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Adopting Serialization

By Hallie Forcinio

Serialized product codes serve as the foundation of ePedigree records and product traceability.



As deadlines for meeting electronic pedigree (ePedigree) requirements approach, a growing number of technology choices help deliver supporting data. The foundation of a drug ePedigree, serialization, is the application of a unique code at the item level. These unique codes can be used to authenticate products and enable tracking and tracing.

In a March 2010 guidance document, *Standards for Securing the Drug Supply Chain—Standardized Numerical Identification (SNI) for Prescription Drug Packages*, the US Food and Drug Administration recommended that each sellable unit carry a unique serial number. In most cases, according to FDA, this identification could consist of the National Drug Code for the product plus a unique serial number with a maximum of 20 characters, printed in both machine- and human-readable forms.

The SNI format is compatible with global standards that call for a serialized Global Trade Item Number (GTIN) for item-level identification. Normally, manufacturers would apply the SNI. If a manufacturer's package is to be broken down for sale, however, the repackager would apply an SNI to each sellable unit and link this number to the manufacturer's SNI.

Creating an ePedigree takes item-level serialization several steps further and affects all partners in the supply chain. "It also requires a lot more integration between equipment and packaging lines and packaging lines and upper level systems," says Robb Roebles, principal product marketing manager at Cognex (Natick, MA), a supplier of machine-vision hardware and software.



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Once applied and recorded, item-level codes must be linked to the unique code applied to each bundle, carton, case, and pallet to create parent-child

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- DataMatrix codes
- Radio frequency identification
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relationships. Serial numbers also must be captured, recorded, and certified at each stop in the supply chain, and these data must be stored in a centralized system that's accessible to all supply-chain partners.

Serialization begins on the packaging line with the application of a two-dimensional DataMatrix code or a radio-frequency identification (RFID) tag. Since a DataMatrix code is easy and inexpensive to apply, it's now more commonly used than RFID. Many processes reproduce DataMatrix codes, including inkjet, thermal-transfer, and laser coding.

After code printing or tag application, a camera or RFID reader and software confirm the correctness of the code and the print quality. As the product moves down the packaging line, a unique code is applied to each level of packaging. These codes are not only verified as correct and readable, but also aggregated to create parent-child relationships. With this data stored in a database, drugmakers and other supply-chain partners can determine that Product A was shipped in Carton X in Case Y on Pallet Z.

The hardware and software associated with code capture and recording also must accommodate events on the line such as rejects or quality-assurance sampling to ensure that no discrepancies occur between the products and the data.

Line-management software sends serialization data, including all good numbers (i.e., commissioned products), bad numbers (i.e., decommissioned products), and parent-child relationships to higher level systems. "Ultimately, this data goes into a system of record that becomes the master historian," says Joe Ringwood, chief operating officer at Systech International (Cranbury, NJ).

Implementing serialization requires hardware such as printers and vision systems as well as software for the line, site, and historian levels. Integration is required to make everything work together. The complexity of the integration depends on what systems are already in place and the approach taken by the manufacturer.

In general, commercial, configurable serialization software will take less time to implement than line, plant, and enterprise systems that must be customized to perform serialization functions. Choosing specific, standard devices also simplifies implementation, particularly if multiple lines or locations are involved. It's also helpful to specify device-neutral software that is compatible with virtually any brand or model of equipment.

"Serialization means you have to know what happens to each serialized package and requires new workflows and processes," says Ringwood. "So the better job done assessing current workflows and defining 'to-be' workflows, the smoother the implementation," he predicts.

Ringwood also advises looking at the total cost of ownership instead of focusing solely on the expenses associated with implementation. "Many decisions have implications down the road," he explains.

Implementing serialization requires months of planning to identify software needs, qualify vendors, perform pilot projects, and integrate hardware and software. Serialization teams should include representatives from automation, information technology, engineering, and plant-floor teams. In fact, says Roebles, the most successful implementations involve and train the plant-level personnel who work with the system daily. Actual implementation schedules vary, but vendors agree that an 18-month validation process is common. "Companies that haven't started planning better start soon or they won't be ready when FDA or a country they sell to sets [ePedigree] rules," warns Roebles.

Devices

Implementing serialization almost inevitably requires the installation or upgrading of hardware such as



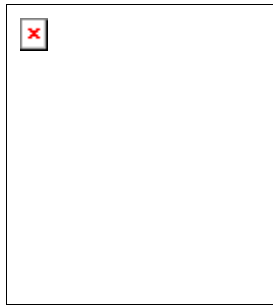
A pedigree solution needs...

printers and vision systems, which must be able to accept, capture, and transmit serialized information. Several integrated marking-verification systems are available.

One system consists of an inkjet printer, a built-in vision system, mechanical transfer devices, and air-powered reject. Compatible with various printers and vision systems, the unit applies serialized data to cartons, verifies that the information is accurate and uploads code data to a database for ePedigree records (XMV Marking and Verification System, Mettler Toledo Hi-Speed, Ithaca, NY). A related system adds a checkweigher for additional quality assurance (CS2 MV System, Mettler Toledo Hi-Speed).

A laser or thermal inkjet printhead prints serialized codes and other information on cartons; verifies print presence, accuracy, and quality with an onboard vision system; and records code data in an internal database. An air knife blows unreadable cartons into a reject bin equipped with a sensor that confirms that the reject has been made. A quick-change mechanism adjusts to a wide range of carton sizes. Software manages individual or multiple vision sensors, coding devices, checkweighers, and other peripherals (Pharma-Marker 450 Track and Trace System Eisai Machinery USA, Allendale, NJ, with vision technology from Cognex and Line Director software from Crest Solutions, Cork, Ireland).

A thermal inkjet coder capable of operating at a speed of 250 feet/min combines speed with sharp print quality to eliminate the need to slow the line to apply two-dimensional DataMatrix codes. A dual processor handles serialization data input and output in real time while integrated sensors confirm code readability. Communication interfaces include RS 232, USB-B, and TCP/IP (Wolke m600 Advanced inkjet, Videojet Technologies, Wood Dale, IL).



A serialization system capable of 360° inspection relies on six cameras to provide high-resolution images. Positioned at the infeed of bundling, case packing, or palletizing, the system reads DataMatrix codes regardless of orientation, captures serialization data from each product, and generates coded labels. Integral software aggregates serialization data from units, bundles, cases, and pallets and transmits them to an enterprise resource planning system for storage in a database. The system also can encode and read RFID tags for cases and pallets (T&T Solutions, Seidenader Vision, Harrisburg, PA).

Software equips Cognex's In-Sight Vision Systems to perform tasks related to serialization and data capture.

Preconfigured software equips camera-based vision systems for serialization tasks such as verification of code accuracy and print quality and capture and exchange of serialization data with other systems. An easy-to-use touch screen operator interface simplifies setup and operation. The software also includes technical controls needed for 21 CFR Part 11 validation, including secure user authentication and automatic audit-trail generation.

Because the microprocessor-equipped smart camera performs processing functions, operators do not need a personal computer or related maintenance products such as virus protection software (In-Sight Track & Trace software, Cognex).

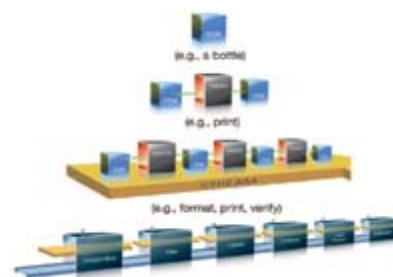
Line management

Line-management software plays a big role in serialization and ePedigree creation. Configurable software can expedite setup and simplify operation. Another time saver is software that is device- and data carrier-neutral and therefore works with virtually any printer, coder, scanner, or vision system and with various barcodes or RFID. Compatibility with other software, particularly high-level enterprise resource planning systems that may be in use, also streamlines implementation.

One method that incorporates all these features looks at any physical object on the packaging line as an item and each related action as a process block. Items move through a series of linked process blocks in a stream. A group of streams make up the workflow of a packaging line.

This architecture makes the software easy to configure and expand without

writing custom code, thereby expediting implementation and reducing costs. It also ensures repeatability, simplifies reconfiguration of workflows as needs change, and minimizes revalidation. "You don't need to be a software developer to install and configure our system," says Stephen Lisa, director of technical product marketing at Systech International. The software mirrors what happens in the real world, "there's not a lot of abstract C++ or ladder logic," he explains (Item Process Stream methodology for Serialized Product Tracking software, Systech).



A software platform from Systech uses a building block approach to map the workflow of a packaging line.

A demonstration line helps drugmakers test the vision systems and software needed to support serialization. Compatible with either two-dimensional DataMatrix coding or RFID tags, the fully automated system includes all the inspection, line control, aggregation, and data management functions needed to successfully serialize product and capture data at each level of packaging from item to pallet (Capture and Control System, Optel Vision, Quebec City, Canada).

Beyond authentication

Serialized identification opens doors beyond authentication and product tracking. A smartphone application not only allows field investigators and consumers to scan or input the code from a package to confirm authenticity, but also can present the product's history and prompt the delivery of promotional information or link to a chat function or customer service.



Technology from Covectra can provide access to product information, including ePedigree records.

Other possible loyalty program services include instructions about how to take the product, dose reminders, and refill reminders. The smartphone application and the associated software and services also capture sales information for brand managers and can connect physicians and pharmacists to prescribing information. Deployable in 30 days, the software requires minimal commitment from corporate information-technology personnel for implementation (Brand Loyalty and Integrity Services, Covectra, Southborough, MA).

Mobile-phone-based technology and serialized codes on scratch-off tags have been tested in Africa. After transmitting the code, a message confirming product authenticity arrives within a few seconds (Mobile Product Authentication technology, Sproxil, Planada, CA, mPedigree, Accra, Ghana).



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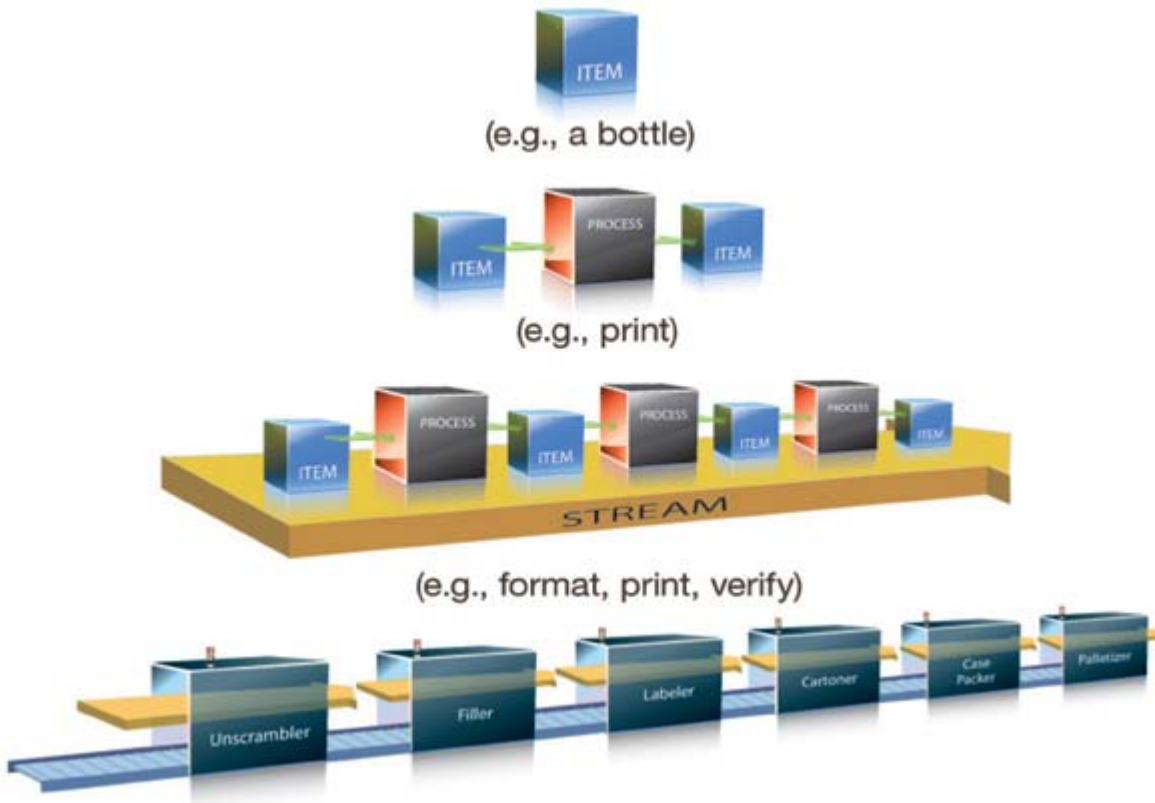
- Devices (e.g., printers, cameras, barcode readers, and radio-frequency identification (RFID) writers and readers)
- Line-management software to provide instructions to the devices and manage and aggregate the data
- Site-level software to communicate between the packaging line and high-level systems
- A data historian to store data
- Data-collection and -transmission capability at each point in the supply chain
- Access to data repository for supply-chain partners.

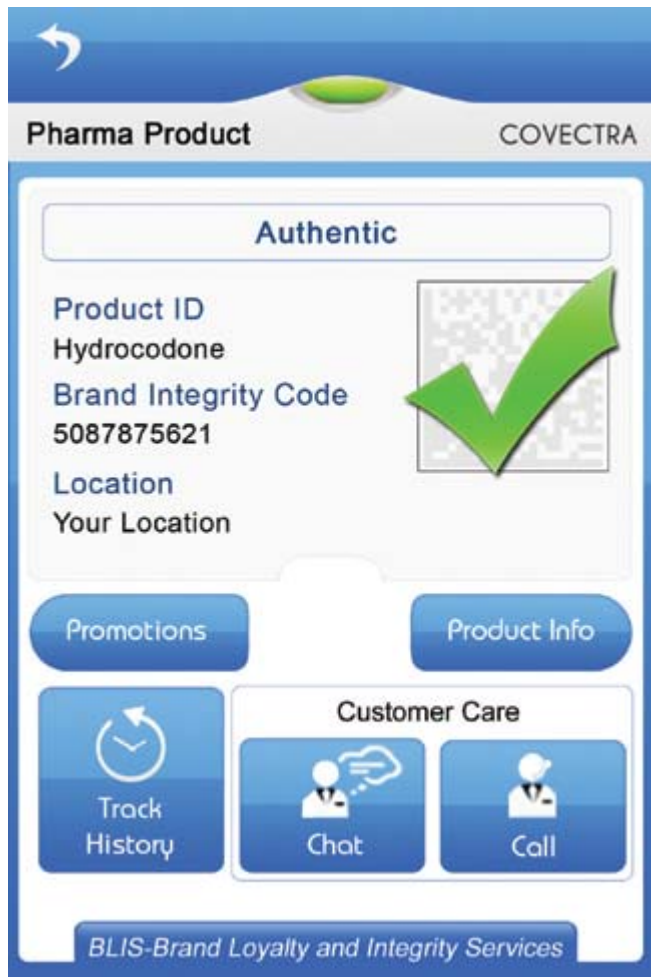
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