



## RFID

RFID is a hot topic within the drug supply chain. Dr Bill Hardgrave and Robert Miller, University of Arkansas, discuss its merits and potential in combating drugs counterfeiting.

# THE SILVER BULLET?



### Authors

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Research Center. Robert Miller is a PhD student in information systems at the University of Arkansas. He has worked on a variety of RFID projects during the past two years and has been instrumental in writing much of the software used to understand and analyse RFID data.

The hype surrounding RFID is at an all-time high and growing. However, contrary to its recent rise in interest, RFID is not a new technology; it has been around since the 1940s and may be the oldest technology ever to receive such an intense level of hype and interest. Many people have probably used RFID and not realised it, for example, car key fobs and employee identification cards used for building or room access are equipped with RFID.

Since its inception, RFID has found success in niche areas, but it is the recent mandates by Wal-Mart, Tesco and other major retailers that have pushed it to the forefront, as consumer packaged-goods suppliers are asked to put passive RFID tags on cases and pallets moving through the retail supply chain.

### Industry driver

Because of the mandates, much of this interest is with the use of passive RFID tags and their application within the retail supply chain. In this setting, RFID is viewed as a better technology than the bar code or universal product code (UPC).

Passive RFID tags work like this: an RFID reader transmits a signal through one or more of its antennas; RFID tags, which hold information on a silicon chip, are inactive until the

radio waves sent by the reader via its antennas charge the tag electromagnetically. The RFID tag answers the reader by sending back its information, which is captured by the reader's antennas.

RFID's use of radio waves and electronically stored information offers several advantages over bar codes. First, a bar-code reader must have a clear and unobstructed view of the bar code before the information can be read. With RFID, this line of sight is not necessary, since RFID works via radio waves rather than optical recognition. Thus, information from an RFID tag can be read through boxes, in bottles and stacked on pallets. Second, with RFID, several hundred items can be read at one time whereas a bar code is limited to reading only one item at a time.

Third, most RFID tags hold 96 bits of information – about three times as much information as a bar code, which allows an RFID tag to hold a product identifier known as an electronic product code (EPC). The EPC subsumes the UPC, and adds a serial number. While a UPC can only identify a product category, an EPC can identify a particular product. In addition to the EPC, information such as times of shipping can be written to the tag.

Fourth, the information on an RFID tag is read/write. As the product moves through the supply chain, information can be added; bar codes are read-only.

In general, RFID offers the opportunity to eliminate individual scanning of items and the overall reduction of human touch points, which makes the process more efficient and more accurate. This then translates into labour savings and/or redeployment of labour and better inventory management (via automatic tracking). The serialisation offered by an RFID tag helps reduce product tampering and counterfeiting while improving the ability to recall specific units of product.

### Counterfeiting task force

The WHO estimates that the worldwide sale of counterfeit drugs is a \$26bn a year. Faced with such a significant threat to the

security of the drug supply chain, the FDA formed a task force in July 2003 to investigate the problem and propose measures for dealing with it. In February 2004, the task force issued a report, *Combating Counterfeit Drugs*, which outlined measures to help combat counterfeiting<sup>1</sup>.

One of the primary measures presented in the report is the use of RFID tagging to support the mass serialisation of drug products. Here, each pallet, case and package of drugs receives an EPC, which acts as a unique identifier that can be used to record information about any transactions involving the drugs from the point of manufacture to the point of dispensing. With the ability to identify specific drugs as they move through the supply chain, and to update the information at each transition point, mass serialisation becomes the key to establishing a chain of custody or pedigree. This would allow retailers to authenticate the products they sell back to the manufacturer, or to any other point in the supply chain.

#### RFID'S ADVANTAGES OVER UPC INCLUDE:

- Using radio waves rather than optical recognition
- Ability to scan hundreds of items at a time
- Provision of detailed information about specific products

A number of governments have begun to mandate these types of pedigree. These mandates require that each partner in the supply chain keeps records showing who has had possession of a drug back to the point of its manufacture. Maintaining a paper-based pedigree would be both time-consuming and labour-intensive. Also, paper pedigrees are susceptible to human error and fraudulent manipulation. Given these limits, the push for electronic pedigree systems is understandable. Although RFID is not required to implement an electronic pedigree, using the two technologies together would greatly improve the accuracy of the data, and thus the level of security.

Some RFID developers, and their pharmaceutical partners, are piloting systems that combine mass serialisation, RFID technology and electronic pedigree software. Although there are proprietary differences, the systems work by first placing RFID tags with unique EPC numbers on pallets, cases and packages. These tagged items then move through a supply chain, which has RFID scanners at each transition point. The scanners read the EPC numbers as they move through these points and then record the numbers, along with the date and time, in the pedigree system. In effect, the pedigree is untouched by human hands, making it secure and extremely efficient.

With such a system in place, it would be a simple matter for government inspectors to validate the chain of custody for a given drug. It would even be possible to have the pedigree system itself note any anomalies in the data as the drug moves through the supply chain. By recording the movement of drugs from start to finish, the opportunity to introduce counterfeit products is greatly reduced. The sheer presence of RFID tags on each item would also act as a deterrent to counterfeiters who would have a difficult time reproducing the tags.

While the FDA considers RFID to be the 'most promising approach to reliable product tracking and tracing', it is by no means a silver bullet. As stated in its 2004 report: 'all anti-counterfeiting technologies can be defeated'. Even under the most comprehensive RFID-based system, it will be difficult to totally eliminate product tampering and counterfeiting. For example, a cloning attack involves removing the legitimate product from its container and replacing it with a counterfeit (the legitimate product is then sold on the black market). RFID alone cannot prevent a cloning attack. However, coupled with other technologies, these types of threats can be attenuated. For example, tamper-resistant seals to detect a structural breach of the container could be used to inform the tag with information about the violation.

Another proposed solution is a challenge-response technique used with many of today's contactless payment systems<sup>2</sup>. Texas Instruments and VeriSign have teamed up to create an encryption infrastructure to offset cloning attacks<sup>3</sup>. Overall, the FDA believes that a more extensive layered approach using both overt and covert technologies, such as holograms, colour-shifting inks and chemical markers, will be required to address the counterfeiting threat.

Besides its ability to make counterfeiting more difficult, RFID has other potential benefits. One of the most significant is its ability to enable targeted drug recalls. Lots containing defective drugs could be more easily tracked by their EPC numbers and then located through the use of RFID scanners. RFID can significantly improve inventory visibility by providing accurate information on stock levels, location and replenishment. Additional advantages include theft identification and deterrence, a reduction in discrepancies between manufacturers and distributors; and in warehouse labour costs.

#### Potential and reality

RFID in pharma holds great promise. The potential for anti-counterfeiting, better drug recall management, and improved supply chain efficiency is obvious. Still, RFID is not the cure-all answer to counterfeiting. It will be difficult for any technology or process to totally eliminate counterfeiting, but RFID offers potentially significant improvements in anti-counterfeiting, especially when combined with other technologies.

These solutions will not be cheap. A report by the Healthcare Distribution Management Association<sup>4</sup> estimates that large manufacturers and distributors could spend as much as \$20m implementing an RFID solution. The upside is potential gains of \$200m to \$1bn annually. However, individual companies or countries cannot reap the benefits by using RFID in isolation. For RFID to be successful, there must be widespread adoption across companies and across the globe. This adoption will be accelerated by international standards and common international laws when they appear. **END**

#### References

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