

RFID Helps FDA Caseworkers Track Important Paperwork

The agency's Office of Regulatory Affairs is using EPC Gen 2 technology to store and retrieve 10,000 investigation files at its San Francisco location, and plans to install the system at 14 other district offices.

By Claire Swedberg

Dec. 12, 2007—The U.S. Food and Drug Administration's Office of Regulatory Affairs (ORA) plans to install RFID technology in 14 of its 20 district offices nationwide in the first quarter of 2008, following a pilot of the system in its San Francisco office. Provided by FileTrail, a file-tracking and records-management solutions provider based in San Jose, Calif., the system will enable the offices to track a total of approximately 150,000 investigation files as they move about the office and among employees.

The system was first installed at the San Francisco office in March 2006, says Mohammad Samimi, quality assurance manager in the ORA's San Francisco district office, and is now fully deployed in that location, tracking about 10,000 files. "This system definitely saves time," Samimi states.

As the Food and Drug Administration's enforcement division, the ORA sends inspectors to specific locations and businesses, and maintains notes about each visit, along with correspondence and reports resulting from an audit or investigation. Because much of this material can't be saved or maintained electronically, the tracking of paperwork is critical. The paperwork is often used for follow-up post-audit activities, such as writing favorable recommendations, or issuing fines or initiating a legal case against a company. The confidentiality of the records is also essential, making document tracking that much more vital.

"Our main problem was it was an alpha system," Samimi says, referring to ORA's process of shelving files according to alphabetical order. In the past, the San Francisco office, like its counterparts in other districts, stored the files on shelves alphabetically, with a clerk assigned to the records room to shelve the files and retrieve them for employees. Staff members would fill out a form upon taking a file. The system, however, allowed the opportunity for errors, with files not returned on time by employees or misfiled in the records room itself. In addition, if a file needed to be returned, it was often a time-consuming process to determine who had the file, then retrieve it from that employee. As such, a worker looking for a file often resorted to sending e-mails to the entire office.

With the new system, much of that process is automated. Samimi says the San Francisco office will continue to employ a part-time clerk in the records room, but ORA employees will now be able to retrieve files themselves.

Each file is given a color-coded label printed with an identification number (in both human-readable text and bar-coded form) and the name of the company being audited, says Tom Pemberton, FileTrail's VP of product strategy. The label also comes with an ultrahigh-frequency (UHF) EPC Gen 2 passive RFID tag. When a case file is created, employees read the tag in a new label, using a desktop RFID interrogator, known as a

DeskTracker, attached to a PC. The tag's EPC number, the time of day and the date are uploaded into the ORA's back-end data system. The records clerk inputs details about the file, which is linked to the unique RFID number and the printed numeric identifier. The clerk then affixes the label to the file and shelves it according to its color code and printed numeric identifier printed on the label.

According to Samimi, a stack of files can be carried past the DeskTracker interrogator and captured in this manner. When an employee checks out a file, he uses the interrogator to read the file's RFID tag, and the bar-code reader (connected to the RFID reader) to scan the bar-code number printed on his ID badge. The self-checkout system has been working well, he says, though the variety of ways in which the system could be used (such as the order in which employees scan files and bar codes) has led the ORA to post instructions at the DeskTracker, listing four illustrated steps for checking out files.

The data resides on the ORA's local server, Samimi says, and is maintained by the ORA. FileTrail's software package allows the ORA to bring up records of a particular file's location, and can alert an employee automatically via e-mail if the file has been kept beyond a predetermined time limit.

Samimi says the office intends to begin employing an Intermec handheld RFID interrogator in 2008, to take inventory in the file room or search for a missing folder throughout the remainder of the office. He also intends to install FileTrail ZoneTrackers (fixed RFID readers) throughout each office, deploying them in doorways to capture tag ID numbers as files enter a specific department. This system, he says, would be especially helpful in circumstances such as when a caseworker turns over a file to a supervisor in another department.

While the 14 district offices will implement the same FileTrail RFID tracking technology, how they do so will vary from one location to another. "Some are bigger; some are smaller," Pemberton says. "Some offices will hire us to do rapid transitioning." A few will install the system and attach labels to files themselves, paying employees overtime to complete the work during off hours, or bringing in temporary employees. Others, he says, will take a measured approach, attaching RFID tags on new folders as they come in.

RELATED_ARTICLES "One of the problems with RFID is it has been treated as a technology that offers its own solution," Pemberton says. However, he notes, successful RFID deployment requires a combination of technologies and practical solutions. The use of color-coded labels, for instance, has been an important step in the deployment, making it easier for file clerks to quickly identify when a file is misplaced.

"One of the challenges we have faced is talking about ROI," Pemberton adds. "The problem of tracking or finding files is difficult to measure and so ubiquitous that many people accept it as a way of life. That makes our challenge very unique, because people don't realize they have a problem."

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