RFID in Pharmeceutical Applications: Headache or Relief?

TECHNOLOGY BRIEF

One one hand, the pharmaceutical industry is no different than any other. Products are made at high speed, are frequently subject to cost pressures and require better and better traceability to address possible recall issues. On the other hand, this industry has very unique requirements, especially when dealing with highly regulated products. It is understandable that the pharmaceutical manufacturing and distribution sector is looking at RFID as a possible solution to most, if not all, of those problems; after all, its more industrial cousins in the automotive, material handling and specialty machine sectors have used RFID technology successfully for well over a decade. What should Pfizer, GlaxoSmithKline and Bayer know, consider and look out for before jumping into RFID?

The Applications

The pharmaceutical industry can benefit from RFID in different ways. It can draw from the experience of other industrial sectors as well as the know-how that can be provided by established RFID hardware manufacturers. On the manufacturing side, RFID solutions have a proven track record of being a reliable, cost-effective means to reduce waste and increase automation equipment utilization. During the manufacturing process, RFID tags attached to carriers are regularly used to record production related information. This is especially useful in cases where environmental and manufacturing variations for each batch must be recorded. Furthermore, orders can be tracked throughout the entire process allowing a higher level of customer service. Closed-loop product tracking is the low hanging fruit and can result in immediate payback as it is a well-established process perfected in many other, unrelated industries.

Borrowing from applications where machining tools are automatically tracked using RFID technology, manufactures of pills can apply RFID and track pill dies and punches. The tag may now hold die usage or allow a system to verify that the correct die/punch combination has been installed. Simple applications, such as servicing or replacing a worn die before it causes damage to the press or before it produces bad product, have the potential for a fast return on investment. One of the main reasons that these types of applications are comparatively easy to implement and justify is that they are *closed-loop*. Tags are purchased once, installed once, and remain within the control of the production facility. Consequently, they are an investment (and not a recurring cost) that can be checked against the expected financial gain.

A novel aspect of pharmaceutical products without equivalent (as of now, at least) in the industrial space is cradle-to-grave tracking of restricted medications and compounds. Narcotics, some pain medication, hallucinogenic drugs and certain nuclear compounds fall into this category. In these cases, a unique RFID tag is attached to the material and read at all hand-off points where responsibility is passed on, from one entity to the next. Reading the RFID tag creates an electronic paper trail showing when an item changed hands. In its most simplistic form, a so-called *Read Only* tag with a unique ID is all it takes. Upon scanning, the UID is read and recorded in a database; adding the necessary associated data is easy. Employee badges may be scanned and PINs could be used to authenticate identities and further enhance security. In situations where detailed information is stored on the tag directly, password mechanisms should be employed. Fortunately, these features are available with today's tags. Unfortunately, however, this application is not necessarily closed-loop; tags may in fact leave the facility and never be returned. Traditionally, open-loop solutions are harder to justify as each tag directly adds cost. Choosing the right technology is very important in these cases and tag cost, while continuously falling, continues to be a big concern. Still, if the cost of tracking a drug by conventional means

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is high enough, the RFID route may not only be a cheaper alternative but also better address regulatory requirements. After all, it is significantly easier to falsify paper records, signatures and potentially illegible dates and times at hand-off points.

Another possible open-loop application for RFID technology, heavily discussed in the literature and at conferences, is electronic pedigree verification. This application attempts to address the growing problem of counterfeit protection not only for the purpose of protecting the intellectual property of companies but also to keep medication of questionable heritage off the shelves and out of patients' hands. For this to work, the tags must now be attached to each box or bottle containing the medication. These are clearly one-way applications where the cost of each tag is critical, especially if the tracked item is sold in very large quantities at a relatively low price. Furthermore, tag access security is even more critical now. It is not sufficient to only identify the uniqueness of the tag, but it must also disallow unauthorized reader electronics to gain possession of the data. If this where to happen, a particularly crafty counterfeiter could simply purchase an original[1] and duplicate it over and over, thus undermining the entire procedure. A very promising new technology that is capable of increasing the security of applications using RIFD chips has recently been introduced by PUFCO. In fact, their method makes it impossible to clone the chip[2] and can, therefore, be used to create data security based on physical properties of the silicon chip itself.

The Technology

The good news for users thinking about implementing RFID at one level or another is the fact that today's technology suppliers favor standardization. The bad news is that there are still many noncompatible standards. Right now High Frequency (HF) and Ultra High Frequency (UHF) are jockeying for users' attention. While UHF has been propelled to the front pages – even the front pages of main stream publications like USA Today and Newsweek – HF solutions are being implemented in ever larger numbers. Unfortunately, that does not mean that any available HF tag can be read by every available HF reader system. Both ISO15693 and ISO14443 are used, have advantages (and thus also disadvantages) but are not compatible. Even tags that are sold as following one such standard are not necessarily accessible by any given reader. Before investing in any manufacturer's RFID technology, users in any field, not only those in the pharmaceutical arena, need to ask some tough questions (see side bar).

Clearly, RFID has been a practical solution for many years. New and lower-cost RFID technologies will allow the pharmaceutical industry to expand the usage of RIFD. Closed-loop applications appear to be an ideal way to gain experience and benefit from a short ROI. Open-loop applications, are viable, but are most likely not ready for prime time due to the high cost of one-time use tags. New developments such as unclonable tags combined with better processing technology will eventually bring cost down and security up. Hardware manufacturers with many years of industrial experience are certainly ready to make use of such tag technologies.

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1 This process is similar to a *replay attack* where the attacking reader does not "understand" the information on the tag but simply creates identical copies (or clones) of the source.

2 This method is based on the observation that at the microscopic level every silicon logic gate behaves slightly differently. To verify a chip, a number of logic gates (called *Physically Unclonable Functions* or PUFs) are etched onto the chip creating a race track for logic pulses. Detailed information about this technology can be found at http://videos.dac.com/44th/papers/1_3.pdf.

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Additionally...

Questions any potential user of RFID technology needs to ask prospective hardware suppliers:

- How open is the read/write to accommodate new tag technologies? If an ISO solution is proposed, does it cover a significant selection of off-the-shelf chips from multiple manufactures?
- Does a change in tag technology require automation systems to be redesigned?
- How long has the supplier been involved in RFID developments?
- Does the prospective supplier have a track record of supplying hardware for many years? (Will replacement parts be available in 10 years?)
- Does the read/write hardware use ASICs that are specific to that supplier only? (This may result in availability problems down the road.)
- Can the hardware interface with the preferred control systems (PLC, DCS …) using open, published standards? (Proprietary solutions drive up initial implantation and long-term costs as the required know-how will most likely not be widely available in the integration community.)

Pepperl+Fuchs IDENT Control is an example of an industrial RFID concept where interoperability and long-term product availability are important design criteria. Not only are the most important industrial (open!) communication standards supported, but the interface unit allows any available tag technology to be implemented without the need to modify user level control software. For semi-open and open loop applications, handheld readers are an integrated part of the tracking process. Tags are suitable for rugged applications.

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