

Implementation of RFID in the Pharmaceutical Industry

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ABSTRACT

The pharmaceutical industry is constantly fighting battles on many fronts, whether it's trying to combat the latest virus, the cost of developing a New Chemical Entity (NCE), or the possibility of the next big merger on the horizon. However, there is one thing that still plagues the pharmaceutical industry and that is its own product. The pharmaceutical industry has always been fighting a battle with product recall logistics, product returns due to overstocking or expiry (which costs drug companies more than 2.7 billion U.S. dollars annually) and counterfeit products (which makes up to 7% of all pharmaceutical products in the international supply chain).[1]

Patient safety is also an issue with packages being designed for the marketplace rather than the patient. Prescription packages can be hard to read and even harder to open. There is also the added threat that patients are not taking the proper dose of their prescription and can be causing even more harm. There is an estimated 125,000 deaths annually from medication non-compliance. [2]

Something needs to be done and Radio Frequency Identification (RFID) is poised and waiting to solve this problem. With RFID units that can talk to patients, record when a medication is taken, and where in the supply-chain a medication might be in case of a recall, we are looking at the next medical break-through and it has nothing to do with medicine but rather the packaging.

INTRODUCTION

The pharmaceutical industry is currently looking for a better way of monitoring their pharmaceuticals not only in the supply-chain but once the prescription is at home in the medicine cabinet. RFID is currently being looked at as the answer to this question. Because RFID has the capability of capturing and relaying data it is what the industry is looking towards to improve quality, reduce costs, and most importantly improve patient safety. With an industry that boasts over \$100 billion in revenue, [3] it is set to take RFID and make it mainstream. If this happens the pharmaceutical industry will have a major influence on how RFID is spread across the world and used.

In this research paper I will give an overview of just how RFID will play such a big role in the pharmaceutical world and how it will be implemented. I will also talk about some of the companies that have already started using RFID and their results. I will also talk a little bit about e-pedigrees, which are one of the hottest topics of RFID in the pharmaceutical world right now with legislation on the ballots right now that will affect Pharmaceutical RFID's future in this world.

With the market for RFID in the pharmaceutical industry set to explode from \$90 million in 2006 to a staggering \$2.1 billion by 2016, making RFID one of the fastest growing industries in packaging. Mainly driven by the need for smart packaging, despite the reluctance of manufacturers to incorporate new cost into their supply-chain operations, these numbers are just too large to ignore. [4]



"The technology has already taken off for anti-counterfeiting in the US with about 30m RFID tags at item level, in small bottles of pills for example, expected by end of 2006 - Viagra and Trizivir are already tagged in the US," according to RFID guru Peter Harrop, chairman of IDTechEx.[3]

Figure 1: RFID Placed Behind Label on Pharmaceutical [5]

Pharmaceutical RFID

The pharmaceutical industry is unlike any other and therefore requires an identification system like no other. This is why RFID is so critical. Because almost every person in the world takes pharmaceutical drugs it makes their reach global and their impact when there is a problem catastrophic. The pharmaceutical industry needs RFID and needs to adapt and implement RFID as soon as possible. In particular, in the pharmaceutical industry, the market for RFID tags is set to increase from \$100 million in 2008 to \$2.1 billion in 2016 [4] driven by the demand for more convenient and anti-counterfeit solutions in pharmaceutical packaging - "smart packaging" – used to ensure product quality and usability, along with improving supply-chain efficiency and security. However, considering how profitable this industry is there is no wonder that everyone in the supply-chain is willing to spend so much to improve the current situation considering how costly and damaging a recall can be.

Many benefits

There are many benefits for the pharmaceutical industry to incorporate RFID into their supply chain. The first being stocking drugs is a difficult task that requires more information and organization than is the case with any other item. Furthermore a more efficient supply-chain would save time and money. With all these reasons aside there is till a greater reason and that is patient safety. With a more accurate way of error prevention with drugs these should be enough of a reason for drug companies to adopt RFID into their supply chain. Companies like AstraZeneca, who have already adopted RFID into its supply chain, have had great success with dispensing over 30 Million RFID enabled syringes of Diprivan. [3]

Not like the food industry

The main difference between the food industry and the pharmaceutical industry is one of priority. The food industry is interested in placing RFID on pallets and cases at the request of the retailers, while the pharmaceutical industry is mainly interested in placing RFID on individual items, bottles and packages. Unlike the food industry its first concern is patient safety and wellbeing. [1]

Table 1: The Market for Pharmaceutical Tagging at Item Level - A Possible Scenario 2006-2010 [3]

Year	Main location	Item	Approximate number of tags million
2006	USA	Some prescription drugs	35
2007	USA, Europe	Some prescription drugs	270
2008	USA, Europe, East Asia	Many prescription drugs	1083
2009	USA, Europe, East Asia	All prescription drugs in the USA. Many prescription drugs elsewhere.	5250
2010	USA, Europe, East Asia	All prescription drugs in the USA. Many prescription drugs elsewhere. Possibly some Over the Counter OTC drugs	16000

This would mean RFID that can be taken with the patient to their home, office, or doctor's office and will still function and be able to help them with their medical needs. However, one of the biggest reasons some pharmaceuticals have incorporated RFID is to help combat counterfeiting. By incorporating RFID pharmacies would be able to eliminate counterfeiting by ensuring that every drug was indeed the correct drug. A term used in industry as pedigree.

Currently most manufacturers are using High-frequency RFID instead of its cheaper counterpart Ultra-high frequency RFID due to the small size they can be manufactured. This allows RFID tags to be placed on individual blister packs which could gather more information about a medication; if it's being taken on time, if it has been tampered with, or what environment each pill experienced during transportation. [6]

FDA recommendation

The FDA has recommended its own form of rules and regulations to be applied to RFID in relation to the pharmaceutical industry. According to the FDA, RFID tags must be in place

on all pharmaceuticals by 2009. However great a goal this is, it will not be reached in time, mainly due to a universally adopted RFID standard having not been chosen. Pfizer, the world's largest drug company, has been the first to implement high-frequency RFID into its supply chain by tagging all packages of Viagra starting in December 2005. [7]

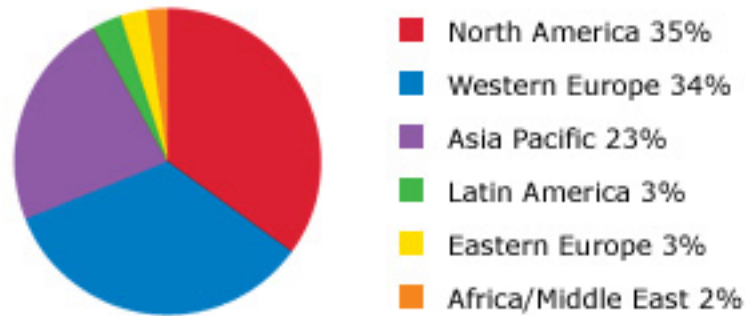


Figure 2: Pharmaceutical Packaging Market by Region 2006 [2]

Smart Packaging

Medication non-compliance costs the US alone about \$100 billion and 125,000 deaths annually. It is responsible for 10% of hospital admission - \$31 billion yearly and 380,000 patients. It is responsible for 23% of nursing home admissions - \$15 billion yearly and 3.5 million patients. [2]

Non-compliance in the drug industry is another costly risk to patient's health. With an average of only 6 minutes spent with their doctors, patients are often confused about their medication and don't fully understand all the implications of not taking that medication correctly. In fact, some don't even fill their prescriptions in the first place. While there are an estimated 30-50% of patients who don't take their medication correctly and 28% of those patients admit discontinuing their medication early. Packaging being easier to read, clearer to understand and more user-friendly are just a couple of ideas that can help. [3]

However, there is a new tool that can help as well. That tool is talking packages. Developed by Envision America, this system is an RFID tag located under the regular label which when a device is held near speaks out information about that drug. This has the capability to help millions of people all around the world. From people who are blind, illiterate, dyslexic, or who are otherwise incapable of interpreting a drug label. According to studies this is about 1/3 of all patients currently taking prescription drugs. According to a study done by the City University in London around 25% of fully able patient still struggled with reading and interpreting the labels on their pharmaceuticals. [8]

Currently, lithography is the primary technique used to print antennas, but will soon be used

to complete electronic circuits. This form of RFID is under the smart packaging umbrella used in industry and will soon start speaking to patients on their own giving patients instructions. Small runs of these new RFID tags are being conducted with screen-printing along with some rotary screen-printing as used on antennas already. However, new inks are on the horizon. With finer electronic and electric inks like the Parelec Parmod silver conducting ink used in flexography, lithography and gravure printing already being used in small scale production. Even semiconducting and dielectric inks are being used by Merck in hopes that they will soon replace the silicon chip in talking RFID tags. This allows for RFID to be more tolerant of its environment along with being cheaper and more easily adaptable for high speed production. [5]

The National Institute of Health held a six-month trial using this new idea of smart blister packs, which contained RFID that would record when the tablets were taken. This trial was done with a great deal of success and is being followed by Fischer Clinical Services who is doing their own clinical trial Mediary of Canada. [5]

FIGURE 2
RFID implementation hurdles

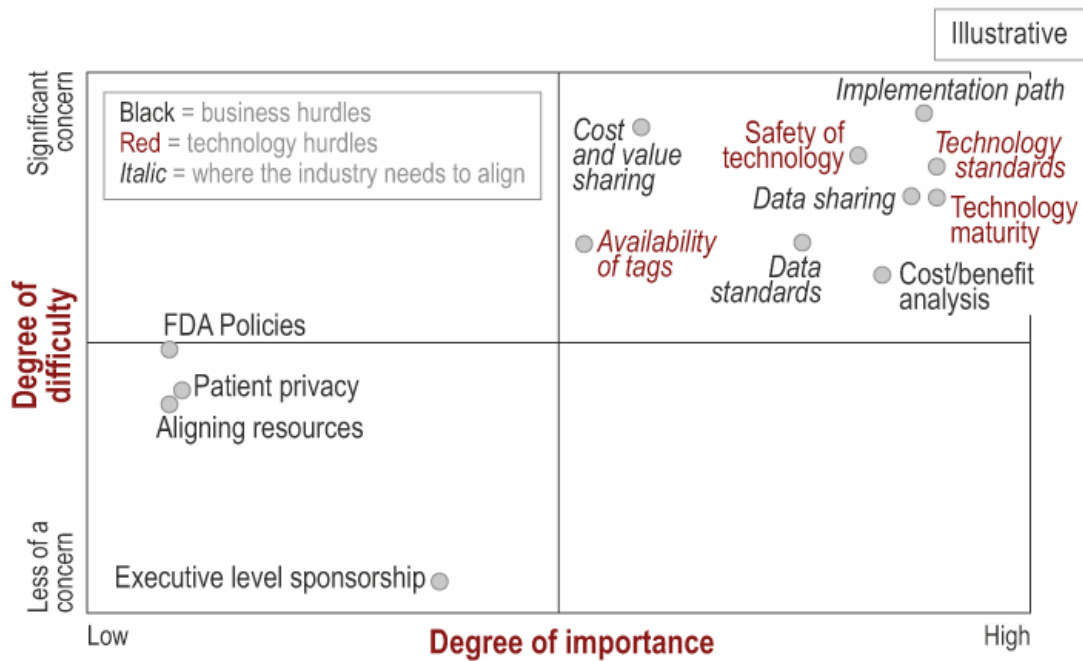


Figure 2: RFID Implementation Hurdles [6]

E-Pedigrees

E-pedigree, a term used in the pharmaceutical world as meaning an auditable electronic device which records every step taken by the package from its manufacture to its final sale at retail. This chain-of-custody is used to determine authenticity of each product and can

significantly reduce the cost of an expensive recall.

When it comes to the laws regarding pharmaceutical pedigrees there is no single law or group regulation, in fact there is a loose patchwork of state and federal laws. The FDA's Prescription Drug Marketing Act of 1987 is at the head of these laws yet is still vague in its regards to pedigrees. Although both state and federal laws require wholesalers and distributors to provide paper-based chain-of-custody this is still not enough. Because this paper-based system is often subject to failure there is a need for a better system to be put into place, this is where RFID comes into play. Federal law has proposed the development of an electronic system to replace the paper-based chain-of-custody, this is the new e-pedigree program. [8]

Although, the State of California has taken a different approach to the e-pedigree program requiring all manufacturers to create a unique serial number for each pharmaceutical unit to be sold in the state. Therefore, beginning January 1, 2009, all pharmaceutical packages will have its own serial number to differentiate it from the other unit manufactured by that company. This serial number will act as a vital key of information that will track and record information about each package. Although not involving RFID, it is a step in the right direction and will be undoubtedly a key milestone in making pharmaceuticals safer and more controlled. Since California is such a large market this will most likely have a trickle down effect on the rest of the country which will then lead to the FDA changing it's regulations over time. [8]

IBM has released a RFID system for pharmaceuticals, which it has said will, "accelerate the adaption of RFID into the drug industry." [8] This new system is a blend of software and services that will automatically capture and track the pharmaceuticals every movement through the supply chain. In doing this it will help reduce the cost tied up with inventory, making recalls, and better control of product flow. Another added feature is that RFID also makes it more difficult for counterfeit drugs to be sold at market, again another safe guard for the patients.

By using their well-known WedSphere software platform and enabling clients to use existing assets, IBM has made a product that can be rapidly adapted to almost any pharmaceutical production line. This new system is the link between the Electronic Product Code (EPC) and the EPC Information Service (EPCIS), effectively tying in all aspects of information. [9]

"IBM's extensive experience with RFID has demonstrated that this technology has unique capabilities to offer in helping protect drugs from tampering," said Paul Chang, IBM's RFID/Pharmaceutical executive. "And in an industry that lives depend on, IBM is leading the way to a safer, more secure supply chain."[8]

Pilot Programs

IBM has teamed up with Cardinal Health in a pilot program to help simulate whether UHF-RFID can be used in a real world setting, such as the pharmaceutical industry. "Cardinal Health's test of RFID under real-world conditions has demonstrated that the technology has real promise to provide an added layer of safety," said Renard Jackson, vice president and general manager of global packaging services for Cardinal Health. "While our pilot demonstrated that using UHF RFID technology at the unit, case & pallet level is feasible for track and trace purposes, a great deal of additional work needs to be undertaken by stakeholders across the industry to address significant challenges including global standards, privacy concerns and the safe handling of biologics. Until those challenges are addressed, direct distribution of medicine continues to be the best near-term approach to maintain the highest levels of security and efficiency in the pharmaceutical supply chain." [8]

IBM and Cardinal Health's first pilot program was one that came back with varying degrees of success. A lot of the RFID reads were fickle and heavily dependent on placement of the package and RFID tag itself. Although no conclusive evidence was determined that RFID at that time was up to par with the strict levels of security needed for the pharmaceutical supply-chain, the ground work was laid for the next generation of RFID to step in and give it a shot.

Viagra's Impact

Viagra by now is a household name and can be found at every place where pharmaceuticals are now sold. Pfizer was the first pharmaceutical manufacturer to start implementing HF-RFID on individual packages of pharmaceuticals in a large scale. Their goal was patient safety and to protect themselves against counterfeiters but they did lay the groundwork for RFID in the pharmaceutical industry.

During packaging each bottle of Viagra is labeled with integrated TAGSYS Flexible Module passive high-frequency (13.56 MHz) tag. 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 then authenticate the drug using this tag. [10]

In implementing this new form of protection it only took 5 months for all unlabelled bottles of Viagra to be dispensed and replaced with RFID tagged bottles. Once the bottles reach the wholesaler or pharmacies they are then read on a secure internet connection, enabled by SupplyScape, by simply entering in the EPC code by the pharmacist. After being received the bottles are now ready to be sold to the patient. Once a patient orders the product a pharmacist will then use the RFID interrogator (one that can read Philips' ICode air-interface protocol, which the TAGSYS tags follow), which is linked to a RXauthentication

Service which will then read the RFID tag's EPC and chipID, then confirming them with Pfizer.[10]

If a product is found to not be authentic by Pfizer then the RXauthentication Service will immediately send a notice to have the medication quarantined. An investigation would then follow suit. However, this new safety precaution is just another step in ensuring the proper medications reach the proper patient without the intervention of counterfeiters.

Table 3: Performance data from Pfizer's use of RFID for Viagra [10]

QC Process Steps	QC Failure Rate	Read Yield
Shipment from Converter		100%
Item Rejections because of HF RFID (all causes)	5 in 1,000	99.5%
Item Rejections because of 2D bar code	3 in 1,000	99.7%
Case Rejections because of HF item aggregation*	4 in 10,000*	99.9%*
Case Rejections because of UHF Gen1 tag**	3 in 100**	97%**
Case Rejections because of linear bar code	2 in 100	98%

* Based on 48 HF reads/case.

** Duplicate-code issues and void label failure rates omitted.

***The data above was collected over a period of one year and is based on several million units of actual Viagra on the production line.

Wal-Mart

Wal-Mart has taken Pfizer's lead in the integration of RFID tags in its pharmaceutical line now requiring two dozen of its pharmaceutical suppliers, including Pfizer to place RFID tags on cases and pallets of its pharmaceuticals. Additionally the FDA has recently endorsed the use of RFID as a means of authenticating and tracking pharmaceuticals throughout the supply-chain. This comes hand in hand with its recent push for an e-pedigree program. Pfizer being at the forefront of this movement is already implementing such policies on its flagship drug, Viagra. [11]

CONCLUSION

The healthcare world is a large complex web of legislation, corporations, and fast growing technology. RFID's place in this world is one that people are starting to take notice of. In healthcare RFID is growing very rapidly and is projected to grow into a \$2.1 billion industry by 2016. From smart packaging, which records when medication is taken by the patient, to e-pedigrees, which authenticate a pharmaceutical, packaging in health care is something that is changing rapidly and RFID is at the forefront. Considering an estimated 50% of patients don't take their medication correctly, either by quantity, time or duration. RFID in the

pharmaceutical industry can't come soon enough.

With the FDA's interest in e-pedigrees and the State of California's new requirement of individual serial numbers for each pharmaceutical unit, the supply-chain's of the past are being changed forever. With RFID's ability to provide itemized information and details without slowing down the packaging line it seems the only viable option for these new legislations, which will undoubtedly trickle down to other industries supply-chains.

The results of the Viagra pilot have further added to the success stories of RFID used in the itemized world of pharmaceuticals. Also, with the demand Wal-Mart has placed on its suppliers RFID is set to start growing rapidly here in the next couple years and will soon be the standard method for supply-chain use globally.

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