits from GS1/EPCglobal's EPCIS standard for visibility of product movement. Establishing ePedigree via EPCIS events and queries enables clients to easily access key data elements that will solve a range of business needs.

EPCIS includes a data model for events and provides a set of interfaces for data capture, data query, and data exchange. EPCIS consists of three basic objectives:

- Storing granular information about objects
- Searching for granular information about the past and present of objects
- Sharing data with applications within and with external enterprises

Looking forward

If you are interested in learning more about IBM's InfoSphere Traceability Server and ePedigree application, visit www.ibm.com/software/data/infosphere/traceabilityserver or contact IBM for a briefing and a demo.

Also, visit www.ibm.com/solutions/sensors for information IBM's Solution for Pharmaceutical Track & Trace.

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