Labeling & Marking for Pharmaceutical Track & Trace

Jack Roe
Vice President & General Manager, Labeling Systems LLC

Government mandates to serialize pharmaceutical products are increasing around the globe.

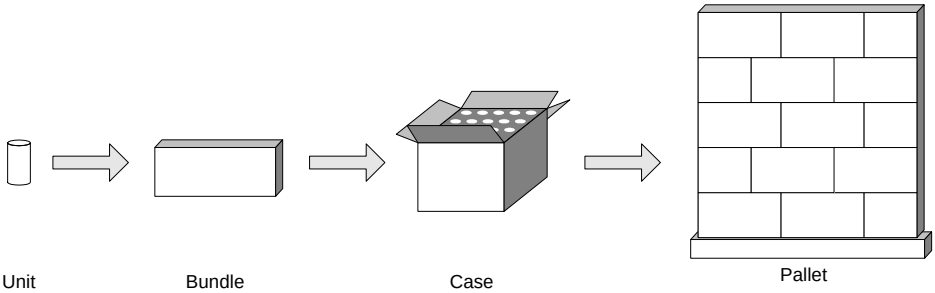
The California State Board of Pharmacy is requiring that 50% of each manufacturer's drug products be serialized by January 1, 2015, with the remaining 50% serialized by January 1, 2016. Turkey has required that all drugs be serialized since January 1, 2010. Brazil will require serialization beginning in January 2011. Italy, Belgium, Greece and France all have programs in place.

There are two predominant drivers behind these serialization mandates:

- Fighting grey market diversion and counterfeiting
- Aid in government reimbursement programs

Details vary from region to region, but in general all mandates require marking the smallest unit of sale with lot and expiration information, as well as a serial number, creating a unique license plate for each unit.

To facilitate tracking units through the supply chain, units are aggregated into bundles, bundles into cases and cases onto pallets, with the parent child relationships maintained in a database.



License plate information for units, bundles, cases and pallets is typically marked on the product in human readable form, as well as being encoded in a 2D code and/or an RFID tag.

Although RFID was central to the discussion just a few years ago, it is becoming less prevalent because of the cost of tags and concerns about meeting the pharmaceutical industry's six sigma quality requirement. 2D codes are becoming the more common choice for encoding units and aggregations.

As these concerns with RFID are addressed, the advantages of the non-line-of-sight nature of RFID and the ability to "x-ray scan" a case to read all units in the case at once, more programs will embrace the error reduction and labor savings that RFID affords.

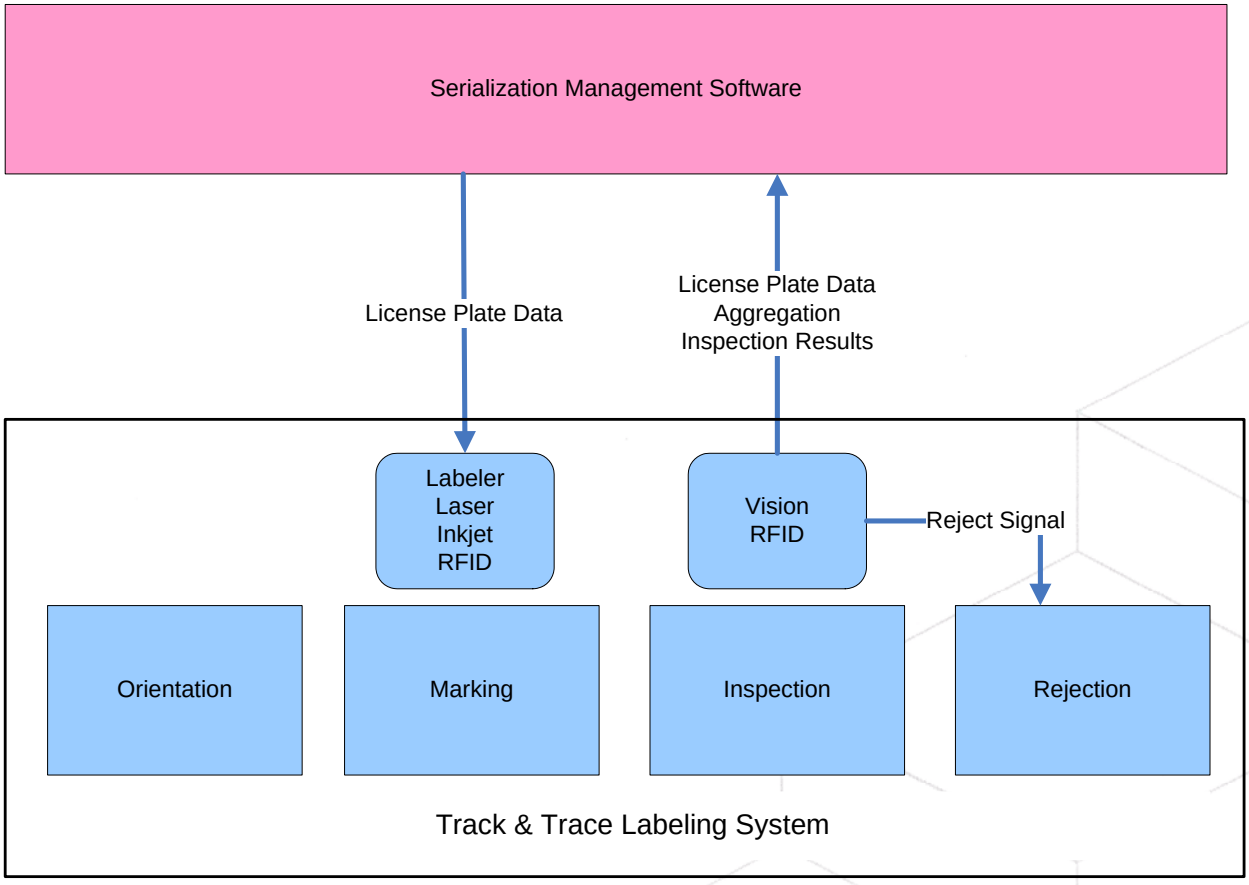
Although pressure sensitive labels, with or without RFID tags, are the most common form of marking for bundles, cases and pallets, laser marking and ink jet coding are more common for units, because of space limitations and throughput speed requirements.

The lion's share of the effort required to implement Track & Trace is spent on data management. Tracking the chain of custody of each unit from manufacturing, through distribution, up to the point where it is administered is a monumental task. The data security to ensure that each unit can be authenticated adds to the complexity.

The first critical piece of the chain occurs right on the packaging line. Precise and consistent product handling, marking, inspection and data gathering are required to introduce accurate data into the front end of the system.

Expertise with product handling, labeling and other marking technologies, barcode scanning, machine vision, RFID, controls and software interfaces are a necessity to make a packaging line track & trace ready.

Disciplined project management to coordinate activities of packaging equipment suppliers, vision manufacturers, RFID experts, software vendors and the end user is also essential to a project's success.



Typical Track & Trace Labeling System Functions		
Function	**Non-RFID**	**RFID**
Print/encode variable information.	Variable information is printed in human readable, barcode or 2D code using laser, inkjet or thermal transfer print engine.	RFID tags are encoded using the optional RFID functionality in the print engine or a stand-alone reader/antenna
Printed and RFID information is inspected while the label is still on the web, prior to label application.	Printed information can be inspected using a barcode scanner, 2D code scanner, barcode verifier or vision system. Vision inspections can include barcode grading, print quality measurement, data matching, etc.	RFID tags are inspected in the print engine prior to printing. "Bad Tags" are printed with the word "Void" for easy identification.
Incorrectly printed labels and bad RFID tags are rejected prior to application.	Labels that fail inspection are tracked through the labeler and accumulated on a collection plate.	Similarly, labels with bad RFID tags are tracked through the labeler and accumulated on the collection plate.
Good labels are applied to product using one of LSI's 27 standard applicators. Bottle wrap, side apply, top apply and corner wrap applicators are typical.	Products are stopped for most serialized case labeling applications. If a bad label is rejected prior to application, the product will wait until a good label is available to be applied. In bottle wrap and unit carton applications, if a label is rejected, the product passes through unlabeled.	Care must be taken to avoid damaging RFID tags during the application process. Location of the tag on the product is important for many RFID applications.
Labels are re-inspected after application.	Labels can be inspected using barcode scanners, 2D code scanners or a vision system. Inspection can be used to determine that a label has been applied to every product, that each product has received the appropriate label and/or that the label is not skewed or wrinkled.	An RFID reader located along the conveyor line can be used to detect any RFID tag that was damaged during application.
Products with bad labels are rejected.	Products that fail inspection are diverted to a reject chute or conveyor.	Same

Typical Track & Trace Labeling System Functions (Cont.)		
Function	**Non-RFID**	**RFID**
Units are aggregated to Bundles.	Unit serial numbers (license plates) for a number of individual units are recorded and assigned to a bundle with its own individual bundle serial number. In many applications, the same hardware is used for both inspection and unit to bundle aggregation.	RFID bundle tags are uncommon.
Bundles are aggregated to Cases.	Bundle serial numbers (license plates) for a number of bundles are recorded and assigned to a case with its own individual case serial number. In many applications, the same hardware is used for both inspection and unit to case aggregation.	For many types of products, RFID is particularly well suited for this task, since the tags on all units in the case, as well as the case tag can be read simultaneously using an RFID reader tunnel. In this scenario, unit tags are read and bundles are aggregated by inference.
Cases are aggregated to Pallets.	In most applications, cases are manually palletized as they exit the labeling conveyor. A barcode scanner located at the end of the labeler can read the case label and assign it to an open pallet.	Though less common, an RFID reader can be used for this task as well.
Counts and Statistics are gathered.	Counts of good labels, bad labels with reasons for failure and other performance related statistics are gathered for display on the system HMI and upload to the host computer system.	Same

Track & Trace from LSI

With more Track & Trace labeling and marking solutions in the field than any other leading labeling equipment manufacturer, LSI is uniquely qualified to integrate Track & Track technology into any packaging line.

LSI seamlessly integrates packaging line equipment, marking and data acquisition devices with Track & Trace software for a complete solution.

LSI Track & Trace system controls are based on the industry standard Rockwell Automation (Allen Bradley) PLC platform.

Solutions are 21 CFR Part 11 Compliant when integrated with compliant serialization management software.

Validation packages (IQ/OQ) are available.

About Labeling Systems

Labeling Systems, a division of Pro Mach designs and manufactures a complete line of heavy duty pressure sensitive labeling equipment. Since inception, LSI has been building machines that stand up to the abuses that a 24/7 production line demands.

LSI's headquarters are located in Oakland, NJ.

For more information call (201) 405-0767 or visit www.labelingsystems.com.