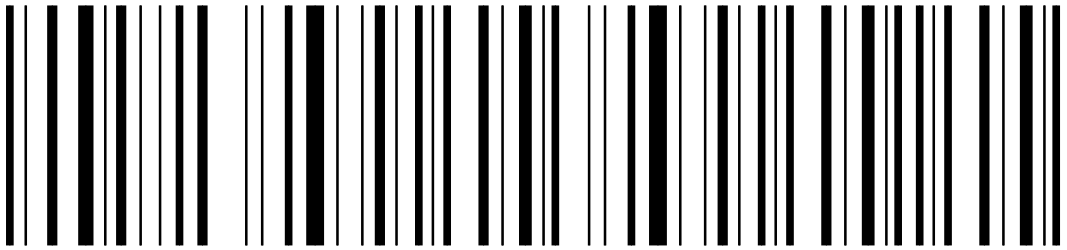
Track and Trace Solutions for the Life Sciences Supply Chain

How bar code, RFID and brand protection labels can improve traceability, safety and business performance



APPLICATION WHITE PAPER

Zebra Technologies

Executive Summary

Momentum is building to revolutionize the track-and-trace systems used throughout the pharmaceutical supply chain. The FDA has issued a rule requiring bar code identification on all unit-of-use medication packaging, and a separate recommendation for at least two forms of anti-counterfeiting protection on packaging. There are renewed efforts to change and strengthen state and federal pedigree regulations. Several industry associations have joined the FDA in encouraging the use of radio frequency identification (RFID) technology to improve drug traceability and security. Meanwhile, several large purchasers have begun to require their suppliers to mark shipments with RFID in an effort to improve product handling and supply chain operations.

These initiatives differ by their preferred form of identification (e.g. bar code or RFID), packaging level recommendations (ranging from the unit-of-use to the pallet) and information requirements (e.g. NDC number, security mark, lot code, expiration date, shipment number, etc.). Manufacturers, wholesalers, pharmacies and other stakeholders in the life sciences supply chain can take advantage of any or all of these marking requirements to improve their own business processes. Best of all, some printing systems can support multiple technologies and provide enough flexibility to satisfy all the requirements without requiring dual labeling or extra equipment.

By developing a solid understanding of the capabilities of track-and-trace technologies and applications, you can leverage labeling systems to provide internal benefits as well as satisfying regulatory and customer requirements. This white paper describes how to take advantage of multiple forms of pharmaceutical labeling to create secure, efficient new business processes. It provides an understanding of the issues and opportunities by:

- Recapping the FDA unit-of-use bar code rule;
- Providing an overview of track-and-trace initiatives for deterring counterfeiting and improving supply chain performance;
- Describing how production tracking, inventory control, distribution and returns, recall management and compliance with Prescription Drug Marketing Act (PDMA) and other documentation requirements can all be improved with track-and-trace systems;
- Illustrating how unit-of-use bar code marking, RFID labeling and brand protection media can be integrated into highly secure and effective track-and-trace systems.

Many organizations in the life sciences supply chain will begin unit-of-use bar code labeling, RFID and secure media to comply with FDA rules or customer requests. By focusing only on the compliance requirement, organizations may overlook opportunities to improve their own production, record keeping and distribution operations. Improving safety, security, efficiency and profitability are not mutually exclusive goals. Marking systems with the ability to combine multiple track-and-trace technologies provide the key to unlocking all the benefits that are available.

Introduction

Track-and-trace requirements and concepts have long been in place throughout the life sciences industry. Stakeholders at all points of the supply chain, from the patient bedside to the point of production, are renewing their focus on traceability in response to growing safety, security and productivity pressures. In many cases, the industry is calling for regulations and guidelines that go beyond what the FDA is proposing. The consensus throughout the life sciences industry is that drug tracking and security systems must change. The broad-based commitment to making improvements, evidenced by new programs and systems being created by hospitals, manufacturers, wholesalers, pharmacies and multiple industry associations, will ensure that more stringent track-and-trace programs are here to stay and will continue to become more sophisticated.

Why the renewed focus on traceability? Consider the following:

- Preventable medication errors cause 7,000 deaths in the U.S. each year according to a widely respected Institute of Medicine report. The *Archives of Internal Medicine* reported approximately one in five doses of medication administered in hospitals and skilled nursing facilities is given in error.
- The FDA has quadrupled its counterfeit pharmaceutical investigations since 2000. The World Health Organization (WHO) estimates that upwards of six to 10 percent of all medicine worldwide is counterfeit.
- The FDA issued 354 prescription drug recalls in 2002, nearly one a day.
- Drug makers who implement RFID control systems can reduce diversion by 18 percent in the first year and lower inventory holding costs by six percent, according to a study by A.T. Kearney.

The industry initiatives for solving these problems are independent, but interrelated. The initiatives that will have the largest short-term impact in the life sciences supply chain are the new FDA bar code rule, user-driven RFID labeling programs, and anti-counterfeiting recommendations from the FDA and industry groups. The information below provides an overview of these programs. Zebra's white paper *New Pharmaceutical Marking Guidelines and Opportunities* provides a thorough background on the programs and their requirements, including detailed information about selecting and using bar code, RFID and brand protection technologies and printing systems.

The Unit-of-Use Bar Code Rule

In February 2004, the FDA announced a rule requiring thousands of drug and human biologic products to be marked with a bar code on the unit-of-use packaging. The complete rule and summary information is posted on the FDA Web site at www.fda.gov/oc/initiatives/barcode-sadr/. The rule became effective in April 2004 and requires existing products to be labeled within two years. New drugs must carry unit-of-use bar codes within 60 days of their FDA approval date. The rule requires the National Drug Code (NDC) number to be encoded in a linear bar code. Two-dimensional (2-D) bar codes and RFID tags cannot be used in place of the linear bar code.

The FDA permits, but does not require, the bar code to include a lot code and expiration date. The FDA acknowledged that encoding lot numbers and expiration date could improve recall management and provide other benefits, a view that has been widely endorsed. The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP), whose members include the American Pharmaceutical Association,

American Medical Association, Healthcare Distribution Management Association (HDMA), Generic Pharmaceutical Association, Institute for Safe Medical Practices, Pharmaceutical Research and Manufacturers of America (PhRMA) and United States Pharmacopeia, recommends that lot or batch control number and expiration date be encoded in the unit-of-use label in addition to the NDC.

Putting lot numbers and expiration dates in a bar code makes it easy to record the information accurately and automatically at any point in the supply chain. This capability improves data accuracy, while reducing the effort needed to record and transcribe the information. The healthcare industry spends $23 billion annually on order management, distribution, transportation and inventory management. Approximately $11 billion of these costs are unnecessary—caused by redundant, non-value-added activities according to a 1997 study on Efficient Healthcare Consumer Response (EHCR). Manufacturers and distributors can help drive these costs out of the supply chain, rather than shifting them to downstream partners, by using automated systems for data capture and communication.

Early adopters among pharmaceutical manufacturers, including Abbott Laboratories, Baxter Healthcare and Pfizer, have envisioned these benefits and have implemented variable-information unit-of-use labeling programs that exceed FDA requirements. These leaders envision tremendous benefits from variable-information printing and are investing to attain them. The uses and benefits will be described in the Application section.

Anti-Counterfeiting Initiatives

Industry groups representing manufacturers, distributors, retailers and pharmacies are all actively engaged in efforts to prevent pharmaceutical counterfeiting and diversion. Many of these organizations contributed to the work of the FDA Anti Counterfeiting Task Force, which issued its final report (available at www.fda.gov/oc/initiatives/counterfeit/) in February 2004. There were no new rules proposed in the report, which advocates that a variety of processes and technologies be employed to safeguard drug products. Tamper-evident packaging, authentication media, stricter pedigrees, improved physical security and increased criminal penalties have all been recommended. However, the concept of track-and-trace systems—built around automatic identification technologies—was championed as the most valuable asset to protect against counterfeiting and diversion.

One of the report's conclusions reads: *"The adoption and common use of reliable track and trace technology is feasible by 2007, and would help secure the integrity of the drug supply chain by providing an accurate drug 'pedigree,' which is a secure record documenting the drug was manufactured and distributed under safe and secure conditions."*

Other industry initiatives and comments to the FDA task force demonstrate there is strong consensus as the value and effectiveness of track-and-trace systems. A comment from HDMA's Product Safety Task Force (PSTF) succinctly summarizes the value of track-and-trace: "*… the key component of track and trace is the ability to uniquely identify individual items. It is this core system element that, in the opinion of the PSTF, makes track and trace the most powerful single strategy currently known for reducing the threat of counterfeiting."* The HDMA's presentation to the FDA task force includes an excellent summary of the benefits of RFID-based track-and-trace systems. The presentation and many other good resources are available in the Government Affairs section of the HDMA Web site, www.healthcaredistribution.org.

The FDA task force recommended that drug packaging contain at least two different authentication technologies. Lot numbers encoded in a unit-of-use bar code are one possibility, RFID labels on outer packs or cartons are another. Both types of labels can be created on secure media that includes taggants and other security features, providing another layer of protection. There are numerous options for mixing and matching different track-and-trace and authentication methods. However, consensus is building within the industry that RFID should be part of the mix. *"Authentication technologies for pharmaceuticals have been sufficiently perfected that they can now serve as a critical component of any strategy to protect products against counterfeiting….Radiofrequency [sic] Identification (RFID) tagging of products appears to be the most promising approach to reliable product tracking and tracing,"* the FDA report states.

R F I D

Many professionals are equally enthusiastic about the benefits RFID can bring to inventory management and supply chain operations. Because RFID improves both security and product handling, RFID may quickly find a permanent place in pharmaceutical packaging. RFID labels can be read through multiple layers of packaging without operator intervention, which can reduce the labor and time required for product handling in the supply chain. The Electronic Product Code (EPC) RFID system (now managed by EPCglobal Inc.) creates a unique serial number for each RFID chip, which can be used as a digital birth certificate to uniquely identify otherwise identical units of the same product.

The Kearney report, which focused on over-the-counter drug makers, estimated RFID systems could reduce manufacturers' distribution labor requirements by nine percent and inventory holding costs by six percent, in addition to the 18 percent reduction in diversion. A series of studies by the developers of the EPC system predicted additional inventory and cost reduction benefits (see the Business Cases and Research Papers sections at www.epclgobalinc.org/ for more information). The Kearney report, "RFID/EPC: Managing the Transition (2004-2007)" is available at www.atkearney.com/.

Belief in these benefits led the FDA to propose an industry timeline calling for full implementation of RFID in the pharmaceutical supply chain, including pallet and case labeling, by 2007. The National Association of Chain Drug Stores (NACDS) and HDMA are among the industry groups who have endorsed this action. In February 2004, nine leading pharmaceutical manufacturers, distributors and retailers announced they formed a new group led by Accenture (www.accenture.com/) to study the potential for RFID to improve manufacturing, distribution and retailing in the industry.

The U.S. Department of Defense, Wal-Mart, Target and other large pharmaceutical purchasers are providing a catalyst to RFID use in the industry by requiring their suppliers to place tags on shipments. Several programs have set a deadline of 2005 for pallets and cases to be tagged. These compliance tagging programs are creating a de facto RFID requirement for pharmaceutical manufacturers and distributors. More information about the programs and what is needed for compliance is presented in *Zebra's RFID Readiness Guide: Complying with RFID Tagging Mandates,* available on Zebra's Web site.

Some RFID activity will likely be required of most stakeholders in the life sciences supply chain by the time the unit-of-use bar code rule marking becomes mandatory. Numerous security measures are already in place and will evolve further by the time RFID and unit-of-use bar coding become commonplace.

A thoughtful approach to meeting the multiple impending labeling requirements can create new processes that will provide unprecedented control and efficiency for recalls, returns processing and inventory control. By reading unit-of-use codes, RFID tags and security marks, instead of just printing them for customers, companies can gain supply chain visibility and improve the quality of their information. Many benefits can be gained through process changes that take advantage of information available on unit, case and pallet labels with little incremental labeling or equipment costs.

Applications

For many pharmaceutical manufacturers, the supply chain is the only place where their products are not tracked at the batch or lot level. Production management, enterprise resource planning, environmental health and safety monitoring and other systems frequently provide or require lot-level traceability. To maximize the quality management and safety benefits, it makes sense to extend batch-level traceability to the final product at the unit-of-use level. RFID makes it practical to provide traceability at other packaging levels that can be accessed throughout the supply chain. Calculations by A.T. Kearney in its report "Meeting the Retail RFID Mandate" suggest OTC drug manufacturers can recoup their capital outlays in RFID systems and produce a positive, sustainable return on investment in slightly over one year by using the technology for internal inventory control and distribution operations. An Accenture study found that improved visibility from RFID could allow manufacturers to reduce their safety stock by up to 30 percent.

In regulated environments where traceability is required, entering data with automated data capture (ADC) technology, such as bar code or RFID, is highly advantageous because it creates 100 percent accurate electronic records. Studies have found skilled typists make an error once every 300 keystrokes, while the error rate for bar code scanning is estimated at one in one million characters. Data can be entered in much less time with bar code or RFID than by manual recording, and scanned data can be transferred to any database or software application without further manual data entry. In announcing the latest delay for implementing the pedigree requirements of the Prescription Drug Marketing Act, the FDA essentially indicated that paper pedigrees will be bypassed altogether in favor of electronic records. Pedigrees have now been delayed until December 2006 (the Federal Register notice is available online at www.fda.gov/OHRMS/DOCKETS/98fr/04-3856.htm).

The following examples describe potential benefits from using bar code, RFID and authentication technologies to automatically capture and provide traceability information for supply chain operations.

Recall Management

It would be nice if drug recalls were rare and isolated events, but in fact they are a common and costly occurrence in the pharmaceutical industry. The FDA's Office of Compliance, Center for Drug Evaluation reported 1,230 Type I and II drug recalls from 1997 to 2002, an average of 3.9 per week for the full six-year period. The FDA issued 354 prescription drug recalls in 2002 alone. Recalls create extensive administrative and logistics burdens that have an immediate impact on operations. The long term cost, measured by reduced consumer and physician confidence, lost sales, and impact on share prices, depends in part on how quickly and efficiently the recall is handled.

The effectiveness of recall management is a direct result of the level of product visibility in the supply chain. The amount of information included on pallet, case, carton and unit-of-use packaging can make the difference between a general, mass recall with notices going out in newspapers and TV news, and a highly targeted, limited recall where consumers may receive notification by a phone call from their own pharmacist or doctor. Encoding lot numbers and expiration dates in bar codes on the unit-of-use packaging enables manufacturers and distributors to trace specific products to specific customers. The labels could be scanned as the products are packaged into larger containers (e.g. cartons or cases) to produce an electronic record that could also be encoded in an RFID tag or 2-D bar code on the outer pack, with the process being repeated as materials are aggregated into larger containers. By marrying lot codes on unit-of-use labels with electronic records created by production control software systems, manufacturers could conduct a recall like this: "We are recalling 50mg tablets of Ourdrugicol, lot number 0123456789, made on March 19, 2003, between 8 a.m. and 1 p.m. on production line 2 at our Anytown, NJ facility. These products were shipped to Acme Drug Distributors warehouses in Memphis, TN and Columbus OH. No other products are affected." When the information is available in an RFID tag, affected products can be found extremely quickly with automated methods that minimize the labor required to search for and identify the items.

Production control systems and auditing procedures enable manufacturers to isolate quality or compliance problems at the batch level. By enabling batch-level traceability throughout the supply chain, specific quantities and shipments can be recalled. This degree of traceability limits the logistics handling costs and administrative burden, so recalls can be resolved more quickly. The audit trail would also limit liability exposure and prevent lawsuits from unaffected individuals. When returned products are received, lot codes can be efficiently checked with a bar code scan, so unaffected products can quickly be redistributed.

Returns Management

Variable information unit-of-use printing could have similar effects on returns management, although the benefits should be greater and more immediate because returns are part of everyday business. The pharmaceutical industry handles $2 billion worth of returns annually, according to an HDMA study. Poor record keeping and the inability to provide audit trails in reverse logistics creates inefficiencies and losses from otherwise acceptable products that can't be redistributed. The scope of the returns management task no doubt is one reason the HDMA's position paper on bar coding includes the following recommendation: *"Use bar codes internally wherever possible. Use of bar codes to identify healthcare products has been shown to reduce labor costs in distribution and dispensing while, at the same time, reducing errors."*

Pharmaceutical returns may be subject to regulations from the FDA, DEA, EPA, OSHA, and the U.S. Department of Transportation plus state and local transportation and biohazard laws. One of the best ways to collect the information and create the audit trail required to satisfy these regulations is to record items with bar code or RFID readers, which can easily be programmed to attach a date-and-time record to every transaction. Lot-level scanning with the automatic time-and-date stamp creates traceability and produces tremendous time and labor savings for data recording. Scanning expiration dates will enable companies to quickly determine if products are eligible for return and if returned products can be redistributed or require disposal or special handling.

By setting shipping or database systems to record shipments to customers by specific lot number, manufacturers and distributors can quickly verify that they are receiving authorized returns by scanning an item label. This practice could also help detect unauthorized or counterfeit products, which would be aided greatly by using some form of brand-protection media. These topics will be explained further in the Authentication section.

Manufacturing Operations

Enterprise resource planning (ERP), manufacturing execution systems (MES), and compliance and reporting systems all need accurate, timely data. Many production facilities already use bar codes to provide the data automatically, accurately and efficiently, track work in process, and provide electronic signatures, batch records and other documentation. However, if lot numbers aren't included on the final product, the link to the electronic record is broken and many of the traceability benefits are gone.

Encoding lot numbers in the unit-of-use packaging and marrying the information with electronic production records can satisfy 21 CRF Part 11 (Electronic Signatures Rule) reporting requirements and provide traceability by raw material batch, manufacturing equipment, time of production, equipment operator and other variables. This data is extremely helpful for recalls but can also be used for process analysis, quality control and other purposes. Manufacturers already track production by lot or batch. By expressing this information in a bar code or RFID tag, they are able to extend their audit trail, realize the full value of their enterprise applications, and enable new applications throughout the supply chain.

Inventory Management

Many pharmaceutical distribution processes are highly automated and make extensive use of bar coding. Modifying these processes to capture expiration dates encoded in product packaging can produce meaningful improvements to compliance with first-in/first-out (FIFO) handling practices, and reduced losses from expired products. Introducing RFID can lead to new automated processes that improve visibility and significantly lower inventory levels.

For example, by capturing expiration dates automatically with bar code or RFID and marrying them in a database with sales records, companies could improve customer service and create new sales opportunities. A software application could automatically send notification to customers when products near the expiration date. The message, or a follow-up contact by a salesperson, could also ask if customers need to reorder to cover potential shortfalls caused by expiration. The program would help customers manage their own inventories, increase sales and reduce the need for rush orders.

The unattended, high-speed reading capabilities of RFID enable tagged items to be recorded, tracked and managed with significantly less labor than required for other inventory control methods. Items can be tracked automatically whenever they are moved using RFID readers on lift trucks, conveyors, dock doors and other portals without requiring any operator intervention, which reduces labor expenses. Inventory records are thus kept accurate and updated in real time, which provides companies the confidence needed to reduce safety stocks. A secondary benefit is that less warehouse space and capital equipment is required to manage lower inventory levels.

Strong expectations of inventory reductions and improved visibility is driving RFID adoption in the retail, consumer goods and defense industries. A study produced by the MIT Auto-ID Center, which developed the EPC system, projected that manufacturers could reduce inventory levels 10 to 30 percent by implementing RFID to improve visibility. The study, "Auto-ID On Demand: The Value of Auto-ID Technology in Consumer Packaged Goods Demand Planning," like many other business case analysis reports, is oriented to RFID's potential impact on the consumer goods supply chain and thus is most applicable to OTC manufacturers. However, the benefits of improved visibility and reduced storage and handling needs can be attained at every segment of the life sciences supply chain. In the words of the FDA task force: *"Radiofrequency [sic] Identification (RFID) tagging of products appears to be the most promising approach to reliable product tracking and tracing."*

The FDA task force also said *"Authentication technologies for pharmaceuticals have been sufficiently perfected that they can now serve as a critical component of any strategy to protect products against counterfeiting,"* a strong endorsement of the effectiveness of RFID, security taggants and other protective measures available for use on pharmaceuticals. The FDA recommends at least two forms of security be used on packaging. Many of the available technologies are complementary, so unit-of-use bar codes and RFID identification labels can also provide anti-counterfeiting protection, especially when they are produced on secure media.

Unit-level traceability can play an important role in fighting product counterfeiting and diversion. Secure packaging and encoding at the unit-dose level can aid efforts by pharmaceutical manufacturers and law enforcement agencies to protect legitimate distribution channels and detect diverted or counterfeit products. For example, in July 2003, Pfizer issued a recall for Lipitor after counterfeit pills were found mixed in packages with authentic ones. The subsequent investigation found that the manufacturer's authentic packaging and required labeling hadn't been used, and that expiration dates had been mislabeled. Printing the unit-of-use bar code label on secure, brand-protection media, and authenticating it throughout the supply chain would reduce and potentially eliminate this type of substitution fraud.

Here's an example. The pharmaceutical manufacturer could use a pattern adhesive to seal individual packages of medication that would leave a tell-tale mark if the package was opened. Unit-of-use bar code labels could be produced on material with hidden security features that require a specialized reader for authentication. Medication packages would then be packed into a cardboard carton for shipping, which receives a seemingly innocent bar code shipping label. The label, however, would have a covert serial number encoded in invisible material for authentication in the field. The label could also contain an encrypted RFID chip.

Relabelers, wholesalers and distributors would authenticate incoming shipments with low-cost portable readers to ensure no piracy or substitution occurred while the shipment was in transit. Random samples of individual packages could also be tested if desired. Before redistributing products to hospitals, distributors could use secure media to produce their own shipping labels, using the same authentication technology or a different one to increase the complexity of protection.

Hospitals could verify incoming shipments at receiving, or check individual packages as they are placed into inventory or dispensed from the pharmacy.

Manufacturers, using portable authentication devices, could conduct surprise audits of distribution facilities and hospitals to determine if and where counterfeit goods enter the supply chain. Manufacturers could also authenticate all returns.

Using bar code or RFID to record lot numbers in supply chain operations could also deter return fraud and diversion. When items are presented for return, they would be scanned to record the lot number. A database lookup would verify whether or not the product was sold to the customer, so the return could be authorized or refused. A similar application could help detect the source of diverted products. When diverted products are recovered, authorities could check database records and follow the audit trail to see who last had possession of them.

Track-and-trace systems are considered the leading defense against pharmaceutical counterfeiting and diversion, but they are not the only tool. More effective use of pedigrees is frequently advocated as a potential solution. Pedigrees can be produced efficiently and provide protection by integrating the operation with identification labeling and authentication systems.

Pedigree Management

Pedigrees are essentially a record-keeping requirement, and are subject to all the limitations and vulnerabilities of paper-based reporting unless they are produced electronically. Perhaps because of these limitations, the FDA has repeatedly delayed full implementation of pedigree requirements set forth in the 1987 Prescription Drug Marketing Act. With automated data capture and validation technologies emerging as practical tools for the pharmaceutical industry, there is renewed interest in pedigrees as a safety tool.

RFID labels could be especially effective as pedigree records because they can provide unique item identification and are extremely difficult to counterfeit. The FDA Task Force reported: *"RFID technology, which would provide a de facto electronic pedigree, could surpass the intent of the PDMA and do so at a lower cost. In light of the rapid progress toward more effective electronic pedigrees that can be implemented within several years, FDA intends to continue to stay its regulations regarding certain existing pedigree requirements to allow suppliers to focus on implementing modern effective pedigrees as soon as possible."*

An RFID-based electronic pedigree system would work by applying an RFID label to pallets or cases. The chip within the label would be encoded with a serial number that uniquely identifies the item and could also be encoded with a customer number or other details about the organization to which the product is being shipped. During shipping operations, the RFID tag would be read, which would update the shipper's inventory records and associate the item with a specific customer order. A date-and-time stamp would be applied to the scan to create a chain-of-custody record that is accurate to the minute.

The receiving organization could read the RFID label to record receipt and update its own inventory records. Again, a date-and-time stamp could be applied. Organizations could compare the time items were shipped to the time they were received to see if there were any unusual delays in the process that could suggest the shipment was diverted or tampered with en route. If the receiving organization redistributes the product, it could use outbound shipment scanning operations as previously described.

The combination of a unique ID and automated data capture creates an accurate, timely and secure pedigree record without creating a labor burden. The system can be completed paperless without any manual data entry or processing requirements.

Sample Management

Samples, which are usually dispensed in physicians' offices, were excluded from the unit-of-use bar coding requirement because they were considered an unlikely source of medication administration errors. However, sample distribution, inventory management and reporting operations could be conducted more efficiently if samples were bar coded. The PDMA requires sample distribution to be tracked and recorded, and JCAHO requires hospitals to track samples by lot and expiration date, so encoding this information could make compliance more convenient.

U.S. pharmaceutical companies spent more than $4 billion in 2000 managing sample distribution and related record keeping and administrative tasks, which does not include lost sales time from reps, who spent an average of 5.5 hours per week completing sample-related paperwork, according to a series of studies. Despite the time and money spent on sample management, more than 80 percent of survey respondents said their information was not accurate.

Companies could improve the quality of their data, limit their risk of being out of compliance with the PDMA and reduce data entry administrative requirements by instituting bar code scanning or RFID reading as part of sample distribution procedures. Sales representatives with scanner-equipped PDAs or laptops could automatically record the receipt and disbursement of all samples. The PDA could also be used to record the signature of the physician receiving the sample. The scanning process would save considerable data entry time, and the captured information satisfies PDMA compliance requirements.

Conclusion

Combining encoded lot numbers, expiration dates and other variable data on different packaging levels creates a secure foundation for a variety of track-and-trace applications. Coding and reading techniques can connect the information required for enterprise systems, supply chain operations and compliance responsibilities, while providing complete traceability from production to patient. Building track-and-trace systems with secure bar code and RFID labeling techniques enables companies to benefit from their marking efforts.

Thermal printers have become compelling tools for successfully meeting increased traceability and labeling requirements. They are the only print technology capable of producing variable information unit-of-use bar code and RFID labels on demand, and can output these labels on a range of authentication media. Thermal is the dominant print technology in industries that rely on bar codes for business-critical production control, distribution and inventory management applications. The ability of thermal printers to use secure media, process variable data, maintain quality in high-speed, small-symbol production environments, produce multiple bar code symbologies and encode RFID chips gives users the flexibility to mix and match identification and security labeling methods without having to invest in dedicated equipment for each technology. Zebra's white paper *New Pharmaceutical Marking Guidelines and Opportunities* describes labeling requirements and printing considerations in detail.

Zebra Technologies is a world leader in bar code printing with an installed base of nearly 4 million units, including systems for unit-of-use bar coding, brand protection and RFID smart labeling. Together with our partners we have the experience, industry knowledge and specialized products needed for successful implementation of pharmaceutical labeling systems. Zebra is also a leader in bar code and RFID standards development who actively participates in the work of life sciences industry associations so that we will be prepared to meet the emerging needs of our customers. Contact Zebra at +1 800 423 0442 or visit our Web site at www.lifesciences.zebra.com/ for more information about our solutions.

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