PHARMACEUTICAL APPLICATIONS FOR RFID'S

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ABSTRACT

Pharmaceuticals are unique in most every way when compared to other goods and inventory types. They have many strict guidelines for management and checked frequently by state and federal officials. In this paper, we'll discuss some of the challenges that come with pharmaceutical inventory management. The use of RFIDs has helped dramatically in all aspects. From 503B manufacturing to hospital pharmacies, third-party companies have provided RFID solutions in both environments that meet regulatory needs while cutting cost. RFIDs have also brought security and safety to the next level by coding products properly and preventing human error. Pharmaceuticals is a product that can create life-threatening consequences with one, simply to make mistake. The future is bright for RFID pharmaceutical applications.

INTRODUCTION

The Use of RFID in Pharmaceuticals

Pharmaceuticals are a unique type of inventory. They have many strict guidelines for inventory management and checked frequently by state and federal officials. The most critical information must be registered within the drugs tag. For many years the information was registered in a simple barcode but "barcodes are not unique codes that can help pinpoint an item in its distribution network, and they do not have high data storage capacity to provide detailed information about an item. Unless an item's barcode is scanned, its tracking records cannot be updated" (Cakici, Groenevelt, & Seidmann, 2011, p. 842). Information such as manufacturer, lot numbers, shipping information, dosage, etc., must be tracked. The main goal of all these regulations is to prevent theft or counterfeiting, conduct product recalls efficiently, and protect public health. Radio-frequency identification (RFID) tags can offer accurate real-time information and tracking of inventory status at the individual item level. This allows an inventory manager, likely a pharmacist, to use automatic counting, shrinkage tracking, and continuous review to improve policies and process which can save the firm a lot of money (Cakici et al., 2011). The case study conducted by Cakici et al. (2011), shows that a firm can save 76 percent of its total inventory management costs by switching from barcodes to RFID and redesigning their business processes (p. 843). According to Bollampally & Dzever (2015), The Value Model can assess the potential of tagging at the pallet, case and even individual packaging levels, as well as determine the value of tracking those units throughout the global supply chain. Pharmaceutical manufacturers who are currently using the model include: Aventis, GlaxoSmithKline, Johnson & Johnson, Merck, Pfizer, Wyeth, Purdue. Wholesale distributors in the industry who have also adopted the model include: Pharma, McKesson, and Cardinal Health. The top three business issues involved include product counterfeiting, production diversion and order reconciliation (p. 178). This paper will cover the

full benefits and impacts of RFID technology in pharmaceuticals, along with real-world applications.

DIFFERENT USES FOR RFID

The Rise in Use of RFID

In the pharmaceutical industry, RFIDs started being used some ten or twelve years ago, but many found them to be too premature and not satisfying their needs with higher cost. Today, those same problems do not exist. Reads are more accurate, cost of tags are down, storage capacity has increased, and systems used to identify tags are more flexible. When presented at the manufacturing level or sooner, passive RFID can help create an audit trail that continuous all the way through the supply chain. There are two primary types of RFIDs - passive and active. Passive relies on fixed readers to serve as its power source while active tags have their own internal power supply. Passive RFID provides a snapshot of location, but active RFID provides real-time tracking. "Passive RFID systems are the most common in pharmaceuticals due to their low-cost tags and ability to track assets throughout the supply chain" (O'Boyle, 2015, p. 18). Passive RFID are also very beneficial for high-volumes of smaller items, such as bottles or syringes, on pallets or in large containers while active RFID tags are best served to track large, high-value items that need real-time tracking and can absorb the extra cost of active tags. "For example, a pharmaceutical manufacturer may use active RFID to know exactly where, within the four walls, a cage of highly tracked Schedule III drug product is located" (O'Boyle, 2015, p. 19). Most pharmaceuticals should be store between specific temperatures and active RFIDs can monitor temperatures when equipped with battery-powered sensors that collect real-time temperature data. If, at any time, the product exceeds or falls below the specified temperature then it can easily be pulled from the supply chain and properly addressed. "Hitachi, Ltd. has proposed many innovative RFID solutions based on the company's achievements developing systems for the medical and pharmaceutical industries, RFID-related research and development, and substantial expertise gained through participation in government and ministry sponsored IC tag pilot studies and trials" (Otoshi, Tomita & Kaneko, 2007, p.83).

Some manufacturers have tried to use benefits from both types of RFIDs by having a duel use of tags. This method creates two, separate data systems that collect information for active and passive independently. While the manufacturer collects information from both, it is collected in such a way that it creates visibility and workflow issues. "A rising trend in RFID is a Hybrid approach in which a single software system marries the data captured from both the active and passive tags to provide a complete unified view of all assets" (O'Boyle, 2015, p. 19). This allows for ideal visibility by providing awareness into all assets and inventory and places the proper RFID technology where it is needed. Since everything is now in one system, rule-based alerts can be set up and even integration with Enterprise Resource Planning (ERP) systems.

503B Manufacturing Application

Manufacturers of pharmaceuticals, in particularly, FDA 503B outsourcing facilities, will play a major role in the use of RFID going forward. The Drug Quality and Security Act was signed into law on November 27, 2013. This new law created section 503B in FDCA, which states a compounder can become an "outsourcing facility". According to the law, an "outsourcing facility"

is a facility at "one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B" (FDA - Outsourcing Facilities, 2015). Drugs compounded under this law can qualify for exemption from two major requirements; FDA approval and labels with adequate directions for use. Although, 503B facilities must still follow good manufacturing practice (CGMP) requirements.

Documentation and tracking is very important to outsourcing facilities to remain in compliance with state and federal law. Material entering and exiting a facility must be recorded and this information must include: the supplier name, manufacturer name, product name, batch numbers, quantity, dates of manufacturing, and expiry etc. RFID tags would save valuable time and money by automating the process of recording this information. One example could be when materials complete the process of testing. After a certain amount of each batch is tested, the material is then released and can move on to the next stage which could be compounding or shipping finished goods. A tag showing the product has passed testing could be added to the batch. This would prevent accidental use of materials that have not been tested, or materials that failed testing. This is also a crucial step since FDA insist on use of tested and approved materials in manufacturing. "RFID tags can help to validate the manufacturing and maintain quality control and quality assurance by documenting that only approved materials as being used" (Potdar, Chang & Potdar, 2006, p. 2863). The benefits of RFID tags carry over to customers (hospital pharmacies) that either do not currently use RFID tags but implementing them or ones that have been tagging items themselves upon receipt. Geoffrey Cox of Medstar Georgetown University Hospital reported the use of RFID tags saving 5.2 hours per day for a tech. That simply amounts to 5.2 hours per day that a tech can do something more productive. He went on to say, having prefilled syringes already tagged from the manufacturer saved roughly 106 minutes per day. This is a huge benefit and cost break for hospitals. It is easier to justify a slight increase in drug cost if it means your employees are becoming exponentially more productive (PharMEDium Prefilled Syringes with Kit Check, 2016).

Hospital Pharmacy Use

As discussed previously, operational processes need to change along with RFID implementation. In this section, the operations of a hospital pharmacy and ways for them to improve, mostly via RFID tags, will be discussed. Most recognize two major categories of hospital pharmacy work: clinical and dispensing. Pharmacist would like to spend most of their time with clinical work while technicians spend most of their time dispensing. As we've already learned, this is not always the case and pharmacies are always looking for ways to achieve optimal balance. According to Zurawski (2016), within each category there are a few levels of work, 4 in clinical and 3 in dispensing. Clinical includes: direct patient clinical management – rounding, clinical decision support, formulary management, computerized medication order entry / review, and drug shortage management. Dispensing includes: IV and chemotherapy dispensing / compounding, unit dose dispensing / compounding, and pharmacy kit/ tray and floor stock replenishment. Of course, the pharmacy has other responsibilities to accomplish but those are task done by other departments within the hospital meaning it is not unique to the pharmacy like the seven levels of work.
Zurawski shared several assumptions from the 2011 Pharmacy Practice Model Summit, below are a few that RFID usage could benefit:

- In the next 5-10 years, hospital and health systems will be under increasing pressure to cut operation costs.
- In the next 5-10 years, hospital and health system executives will require pharmacy department operations to be more efficient.
- Within the next few years, financial pressure on hospitals and health systems will force them to pursue significant changes in how their pharmacy resources are used.
- In most hospitals and health systems, improvements in technology will be required for pharmacy departments to fully achieve optimal deployment of pharmacist and pharmacy technology resources.

How can pharmacies use the seven levels work model to their advantage? First, letting it be known to the rest of the hospital leaders will educate them of the in-depth processes that a pharmacy completes. "Second, this model can then be used to go deeper into explaining the specific tasks, knowledge requirements, policies and procedures that govern each level of work" (Zurawski, 2016, p. 9). New regulations, hospital policies and increased clinical duties all impact staff capacity requirements and the extent of this impact can be explained with this model. Pharmacy leaders are constantly trying to find trade-offs that can be presented to administrators to increase proper staff or implementing new automation initiatives, such as RFID tags. The lowest level, kit / tray and floor stock replenishment, can see some of the largest benefits of automation because it is highly manual and repetitive. "For example, hospitals report capturing 72 to 96 percent time savings when using Kit Check" (Zurawski, 2016, p. 10). Time savings of that magnitude can amount to $4.20 to $9.30 per kit of expected cost savings, according to Summerfield & Xiao (2015). Another benefit of automation, which will be discussed more in the case study, is patient safety. RFID tags provide a level of accuracy that is consistently higher than humans. Error rates ranged from a low of 5 percent to a high that exceed 60 percent. Rates this high is not acceptable in modern healthcare and no one would consider them acceptable, especially the FDA or state pharmacy boards. When human error rates are compared to user data provided by Kit Check, the difference is astounding. Brigham & Women's Hospital in Boston reported in 2015 that it had tracked over 240,000 pharmacy kit medications without a single error using Kit Check. The data is clear and hospital pharmacy efficiencies lies in automation with the assistance of RFID tagging.

THE IMPACT OF RFID

Kit Check Case Study

Situation – Pharmacist at St. Rita's Medical Center were tired of spending two hours every day checking expiration dates on drugs. According to Pharmacy Supervisor Lisa Brady, PharmD, they felt like their time could be used doing more clinical work. This includes getting out and talking with patients and clinical dosing (Kit Check Case Study, 2016). St. Rita's Medical Center is a 425-bed hospital in Lima, Ohio, with 236 pharmacy trays in circulation. The process worked like this: a used tray from the floor would be returned to the pharmacy, a technician would determine what drugs needed to be replaced in the tray according to the list of required drugs. The technician would also manually check drugs that were close to expiry and would replace them as well. Then, as mentioned above, a pharmacist would manually check the tray again for any errors. The inefficiencies take a lot away from the pharmacy which led to the use of Kit Check.

Solution – A pharmacist watched and video online about Kit Check and how it worked. After it was brought to Brady's attention, she immediately saw an opportunity. If all the drugs St. Rita's Medical Center were using had RFID tags and housed in a Kit Check cabinet, they could easily monitor all their stock. Kit Check software could determine if medications were missing, extra or nearing expiration in the matter of seconds instead of technicians and pharmacist spending hours checking and double checking for the same issues.

Results – St. Rita's Medical Center implemented Kit Check software and tags along with process changes in October 2014. As of December 2015, St. Rita's Medical Center had used Kit check to restock over 5,500 pharmacy trays and cut pharmacist processing time by 79.6 percent. "That is about 730 pharmacist man hours saved per year from automating the previously manual task – the equivalent of gaining one-third of an additional pharmacist per year." (Kit Check Case Study, 2016). Along with saving man hours, St. Rita's Medical Center also cut cost by reducing the amount of waste due to expired drugs and medication error. When considering expired, errors, and labor, St. Rita's Medical Center had an estimated first year return on investment (ROI) of 75 percent and a seven-year ROI exceeding 90 percent. St. Rita's Medical Center not only made changes that benefited their operations but the "Ohio State Board of Pharmacy approved that RFID technology can eliminate the pharmacist double check process" (Gerber, 2015, p. 1). Not only did this attribute to the labor savings but it also allowed pharmacist more time to be involved with patient care activities.

Security

The topic of security is very important when dealing with pharmaceutical products which are among the most expensive retail merchandise. Having a highly secured "supply chain will increase integrity, improve consumer confidence, and aid regulators in tracking pharmaceutical products, thus producing a pharmaceutical drug pedigree" (King & Zhang, 2001, p. 1). The large price difference between manufacturers and retail provide an opportunity for theft and trafficking. According to King, pharmaceutical products from Canada, can be manufactured at a lower price than those made from the U.S. (2007). This creates an environment where counterfeiters and smugglers can profit greatly. As a result, manufacturers are developing devices and processes that identify and track their product for accurately and efficiently. The pharmaceutical supply chain is made up by the distributors, manufacturers, warehouse, pharmacy and consumer. We can identify six requirements that need to be addressed with the use of RFID to ensure the integrity (King et al., 2007).

Anti-adulteration – adulteration crimes include mislabeling, dilution, misbranding, counterfeit, etc. Some drugs carry a high market value which makes them more susceptible to adulteration crimes. Auto-ID Inventory – traditionally, bar code scanning was used to identify products and mark location. This process needs to move to the use of RFID to save on labor while increasing accuracy through automation. Proper disposal of drugs is also very important. RFID tags can store this information to ensure it is done correctly. Traceability – including this aspect will protect against theft in multiple ways. Knowledge that product contains tracking will hopefully deter would be crimes and if a crime is committed, it should help law enforcement locate the stolen drugs. Accountability – making certain information mandatory for further production or sell creates

accountability by manufacturers. If the information they include is wrong or missing, the process shuts down and that product won't continue further in the supply chain. The result is accurate and reliable record for each drug. Privacy Protection – privacy is not an issue for all aspects of manufacturing, for example, 503B facilities only sell to hospital pharmacies in bulk which makes privacy the pharmacies responsibility. The main goal would be to create tags that are indistinguishable from other drugs or even other tagged items. Only an authorized person should be able to identify the product via RFID contact. Compliance Detection – some drugs are classified as CII drugs (examples: hydrocodone, oxycodone, dihydroetorphine, and fentanyl) and require more compliance than other drugs. The FDA and other agencies want to be able to track the manufacturing and sell of CII drugs. RFID could make this process much more streamlined, saving man hours.

New Regulations

Certain regulations have recently become active that changed the way hospitals received drugs. "Previously there were not federal or global standards that quidded the pharmaceutical industry on standardization of drug pedigrees" (Kimble, Stanton & Naylor, 2016, p. 5). That is astounding considering the use of drugs in many medical applications. Because of this, according to Kimble et al., The World Health Organization (WHO) has stated that about 10 percent of the pharmaceutical trade globally has been confirmed counterfeit. Kimble goes on to stat, the global market is expected to see a 90 percent rise in the amount of counterfeit drugs from 2014 to 2019, and it has been reported that about $75 billion annually will be spend on purchasing and dealing with counterfeit products. In addition, legitimate manufacturers lose $32 billion yearly in revenue because of fraudulent drug activity. (2016, p. 4). Proper regulation could help cut back these unacceptable numbers by forcing the implementation of RFID in the pharmaceutical supply chain. "One of the biggest barriers to full scale RFID in the Pharma supply chain has been the pharmaceuticals companies' perception that the ROI is not achieved in the short term" (Kimble et al., 2016, p. 4). Historically, this was the case, since it was very expensive to use RFID when purchasing the hardware and software needed to properly implement it. Attaran stated implementing a successful RFID strategy in a large manufacturing company can cost $10 to $25 million. He continues to say there is no ROI for companies that implement the technology if compliance is the only pursuit (2012, p. 145). Counter to Attaran is the fact that some companies will have a large ROI. For example, after RFID was implemented at RiteCare Pharmacy, the cost of warehouse inventory was reduced by 60 percent, order fulfillment time was cut in half, and salary expenses were decreased. Accuracy, scalability, productivity, and customer satisfaction increased, proving the potential for a positive ROI with RFID implementation (Kimble et al., 2016). On January 1, 2015, new track-and trace rules for manufacturers and repackagers went into effect and on July 1, 2015, the drug supply chain began providing information about each time a product is handled or sold in the US market, including lot number and transactional data (Kimble et al., 2016). RFID can be maximized going forward as new, key rules are created and put in place. As the technology becomes more affordable and expanded upon by first-adopters, it should appeal more pharmaceutical manufacturers creating momentum to make the change from paper records to e-records.

CONCLUSION

The Future of RFID

The Internet of Things (IoT) will introduce a new scope of opportunities for the pharmaceutical industry. IoT-enabled cabinets and storage bins in pharmacies stock with RFID tagged products will allow manufacturers instant access to on-hand reports. This will automatically replenish inventory, track expiration, and monitor temperatures. Similar technology could eventually revolutionize the consumer world, as well. "(RFIDs) in conjunction with a smart medicine cabinet, that reads information transmitted by the drug labels, patients can be reminded to take their medicine at appropriate intervals and patient compliance can be monitored" (Sundmaeker, Guillemin, Friess & Woelffle, 2010, p. 53). The future from RFIDs in pharmaceuticals is exciting but it is important to keep in mind when contemplating RFID implementation is to match the technology with its use and not the other way around. Forcing new technology into an already efficient process could cost more money than it is worth. RFID will continue to grow and opportunities will expand for the pharmaceutical industry. Improving customer safety and profitability through efficiencies that RFID provide is a win-win for pharmaceuticals.

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