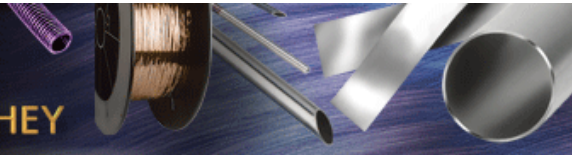


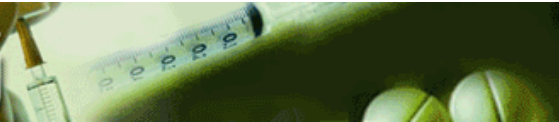
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NEWS**Automated Packaging Systems Inc.**, a provider of bagging systems for semi- and fully automatic packaging lines.**Carton Service-Packaging Insights**, a designer and producer of unique custom packaging for prescription and over-the-counter (OTC) drugs and dietary supplements.**Preparing for the Golden Rule**

If the electronic pedigree rules from California's State Board of Pharmacy stay their course, the next year will be pretty busy. California's laws, which will require drug manufacturers to generate electronic pedigrees down to the smallest saleable package, are still slated to take effect January 1, 2009. The mandate calls for unique identifiers for each package, nonproprietary data formats, and interoperability among trading partners. Wholesalers may not sell products without pedigrees into California, and California pharmacies may not purchase them.

With the drug industry still in its RFID-piloting phase and little item serializing taking place throughout the industry, meeting California's epedigree laws will be tough for drug companies. Some manufacturers, in fact, almost seem willing to pull their products out of the California market before investing time and money in item serialization. At the board's September 20 meeting on electronic pedigrees in Los Angeles, a generic drug representative pulled me aside and said that her company may have to withdraw its 1000-plus products from California because it cannot comply by 2009. And other meeting attendees alluded publicly to an even bigger threat to healthcare in California—drug shortages of noncompliant products should the rule take effect before most of the industry is ready.

"Meeting California's epedigree rules will be a relatively large undertaking," says David DeJean, director of serialized products for Systech International (Cranbury, NJ). "There is no grandfathering of already distributed products allowed, so wholesalers will be asking for drug manufacturers to comply with California by next summer. So we are really looking at a ten-month period."

Drug manufacturers do have a lot of work ahead of them. But there are solutions that may help companies comply (or get as close as possible to complying) in time

to meet California's deadline.

Systech is part of a new group formed to help drug manufacturers prepare for epedigrees. The California Express Solution teams up SupplyScape (Woburn, MA), Nosco (Gurnee, IL), Systech, and HP to provide an integrated solution for complying with California's requirements for product serialization and electronic pedigrees.

"All of industry may not be ready in time, but companies can start by deploying electronic pedigrees," said Graham Clarke, vice president, business development, for SupplyScape, during a September 18 Webinar on California Express. "They can leverage lot and batch numbers and add serialization later," he explained after the Webinar. "Regardless of whether manufacturers can get there in time, they need to develop a plan on how to get there and be proactive in discussing their plan with California's state board. Manufacturers should not surprise the board with a lack of or partial compliance."



As part of the California Express Solution, HP can facilitate development and integration of necessary architecture and enterprise resource planning/warehouse management systems (ERP/WMS); the company also manufactures digital technology used to print serialized labels and packages. Nosco can provide preserialized packaging, while Systech can track and manage packaging-line serialization data at every packaging stage. SupplyScape can deliver the epedigree data management system to enable manufacturers to send epedigrees to wholesalers, pharmacies, and other trading partners; to date, the company has delivered more than 200 million electronic pedigrees to more than 70 clients. HP's Security Solutions Center in Puerto Rico will be available to the team for project development, reported Webinar speaker Janine Brown, principal consultant for HP.

The team is gearing up to help manufacturers meet a number of challenges. One Webinar attendee asked how packaging lines may need to be changed support compliance. Speaker DeJean explained that the biggest challenge will be to get existing packaging lines to perform serialization. "It could take 20-26 weeks," said DeJean. The California Express Solution team can "assess such work early on in the blueprint phase." California Express supports preserialization and on-line serialization, said DeJean.

Manufacturers may choose to approach pedigrees and item serialization in steps. For companies not yet equipped to serialize products on their packaging lines, Nosco offers preserialized labels and cartons. "It is easier to get started with preserialization," says Craig Curran, director of strategic initiatives for Nosco. "It can speed things up, and it can reduce capital costs. Companies can then move to line serialization later on should the application call for it." The preserialized 2-D Datamatrix bar codes or RFID tags can create a data registry that can be provided to pharmaceutical manufacturers for use in production.



DeJean adds that companies may also want to consider starting serialization with "local databases" that can assemble pedigree data for pick-pack-and-ship operations and feed the data into pedigree messaging solutions like SupplyScape's but do not immediately link into enterprise resource planning (ERP) software. "This way, you can ease into ERP processes. Changes to ERP systems can take time. If you can take a phased-in approach and limit the impact to other systems, you can be successful in meeting California's timeline."

Whether or not a company chooses to receive preserialized packaging with a certified file or produce 2-D codes or write RFID tags in-line often depends on the number of packaging lines and SKUs. The investment in retrofitting packaging lines could be significant.

The California Express Solution team is holding workshops around the country to help manufacturers understand these and other options. For instance, cost

comparisons between line serialization and preserialization and between RFID and 2-D bar codes are provided. For participants who want details more specific to their own operations, two-day on-site assessments are available. "We can give companies a status report on their California readiness. We formed the team just so manufacturers would not have to spend a lot of time researching their options," explains Clarke.

Adds DeJean: "We are working toward getting companies to market implementation. The team is presenting a commercially scalable, available, and sustainable infrastructure."

The California Express Solution team will be following EPCglobal's Pedigree Messaging Standard format. It can also support EPCglobal's EPCIS standard, and it will support EPCglobal's Track and Trace standards once they emerge. Finally, the team offers certified integration with the SAP platform.

At the L.A. epedigree meeting, the California state board seemed very reluctant to delay legislation until 2011. "Consumers must be protected from counterfeit drugs," said state board member Robert Swart. "To continue to delay implementation is not on our agenda—2009 is the date," added board member Stanley Goldenberg. While Curran feels that it is unrealistic to think that every company and every product can comply by 2009, he says that companies should still get started promptly. "Pick one commodity or brand and figure out first how to comply with that product and packaging line," he advises.

"Manufacturers are accepting what they have to do, and there are leadership examples," notes Clarke. He points to early adopters of item serialization, such as Pfizer, whose Peggy Staver spoke at this week's California Express Solution workshop in Chicago. "Manufacturers have the longest road to hoe, and they would like their options to be clearer. Our goal with California Express Solution is to explain the requirements and clarify all options."

For details on upcoming workshops and the solution, visit www.GetEpedigreeReady.com.

Daphne Allen
Editor

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Material of the Month

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Machine of the Month

Blister Printing

A pharmaceutical-grade printing unit can be run in-line or as a standalone unit to print anti-counterfeiting solutions for pharmaceutical packaging. Its complete digital printing technology prints each pack with a randomly generated unique number that is 100% traceable to the original time, date, and location of packaging. This traceability can be combined with other color, bar code, graphic, and UV features to provide a safe and secure product identifiable as genuine anywhere in the supply chain. Application highlights of the DTS 1200 printing unit include 1200-dpi resolution in the range of 0.5?20 meters per minute, with up to four simultaneous PMS-color dynamic printing of variable and real-time data. CSAT America LLC, 888/904-2728, www.csatamerica.com.



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