

Traceable Solutions for Medical Packaging

The demand for safety and integrity in the area of **medical packaging** has taken on new and significant implications in the past few years. Always an area of concern, medical packaging has addressed issues like child safety, correct dosage, patient traceability, tampering and diversion of pharmaceuticals. Now, major additional concerns of drug counterfeiting and concerns around terrorism bring a new sense of urgency to medical packaging manufacturers and hospitals, clinics, assisted living facilities, doctors' offices and, the individual consumer.

Proponents of unit dose packaging like the Healthcare Compliance Packaging Council (HCPC), the National Quality Forum (NQF) and others recognize the role that packaging plays in safeguarding healthcare. And of course, various government agencies, most notably the Federal Food and Drug Administration (FDA) have very stringent packaging regulations and enforcement.

It is easy to see why the pharmaceutical industry in particular will be one of the drivers of new packaging identification technology like RFID, expected to be a viable means of medical packaging traceability. And although RFID is an evolving technology, it may be a few years before it is a practical solution at the unit dose level. Currently, RFID is being used at the pallet and case level for traceability, but there are still technology issues to be resolved. We will see bar coding and RFID technologies co-exist for several years.

While safety and compliance are critical issues, the drive to keep costs under control and manufacture and package product in the most efficient manner is an additional dimension that manufacturers, as well as pharmaceutical distributors, pharmacies and others must constantly address. Convenience at the point of usage also drives certain packaging requirements, particularly in a hospital, clinical or assisted living environment.

A Critical Safety Component

As individual consumers, we may not recognize the impact of medical packaging on our quality of healthcare. The opening of a child-proof cap or the familiar blister unit dose packaging on over the counter medicines may be the extent of our daily interaction with medical packaging, at least for the majority of us. But when the full extent of the issues facing medical packagers as well as patients and consumers are realized, packaging becomes a very real issue that makes increased **traceability** a requirement.

There are considerable steps yet to be taken to ensure packaging traceability. At this point, for example, only some manufacturers have affixed unit-of-use barcodes to hospital injectable drugs and/or IV solutions.



Tracing pharmaceuticals from their origin at a chemical plant to the patient bedside is the ideal, and may be eventually attainable when RFID is completely embedded throughout the medical packaging world. A more extensive implementation of unit dose packaging, particularly in the United States, is another packaging solution that offers additional protection.

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The Concerns

Traceable packaging can address many safety as well as business concerns. In an ideal packaging environment, with full traceability from process to patient (or consumer) these concerns can be addressed:

- *Fraudulent Products* – Drug counterfeiting is a problem that must be addressed. Internet drug sales contribute to this issue. At this time Viagra is the most counterfeited drug on the market due in part to internet sales. The World Health Organization estimates that fraudulent drug sales will reach US \$75 billion globally in 2010. Tracking the pharmaceutical pedigree continues to gain in importance.
- *Expired Products* – Medicines sold as fresh after their expiration dates is a problem easily addressed if traceable packaging is implemented.
- *Diverted Products* – Again, a system of traceable packaging can keep track of pharmaceutical locations in the complex distribution system.



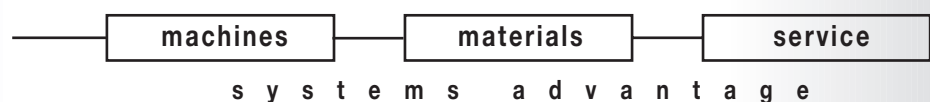
Fraudulent Drugs – \$75B in 2010

Source: World Health Organization

If we look at a few concerns within clinical, hospital or assisted living settings there are several issues addressed through traceability. For example:

- *The wrong medicine to the wrong patient* – In an assisted living facility it is estimated that approximately 44 percent of the patients require seven or more medications per day. The potential for error is dramatic, as are the potential consequences. With the level of medications dispensed in hospitals and clinics on a daily basis, making sure the correct medicine goes to the correct patient every time is a critical issue.
- *Incorrect Dose* – The issues are obvious here and traceability, where the dosage is one of the identified properties, is a solution.
- *Drug Incompatibility* – Being aware of other medications taken by patients, or conditions like food requirements are concerns that can be addressed to some extent by traceable packaging.

Potential for Error
“In an assisted living facility... 44 percent of the patients require 7 or more medications per day.”



A final perspective to consider on the value of traceable packaging in medicine revolves around the business concerns. These are just a few of the areas where packaging traceability can add value from a business perspective:

- *Supply Chain Management* – The ability to track inventories, ensure proper supplies, and improve inventory management are all benefits, particularly as RFID packaging becomes available at the individual bag level.
- *Inventory Control* – A key part of supply chain management, tracking inventory throughout the cycle, will result in definite cost saving realizations.
- *Drug Recalls* – The ability to better manage drug recalls is a benefit not only to the manufacturer but to the government as well. Traceability will ease this complex process.

While we have pointed out a few of the concerns and the accompanying benefits that traceable packaging can provide to the medical packaging industry and the consumer, there are many steps yet to be taken.

Looking for Remedies

With all of the concerns revolving around medical packaging, there are a number of actions in process that are addressing the concerns. The added impetus of concerns about terrorism and the drug supply, as well as an increase in counterfeit drugs with the potential for causing considerable harm, is driving action on several fronts.

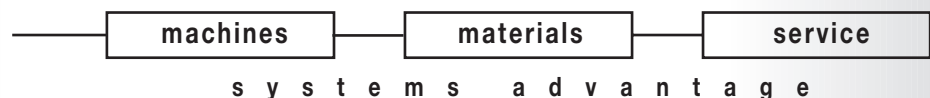
The **National Drug Code** is a universal product identifier for all human drugs. With FDA involvement, this 10-digit code identifies the labeler/vendor, product, trade package size, the specific strength, the dosage and the formula for a specific firm.

The implementation of **drug pedigree legislation** is another step toward safer and traceable pharmaceutical distribution. The FDA has made pedigree tracking recommendations and several states have now passed drug pedigree legislation. Many other states have introduced legislation that is expected to pass.

The implementation of **unit dose packaging** is another deterrent to the deliberate or accidental misuse of pharmaceuticals. In quoting from the American Hospital Association (AHA) document describing, “Successful Practices for Improving Medication Safety” the Association recommends “fully implementing unit dose systems.” Ideally packaged by the manufacturer, this can also be done by the pharmacy. The many safety advantages make this tactic highly desirable in the

hospital, clinic or assisted living environment. The Healthcare Compliance Packaging Council strongly urges unit dose packaging as does the National Quality Forum. The FDA describes unit dose packaging to be a packaging format that can accommodate bar codes on package labels for each dosage of medication dispensed to patients. Automated Packaging Systems offers a number of polybag solutions for bar coding and unit dose packaging.

Unit dose packaging with bar code imprinted on polybag.



The Role of Packaging Technology

Packaging technology must be capable of meeting the growing needs of pharmaceutical and medical packaging in terms of traceability. The growth in the acceptance of bar coding along with the improvements in technology and the printing process are helping to make pharmaceuticals traceable. Bar coding is currently the methodology for tracking unit dose packaging. There are of course technology issues as bar coding requires “line of sight” to be workable. It also requires multiple scans to track a drug from the manufacturer to the patient. It can even require multiple scans within a given facility to track progress to the patient bedside. The problems with wrinkled or damaged bar code labels can also make scanning difficult. In the US the lack of unit dose packaging of prescription drugs from the manufacturer results in bulk shipments with a much higher opportunity for diversion or misuse or counterfeiting. The implementation of unit dose with bar coding is a step toward improved traceability.

RFID “Tag-It” Smart Label

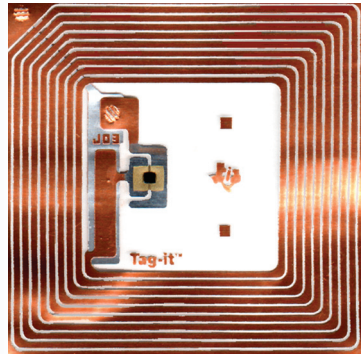


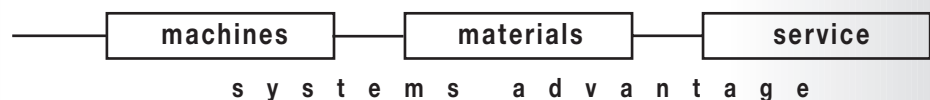
Photo courtesy of Texas Instruments

The next major technology level will be the use of RFID or “Smart Tags” to track medical packaging. Driven in the retail arena by a mandate from Wal-Mart as well as the Department of Defense initiative, RFID still needs to overcome tag pricing levels as well as costs of installing the infrastructure. Additionally, there are technology issues to overcome, like successfully reading packaging in metal cans or liquids. The value of realizing higher levels of traceability, plus the eventual time and cost savings in supply chain management will make RFID a medical packaging technology choice in the near future. The FDA has already outlined potential timelines for the implementation of this new technology.

Additional anti-counterfeiting technologies are being developed, including printing ink additives with forensic traceability, and the use of taggants. We also see manufacturers developing different types of drug-dispensing cabinets and automated drug dispensers. Tools like the Pyxis MedStation®, an advanced point-of-use system that automates the distribution, tracking, management and control of medications, can increase security and accountability, impact positively the quality of patient care, and even improve patient billing accuracy. Perhaps the most significant opportunities will be in the rapidly growing managed-care marketplace, where patients receive an average of seven medications per day and the cost of care is critical.



Conceptual drawing of automated drug-dispensing cabinet with traceable RFID for increased accuracy and security.



Counterfeiting... A Growing Concern

Unfortunately, today's Internet technology is opening opportunities for drug counterfeiters to make incredible amounts of money. Selling counterfeit, expired or otherwise unsafe medicines has become a very profitable enterprise and a key driver for improved and traceable pharmaceutical packaging. A few facts about this important issue:

- Counterfeit drugs make up more than 10% of the global medicines market (Source: FDA).
- In poor and underdeveloped nations up to 30% of the medicines consumed are counterfeit (Source: World Health Organization).
- Estimated annual earnings from the sale of counterfeit drugs is expected to reach \$75 billion by 2010 (Source: World Health Organization)
- "Because the capabilities of counterfeiters continue to evolve rapidly, there is no single "magic bullet" technology that provides any long-term assurance of drug security. However, a combination of rapidly improving "track and trace" technologies and product authentication technologies should provide a much greater level of security for drug products in the years ahead." (Source: FDA).
- "The diverters pave the way for counterfeiters who use pill-punching machines and special inks to produce near-perfect copies of the most popular and expensive drugs." (Source: The Washington Post, October 19, 2003).

Our Role in Medical Packaging

Automated Packaging is currently working with several pharmaceutical manufacturers and distributors and companies requiring different types of medical packaging, helping to solve packaging challenges. With packaging machinery and materials capable of packaging diagnostic kits in identifiable, preformed reclosable bags, or unit dose drug packaging with bar codes imprinted on the bag for identification and traceability, we realize the importance of helping in the task of providing traceable packaging solutions. Our efforts to fill RFID packaging requirements will continue as we develop products that safeguard healthcare processes and patient safety.

One issue that we believe is of critical importance to providing traceable packaging solutions is the integration of the various technologies, methodologies and processes. This requires a common position among pharmaceutical manufacturers, customers, packaging equipment providers and regulatory agencies that safeguarding healthcare is our most critical concern. If you have a unique application that requires a custom packaging solution, we would like to help you develop a solution to fit your individual needs.



High Speed Print-n-Pack System

The Autobag AB 180 is the fastest machine of its kind, packaging at speeds up to 80 bags per minute. It has been engineered with next generation electronics that provide improved control, faster operating speeds, enhanced reliability, built-in diagnostics, and minimized downtime.



Next Bag Out Packaging Systems

The Autobag AB 255 and AB 180 OneStep™ Systems are ideal for pharmacy mail order fulfillment applications. These OneStep baggers integrate with shipping and customer databases for 1:1 fulfillment operations. An integrated AutoLabel™ imprinter is positioned directly over the next bag to be loaded, increasing packaging accuracy and efficiency. These systems are available in a combination of wide, narrow, vertical and horizontal configurations, and use system-matched Autobag bags-on-a-roll, including USPS approved mailbag film.



Versatile Inline Bagging System

The SPrint™ SidePouch™ bagging system provides maximum versatility and efficiency for a wide range of hand-load or auto-load applications. This system is ideal for kit packs and specialty bags, including reclosable zippers, reclosable flaps, and resealable tape.

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