

Using Mobile Bar Code Technology to Improve Drug Sample Management Efficiencies and Compliance



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Introduction

Last year, US pharmaceutical companies spent \$16 billion dollars supporting the distribution and marketing of prescription drug samples to physicians. A full 50% of those costs went directly to communicating the value of the products, and another 26% went to the detailing, distribution, and management of the samples. Over the course of a typical month, the average pharmaceutical sales representative will visit 150 physicians, distribute thousands of packages of drug samples, obtain FDA required signatures on 150 sample distribution forms, receive scores of new sample cartons to their home-based office, and expend as much as 25% of their time tediously managing a paper-based process for tracking.

"I thought I was being hired to be a professional...yet night after night I sit at home filling out these stupid forms. There has to be an easier way!" said one of the many sales representatives that I interviewed for this white paper.

In addition to the significant marketing and time investment associated with managing the actual drug samples, pharmaceutical companies are also required to comply with a stringent set of FDA regulations that were established with the enactment of the Prescription Drug Marketing Act (PDMA). Compliance with this legislation is often a manual, error-prone, and time-consuming process that adds inefficiency and frustration to the jobs of pharmaceutical sales representatives, their managers, and other functions including sales operations, marketing, manufacturing, and finance

The PDMA was designed to minimize the threat to the public health posed by prescription drug diversion and counterfeiting. It requires that samples distributed by pharmaceutical representatives be signed for and tracked to create audit trails. This helps to ensure that the correct physician receives the correct samples. If a pharmaceutical company is found to be non-compliant, they could face significant penalties, fines, and possibly even prison terms. Additionally, the ability to track drug samples helps reduce the risk of medical errors, in the case of a product recall. The cost of a drug sample recall can be astronomical if all samples have to be collected because the tracking system isn't good enough to identify the specific lot number. One executive told me that there was recently a recall for a manufacturing issue and instead of just recalling the specific lot numbers, they had to order a total recall because they simply had no confidence in the current tracking system.

Current Process of Drug Sampling

The sampling process is repeated on a daily basis across the healthcare industry with billions of dollars expended each year. At most companies, a sales representative goes through a daily routine similar to the following:

1. The pharmaceutical sales representative arrives at a physician's office.
2. The representative **manually** fills out a pre-printed sample distribution form including physician information, sample product information, and the proper quantity of all samples to be distributed.
3. The representative then conducts a 3-5 minute "detail" with the doctor about the product he or she is promoting, encouraging the physician to write more scripts for the product.
4. After the physician makes a request, the representative ends the call by giving the physician the intended samples, and asks the physician to **manually** sign for the samples on the distribution form.
5. At the end of the day, the rep will review each distribution form to check for accuracy, and then **manually** type all of the data from every form into their Sales Force Automation (SFA) system on their laptop.
6. The representative then removes a copy of the triplicate form for their own records which must be kept for seven years, and mails a copy to a central processing location.
7. The data sent to the central processing location is then **manually** entered for a second time into a database by a team of data processors. Since this is a manual process, there is an increased chance for data input errors. Each discrepancy found must be reconciled afterward during an audit to meet PDMA standards. It can often take weeks, even months, before this information is corrected to match the sales representative's inventory, and even longer for the marketing manager to gain access to it.
8. Finally, the representative will place a **manual** order, writing everything out on yet another pre-printed form, to replenish their own sample inventory.

And of course this is the scenario of a "good" representative who follows all the rules. Too many executives have told me that maybe 20% of their representatives follow the rules.

How Bar Codes Are Changing the Future of Pharmaceutical Sales

Today, we live in a cyber world of on-demand information and increased productivity. We can buy houses, cars, life insurance, and just about anything else online. Yet, for some unexplainable reason, there has been a great lag in adopting technology when it comes to managing drug samples. Unfortunately, there are too many people happy with the status quo of operating large and oftentimes inefficient departments who scream, "If it ain't broke, don't fix it!" Remember, there was once a time in corporate America where you had a Vice President of the Typing Pool.

The evolution of technology will play a crucial role in the massive improvement of drug sample management. Pharmaceutical companies have a tremendous opportunity to integrate bar codes, mobile scanning devices, and the Internet to create a complete, operationally efficient, and compliant process.

This type of process will be able to collect critical marketing information and fully track the physical distribution of drug samples from the sales representative to the ultimate consumer. This method can replace current manual systems with automated processes allowing a representative to:

- Dispense drug samples to physicians
- Transfer samples from one representative to another
- Perform inventory counts
- Receive new inventory shipments
- Replenish their sample supply
- Reconcile their inventory discrepancies
- View valuable sampling data
- Ensure accurate tracking capabilities in the event of a drug recall

This type of system will fulfill all regulatory requirements and provide both real-time inventory tracking, as well as critical marketing information, which is very essential during a product launch.

How it Works

A system such as this works by collecting inventory transactions at the field level, through mobile bar code scanning technologies that are built into a personal digital assistant (PDA) using proprietary software. Each time a sample is distributed; the bar code on the

sample would be scanned, time and date stamped, and recorded in the sales representative's activity log. To eliminate the need to enter additional information about the transaction, the sample's source and destination information could be previously stored and easily selected in the system. At the end of the day, the representative would place their PDA device into its docking cradle, where it would automatically synchronize through a standard Internet connection, and could directly update a company's online inventory system.

Now, let's take a look at the sample process when utilizing mobile bar code scanning technology:

1. A pharmaceutical sales representative arrives at a physician's office.
2. The representative then conducts a 3-5 minute detail with the doctor about the product he or she is promoting, encouraging the physician to write more scripts for the product.
3. After the physician makes a request, the representative ends the call by giving the physician the intended samples. He/she scans the bar code on the drug sample package, and asks the physician to sign directly on their PDA, where the physician has been previously validated with their biometric signature.
4. At the end of the day, the representative simply synchronizes their PDA. This automatically updates all of the day's information into the company's online inventory system, which only takes a matter of seconds. Not only is the data transfer completed quickly, it also eliminates the multiple data entry errors prevalent in most current systems.
5. Finally, the system automatically generates a replenishment order, assuring that the representative always has the correct inventory levels.

Mobile bar code scanning technology can revolutionize the way pharmaceutical companies market themselves. The implications of this new technology transcend the organization by crossing many different divisions including sales, marketing, operations, manufacturing, and finance.

Medical Error Prevention

In addition to the values already described in this document, there is another value that has been getting a lot of attention from Health and Human Services Secretary Tommy Thompson; medical error prevention. My research indicates that because of a lack of faith in current drug sample management tracking methods, when a product is recalled for a bad label, or a batch was contaminated in the manufacturing plant, pharmaceutical companies typically are having their representatives take back most, if not all of the samples that could be associated with the recall. Instead of accurately tracking actual lot numbers through bar codes, most pharmaceutical companies rely on the data that is entered by the representative. One industry insider told me that that, "If 40% of the data is truly accurate, I'd be surprised." Obviously the expense of unnecessarily recalling drug samples can become quite costly, and could be prevented by utilizing bar codes.

As a result of the emphasis on medical error prevention and in support of Secretary Thompson, the FDA is conducting hearings for the purpose of gathering information to mandate bar codes on all human drug products including samples. LScan believes that the FDA will make a ruling by the end of the year that all human drug products have bar codes on them within one to two years.

Return on Investment

LScan believes that implementing this type of solution will save pharmaceutical companies significant dollars. My research has concluded the following:

- The typical representative, using a manual, paper-based system for drug sample management, spends 2-3 hours per week on unnecessary administrative work.
- At an average cost of \$70 per hour, those administrative hours calculate to an expense of about \$11,000 per year, per representative.
- The printing of the paper forms and actual postage to mail them back and forth averages about \$495 per representative, per year.
- Given 12 extra hours a month to sell, the typical representative can generate at least 4 new Rx's per month, which averages about \$10,000 - \$20,000 (depending on the product) in additional top line revenue per rep, per year.

- The fully loaded cost of a bar code scanning application for sample management is about \$1,200 per representative, per year. **Therefore, the ROI for implementing a solution is at least 10:1** and even higher when you consider the increased revenue generated by the representatives, because they have additional time to sell. Throw in other factors, such as reduced turnover, improved capabilities for handling a product recall and the ROI could be significantly higher.

About the Author

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