



A Prescription for RFID Success in the Pharmaceutical Industry

Words like “counterfeiting”, “gray market”, and “out of stock” are anathema to any industry, but for pharmaceuticals the implications are particularly serious. Radio frequency identification, or RFID, has the potential to nearly eradicate such issues.



There are many challenges facing the pharmaceutical industry of the 21st century. Patents on major drugs continue to expire, while companies struggle to produce innovative breakthroughs to offset the impact of generic substitutes. The regulative environment is becoming more intense, as the FDA looks to impose more stringent safety standards when approving new drugs. In addition, rising anger over the price of prescription drugs, and increasing outcries for legal importation of drugs across borders, looks to further reduce revenue growth (*Source: Frost & Sullivan website*).

The Authentication Drive in the Pharmaceutical Industry

There is much concern in the industry and from its large healthcare clients and their patients, about whether a drug that has been prescribed is authentic or not.

This degree of authentication not only applies to getting the drug as described on the packaging from the company that produces the drug, but also covers ensuring that the drug dispensed has not come from an allocation made to the Third World or from repackaged out-of-date stock. The pharmaceutical industry estimates that between 2 and 7 percent of all drugs sold globally are counterfeit.



Printed labels and barcodes can be easily replicated and lend themselves for counterfeiting.



Expensive and specialized drugs are counterfeited more often than others and can cause irreparable harm to the patient.

When a situation like this occurs, there is serious impact on the drug company's share price. This is well illustrated by what happened to Eli Lilly when an attack on Zyprexa occurred in 2002.



The US Food and Drug Administration's current anti-counterfeiting tasks include investigating new methods to secure the pharmaceutical supply chain, by examining new technologies that utilize RFID/EPC.

To address and combat the increasing occurrence of counterfeit drugs, US federal and state regulators are pursuing solutions that require the tracking, recording, and communication of a drug *pedigree*. RFID technology makes it easier to ensure that drugs are authentic, and it also creates an electronic pedigree, or record of the chain of custody, from the point of manufacture to the point of dispensing. Electronic pedigrees will improve patient safety and protect the public health by allowing wholesalers and retailers to rapidly identify, quarantine, and report suspected counterfeit drugs and conduct efficient, targeted recalls.

FDA considers electronic pedigrees to be a type of "electronic safety net" which utilizes technology that allows illicit drug transactions to be rapidly identified and, potentially, transmitted to the FDA thereby improving FDA's ability to conduct investigations of suspected counterfeiting or diversion of prescription drugs.

The FDA stated in 21 USC 353: "Each person who is engaged in the wholesale distribution of an Rx drug **and who is not an authorized distributor of record** of such drug shall, before the sale, provide to each wholesale distributor a **statement identifying each prior sale of the drug**". In addition, 21 CFR §203.50(a) states: "Before the completion of any wholesale distribution by a wholesale distributor [who is not an authorized distributor of record], the seller shall provide to the purchaser a statement identifying each prior sale, purchase, or trade of such drug". This pedigree, as it has become known, has to contain the following information:

- Proprietary and established name
- Dosage



- Container size
- Number of containers
- Drug's lot or control number(s)
- Business name, address, and dates of all prior transaction parties, starting with the manufacturer

Although the U.S. government stopped short of introducing legislation to force pharma companies to adopt RFID, several state governments, including Florida, Nevada and California, have passed laws requiring drugs to be tracked throughout the supply chain. The story is similar in Europe, where member countries have nine RFID initiatives that will be implemented in the next few years.

The Florida regulations also include the following requirements:

- Every party engaged in the wholesale distribution of a prescription drug (except the manufacturer of that drug) must provide a pedigree.
- Pedigrees must be provided prior to wholesale distribution.
- A drug for which the required pedigree is nonexistent, fraudulent, or incomplete is considered "adulterated," and it cannot be sold. The law stipulates that parties involved with adulterated pedigrees are at risk for felony prosecution if they:
 - Fail to authenticate the pedigree and attempt to further distribute a drug.
 - Falsely swear or certify that pedigree papers have been authenticated.
 - Falsely represent factual content of a pedigree or knowingly omit required information.

California's regulations come into effect on January 1, 2007. They state that each wholesaler or pharmacy must pass a pedigree with each sale, trade, or transfer of a drug, and that each wholesaler or pharmacy must receive a pedigree with each acquisition of a drug. Nevada's regulations state: "A wholesaler, before each sale to another wholesaler or pharmacy, must provide a Statement Identifying Prior Sales (pedigree) with each sale to another wholesaler or pharmacy, if the wholesaler... Does NOT have an ongoing relationship with the manufacturer from which the drug was purchased; or the drug was purchased from another wholesaler."

At least 22 states (AZ, AK, CT, GA, IL, IN, IA, KS, KY, ME, MD, MN, MO, NE, NV, NM, NJ, NC, OK, OR, UT, and TX) are currently reconsidering changes to licensing.

RFID has a great deal to offer the pharmaceutical industry. It's a promising business tool for solving some of the industry's most pressing problems. The objective driver for using RFID is return on investment (ROI), through the following:

A higher rate of speed/fewer manual processes:

- No line-of-sight required
- FAST, R.A.S. data collection
- Simultaneous reading of multiple items



Pharmaceutical RFID tag

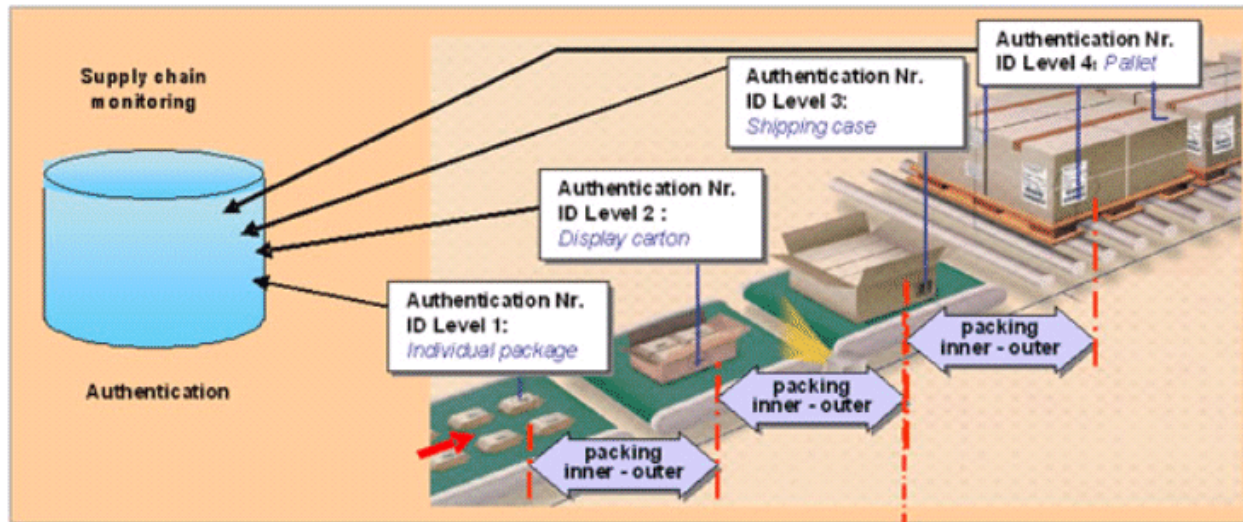
- Can operate in extreme environments

Reduced asset pools:

- Automated data collection (full track & trace)
- Gathering of data while interfacing with databases

Reduced losses:

- *Very* challenging for criminals to copy/defeat
- On-chip data security
- Covert (embedded solution)



Authentication at all stages down the production line

Today's ePharma RFID systems typically track the location of pills from RFID tags or barcodes, and the change of custody at all change of ownership points. Specifically, the system supports serialized and non-serialized pedigrees, as well as item-level and/or case-level serialization. Any man, woman or child with an e-mail address has likely deleted scores of spam for discounted Viagra from questionable sources. It is a major target for counterfeiters. But Pfizer, the pharmaceutical giant that manufactures the drug, has announced it is using RFID to fight Viagra fakes. Viagra and Trizivir are already tagged in the US. Trizivir an HIV medicine, is one of the 32 drugs listed as most susceptible to counterfeiting and diversion. As each bottle of Viagra moves down the packaging line, a label with an integrated passive high-frequency (13.56 MHz) tag is applied. An RFID interrogator then encodes an EPC to each label, after which a second interrogator verifies the tag has been successfully encoded and can be read. The interrogator also reads the unique ID number stored on the tag's chip by the chip's manufacturer, enabling Pfizer to record both the chip ID and the item's EPC in a database. Pharmacists and wholesalers will use the tags to authenticate the drug. If the EPC was not issued by Pfizer, or if the chip ID does not match the one in Pfizer's records for that EPC, the RXauthentication Service sends a notice, through the RXauthentication application, to the pharmacist or wholesaler to quarantine the product. RXauthentication Service also contacts Pfizer's Medical Information

Services, a group of Pfizer employees who process suspected cases of counterfeit drugs and would likely ask the druggist or wholesaler to send the suspected bottle of Viagra back to Pfizer for investigation.

In Europe, Stora Enso are item level tagging drugs for Orion Pharma, and the British National Health Service (NHS) has used RFID to tag medical instruments in hospitals.

Production and Supply Chain Visibility

The pressure of the FDA and the US states over product authentication through pedigrees, and the inefficiencies of using paper-based systems, means that pharmaceutical companies will need to introduce RFID-based solutions. Those organizations that are looking to exploit technology, as well as enhance the ROI, will look at other uses of RFID technology to assist in visibility and identification, as illustrated in this paper.

RFID offers new levels of visibility for companies that want to track physical items between locations. In the supply chain, goods tagged at the point of manufacture can now be traced from the factory to the retail shop floor, thus providing a real-time view of inventory for all supply chain partners.

The potential of RFID technology is enormous. Realizing the value however, requires a business-wide approach:

- **Maximize the value** through understanding the full breadth of the implications and opportunities presented by the technology. Look beyond the obvious.
- **Minimize the risk of failure** through appreciating the pitfalls involved in RFID technology selection, integration, and implementation in the end-to-end supply chain. RFID solutions involve different vendors with a wide variety of potential products which must be specifically architected to each customer. A specialized system integrator will solve these issues with a single integrated approach.

Drug companies are already tagging pharmaceuticals so that they can monitor where drugs are lost and stolen. Astra Zeneca has already tagged more than 50 million syringes to ensure that patients are given the right dose of products.

In the first quarter of 2009, DPT Laboratories, a contract drug developer and manufacturer specializing in semi-solid and liquid pharmaceuticals, plans to conduct a track-and-trace and serialization pilot leveraging radio frequency identification at its San Antonio facility for one of its customers, [Galderma](#), a pharmaceutical company focused on treatments for skin conditions. DPT Laboratories is working with an RFID Systems Integrator on the pilot.

One of Galderma's products—a topical ointment packaged in tubes—will be involved. Once the tubes are inserted into the cartons, a conveyor will move them past an RFID interrogator. As each tag's



readability is verified, its ID number will be captured and sent to a back-end system that can then utilize that data to create an e-pedigree and invoice. According to Green, DPT Laboratories will outsource that back-end system to a third-party company, and has narrowed the choice to two firms, [Axway](#) and one other.

The individual cartons will then be packaged into a case, to which an RFID label will be attached.

The Smart Cabinet

Ensure automatic replenishment by using a "Smart Cabinet" placed in a hospital (it works like the Smart Fridge we've all heard about).

Smart Cabinets are being used for Pfizer's Viagra and for GlaxoSmithKline's (GSK's) Trizivir in order to monitor the item usage of each vial. Authorized access and access tracking to the smart cabinet can also be enabled by pairing with a RFID-enabled employee identification badge. The Smart cabinets use both HF and UHF frequencies.

RFID tagging and can occur at different packaging levels. Here are just a few examples:

- Pfizer uses RFID at the item level: a HF RFID tag is affixed to the bottle and emits at a short range (less than 1 foot).
- Pfizer uses RFID at the case level: a UHF RFID tag which emits up to 12 feet.
- Other companies can also use pallet tags: If they want to locate a product at a very far distance, within an entire distribution center for example, it can use an active RFID tag that sends its signal up to 300 feet away.

Monitoring life critical drugs is serious business. Using RFID in the hospital's Smart Cabinet enables the distributor and hospital administration to monitor and control authorized smart cabinet access and the exact item usage of each bottle as its being deployed and is even higher value to Pharma companies who provide drugs to hospitals on a consignment basis. This means real time knowledge that allows Just-in-Time on demand replenishment. This can save lives.

Walgreens is also using RFID technology in day to day production toward its goal of 100% shipping accuracy from distribution center to store.

Product Diversion

For Pharma companies, product diversion may be as big a problem as counterfeit products. Free market countries where pharmaceuticals are sold at market prices may be less or more than other countries which impose government controls and pricing. This results in market incentives to divert product from a lower cost source and arbitrage the higher price country. This reduces profitability of pharma companies and introduces further support for pedigree tracking via RFID. Forensic teams can now scan products in other countries and interface with a database to verify where that product should be in the supply chain. RFID can bring complete integrity around those products, the temperature and the location and the quality of the shipment and achieve compliance with the regulations progressively being adopted.

FALKEN Secure Networks(FSN)—Your partner for RFID automation

If you choose to pursue RFID implementation in your organization, here is the FALKEN Secure Networks commitment to you:

- FSN will provide solution architects to work with you to define system requirements for your particular installation. Multiple locations can be networked together for a central and real-time view and centralized management.
- FSN will do a RFID site survey to validate radio frequencies, tag types, system design and performance
- FSN will provide all necessary hardware and software to make the system work for you
- FSN will integrate the system with your existing enterprise management software
- FSN will provide documentation for the system, including operating procedures
- FSN will train your people
- FSN will provide warranty and continued system support

For RFID-enabled Document Tracking and Management, FALKEN Secure Networks (FSN) and partners bring together the right technologies to give you control over your files and make your office run more efficiently. Our automated and secure processes save time and labor, and prevent problems before they occur. With FSN ,you get the latest, non-proprietary secure RFID technology with the most powerful and flexible RFID file tracking software available.

Contact Us

FALKEN Secure Networks is a specialized System Integrator, RFID Solution Architect, and Value-Added Reseller with focused expertise in the RFID site survey, cost-effective design, and turn-key project implementation.

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