

Pharmaceuticals Race to Develop Drug Tracking System on Eve of FDA Deadline RFID Technology Is No Panacea

Drug counterfeiting is a multi-billion dollar business, siphoning revenue from the pharmaceutical industry and endangering the lives of consumers. It is estimated that nearly \$39 billion, or 11 percent, of global pharmaceutical commerce will be counterfeit this year.

In an effort to protect the nation's drug supply, the U.S. Food and Drug Administration (FDA) will begin enforcing its regulations requiring the documentation of the chain of custody of drug products in 2007. The FDA recommends the use of "electronic track and trace technology" for monitoring the movement of prescription drugs from manufacturers to point of sale.

Drugs can change hands as many as 10 times throughout the pharmaceutical distribution chain. Unsavory third-tier distributors take advantage of the lack of auditing to substitute fake drugs in their shipments. An electronic or e-pedigree that follows each pallet, case and unit would help ensure each product is the real thing when it reaches its final destination.

Although the FDA is not dictating the method of authentication, it strongly recommends the use of Radio Frequency Identification (RFID) chips, barcodes or some combination of the two. The idea is that products would be tagged with RFID chips or barcodes and followed throughout the supply chain. RFID chips provide an advantage over barcodes in that they can potentially give each pill, for example, a unique ID.

RFID not yet ready for prime time

The use of RFID technology, however, has not become as pervasive as the pharmaceutical industry would have liked. "For now, RFID tagging is not economically feasible to do it at the level needed. Tags may cost anywhere from a quarter to a dollar, which makes it cost-prohibitive for some products," says Kelly Cook, who works in health sciences at EDS.

Aside from still being too expensive, other problems surround RFID technology. The ability to read or get a signal from RFID chips is not at 100 percent. There is also a concern that the signal emitted by these chips might degrade the efficacy of the products. And, to date, standards for RFID technology haven't yet been ratified.

The State of Florida set its own deadline for compliance, giving distributors and wholesalers until July 1 this year to implement an e-pedigree solution. Pilot programs using RFID technology were conducted. A month before the deadline, the largest three distributors, which control the movement of 80 to 90 percent of Florida's prescription drugs, said they couldn't do it. Rather than stop the supply of much-needed drugs, the state extended the deadline.

Cook says there is an alternative, cost-effective approach to RFID that can be implemented in weeks versus months. Called “virtual serialization,” it leverages a company’s existing technology infrastructure and barcode technology – without requiring a huge capital outlay.

“Using this approach, companies can demonstrate compliance with federal regulations and gradually scale up to an RFID solution as it becomes more affordable,” says Cook.

Multiple benefits of tracking drugs electronically

The benefits of tracking drugs go beyond compliance. Take the situation where thousands of tainted products must be recalled and sales immediately halted. A company that has implemented an e-pedigree program would be able to determine with precision which products were safe and which products needed to be recalled. Further, this could potentially save some companies \$10 to \$15 million a day in lost sales.

Similarly, this technology could help prevent terrorists from infiltrating the drug supply chain to deliver potentially thousands of lethal drugs to unsuspecting consumers.

Companies that authenticate their products with an e-pedigree will have a competitive advantage over those that cannot. Cook explains: “If you’re a purchaser, you’re going to ask yourself who you want to buy product from, those that are fully compliant with FDA regulations or those that aren’t. Companies will be able to increase their market share by selling that capability as a business value.”

Finally, using technology to track products makes good business sense. Knowing where your products are in the supply chain can help with overall operational excellence. By analyzing the movement of goods, companies can determine existing bottlenecks, for example, and wring additional costs out of their distribution systems.

At the end of day, the business value an e-pedigree solution brings and the risk it mitigates far out-weigh the costs of implementation.