Thwarting counterfeiting in the pharmaceutical manufacturing industry

Protect your brand and increase operational efficiency using radio frequency identification

Executive Brief
Executive overview

The potential scenarios and possible implications of pharmaceutical counterfeiting are, if nothing else, astounding and often unthinkable. Unfortunately, they are all too real. Consumers who take a counterfeit medication may be at risk of severe health consequences: unexpected side effects, worsened medical condition or even fatality. And the fallout for the pharmaceutical industry is no less severe in terms of revenue loss and company reputation. Lost sales and market share, damaged and difficult-to-recapture brand value, high costs of executing a product recall and potential for large fines resulting from lawsuits. Bioterrorism presents yet another chilling aspect of counterfeiting, with the possibility and threat of poisons being introduced to the drug supply.

Although the U.S. Food and Drug Administration (FDA) believes that domestic drug counterfeiting is not yet widespread, the agency has seen a spike in counterfeiting activities as evidenced by an increase in counterfeit drug investigations, from approximately 5 a year in the late 1990s to over 20 per year since the year 2000.1 Globally, the World Health Organization (WHO) estimates that 7 or 8 percent of drugs worldwide are counterfeit, with reports indicating that as much as 50 percent of some countries’ drugs are counterfeit.2 This trend will likely continue as the market presence of targeted treatment solutions—more expensive treatments aimed at selected populations—expands, providing a wealth of high-value-added products as potential targets.

Consumers expect that the medicines they buy are authentic. But the truth is it’s possible that they’re not. Many counterfeits contain no active ingredients; rather, they contain inert substances, giving the patient no therapeutic benefit. Counterfeit medications may also contain incorrect ingredients, improper dosages of the correct ingredients or hazardous ingredients. According to WHO, approximately half of all counterfeit drugs either contain no active ingredient or contain the wrong one.3

IBM solutions for Radio Frequency Identification (RFID) can help you incorporate dynamic tracking information into your supply chain to acquire a clear, accurate view of products as they travel from the manufacturing plant to the consumers’ hands. By integrating new technologies with existing security methods, you can give all parties in your supply chain access to realtime, recorded authentication about a drug’s entire history. This executive brief explains the benefits of an RFID solution for pharmaceutical manufacturing and how IBM Business Consulting Services can help you take advantage of technologies to transform your supply chain.

Counterfeiting, reimportation and diversion: leaving the door wide open

Most commonly, counterfeited drugs are manufactured in various countries and then enter U.S. and European supply chains via poorly regulated and monitored wholesalers. Although the majority of drugs are distributed through a limited number of mainstream wholesalers, thousands of small wholesalers make up a booming secondary market. While these secondary wholesalers may create operating efficiencies, their size and number also make it easy to lose track of product shipments in the distribution chain, creating opportunities to introduce counterfeit drugs. In an effort to impede such operations, the North American market may use alternate approaches such as requiring drug pedigrees or embracing the European market standard of unit-of-use packaging. While unit-dose packaging will decrease some opportunities for counterfeiting, it will not obviate the need for product safety and tracking assurance, since repackaging technologies are as sophisticated as legitimate packaging technologies. And unit packaging would not affect the problems of diversion or reimportation.

While diversion and reimportation are different issues, they present related problems. Gray markets result from reselling products that have been diverted from legitimate channels—such as foreign countries, nonprofit health providers and nursing-home pharmacies—that receive the drugs at greatly discounted prices. Some of them are reimported into the country of origin at a discounted price. Today in the U.S., you cannot read a newspaper, listen to the radio or watch TV without seeing a report about the flow of pharmaceutical products into the country from Canada and elsewhere. Although by law, prescription drugs exported to foreign countries from the U.S. can be reimported only by the drugs’ manufacturers, approximately 20 million packages containing pharmaceutical products make their way into the U.S. each year. Because these products were intended for sale in a country other than the U.S., they may not have FDA-approved labeling. Consumers who purchase these products because of substantial discounts subject themselves to drugs that may not have been managed under appropriate storage and distribution conditions, such as temperature, humidity and photostability levels. Reimported drugs may have been mishandled and maintained under suboptimal conditions or mixed with counterfeit product, making them impossible to trace in the event of a recall.

Thwarting counterfeiting in the pharmaceutical manufacturing industry

IBM Business Consulting Services

The need for additional, more-thorough track-and-trace capabilities will become critical as manufacturing and the pharmaceutical supply chain grows even more complex. An increased number of products within various distribution channels, along with a greater need to control the environmental sensitivity of biologics, will undoubtedly become the norm, not the exception. Unfortunately, with today’s security technologies, there is simply no way of validating or tracking a drug’s complete path from raw material to consumer purchase.

The problem will not resolve itself. As long as the following circumstances exist, counterfeiting and diversion will continue.

- Sophisticated technologies for duplicating packaging and labels
- Numerous small wholesalers buying and selling drugs
- Increase in high-cost drugs and blockbuster products
- Weak legal penalties and lack of enforcement
- Abundance of Internet pharmacies
- Differential pricing on a global basis.

Technologies and processes that address these issues will be critical to the success of companies in this industry worldwide.

The price of counterfeiting: more than profits

The costs and risks of drug counterfeiting to both public health and pharmaceutical companies are extremely high and growing: public health and consumer confidence have eroded, and pharmaceutical companies suffer from both loss of revenue and brand value. If for some reason, a drug becomes suspect, the incentive to switch to another brand is strong—and with multiple products available to consumers, it’s easy to switch. From a marketing perspective, your biggest loss could be in customer confidence. And the risk of significant lawsuits looms large. Even more unsettling is the potential threat of a terrorist organization introducing lethal counterfeits into the supply chain. Counterfeiters can buy the same sophisticated equipment for creating packaging and labels as that used by legitimate manufacturers, making it extremely
difficult to distinguish counterfeits from authentic product. Merely the threat of a
deadly counterfeit (even if it were completely unfounded), would result in the recall
of entire lots, leaving your company with a massive loss of income, underscored by
substantial loss of consumer confidence. To combat the threat of counterfeit drugs,
you may need to augment or replace your existing security measures with new
technologies designed to safeguard your brand.

**Using technology to combat counterfeiting and diversion**
The threat of unsafe drugs can be reduced through the implementation of a
variety of technologies—such as packaging and labels, bar coding and in-product
marking—but when compared to others, one relatively untapped technology offers
unique efficiencies: RFID. Any successful anti-counterfeiting technology must be
cost-effective, adaptable and scalable. RFID readily fulfills the last two components
and addresses the first as the implementation costs of the technology continue
to decline.

By identifying unique items using radio waves, RFID technology improves upon the
25-year standard of product identification and tracking through bar codes. Because
radio waves don’t require line-of-sight (for a bar code to work, a scanner must see
the bar code, which means that the bar code must be oriented toward a scanner
to be read), an entire pallet of product can be identified and tracked instantly, just
by passing through a reader mounted on a warehouse door. The capacity of RFID
tags to contain enough data for the identification of unique items, combined with
the ability to layer encryption and additional features, lets you increase operating
efficiencies and decrease labor costs while simultaneously increasing security levels.
How RFID works

The most common means of identifying products using RFID technology is to store the product information, including its unique identifying serial number, on a microchip attached to an antenna, together known as the RFID tag. When interrogated by a reader, the tag transmits the identification information to the reader, which converts the radio waves returned from the RFID tag into language a computer can understand and use.

This information enables two of the most important methods of combating counterfeit drugs—instant authentication and robust track-and-trace. No other technology alone can provide this robust level of security. With RFID, each unit has a unique electronic product code (EPC) that allows authentication at any point in the supply chain (from
the raw material of chemical precursors to the finished, consumer-ready product at a retail pharmacy). The EPC can enable all parties in the supply chain to have access to realtime, recorded information about a drug's current and historical locations, time spent at all locations, record of ownership, packaging configurations, environmental storage conditions, delivery dates and other pertinent information. For diverted drugs, RFID can identify the source of diversion, where the product left the accepted distribution channel, where it re-entered and, within limitations, whether it is the same product—none of which any other security method can offer.

When RFID is incorporated as part of a comprehensive brand protection and security strategy, its benefits become manifold. With RFID technology, you can:

- Monitor the manufacturing process in compliance with regulatory requirements while protecting against fraud (and safeguarding your brand equity).
- Validate drug authenticity throughout the supply chain, in realtime.
- Decrease exposure to legal liability and increase positive revenue impact from recovering sales lost due to shortcomings in previously implemented security technologies.
- Reduce inventory shrinkage while reducing labor costs.
- Implement product recalls, should the need arise, or proactively remove expired product from the marketplace.
- Mine the wealth of information from increased supply-chain visibility to improve forecasting and planning.
It’s worth noting that, in an effort to validate the path a drug takes throughout the supply chain, some states are legislating paper pedigrees for drugs. While this is a prudent approach, a paper pedigree can be lost or easily tampered with—unlike an electronic pedigree created by RFID. While the FDA is not endorsing any one particular counterfeiting technology, it has identified RFID as a potential key technology for track-and-trace throughout the supply chain.

Creating an industrywide win with RFID
When determining whether RFID is an appropriate technology for your company, you must first understand and identify your security goals. To understand and apply the value of RFID to your company, IBM Business Consulting Services suggests first asking yourself the following questions as you begin to determine the key elements of your security strategy and to prioritize and focus your efforts:

- What is the nature or source of the primary security risks I need to address—counterfeits entering a national supply chain or diversion or even both?
- Instead of leaving any of my brands and markets open to risk, how can I implement a security solution across all my lines?
- Where does authentication need to occur—in distribution centers or in the field? How can I achieve the full value of a security solution if my answer is both?
- Is identification of key raw materials or work-in-process necessary or is item-level verification of final product required?
- How can I implement security technology from the beginning of the manufacturing process to the end at packaging? How do I integrate RFID with other packaging and security technologies?
A business case for RFID should consider the resulting tangible benefits of reduced counterfeiting and diversion, which include revenue impact and supply-chain costs, as well as the intangible benefits of brand protection and risk reduction. Implementation scenarios should also be considered, taking into account the degree and number of participating companies in the supply chain and the products for which implementing RFID technology would produce the greatest initial return on investment.

A continuous chain of assurance with RFID

When compared with other existing security technologies (for example, bar codes, in-product marking, tamper-evident packaging), RFID offers more robust and capable efficiencies. Manual involvement is decreased, because line-of-sight is not required for product scanning. Less product waste occurs, since verifying authenticity doesn't require product destruction. And unlike bar codes, EPC codes not only identify unique products, but are themselves unique and cannot be duplicated. They can also be encrypted for additional security. RFID tags carry substantially more information than bar codes, are scalable and reusable for much longer active-use lives and have faster read times for high throughput. While not a standalone solution, when implemented along with a layer of traditional security technologies and integrated with your other enterprise applications, RFID can give you a significantly more efficient means to accomplish your product-safety and brand-protection goals.

It's important to acknowledge that existing track-and-trace technologies will not be displaced overnight. As a result, companies, including IBM, have developed solutions that incorporate both RFID and bar-coding technologies. IBM Track and Trace, for example, is a combination RFID- and bar-code-capable solution to track goods that move through a multienterprise supply chain. Units can be tagged at an
individual level, at the manufacturer’s facility or at a bulk level, upon distribution to end customers. The result? Companies can leverage their existing infrastructures to simultaneously report on goods movement and status while feeding realtime tracking data to multiple enterprise resource planning (ERP), supply-chain management and warehouse management systems (WMS). Unique IDs support creation of an international pedigree that can be verified at any point in the supply chain, creating a continuous chain that can be checked with confidence.

A path for your success
The value of implementing an RFID solution will depend on the business-case dynamics exclusive to your company and products. IBM Business Consulting Services staff can lead your business through the entire process, from start to finish. We work with you during three key RFID implementation phases:

• Business case and deployment strategy—Business Consulting Services staff identify the tangible business benefits that RFID can offer your company. We discuss implementation designs that can reduce business impact and assess your existing technology infrastructure for a more cost-effective, efficient software strategy.

• Solution build and pilot program management—We can develop and implement the pilot installation, including solution architecture and hardware and application integration. Following thorough testing of the pilot implementation, we help ensure that data is appropriately captured from the tags and transferred into your back-end systems quickly and accurately.

• Enterprise rollout and integration—During the final implementation phase, we estimate capacity and performance needs, establishing benchmarks for testing your solution once it’s deployed. Business Consulting Services staff plan and manage your enterprisewide deployment, from installing the data warehouse and setting up data management services to integrating new processes with your appropriate supply-chain partners.
Making technology work for you
IBM can design customized, scalable solutions for multiple manufacturing facilities, distribution centers and warehouses that fit seamlessly with your existing infrastructure. Through solutions that integrate RFID tags and multifrequency readers with existing data-capture and back-end systems, you can implement cost-effective RFID technology across your enterprise.

Figure 1: IBM Radio Frequency Identification architecture components complement technology currently in use.

IBM has designed and built a scalable and flexible RFID architecture that can work with the technology you currently have in-house, letting you implement RFID technology across your enterprise in a cost-effective manner. As indicated in Figure 1, information is sent by multiple readers at remote locations (for example, distribution centers, pharmacies and stores) to edge servers connected to local application server databases. This data is then integrated at the enterprise level by a server that connects this data with your key internal databases, applications and platforms (for example, an ERP platform, a WMS or a manufacturing execution system), where the server connects to your external partners through tools like portals and the Web.
A leader in RFID solutions for more than ten years, IBM developed some of the original patents that support the current tag and reader technology and drive today’s industry. IBM is itself an RFID-enabled enterprise, using RFID technology as a key technology that enables the full automation of its semiconductor chip fabrication plant in Fishkill, New York.

Because successful EPC implementation requires industrywide collaboration and commitment to standards, IBM has been a member of the Auto ID Center and a representative on the Technology Board since 2000 and is an active participant in EPCglobal. Our alliances with leading hardware and software developers in the RFID industry allow us to offer superior solutions backed by best-in-class technology. IBM consultants represent both functional and technical specialists, who have provided support to 75 percent of the top pharmaceutical firms.

**Protect yourself, your consumers and your bottom line**
Counterfeit prescription drugs are not only illegal, they’re unsafe. When indistinguishable from the authentic versions, counterfeit drugs pose potentially serious health threats to consumers, and can lead to lost revenues and damaged reputations for the companies that manufacture them. IBM offers a broad portfolio of capabilities—business-case development, solution prototypes, process reengineering, software installation and enterprise rollout—creating an end-to-end solutions that are designed to help you remain focused on keeping your business running profitably and safely.
For more information
To learn more about IBM Business Consulting Services, contact your IBM representative or visit:

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To learn more about IBM Solutions for Radio Frequency Identification visit:

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