



Whitepaper

Pharmaceutical Shifts Towards UHF RFID for Savings

The pharmaceutical industry in the United States dispensed more than \$260 billion worth of prescription medications in 2008, and in the global marketplace the total is more than twice that amount. Distributing regulated pharmaceuticals is done through a complex supply chain involving thousands of trading partners who conduct business through multiple transaction levels. At all of these levels there are benefits to be derived from RFID technologies, beginning with the effort to stem the influx of counterfeit drugs.

Saving Billions of Dollars—and Lives

In the United States alone there are more than 100,000 pharmaceutical dispensing sites. Between the time a pill rolls off a production line and is encased inside a bottle at a manufacturing plant to the moment that medication is ingested by a patient, various packagers, primary and secondary distributors, retail pharmacies, hospitals and others may have handled the drug.

It is not all about ePedigree

For most members of the pharmaceutical industry, the mention of RFID automatically invokes the concept of ePedigree regulations. With all the ongoing talk of ePedigree legislation, this is understandable.

This whitepaper will show pharmaceutical industry members how RFID can cut costs and improve efficiencies in your operations today, regardless of ePedigrees. By emulating the success and best practices manufacturers, wholesalers and retailers in other industries have found using RFID, there is no reason to wait for a law to force you to use a technology that will provide value now.

Of course, since this explores how RFID relates to the pharmaceuticals, discussion of ePedigrees is essential. You can read up-to-date information on that here as well. But keep in mind as you read this, RFID and ePedigree are not synonymous, even in pharmaceuticals.

Each transaction handoff represents a vulnerable point in the supply chain where counterfeit products can be introduced, and where authentic drugs can be diluted or diverted to more profitable channels. Fraudulent pharmaceutical drugs have become a worldwide criminal enterprise costing legitimate manufacturers more than \$32 billion a year in lost revenue, while also presenting a growing international threat to public health.

Around the world thousands of people die every year from ingesting prescription medications that are either dangerously contaminated or ineffective in treating a patient's illness or disease. If nothing is done, counterfeit drugs sales are estimated to become a \$75 billion business by 2010, according to the Center for Medicine in the Public Interest.

Securing chain of custody

The sheer size of this problem, along with its impact, is a major concern for both the pharmaceutical industry and government agencies. In response, a consensus has formed around the need to precisely "track and trace" a prescription drug's "chain of custody" from the time a pharmaceutical product leaves the factory to the moment a patient receives the medication. This tracked chain of custody is known as the product's pedigree.



By using RFID technologies, electronic histories known as ePedigrees can be established. And by monitoring where and when products are manufactured, along with where they're shipped to and providing the means to verify their authenticity, the chances of unregistered counterfeit items making their way into the supply chain are greatly reduced.

Across the United States, federal and state laws advocating ePedigrees have been proposed and enacted to address the criminal activities and increasing threats to public health posed by counterfeit drugs.

While legislative compliance may have been the impetus to ePedigrees, UHF RFID is already resulting in cost savings and efficiencies in the production, distribution and dissemination of pharmaceutical drugs that can have far-reaching benefits.

UHF transforms the RFID value proposition

By using UHF RFID, the same electronic track and trace measures used to combat counterfeiting can provide other cost-effective propositions throughout the supply chain. The participants in the original, FDA-supported RFID pilots conducted in 2004, have never stopped using it. Some RFID programs have already rolled out. For example, employing a different type of RFID, the CVS drugstore chain has contactless payment readers on every counter in every store.

Central players have concluded that RFID will bring valuable cost savings and safety benefits independent of mandated ePedigree rules. RFID technology solutions can help manufacturers, distributors, pharmacies and others in the pharmaceutical industry achieve greater operational efficiencies, productivity gains and cost savings.

Their testing has shown the accuracy and reliability UHF brings to RFID has been profound. It can improve productivity in shipping and receiving; lower labor handling costs; increase the accuracy of shipments; and reduce the costs associated with product recalls. The primary RFID-related standards organization, EPC Global, has solidified their Class 1, Generation 2 UHF protocol as a universal supply chain medium. This standards group, supported by the major pharmaceutical businesses, is finalizing a UHF-based data exchange (EPCIS) RFID standard for ePedigree.

The three largest pharmaceutical distributors who control most of the marketplace – McKesson, Cardinal and AmerisourceBergen – encourage use of UHF-based RFID. McKesson is promoting the value of Gen 2 UHF in a program called “On Track,” which has partners throughout the industry. The largest brand in drug retail, Johnson & Johnson, is firmly committed to UHF based RFID, and announced they are rolling it out throughout their corporation, ultimately to manufacturing and distribution facilities around the globe.

In September 2008, Walgreens began rolling out UHF-based RFID system-wide. Designed to replace all paperwork and barcode scanning during shipment loading, the system leverages RFID technology in day-to-day production towards the goal of achieving 100% shipment accuracy from distribution center to retail store. With over 6,300 drugstores across the U.S., the nation’s fastest growing drug retailer recently launched the first of its next-generation distribution centers in Anderson, SC. Walgreens is in the process of tagging more than 170,000 assets at its Anderson DC, spanning 45 shipping doors, dollies and cart stations. At full capacity, these assets will be used to ship approximately 80,000 cases daily to more than 700 Walgreens stores across the Southeast, making it one of the largest RFID deployments to date.

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Government's ePedigree Laws and Requirements— Present and Future

“Chain of custody” integrity can be achieved through an integrated information technology system which authenticates source and transaction information. An efficient ePedigree system would effectively deter the introduction of counterfeit drugs into the supply chain.

While the concept of drug pedigrees has been around for more than a decade, federal regulatory standards for data formats and the technology requirements (e.g. UHF RFID) to generate them have not been finalized, though several Food and Drug Administration (FDA) initiatives are underway. Several states, with California leading the way, are also moving ahead with electronic drug pedigree requirements.

In 2004 the FDA issued a report on “Combating Counterfeit Drugs” which concluded that the use of RFID technology to establish an electronic pedigree was the “single most powerful tool available to secure the U.S. drug supply.”

While the FDA's 2004 report envisioned that all pharmaceutical drugs within the United States might incorporate RFID tags at the pallet, case and unit levels by the end of 2007, it has not happened yet. ePedigree mandates at the federal level have been considered since prior to this report and such discussions are guaranteed to continue into the future. Meanwhile, the commercial participants in the industry supply chain are making plans to actively incorporate appropriate, anti-counterfeiting measures that will likely blend into FDA initiatives.

Some states currently have existing pedigree requirements that amount to little more than requiring pharmaceutical supply chain trading partners to provide reports in formats such as pdf, text files or spreadsheets. Keeping track of a chronological “chain of custody” by gathering invoices, pdf's and stamping waybills however, is a slow, laborious and often inaccurate process. These so-called “paper based pedigrees” are also generally ineffective in preventing counterfeit drugs because the documents can be easily copied or altered. As a result, the next generation of

more effective ePedigrees will be built upon a new layer of automated, authenticating, identification technologies, namely RFID.

How will these proceedings effect partners along the pharmaceutical supply chain?

As overlapping federal efforts slowly work their way through the legislative process, states are creating their own drug pedigree and identification laws. More than 10 states have already passed some form of ePedigree legislation and 25 others are in the process of considering such laws.

California, which accounts for up to 15% of the total U.S. market in prescription drugs, has moved ahead with the most notable initiative. The California legislation requires electronic serialized product pedigrees on all prescription drugs at the item level (i.e. each salable item has a unique identity or serial number) and a secure chain of custody of all transactions involving that drug. The chain starts with the pharmaceutical manufacturer and continues “until final sale to a pharmacy or other person furnishing, administering or dispensing the dangerous drugs.”

Manufacturers and distributors need to initiate actions to ensure that they and their trading partners will be prepared for coming laws. Otherwise, they take the risk of not being able to conduct business in the nation's largest market, California. Regulations initiated by this bell-weather state, whether in pollution controls, tax reform or other major issues, often become the law of the land.





Serialization, Authentication and ePedigrees

As state and federal ePedigree mandates develop, pharmaceutical companies will likely be required to affix unique serial numbers to items during the packaging process and to implement technologies that can electronically ascertain and track the serialized products. By associating each product unit to a unique electronic serial number, pedigree information can be added and the product tracked through every step of the supply chain. To accomplish this process three technology options are available: 2-D Data Matrix, High Frequency (HF) RFID, and Ultra High Frequency (UHF) RFID.



2-D

➤ 2-D data Matrix: This technology uses high density, two dimensional (2-D) read-only printed symbols, representing alphanumeric characters. A 2-D symbol is scanned by specialized camera-based imagers. They are not readable by traditional, linear barcode scanners.

➤ HF RFID tags operate at a frequency of 13.56 MHz and have a very limited read range (generally on the order of inches). HF RFID technology only makes use of the near field component in which there is a magnetic inductive coupling of energy between a reader and tag. These antennas are generally comprised of resonant loops or coils which are more costly than simple UHF dipole or loop antennas. The available useful energy is limited to close proximity; hence the relatively short RFID range.



HF RFID

UHF RFID



➤ UHF RFID tags typically operate in the 840-960 MHz frequency band. Unlike the HF variety, UHF RFID functions well in either the near or far field, and offers read ranges from close contact to several meters. With far field coupling there is electric field coupling of energy between a reader and tag. And with the near field component, there is a magnetic inductive coupling of energy between the reader and tag. The antennas are typically constructed with a simple dipole, loop, or patch antenna, and both

near field and far field coupling are often combined in a single antenna. The useful energy can be quite extensive and can thus achieve a relatively long RFID read range.

Authentication preserves integrity in the supply chain

Tracking the smallest individual pharmaceutical units throughout the supply chain is one of the greatest benefits of RFID to manufacturers, wholesalers, distributors and consumers.

Legislative serialization options include the use of 2D Data Matrix, which can be easily duplicated. In contrast, UHF RFID offers the manufacturer the option of a permanently locked, factory commissioned unique serial number (referred to as the UTID) embedded within the electronic RFID silicon chip.

The unique UTID signature, in addition to an optionally locked drug identification serial number, assigned by the manufacturer, provides the consumer with yet an additional level of authenticity, as drug manufacturers record the UTID and assign their unique product identifiers, shipment contents are aggregated and ePedigrees are used to record pertinent information.

Privacy concerns

With so much misinformation about RFID being dispersed on the internet and elsewhere, some may be concerned that RFID enabled pharmaceuticals might jeopardize privacy.

The contents of each tag consists of a series of 1's and 0's, a serial number which is meaningless to anyone unless matched to a secure, master database. If an unauthorized party scanned the tags of a customer leaving the pharmacy, nothing about these items would become known to the intruder. Furthermore, tags used on item level drugs are often small, or near field varieties, which result in very short read range distances.



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The ePedigree proposition

RFID has several advantages over barcodes, a technology that originally spurred a revolution in the automated identification of electronically scanned items. RFID offers a wireless, re-writeable memory that can store vast amounts of information vs. traditional barcodes, which are write-once labeled applications and easily duplicated. As each serialized item passes through the supply chain, it is a simple process with RFID to add information with the necessary details of where the drug has been to satisfy the chain of custody.

In addition to its utility in complying with forthcoming ePedigree mandates, RFID also offers greater accuracy, convenience and efficiencies when compared to 2-D. And with UHF RFID, user memory may be set to accommodate password-protected data viewing options. Since the actual ePedigree data resides in a master database, RFID offers maximum flexibility for coding each tag accurately.

Comprehensively, a serialized identifier will be comprised of numerical sequencing that, when matched to a master database, provides detailed

information about the source of a drug, its name, federal manufacturer registration number, business address, the quantity, dosage, form and strength, the transaction date(s), sales invoice number, container size, number of containers, expiration date, lot number, shipping information, and the name and address of the person(s) certifying delivery or receipt. Finally, if the prescription drug is returned to the manufacturer or wholesaler, that too will be documented in the ePedigree.

The basic data elements of an e-pedigree are:

- > Lot
- > Potency
- > Expiration
- > National Drug Code and Electronic Product Code
- > Manufacturer
- > Distributor, Wholesaler or Pharmacy
- > Unique Serialized Identifier of the Unit
- > Transaction Information
- > Trading Partner Information
- > Signatures & Certifications





Benefits to Pharmaceutical Wholesalers and Retailers

While many pharmaceutical companies are focused on the compliance costs of adopting serialized RFID ePedigree systems, industry leaders are focusing on benefits available even without ePedigree mandates. Of course there is an initial expense in deploying RFID – though not nearly as much as some over-the-top analyst reports might lead one to believe. As a company considers an investment in the hardware and software infrastructure RFID requires, it makes sense to take advantage of that in every way possible by looking at UHF RFID.

ePedigree Value to Pharmacy

- › Authenticity
- › Order confirmation
- › Transparent process
- › Lot validation
- › Date code validation
- › Patient safety

Many benefits of RFID have nothing directly to do with ePedigrees. By selecting UHF, the ability to leverage investments in RFID and optimize operations provides short term ROI long before a cohesive, RFID-enhanced pharmaceutical supply chain comes to be.

Remember, beside ePedigrees, other products in warehouses and retail stores can benefit from their own unique ID's. Tapping into the globally established, EPC UHF-based standards offers performance gains and cost savings even if mandates are never instituted.

Aside from the mandates, RFID implementations are really about business efficiencies and process advancements at the edge of the enterprise – on the loading dock, the factory floor, and in improved transactions throughout the supply chain. Fundamentally, RFID is about enabling business process improvements.

The question isn't: "What is it going to cost us to comply with ePedigree mandates?" The question is: "Can we afford not to take advantage of this proven UHF technology?"

Operational efficiencies

Necessary RFID infrastructure hardware may include fixed and handheld readers, reader-empowered portals, and control devices. When integrated with enterprise

software and other company databases, the resulting solutions can deliver benefits that impact almost every operational activity.

An RFID system can serve to increase the speed and accuracy of inventory accounting by reducing the human interactions required to identify and track items. The goal is always visibility and speed – through accurate, timely data – from which plans can be made and executed.

By utilizing Gen 2 UHF RFID, individually tagged items can be read while still packaged inside cases. The routine, labor intensive and time consuming practice of opening each carton and scanning every item inside to confirm what was received is exactly what was expected, can be eliminated. Today, it is normal for more than half of the cartons flowing through a warehouse or DC to be opened and scanned. With RFID this is unnecessary and saves untold man-hours of labor.

If an item is needed to fill an order or an item is misplaced, there is no more need for line of sight access to scan every box one at a time until the item is found. Using a handheld RFID reader, workers can search dozens of feet of shelves instantly, side-to-side and top-to-bottom. Even cartons that reside behind others can be scanned, sight unseen. When the item's identifier is located, the handheld sounds "like a Geiger counter" when it is found.

Inventory control

The more you increase the accuracy of item tracking, the more you reduce costs. In its simplest terms, a Walmart executive described RFID inventory control benefits in a nutshell: "You know how frustrating it is looking for something for 15 minutes and then you see it's right in front of you?"

Inventory can range from 45-90% of business capital. The key is leveraging your RFID installation for maximum results. The same infrastructure that can read ePedigrees can improve the control of virtually any inventory a company carries.



- › Daisy Brand dairy products, using Alien UHF RFID tags, finds that loading each 24-pallet truck is down to 20 minutes from a full hour.
- › By adding Alien UHF technology on plastic totes carrying internal goods, Turkish apparel manufacturer Gel-Al measured a 40% productivity gain.
- › FloraHolland, the giant Dutch cut flower provider, using UHF RFID in a one million sq. ft. DC, saw ROI in year one and now saves \$200,000 annually. They also identified, and fixed, costly bottlenecks in their processes.

Add these types of internal savings to the coming benefits related to ePedigrees, and the results are profound. The time saved using RFID-enabled tote deliveries at pilot pharmacy locations might have been anticipated by global supermarket leader Ahold of The Netherlands. They expected to save valuable man hours of counting, scanning, and entering data every week. Their biggest surprise was how much time they found it saved the pharmacists, themselves.

Consider the value of the information on inventory you currently collect, and imagine how useful the information you are not currently getting might be. RFID adopters need to bring a larger set of expectations, because if you never had certain inventory data available before, it can be difficult to know if anything is missing. What new insights might convert into action items. For example, reliable inventory feedback loops can alert buyers and sellers when particular stock items need to be replenished.

In the age of online collaboration and information sharing, many will share the same tags and data throughout the virtual supply chain. This will increase the accuracy of item tracking and reduce costs.

Value to Retailer

- › OOS
- › Visibility
- › Shelf life
- › FIFO
- › Lot/date code access
- › Promotional displays

UHF RFID tags can be read through packaging, and without direct line of sight between object and reader. They can also withstand exposure to scuffing, dust, heat, moisture and contaminants that make bar codes unusable. As a result,

RFID tags will provide visibility into many new areas of inventory tracking in what were previously blind spots in warehouse operations.

Out of stock or out of date

For retailers, any significant reduction in out-of-stocks could be most meaningful. The manufacturer and wholesaler may get the sale if the customer buys at the store down the block, but for the retailer it is a net loss. Studies show a significant portion of the time, the products missing from the shelf are near at hand in the back room, forgotten, unscanned or misplaced.

Shelf life expiration management can be controlled with exactness in the warehouse and the stockroom. Serialized product ePedigrees will enable workers to select the oldest product first for shipment or delivery to the customer, rather than the path of least resistance which often leads to LIFO – Last In, First Out. Drugs can be sold before they have the chance to expire. Similar procedures in place today at Boeing, using UHF RFID for tracking unstable chemicals with short lifespans, are saving them millions in expenses each year.

When consumer packaged goods manufacturers invest in advertising blitzes in combination with point-of-purchase displays, sales increases of 20% are not uncommon. One East Coast retailer reported increases of 50%. Yet recent surveys show that often as many as one-third to one-half of the displays never make it to the retail floor. Using RFID, displays can be monitored through a retailer's central system, making sure displays are deployed on time and the resulting sales increases are not lost.

Shipping & receiving

RFID readers or antennas are usually arranged around all docks and passageways through which products enter or leave a location and by warehouse racks and other storage locations. They can track items as they enter or leave the facility, or an area within it. Incoming shipments can be automatically queried for specific containers. If a sought-after item is present, it can be quickly located and selected.



Utilizing far field capabilities of UHF Gen 2 RFID tags, items, cases or pallets can be read as they are assembled for a customer order or shipment. Errors are minimized and the readings can be used to automatically produce a shipment manifest. The manifest information encoded in the tag can then be read by the receiving organization to simplify the receiving process and to match it with the ASN.

As a shipment goes through a reader at a portal, the contents of that shipment instantaneously appear on the screen of the shipping manager. Better yet, software can be configured so that if a load is about to be placed on the wrong truck, a light or buzzer will alert the workers to re-examine their instructions. The time-wasting cycle of shipping goods back to the DC, then reshipping them to the proper destination, is eliminated.

Having complete shipment data available in an RFID tag that can be read instantly without manual intervention is very valuable for high volume distribution environments. Incoming shipments can be automatically identified as they pass through the dock doors, verified instantly against the purchase orders and ASNs, and if items are missing from a case or a pallet, that can be noted immediately. Specific containers can also be flagged for immediate attention upon arrival, and if a particular item is being sought, it can be quickly located with handheld RFID readers.

Exception handling

One of the most effective ways to use RFID technology is for exception handling. Exceptions are typically situations where people have to stop what they're doing to fix a problem. Whether you are in a manufacturing facility, distribution center, retail store, or office environment, exception processing is costly for companies.

Exceptions can shave profits with insidious manpower, administration, worker frustration and customer dissatisfaction costs. Workflows are interrupted, often leading to secondary operations requiring the re-packaging of materials and re-confirming contents. The subsequent results are considerable cost savings in time and labor.

By combining RFID generated events with real-time notification systems, operations personnel can more quickly respond to situations before they become a headache.

Shrinkage

RFID capabilities can also decrease the number of items lost to stock shrinkage. Trash receptacles and dumpsters – which are common egress channels for employee theft – can be equipped with readers as part of this effort. To secure inventory from theft, RFID readers can also be configured to sound alarms or send notifications if items are removed from storage without prior approval.

To secure inventory from theft and diversion, readers could detect if items are placed in unauthorized areas of the facility or removed from storage without prior approval. An Auto-ID Center study found consumer goods manufacturers would reduce shrink (inventory loss) by an estimated 10 percent by implementing secure storage areas.

ePedigree authentication

When ePedigree is finally added to the inherent advantages that exist today with UHF RFID, the value scale is increased yet another notch. With the addition of this authentication of each individual pharmaceutical item, an Advanced Shipping Notice (ASN) is electronically forwarded to the next recipient in the supply chain where the serialized product is verified against the ASN, and the Pedigree certifies authenticity.

Inaccurately accounted serialization, received by wholesalers and retailers can result in costly downtime and retail shortages until the matter is resolved. Pharmacists need a solution which is virtually transparent to their day-to-day operations to enable them to concentrate on their customers. Pharmacists often find the process of confirming orders, and validating lot and expiration dates to be a labor intensive effort. Unfortunately this manual process can also result in errors.



With RFID, not only can the pharmacist quickly authenticate medication, but the once manual process of validating orders can be automated, operational efficiencies and accuracy are dramatically improved.

Intangibles add up

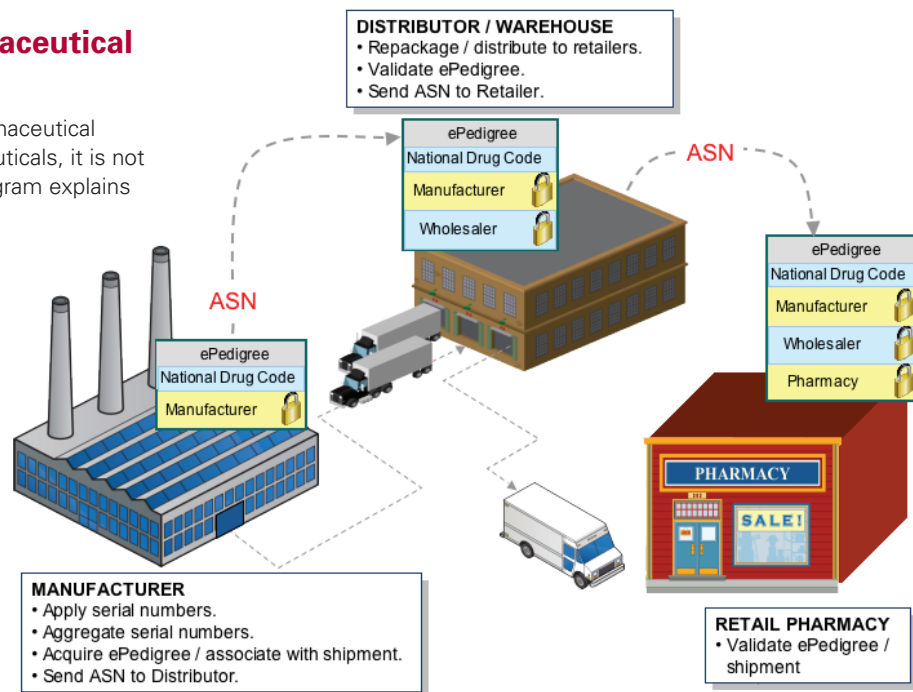
Walmart has found a resulting byproduct of this UHF track and trace technology. "With RFID you also eliminate the more mundane and unsatisfying tasks, like scanning for merchandise. Associates feel better about being more successful in their jobs." Retaining

hourly wage earners can be difficult under the best of circumstances; and the resulting downtime, hiring and training costs are significant.

Best Buy sees supply chain savings as just representing the tip of the iceberg. They believe the larger benefits come from making life simpler for customers and allowing "the Blue Shirts," their ubiquitous Best Buy sales staff, to "have more fun" rather than searching the backrooms. The company looks to their sales staff as being the key to their current success and future growth.

Picturing the Pharmaceutical Supply Chain

With more than 100,000 pharmaceutical dispensing sites for pharmaceuticals, it is not quite this simple—but this diagram explains how it all fits together.



› Manufacturers apply and aggregate serialized item tags and generate an ePedigree for appropriate items, locking in the serialized item assignments. The correct serial numbers are automatically associated with each shipment and an Advanced Shipping Notice (ASN) is forwarded to the Distributor.

› Distributors confirm receipt of the product in accordance with the ASN, without having to open the cartons; and they validate the authenticity of the ePedigrees.

They then repackage and distribute product to the retailers, aggregating the serial numbers and ePedigree information, locking in the serialized item assignments. The correct serial

numbers are associated with each shipment and an ASN is forwarded to the Retailer. Now the item ePedigree is locked and traceable to both the original manufacturer and the Distributor.

› Retailers' receiving software automatically confirms receipt of the product in accordance with the ASN, and validates the authenticity of the ePedigree. Problems or anomalies are instantly detected. There must be a perfect match of all relevant elements before the item is given to an end-user/patient.

At this point, the item ePedigree is locked and is now traceable to the distributor, manufacturer and the retailer, creating a true chain of custody.



Benefits to Pharmaceutical Manufacturers

RFID serialized tagged products can save pharmaceutical manufacturers millions in the area of manual chargebacks. Manufacturers often sell products to wholesalers at one price while also agreeing to sell the same products in special markets, such as government organizations, nursing homes, hospital chains – at another lower price. In this long standing practice pharmaceutical manufacturers reimburse the wholesalers for the difference between the initial fee and the pre-negotiated special market lower rates – and this chargeback requires extensive accounting on both sides of the relationship.

Value to the Supplier

- › Chargeback reconciliation
- › Product recalls
- › Packaging efficiencies
- › Refund management
- › Brand image protection
- › Reduced liabilities
- › Channel management

Manufacturers and wholesalers maintain large staffs to process and submit these claims. This labor intensive process is both inefficient and expensive, and opens the door to duplicate refunds as diverted products find their way into the primary chain. With serialized items, the accounting on chargebacks would be more precise and made easier

for all involved.

A similar process is conducted on products returned to manufacturers and their wholesalers. Since prices change frequently and manufacturers typically pay out the current list price on refunds, there is generally no easy way, without item level serialization, to determine what the price was when the item was originally purchased. Three percent or \$15 billion of pharmaceuticals are returned every year and almost all are credited with the current list price. The considerable overpayments by the manufacturers on these returns could therefore be significantly reduced if the items were serialized with RFID.

Managing product recalls

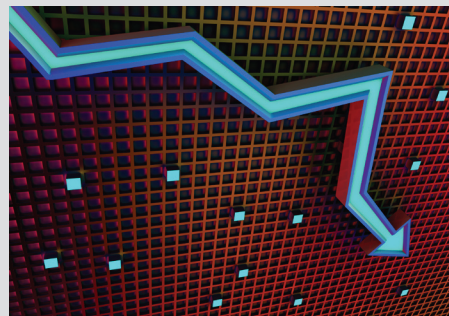
Every year hundreds of pharmaceutical product recalls occur, with most incurring millions of dollars in administrative costs and lost sales. From tracking drugs distributed through the supply chain to initiating the

actual recall and surveying the incoming returns with detailed accuracy, managing the entire process can require enormous costs.

Utilizing unique item identities established through serialization, pharmaceutical product recalls can be more precise and therefore less expensive. Current inventory accounting methods do not generally distinguish one drug package from another, or know exactly where they are located in the distribution chain. With ePedigrees that situation will change.

One large scale recall cost the manufacturer \$55 million to assure the public that all the tainted products within a particular batch had been gathered and destroyed. If the tainted batch had been accurately tagged and traced however, the recall could have been significantly reduced in scope by only recalling those drugs in the marketplace that were suspect, rather than having to recall every single item distributed.

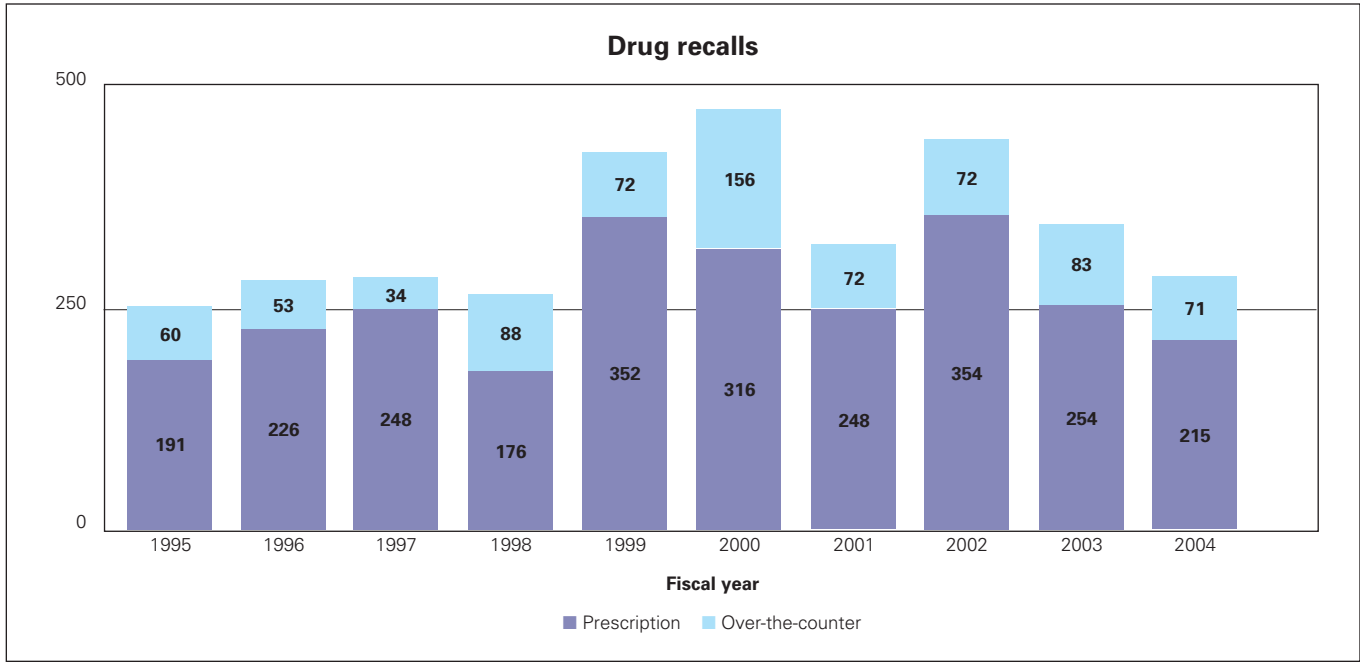
Price after recall



On September 30th, 2004, Merck announced recall of all bottles of Vioxx, a popular arthritis pain medication.

In one day, one company lost \$26,000,000,000 in market value!

Date	Stock Price	Market Value
Sept 29th	\$45.07	\$97.1 Billion
Sept 30th	\$33.00	\$71.1 Billion



Every year hundreds of prescription and over the counter medications are recalled, which cost U.S. Pharmaceutical Manufacturers millions of dollars in administrative costs and lost sales. By providing track and trace capabilities at the item level, RFID enabled product recalls can be done more efficiently and cost effectively.

(Source: FDA, Center for Drug Evaluation and Research Report to the Nation 2004)

Protecting the brand image

While the initial economic costs in conducting a recall are very significant, the long term damage to a brand's image and the loss of consumer confidence can be even more damaging economically. According to a University of Wisconsin study, lost shareholder value following a recall amounted to 12 times the cost of the actual expenses incurred in recalling the products.

With the World Health Organization estimating counterfeit drugs equal 10% of the global pharmaceutical market, 25% in developing countries, the potential problems for manufacturers are far reaching indeed. During a recall, valuable brands face international notoriety from the need to find every single item of that brand. The brand protection gained by locating suspect drugs using serialization, lot and date codes – instead of press releases and widespread alarm – is self-evident.

Reduced legal liabilities

In addition to protecting a brand and patients from the risk of adulterated and counterfeit drugs, drugs with serialized RFID feature, for the first time, packaging that can be traced to the manufacturers' facilities; in some cases, it might be more important for liability purposes, packaging can be proven not to have originated there.

By raising the bar beyond the ability of most counterfeiters, reduced potential legal liability represents another valuable benefit for implementing RFID based ePedigrees.



Why the Industry is Focusing on Ultra High Frequency RFID

Recent surveys indicate more than half of those companies who have researched RFID, but are not currently using the technology, have not refreshed their knowledge within the past two to three years. Unfortunately for them, much of what was true two years ago as RFID was moving from the “hype cycle” to actual worldwide usage, is completely outdated.

From 2005 to 2008, UHF tag costs have dropped 70% on average and reader costs are down 50% or more. At the same time, read reliability has increased by 300% and vendor interoperability is now very extensive.

UHF can be used with

- › Items
- › Cases
- › Pallets
- › Liquids
- › Blister packs
- › Syringes
- › Vials

Until now, an impediment to the spread of RFID in pharmaceuticals was the concern companies had about investing in the wrong technology. Certainly nobody wants to equip their operation with multiple technologies (e.g., 2D, HF and UHF) when UHF can accommodate near field and far

field reads at the item, case and pallet levels. And now, with the three distributors that account for about 90% of pharmaceutical sales in the U.S. invested in UHF, and major industry leaders like CVS and Walgreens doing the same, the risk factor has been minimized.

Why UHF is preferred over HF

Simply put, UHF offers a streamlined solution for the applications most necessary to give pharmaceutical industry members the return on investment they demand. The global, open UHF Gen 2 standard simplifies options and assures multiple hardware, tag and software sources. Production flow restrictions often found with other technologies are also alleviated.

An effective pharmaceutical supply chain tracking and tracing system may require both near field item level scanning and far field case and pallet level applications. While passive HF RFID tags are readable from a few inches away and are effective for near field scanning, they are not suitable for the more demanding, long range case and pallet needs. Passive UHF tags can be

read close up, or from several feet away, and are very effective at item, case, and pallet applications.

UHF singulation concerns of the past – the act of isolating tags in close proximity to an antenna – have been resolved. One advantage of UHF is the ability to quickly scan and inventory large populations of tags, but in some instances, singulation is desired. Advancements such as Alien Technology’s Intelligent Tag Radar™ (ITR) allow the user to scan large areas of interest, or identify the relative position of a tag with respect to the reader’s antenna, thereby offering singulation as a new tool for the user.

Tag data can be permanently locked and/or set to restrict data access by unauthorized parties. By using optional user memory, select portions of data can be password protected for viewing or programming privileges. An additional 512 bits beyond the unalterable 64-bit UTID serial number and 96 bit EPC data are now also available.

The authentication process is painlessly administered by passing the product in proximity to the RFID reader. The combination of the authentication identifier and the user defined memory serves as a non-refutable anti-counterfeit measure. Dynamic RFID tags can be updated and recorded to, with new information at every transaction point if needed.

Water and liquids

Early UHF tags occasionally encountered problems around materials like metal and liquids. This led HF proponents to assert their technology was more reliable in those environments. Due to technology advances made in the last few years however, Gen 2 UHF tags now perform as well as or better than HF around these materials, with the added benefits of universality and costing less on a per-tag basis.

Technically, near field HF RFID utilizes the magnetic field to power tags. Far field UHF RFID uses the electric field to power tags. While it is true that far field UHF electromagnetic waves tend to get absorbed by



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liquids directly in the reader field, the magnetic coupling of near field UHF is not subject to RF absorption. In the magnetic near-field applications, UHF Gen 2 tags work well adjacent to products filled with lotions, gels

or liquids. Even challenging items in close proximity to one another such as small liquid filled 1ml vials can be read within a case.

Metals

All electromagnetic fields are affected by metals – which include HF and UHF RFID. But only UHF Gen 2 tags can take advantage of metal within the scanning field. With UHF, the tag antenna can be easily designed to work with metal, actually allowing the metal to help couple the electrical field into the tag.

Metalized products common to the drug business, and in packaging for non-pharmaceutical products sold by the same retail outlets, can become an RF asset instead of an RF spoiler. Metalized blister packs can serve as an antenna for the tag, so even they can be effectively utilized with UHF.

What's Next Once the Supply Chain Exists?

Today's pharmaceutical distribution center is no longer a warehouse with activities contained within four walls. Wholesale distributors today manage virtual trading networks with inventory tracked at a supplier's depot, on the road, on the loading dock, and at various locations as the items move within the warehouse.

For wholesale distributors, RFID technologies using UHF tagging enable new re-engineered workflow improvements that can be applied directly to the bottom line. The same tags used to identify serialized pharmaceuticals, for example, can also trigger automated shipment tracking applications. With this technology, it is possible to cut out much of the paperwork and labor involved with partner transactions, while also reducing human errors and improving productivity.

Utilizing RFID, distributors can obtain greater visibility into their warehouses, and potentially into their customers' inventory, which will allow them to make just in time deliveries. And with improved visibility into distributors' warehouses, manufacturers can adjust their inventories and shipments accordingly, which will produce up to the minute inventories up and down the supply chain.

When RFID tags are integrated with Electronic Product Codes (EPC) and Advanced Shipping Notice (ASN) information, optimizations will be achieved through facilitated online collaborative processes and information sharing established across the pharmaceutical industry supply chain. Not only will a previously unknown degree of efficiency be established, the bar will have been raised to virtually unscalable heights for those looking to pollute the pharmaceutical supply chain with counterfeits and other dangerous elements.



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Where to go for resources.

FDA site on Counterfeit Drugs: <http://www.fda.gov/oc/initiatives/counterfeit/>

ePedigree - Coming soon to a pharmacy near you: <http://www.checkdrugs.com/ePedigree.aspx>

Graphic on the states and where they are in the ePedigree legislative process is at: http://www.healthcaredistribution.org/gov_affairs/state/state_legis-static.asp

"RFID Protecting the Pharmaceutical Supply Chain" central information page: http://www.rfidsb.com/index.php?page=rfidsb-pharma&c_ID=248

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