

RFID Benefits for Drugmakers

At a recent educational seminar organized by Cap Gemini Ernst & Young, pharmaceutical manufacturers discussed the far-reaching advantages and potential pitfalls of RFID technology.

Dec. 22, 2003—Cap Gemini Ernst and Young, a Paris-based provider of outsourcing, consulting and technology services, says the benefits that pharmaceutical companies will get from deploying RFID go beyond just more efficient supply chains. RFID will help improve the process of developing drugs and running clinical trials of drugs, increase patient safety and cut down on counterfeiting and diversion of product whereby drug shipments are stolen in transit and illegally resold. But at a recent educational seminar, drugmakers expressed concerns about the cost of deploying RFID systems and the regulatory requirements surrounding its use.

"We built out the business case and found that there is true economic value," says Colin Towner, CGE&Y's life sciences RFID leader. "It's not just in track and trace, but in manufacturing, clinical, reducing theft and counterfeiting, and so on."

Early this year, the Auto-ID Center, the MIT-based group developing the Electronic Product Code and related technologies, asked CGE&Y to develop a business case for the implementation of RFID technologies in life sciences. CGE&Y worked with Sun Microsystems, Auto-ID Labs and EPCglobal to organize an educational event in Princeton, N.J., at which it presented its report. Representatives from 11 pharmaceutical companies broke into groups to discuss implementation issues. Among the key findings of the discussion groups were:

- * The four key features of RFID that can deliver business benefits to pharmaceutical companies are the ability to identify individual bottles and containers of drugs; to eliminate line-of-sight requirements to read product information; to remotely track movement and location of drugs; and to provide assurance that the ID on the bottle has not been forged.
- * Creating a buyers' consortium of pharmaceutical manufacturers who must comply with the Wal-Mart mandate could drive greater adoption of RFID by enabling companies to buy tags at lower prices.
- * For an average clinical trial of a drug, applying RFID can speed the trial's completion by up to 5 percent, as well as reduce start-up delays and decrease trial errors and dropouts of trial participants.
- * As reimportation of U.S.-made drugs back into the United States becomes a major political issue in the United States and diversion continues to be widespread in Europe, RFID adoption can help to reduce gray and black markets sales.

While the benefits for pharmaceutical companies could be significant, the manufacturers had some special concerns about how RFID will be used in the highly regulated industry. The U.S. Food and Drug Administration has Current Good Manufacturing Practice rules that require the validation of computer systems to assure the accuracy and integrity of data. It's not clear how RFID systems, which are integrated with computers, can be validate so that government regulators are sure the right tag was read and not a nearby tag.

"The companies have to develop and deploy the system and then provide documentation to the FDA to get approval," says Towner. "Until you do it, you won't know it's okay."

Towner says that the pharmaceutical companies also had a lot of questions about the security of system and the information. "One issue is the tag itself," he says. "How do you know it's authentic [not a counterfeit tag]? Another issue is around the sharing of information with partners such as Wal-Mart. How do you ensure that Merck doesn't get to see information on what Pfizer is shipping?"

Towner says the companies are also concerned about the cost of RFID tags and how much they will have to spend to comply with Wal-Mart's mandate, but it is not as big an issue for the pharmaceutical companies as it is for consumer packaged goods companies. That's because the value of pharmaceuticals is much higher and also because drugmakers can make distributors—such as McKesson, one of the largest pharmaceutical distributors in the U.S.—deploy and absorb the cost of the tags

Forcing distributors to put tags on products to comply with Wal-Mart is "a strategy pharmaceutical manufacturers can take as they figure out how to deploy the technology," says Towner. "But we would advocate that you are no better off than you are today if you do that. In our research we used conservative figures—25 cents for an RFID tag and another 25 cents to put it on the product—and we still came up with a return on investment for these companies."

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