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GS1 Group Completes Early Phase of E-Pedigree Model

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The organization's 2015 Readiness Program includes 50 companies in the pharmaceutical supply chain simulating the movement of products from a manufacturer to a drug store, as well as the electronic data that is captured, stored and shared along the way.

By Claire Swedberg

May 19, 2010—GS1 Healthcare US's Secure Supply Chain Task Force has developed a pharmaceutical supply chain model as part of a program known as 2015 Readiness. The model is intended to prepare members of the U.S. pharmaceutical supply chain to use a standard serialized track-and-trace system (known as an electronic pedigree, or e-pedigree) related to the movements of pharmaceutical items. Since January 2010, a group of 65 individuals representing 50 companies have been helping to craft a simulated supply chain that runs on software commonly used by businesses for Six Sigma processes, to improve efficiency. With the software, a user can map out a supply chain and send items with unique ID numbers, either on RFID tags or on 2-D bar codes. The program aims to develop a model for anyone in the pharmaceutical industry who is responsible for IT, logistics or packaging, as well as manufacturers, retail pharmacies and wholesalers. The model has been developed to simulate a typical forward-moving supply chain, and the group will now further refine it to allow for exceptions and scenarios involving product recalls and returns.

California's e-pedigree law, expected to go into effect in 2015, will require the collection of information related to every pharmaceutical item—including its description, place of origin and expiration date, as well as each sale or trade of the drug, along with the date of those transactions and the names and addresses of all involved parties.

Robert Celeste, the director of GS1 Healthcare US

The 50 companies represented on the task force include drug manufacturers, distributors, retailers and health-care groups, all of whom have become GS1 members. The simulated supply chain application the group is developing supports the intent of the e-pedigree law, says Robert Celeste, the director of GS1 Healthcare US, though the entire supply chain has not yet been simulated. The group may also need to incorporate additional steps into its model. For example, the model might be expanded to include staging areas, where products may wait temporarily as they change hands in the supply chain, in order to comply with some of the pedigree requirements. Such staging areas do not typically exist in the current pharmaceutical supply chain, but might become necessary in the future.

Those hoping to use the model to implement the e-pedigree system in 2015 can gain access to some results of the group's work at a two-hour mini-workshop that will explain the simulation and what it has found. The workshop will be held on June 8 at GS1's UConnect 2010 conference, in San Antonio, Texas.

By fall of this year, Celeste says, the model will be close to completion, and GS1 will offer two two-day

workshops allowing members of the pharmaceutical supply chain to learn details of the model, including the work still ahead for the group—namely, how to handle recalls and supply chain exceptions. The workshop will enable users to see how the e-pedigree system would work, learn the potential challenges to using simulation software, and test their own ability to utilize and understand the system—finding a missing item in the supply chain, for example.

The work is being prompted by California's passage of an e-pedigree requirement for 2015 that will require all members of the supply chain to share data via a single ID number for each bottle of pharmaceutical product. The mandate is intended to reduce incidences of product counterfeiting, theft and other problems, such as the expiration of items delayed in the supply chain, as well as invoice disputes between manufacturers and customers (such as pharmacies) regarding what was shipped and received. The establishment of an e-pedigree system is also intended to make return and recall processes more efficient, the organization reports, by making it easier for members of the supply chain to trace back a recalled item's transit route.

By 2015, the California Board of Pharmacy is requiring pharmaceutical manufactures to track, at the item level, 50 percent of the products they ship that are destined for California, applying a 2-D bar-code label or an RFID tag on each saleable container, and encoding that label or tag with a serial number linked to the product, its expiration date and the manufacturer's name. In 2016, the remaining 50 percent of products must sport such bar-code labels or RFID tags as well, and wholesalers will also need to be using the system, inputting data regarding their receipt and shipment of the products on a shared system, such as software based on EPCglobal's EPC Information Services (EPCIS) standard. (The task force's simulated supply chain model is based on EPCIS-based software, to allow the sharing of data within and across enterprises.)

In 2017, California's drug retailers will need to be using the e-pedigree system as well, in order to identify when they are in receipt of product. Although the regulation is only being implemented in that state, "manufacturers don't just create product destined for California," Celeste notes, so if one state mandates e-pedigree compliance, drugmakers are likely to make all of their products compliant, whether destined for California or elsewhere. "Most conversions [into e-pedigree compliance] are already underway," Celeste says. "All large manufacturers are aware of this and making plans," with generic drug manufacturers and smaller pharmaceutical firms following closely behind.

In some cases, companies are testing the attachment of an RFID tag on each item, while more commonly, they are applying tags only to cases of items and the pallets on which those cases are loaded. The case and pallet tags could then be linked to the unique identifier on every bottle contained in each case or on each pallet, whether that identifier is in the form of a bar code or an RFID tag.

The GS1 Healthcare US Secure Supply Chain Task Force was organized to develop a software application that simulates the supply chain, and that would allow companies to test product movements using e-pedigrees, as well as testing any exceptions that might occur. With this information, they could then begin working on the challenges facing supply chain members to implement this system. "What

we're trying to do now," Celeste explains, "is create a simulation of the supply chain with software representing behavior of supply chain partners," using EPCIS software for sharing data, as well as Discovery Services (a data exchange standard under development by GS1) and a map of the supply chain to determine which existing supply chain processes will meet the e-pedigree standard and which will require adjustment. The process, he says, enables wholesalers to see a manufacturer's mapping of logic, and vice versa, in a simulated environment, and to determine how their actions will affect the entire supply chain.

For example, a drug company could use the basic simulated supply chain to map out its own typical transit scenario, including its own packing and shipping processes, and then watch the items (signified by a small dot on the screen) move through the supply chain, thereby identifying problems that could arise. As the items move through the simulated supply chain, their ID numbers populate another screen to indicate each action completed. The model also enables users to build in their own likely events, such as overages, shortages, or counterfeit or diverted product, and then watch the effects of such an occurrence further down the supply chain.

As the group developed the forward logistics portion of its model development, it tried to resolve a variety of questions. For instance, at what point is a product considered received—when it physically arrives, or when the e-pedigree data is updated? And what should a wholesaler do if a drug arrives ahead of the pedigree data that spells out where that item is going, and where it had been? The group is considering suggesting the development of a staging area at these locations, where such goods could be stored pending data in the EPCIS system.

The group is now focusing on how exceptions that can slow down the process—such as a missing item within a case—will be managed. "We have completed quite a bit of work on defining exceptions," Celeste states. Exceptions would include anything that could slow or halt the progress of a product through the supply chain. "Through the 2015 Readiness Program, we are uncovering these exceptions and planning for them." Some examples of possible exceptions would be a case that the pedigree indicates contains 12 bottles, but that is found to have only 11 upon opening, or a case that is supposed to have 10 bottles but is actually found to have 12. Another example would be RFID tags or bar codes on bottles that are unreadable by a member of the supply chain. The group will attempt to suggest ways in which these exceptions can best be managed, without slowing the progress of products through the supply chain.

The Healthcare US Secure Supply Chain Task Force initially had both GS1 and non-GS1 members, though non-members must pay a fee to join. Since the task force organized, however, all non-members have become members as well.

By 2015, Celeste says, each supply chain partner will need to decide on a data-capturing strategy, such as where data should be captured and how it should be shared, to determine, for example, which business step is represented when that information is captured through an RFID read or bar-code scan.

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