Serial Innovator

With anti-counterfeiting legislation pending, investment in serialisation technology is imperative, argue Frederic Menardo of Systech International and Graham Smith of Aegate

The European Parliament and Council are in the process of developing legislative amendments to the Directive 2001/83/EC regarding the prevention of entry into the legal supply chain of medicinal products that are falsified in relation to their identity, history or source. The new legislation, expected to be completed before the end of 2010, strongly emphasises patient safety. Thus, the proposed amendments affect all areas within the supply chain – from brokers and distributors to internet pharmacies. The amendments include securing the individual dispensed packs given to the patient and making safety features that permit the identification, authentication and traceability of medicines mandatory for prescription medicines. The only technology that supports all three of these initiatives – identification, authentication and traceability – is serialisation.

Once the European Commission passes the legislation, all 27 European member states must implement local legislation within 24 months. Therefore it is imperative that pharmaceutical manufacturers begin implementing serialisation solutions. These solutions must ensure the accuracy of serialisation data and support serialisation at the line speeds required to maintain the packaging line throughput.

IDENTIFICATION, AUTHENTICATION AND TRACEABILITY REQUIRE MORE THAN ITEM-LEVEL IDENTIFIERS

Item-level serialised product tracking solutions that assign, encode and record unique identification numbers support serialisation initiatives such as authentication and traceability. Authentication is the ability to verify that a drug product genuinely came from the manufacturer or other legalised source within the supply chain. To authenticate a product, the pharmacy reads its serialisation code. This code, when linked to a database, can identify an individual pack and determine that it has not been copied, is in date, has not been recalled, and is legally available for sale.

In addition to authentication, serialisation coding enables traceability within the supply chain. Traceability allows authorised individuals to verify samples of packs to confirm their authenticity before they are distributed, as well as locate and remove the packs from the supply chain if issues are detected. The initiative also helps identify where in the supply chain a counterfeit drug entered. Both authentication and traceability initiatives place sufficient barriers across the supply chain, making it significantly more difficult for counterfeit drugs to enter the chain and reach patients.

Authentication and traceability require serialisation data of a high quality to ensure that every item can be identified before dispensing it to a patient. Therefore, aside from simply placing a unique number on a package, serialisation is a technology that encompasses the following three imperatives:

Figure 1: Example of a serialised product record

- Being aware of which numbers have been assigned and placed on which products and which batches of products
- Knowing that the serialised products are in the supply chain or have been consumed
- Updating the status of specific serialisation numbers in the case or recall, illegal importation, or theft

In order to achieve these three imperatives, companies need excellent quality control procedures that ensure a high quality of data; otherwise, errors will make authentication and traceability impossible. When applying unique serialisation

coding, the primary errors that could occur are:

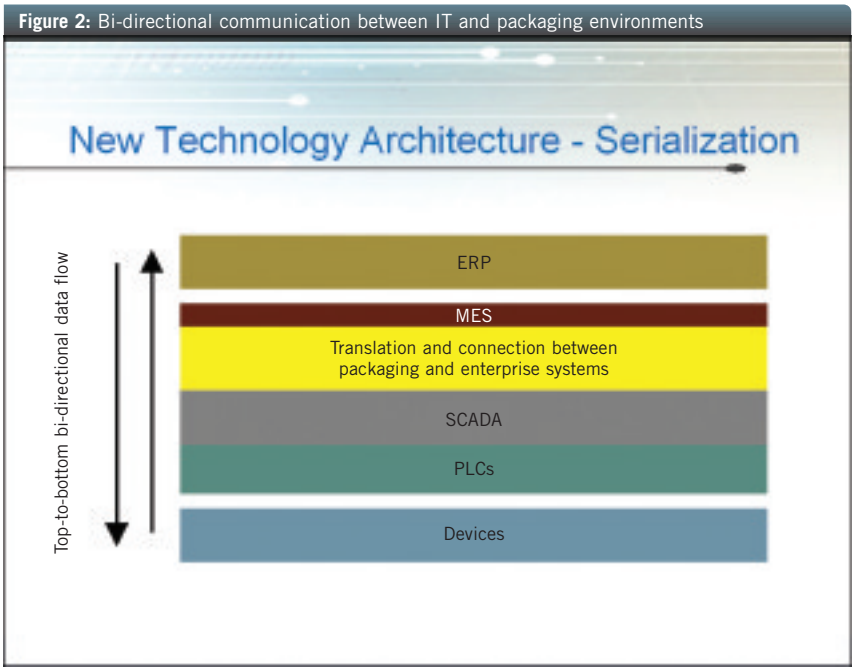
- Missing information
- Overlapping ranges of serialisation numbers – which also includes a range of numbers supplied by another pharmaceutical manufacturer

The ways of ensuring that the integrity of the data is maintained throughout the packaging process include:

- Controlling what numbers are issued to a particular packaging line for a particular process
- Ensuring the numbers are secure from counterfeiters by following strict staff policies
- Assigning numbers randomly rather than in sequential order
- Accurately accounting for numbers that may have been assigned to packages that were rejected during packaging, both on and off-line
- Associating serial numbers to the correct lot/batch information
- Delivering serialisation information efficiently to IT systems so that they can be managed on an efficient basis and made available for authentication and reporting purposes

Aligning serialisation data with distribution data at the enterprise level is dependant on a serialisation solution's ability to enable bi-directional communication between the IT environment and the packaging environment. Some manufacturers have begun employing a serialisation solution that acts as a gateway between enterprise IT systems and packaging line operations. The solution connects with the manufacturer's enterprise repository of serial number data and provides that data to the packaging line when it is needed. At the line level, the solution assigns and verifies unique identification numbers at the item level, tracks items through the packaging process, and, if required, can establish relevant parent-child relationships between an item, its case, and its pallet. The solution then collects precise item level data from the entire on-line and off-line packaging operation, ensuring the integrity of the serialisation data before it is delivered back to the enterprise IT systems. Regardless of the speed or availability of enterprise servers, the packaging operation can continue running at maximum speed throughout.

Figure 2: Bi-directional communication between IT and packaging environments



This bi-directional capability can become critical even for successful authentication models. As an example, a manufacturer produces a batch of 10,000 units. Each unit has a unique identifier. The units are packaged into cases of 50 units, each for a total of 2,000 placed into the finished goods inventory. The manufacturer ships 1,000 cases to various distribution channels. While in transit, a shipment of 100 cases is stolen. What information should be available in an authentication database? In addition to containing information about the unique items within the 1,000 cases shipped into the supply chain, the authentication database must also be made aware of the unique serialisation identifiers of each of the items that were stolen. This ensures that if the stolen items appear in the supply chain, or at the point of dispensing, authentication would immediately identify these and notify the authorised person.

TAPPING A PES INFRASTRUCTURE FOR AUTHENTICATION & BEYOND

To ensure that bi-directional communication can occur between IT and packaging when executing serialisation, manufacturers need a packaging execution system (PES) infrastructure. A PES integrates all packaging line information systems, including vision inspection, line management and serialisation. By managing data between the packaging line and the enterprise, a PES architecture protects data integrity at the enterprise level while ensuring the packaging line throughput. In turn, manufacturers achieve serialisation while maintaining operational efficiency.

CALL TO ACTION

European requirements for authentication and traceability are fast approaching. To prepare for these mandates, manufacturers need solutions that can quickly and cost-effectively meet both current and future demands. They should consider solutions that meet the following criteria.

Productised

As packaged software, a productised serialisation solution is ready to be installed quickly when it is bought, thereby increasing efficiency and speed of line set-up. In addition to speedy installation, productised solutions are replicable, making each packaging line consistent. As more countries globally implement serialisation requirements, manufacturers benefit from investing in a serialisation solution that is quickly installed and replicable line-to-line or plant-to-plant. This repeatability reduces design, deployment, maintenance and associated training costs. Moreover, since it does not require a new code to be written, productised software is upgraded easily.

Configurable without Requiring Customisation

Configurable serialisation software is designed with elements that can be assembled and realigned to quickly accommodate changing demands without requiring code re-writes. This makes it easier to handle multiple code schemas to comply with various regulations, enables in-house personnel to easily maintain the solution, and speeds implementation.

Configurable solutions easily plug into any packaging line environment and support a wide variety of packaging line functions without requiring code re-writes or line revalidations. By investing in configurable serialisation software, manufacturers employ an adaptable and flexible solution that addresses current needs and that can also meet changing demands as more complex regulatory requirements surface.

Expandable

An expandable serialisation solution easily grows to meet new requirements. Expandable serialisation software is modular because it allows manufacturers to increase capabilities as they need it. This allows companies to embrace new capabilities by leveraging existing investments in infrastructure rather than making large, expensive changes to the technology. Expandable solutions are also scalable, enabling the same solution to manage small or large throughput. Scalability also allows manufacturers to move quickly from pilots to full-scale implementation.

Real-world examples of authentication and data integrity

In an effort to protect patient safety and prevent counterfeit drugs from being dispensed, numerous pharmacies have begun employing a specialist medicines authentication system. This is a real-time system where each unique serialisation code affixed to a pack of medicine – similar to a passport number – is read and authenticated by a healthcare provider before dispensing. In effect, authentication puts barriers in place – a final check before the patient is handed a drug for consumption. This process confirms that the medicinal item carrying the code has not been seen before, thereby detecting any copies. It also confirms that the product has not been recalled and has not expired. These aspects are extremely important for patient safety and can be observed in Figure 3. Each red dot is a location spot of 76 copies that were detected in the Belgium market in 2009. Fortunately, investigation revealed this was not a suspicious product – the cause was an over-labelling error, which was only detected because the authentication system is in use in Belgium.

Figure 3: 76 scans

In each country where this authentication system operates, the national pharmacy association, the regulator, and the pharmaceutical industry are able to input safety information into the system, which is delivered on their behalf at the time of dispensing. Therefore, additional notifications, such as regulatory changes, can also be delivered using the same mechanism. All data is held securely, compartmentalised and protected. Approximately 1 million serialisation codes are being read every day, each within less than half of a second.

CONCLUSION

Using identification, authentication and traceability initiatives on the packaging line and through the supply chain to the pharmacy level requires high quality serialisation data. Manufacturers need to invest in serialisation solutions that maintain the integrity of the data throughout the packaging process. By implementing productised, configurable and expandable solutions that leverage a PES infrastructure, manufacturers can protect data integrity while also meeting new demands quickly and cost-effectively and maintaining operational efficiency.

About the authors

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