



What Can Radio Frequency Identification Do for Pharmaceutical Packaging?

Hallie Forcinio

With the demand for automatic identification technology on the rise, radio frequency identification is the latest technology introduced. These chips carry and transmit data, are tiny in size, and offer many benefits.

Pharmaceutical-related bioterrorist acts combined with the need to reduce medication errors, improve patient compliance, and minimize counterfeiting have boosted interest in automatic identification technology among regulators and manufacturers. Although bar coding offers many benefits and will no doubt be more widely used as pharmaceutical companies improve product tracking and tracing capability, another technology, radio frequency identification (RFID), waits in the wings.

RFID tags consist of a chip to carry the data and an antenna to transmit it. Tags can be passive or active. Passive tags rely on a radio frequency field generated by a reader to transmit data, and active tags include a power source so the tag can transmit information continuously or at preset intervals.

Software is required to organize the data collected and to link to other systems such as patient care, warehouse management, transportation management, or enterprise resource planning (ERP).

Benefits of RFID tags

RFID tags can be produced in very thin forms, which can be incorporated in pressure-sensitive label structures applied by conventional labeling equipment. Chips are small in size; some are comparable to a piece of glitter. Unlike bar codes, multiple RFID tags can be read simultaneously at a rate of hundreds per second and do not have to be within the line of sight of the scanner to be read. In addition, some tags are rewritable so data can be added as a package moves through the supply chain or doses are taken.

RFID technology offers the potential of being able to communicate with so-called smart shelves

or cabinets. This can help retailers and healthcare facilities monitor stock levels, avoid out-of-stock situations, and automate reordering and inventory counting. At home, smart medicine cabinets could serve as a compliance aid, helping consumers take the right medication at the right time and providing alerts about possible conflicts with other medications. Once a package is emptied, the tag can communicate with recycling systems to ensure the packaging is sorted into the correct recycling stream.

Actions taken to improve RFID

Obstacles to the widespread adoption of RFID include the high cost of the tags, readers, and infrastructure; a lack of standards; the use of different frequencies in various parts of the world; and privacy. The proximity to liquids or metal can disrupt RFID signals. However, tag and hardware costs are beginning to plummet and efforts toward standardization and privacy protection are moving forward with the support from various industry groups.

The Auto-Identification Center at the Massachusetts Institute of Technology (Cambridge, MA) is one organization that is actively working with RFID technology. The center consists of a number of consumer product companies and retailers as well as makers of tags and readers.

This group of technology users and suppliers has developed a complete package for item-to-item communication. The package includes a 96-bit electronic product code (ePC), which holds enough data to provide a unique identifier at the item level for all current and future products, reading capability, a Web-enabled object-naming service directory that contains additional information about each item, and a product markup language for communication between inanimate objects.

RFID in use

Initial packaging-related uses of RFID technology appear to be focused on returnable containers in closed-loop scenarios. TrenStar, Inc.

Hallie Forcinio is *Pharmaceutical Technology's* Packaging Forum editor, 4708 Morningside Drive, Cleveland, OH 44109, tel. 216.351.5824, fax 216.351.5684, editorhal@cs.com.

The electronic product code provides a unique code at the item level, making counterfeits more difficult to create and fakes easier to identify.

(Chicago, IL), for example, has shown how pharmaceutical manufacturers could handle returnable–reusable vessels or packaging. The company has assembled a pool of tagged beer kegs that it manages for a growing number of United Kingdom and European brewers. Instead of purchasing and managing the kegs themselves, brewers pay per fill, and TrenStar oversees delivery, pickup, cleaning, and maintenance. With readers installed at depots and carried by delivery personnel, kegs are tracked through the system and data are collected about each unit. As a result, brewers can pinpoint the whereabouts of any keg in the system by checking the TrenStar extranet site. Reports about how long a keg sits in any given location can be generated. This tracking and tracing capability reportedly has cut container losses by half and cycle time by a week. The capability also has minimized diversion and increased sales because the product is less available through unofficial channels. The system makes it easy to determine how much beer remains when

the keg is returned and enables the company to recoup the excise tax paid on the unsold portion. The historical record maintained in the tag ensures that the keg receives the right level of cleaning and maintenance attention at the appropriate intervals.

Other activity in RFID tagging focuses on the ePC technology, which has been successfully demonstrated at the pallet and case level. Participants are now studying how it works at the item level. Wal-Mart (Bentonville, AR) and Procter & Gamble Co. (Cincinnati, OH) have begun a smart-shelf test at a Wal-Mart Super Center in Broken Arrow, Oklahoma, to show how RFID can provide real-time sales information to its ERP system to automate replenishment. RFID-tagged Max Factor Lipfinity lipsticks are merchandised in a 4-ft display area equipped with radio frequency readers and antennas. Readers on the shelf monitor the position of each product and can send an alert to a store manager's personal data assistant (PDA) or other device if stock levels fall below a certain number so that the shelf can be replenished before an out-of-stock situation occurs and sales are lost. An alert also is generated when too many items are out of place on the shelf or a large number are removed at once indicating the possibility that the product is being shoplifted.

The Gillette Co. (Boston, MA) is tagging certain razor-blade packs to test a smart-shelf concept in US and UK stores.

RFID technology

Ideal characteristics

- thin form to enable incorporation in a label
- can be read at a rate of hundreds per second
- does not have to be within a scanner's line of sight to be read
- rewritable (data can be added as a package moves through a supply chain).

Potential uses in healthcare facilities or distribution centers

- communicates with smart shelves or cabinets
- monitors stock levels to avoid out-of-stock situations
- automates reordering and inventory counting

- more difficult to create counterfeits; easier to identify fakes
- monitors heat, light, and moisture inside the package to ensure product shelf life.

Potential uses in homes

- facilitate patient compliance
- in collaboration with smart medicine cabinets, could provide alerts about possible conflicts with other medications
- identifies packaging materials so an empty package can be sorted properly for recycling.

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The company wants to minimize out-of-stock situations as a result of shoplifting, theft out the back door, delays in restocking from the back room or warehouse, and late deliveries. Gillette plans to begin applying tags at the pallet and case level later this year and has ordered 500 million 915 MHz tags to support its implementation (915 ePC Tags, Alien Technology Corp., Morgan Hill, CA). The tags consist of nano-sized block integrated circuits that are assembled into plastic film in a patented process called *fluidic self-assembly*. Lower silicon costs and parallel assembly reportedly result in costs of 10 cents/tag or less.

Future possibilities

According to a white paper, "Smart Medicine, the Application of Auto-ID Technology to Healthcare" by David Brock, co-director of the Auto-ID Center, RFID has significant potential in healthcare settings. Possible applications include automating the monitoring of radioactive isotopes and recording and validating the drug administration, thereby ensuring what the industry calls the "five rights" (right drug, right dose, right patient, right time, and right administration route).

Because the ePC provides a unique code at the item level, creating counterfeits becomes difficult. In addition, fakes are easier to identify because nongenuine products either lack an electronic identity or duplicate a number, thus prompting an alert from the system. A recently patented blister-pack concept embeds an active or passive RFID tag in the packaging to permit product tracking and tracing, monitor patient compliance and in-package environmental factors, and prevent theft and medication errors. When a cell is ruptured to remove a dose, a signal antenna communicates the event to a fixed or handheld transceiver (Drug Delivery Management System, DDMS Holdings, LLC, Ponte Vedra, FL).

The RFID tag also can incorporate sensor technology to monitor heat, light, and moisture conditions inside the package to ensure that a product's shelf life is not compromised. Data collection depends on wireless devices and communication using the internet. The tag has the potential for communicating with a cell phone or PDA to help manage care or provide dosage re-

mindings. With one patent in hand and a second pending, the company hopes to have a prototype to demonstrate before the end of 2003. Initial applications will likely be in clinical trials in which compliance monitoring and record keeping are critical.

As time passes, tag costs will continue to drop as printing antennas using conductive ink becomes more practical and nanotechnology shrinks the size and cost of the chip. Another technology aimed at reducing costs replaces silica chips with polymer-based electronics.

Research is being conducted in RFID-compatible storage units and appliances, which could communicate with RFID tags and consumers. In a paper entitled "Magic Medicine Cabinet: A Situated Portal for Consumer Healthcare," Dadong Wan, a research analyst with Accenture (Northbrook, IL), describes an appliance that combines face recognition, vital sign monitors, voice synthesis, and RFID-based smart labels. These features enable the appliance to verbally remind consumers to take their medication at the appropriate time or to check their physical conditions such as blood pressure or glucose levels. The interactive unit also could schedule an office visit with a caregiver if the situation warranted.

Although bar codes continue to receive more attention from pharmaceutical manufacturers and regulators, especially with FDA's proposed rules regarding bar-coding of unit-dose pharmaceuticals to prevent medication errors pending, the convergence of various tag, reader, infrastructure, and standard advancements make RFID a strong contender to address future automatic identification needs. **PT**