

**The contract drug developer and manufacturer has been exploring both RFID and 2-D bar-code serialization, and is preparing an RFID pilot for one of its customers, dermatologic drug company Galderma.**

By Beth Bacheldor

Nov. 17, 2008—[DPT Laboratories](#), a contract drug developer and manufacturer specializing in semi-solid and liquid pharmaceuticals, says it is planning an RFID pilot with one of its customers for early 2009. Leading up that project, the company has been regularly polling its customers regarding their RFID, serialization and electronic-pedigree (e-pedigree) needs, and is currently studying the technology.

Much of the work is driven by California's e-pedigree legislation, slated to take effect 2015 to 2017. An e-pedigree is an electronic record used for tracking the movement of prescription drugs through the supply chain, with the goal of combating counterfeit or adulterated prescription drugs. As defined by California's state law, an electronic pedigree requires serialization of individual items, so that each item has a unique ID number. Such a unique ID could be printed as a two-dimensional bar code on a label attached to the item. But many of the companies affected by the law, including DPT, report that RFID is currently the most efficient way to achieve serialization for the creation of an e-pedigree. That's because with RFID labels, all individual items won't need to be individually scanned by line-of-sight readers, as they would with 2-D bar codes.

In addition to California, the [U.S. Food and Drug Administration](#) (FDA) has set a deadline of January 2010 to put in place a pedigree system that would protect the pharmaceutical supply chain (see [All Eyes on FDA for Drug E-Pedigree](#)). Although the FDA is also considering paper-based pedigree systems that do not employ RFID or bar-coding, the agency has shown an interest in RFID technology. Systems as outlined in both California's and the FDA's pedigree laws would need to be comprehensive because they would have to track items from the point of manufacture to the point of sale.

DPT Laboratories' business model puts the company in a unique position. It must be able to respond to the needs of its customers, some of which may ask it to handle the creation of an e-pedigree. But because those clients have yet to figure out their own e-pedigree plans, DPT Laboratories has to make sure it doesn't drop the ball. "What we need to be is all things to all people," says Alan Green, DPT Laboratories' logistics director, adding that his firm will likely need to support 2-D bar codes and RFID in most of its production lines at its San Antonio, Texas, and Lakewood, N.J. plants.

DPT Laboratories has polled its customers about what they wanted regarding e-pedigrees and RFID—first, a year ago, and as recently as about three months ago. "The stock answer we get is, 'We have no idea. You tell us,'" Green says. "Another response we got was they plan to go the cheapest route—2-D bar codes—because they don't know what the future holds, and still others told us they will go with RFID."

DPT must also take into account the needs of its sister company, [Healthpoint](#), a specialty pharmaceutical firm that manufactures drugs and medical products for diseased and traumatized skin and related soft tissue. DPT Laboratories handles product manufacturing for Healthpoint. "Even if none of the other customers want us to do their e-pedigrees," Green says, "our sister company does."

In the first quarter of 2009, DPT plans to conduct a track-and-trace and serialization pilot leveraging radio frequency identification at its San Antonio facility for one of its customers, [Galderma](#), a pharmaceutical company focused on treatments for skin conditions. DPT Laboratories is working with RFID vendor [Blue Vector](#) on the pilot.

The pilot will be small, Green says, and only one of Galderma's products—a topical ointment packaged in tubes—will be involved. The RFID tags, which Green says most likely will be compliant with the EPC Gen 2 standard, will be affixed to the interior of the individual cartons in which the tubes are packaged. "What is nice about having the tag on the inside of the carton," he explains, "is that none of the artwork will have to be changed on the carton, so we don't have to go through FDA approvals."

Once the tubes are inserted into the cartons, a conveyor will move them past an RFID interrogator. While details are still being considered, Green says the reader will detect whether a tag is operable; if not, there will likely be a robotic arm or some other mechanism that sweeps the product off the line. As each tag's readability is verified, its ID number will be captured and sent to a back-end system that can then utilize that data to create an e-pedigree and invoice. According to Green, DPT Laboratories will outsource that back-end system to a third-party company, and has narrowed the choice to two firms, [Axway](#) and [SupplyScape](#).

The individual cartons will then be packaged into a case, to which an RFID label will be attached. The case's RFID tag will contain a unique ID number s correlated with all of the tag numbers of the individual items within that case. A similar process will be carried out when the cases are packed onto a pallet, which will get its own tag. Tag reads will be performed to ensure, at each step, that nothing has changed with regard to the cartons within a case, and the cases on a pallet.

Green says the pilot will help determine how to sequence the items as they move down the production line. "We don't want the RFID process to create a bottleneck," he states. "We also want to test everything to make sure the RFID equipment works as we need it to. If everything works well, than we'll start to expand the pilot, first in San Antonio and then in Lakewood."

Implementing RFID, serialization and e-pedigree technologies won't be cheap, Green says. The company, which has a total of about 100 customers that will need to do something to meet pending laws, currently produces approximately 50 to 60 different product SKUs that will need to be serialized for California. "We're not a huge company," he says, "but we are looking at an implementation, covering about 50 items on seven production lines, that will cost more than \$1 million in investments, and that is just in our San Antonio site. But what about the Pfizers of the world, when there are 300 or more production lines around the world? Then you could be talking \$300 million."

Green believes the expense will ultimately get rolled up into the cost of prescription drugs. "Eventually, the consumers are going to have to pay," he says.

It's those high costs that have some drug companies looking intently at 2-D bar codes, which Green says cost considerably less than RFID tags. Printing a 2-D bar code on a label costs about one-tenth of a cent, Green notes, whereas the price of RFID tags—even at high volumes—is still as much as 5 cents per tag.

The problem with 2-D bar codes is that unless inference is allowed, cases will have to be opened at each point along a supply chain, in order to manually read individual items' bar codes and ensure that each case actually contains the items indicated by the case label. Inference would enable a distributor, for example, to accept a trusted manufacturer's shipping notices listing the items in each case, and to presuppose, for instance, that a case expected to contain 72 items does, indeed, contain that quantity. The California legislation neither prohibits nor condones inference, and Green says no clear decision has yet been made.

If inference is not allowed, Green also says it is likely that "the major wholesalers and distributors, although they haven't said it yet, will charge manufacturers if they have to rely on line-of-sight processes to scan bar codes." What's more, he adds, there is already significant influence from major retailers (including [Wal-Mart](#) and others) to use RFID since those companies are already making big investments in the technology and already require suppliers to use EPC Gen 2 tags on cases and pallets. "I think the wrinkle here is that wholesalers and distributors and big retailers will demand the use of RFID," he says.

Regardless, Green indicates, DPT Laboratories and its customers are closely watching what the FDA will do. And with California's law looming, they'll need to be ready. "The obvious is that eventually, this [serialization and e-pedigrees] will be as common as putting a cap on a tube," he states. "It will be a necessity, a fact of life. But I'm going to be looking beyond the obvious to find ways to use the technology to improve our inventory control, to be able to take physical inventory in no time at all, and to improve traceability of all our goods, both raw materials and finished goods. Whether we get 100 percent return on our investment, I don't know. But we're looking beyond the obvious."

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