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Staying on track

Joe Ringwood, Chief Operating Officer of Systech International, New Jersey, USA, describes the benefits of an anti-counterfeiting system.

The number of counterfeit drugs entering the supply chain around the globe is escalating. The World Health Organisation estimates that five to eight per cent of worldwide trade in pharmaceuticals is fake. With counterfeiters having increasing financial and technical means, they are producing high quality packages. As well as endangering people's health, drug counterfeiting costs pharmaceutical companies substantial amounts of money each year.

To combat this, manufacturers are implementing item-level serialised product tracking solutions that assign, encode and record unique identification numbers for radio frequency identification and 2D barcode track and trace initiatives.

Tracking and tracing allows companies to see the location of a product, its whereabouts on a specific date, and who had access at what time. This makes it significantly more difficult for counterfeit drugs to enter the system.

Maintaining communication

As well as placing a unique serial number on products, the system must capture and record the serial numbers of unit level items and the cases and pallets where they are placed. These numbers must be stored in the manufacturer's enterprise resource planning (ERP) system giving them and their supply chain partners access to the data to track and trace each product along the supply chain.

Storing serial numbers in an ERP is dependant on bi-directional communication between the IT and packaging environments. The IT sector passes on data to the packaging line, which sends information back to the IT systems. Because IT and packaging have traditionally been maintained separately

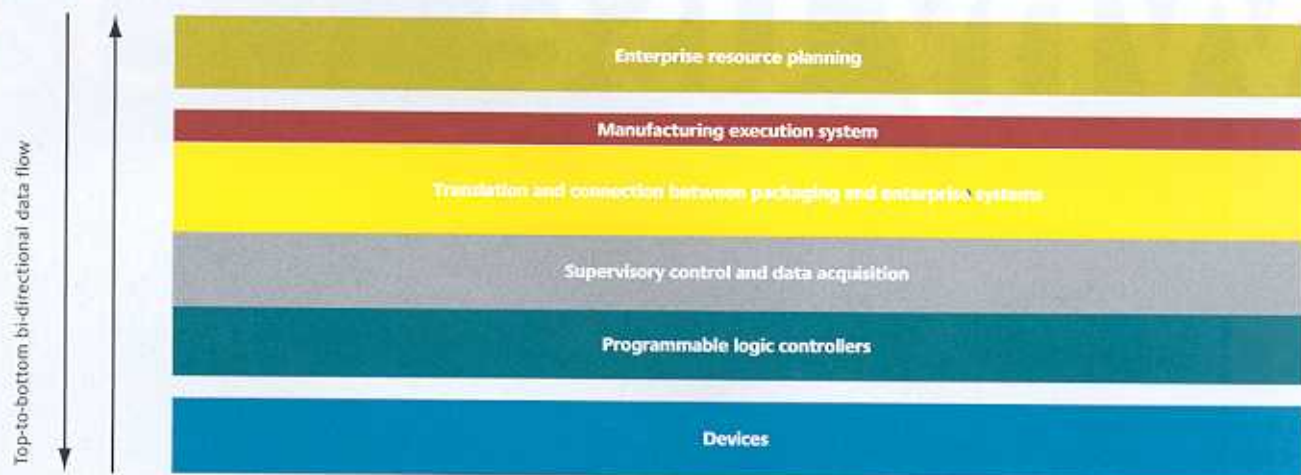


with little interaction, this bi-directional communication requires new control systems.

This gateway connects with the manufacturer's enterprise repository of serial number data and provides information to the packaging line when needed. At the line level, the unique identification numbers are assigned and

verified, items are tracked through the process, and establish relevant parent-child relationships between item, case, and pallet. The system then collects precise item level data from the entire on- and off-line packaging operation, ensuring the integrity of serialisation data before it is delivered back to the enterprise IT systems. Regardless of the speed or

New technology architecture - serialisation



availability of enterprise servers, the packaging operation can continue running at maximum throughput.

Tracking infrastructure

To ensure bi-directional communication when executing serialisation, manufacturers need a packaging execution system (PES). 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 protects data integrity at the enterprise level, while ensuring packaging line throughput.

In addition to assigning and recording serial numbers and enabling effective

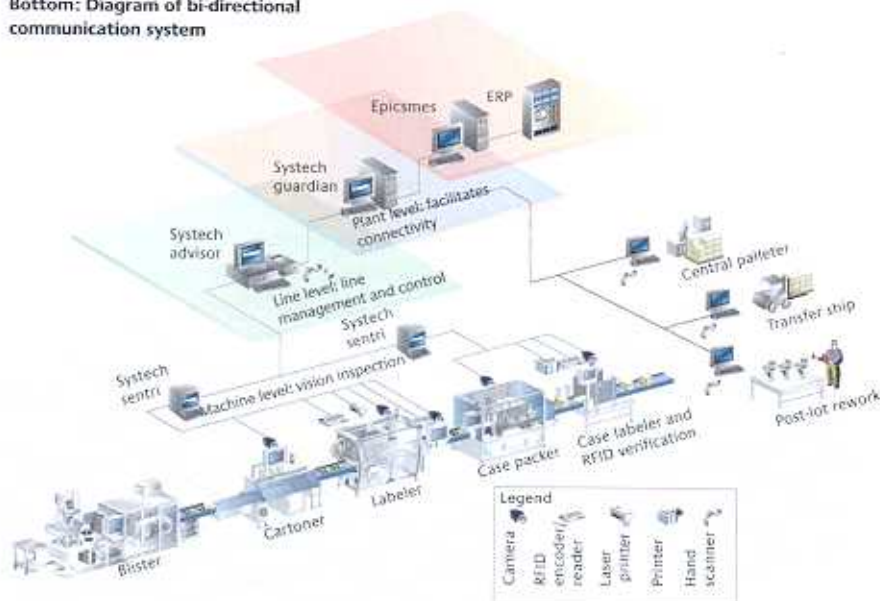
bi-directional communication, a serialisation solution must also maintain efficient packaging operations. Therefore, it must meet the following criteria –

- **Productised** – As packaged software, a product serialisation solution is ready to be quickly installed, thereby increasing efficiency and speed of line set-up. Such solutions are replicable, making each packaging line consistent. This reduces design, deployment, maintenance and associated training costs.
- **Configurable** – The software is designed to be assembled and realigned to quickly accommodate changing demands without requiring code re-writes. This minimises the need to perform line re-validations. As a result,

there is less downtime, increased productivity and reduced costs.

- **Configurable solutions that are adaptable** – Adaptable software easily plugs into any packaging line environment and quickly handles line component or device changes. For example, if a manufacturer has been performing 2D barcode and then adds RFID to the serialisation line, they may need to add three new components. Because it already contains the necessary elements, a configurable solution can easily adapt to the new parts.
- **Expandable** – An expandable serialisation solution easily extends to meet new requirements. The modularity allows manufacturers to increase capabilities as they need, such as post-lot requirements for serialisation. Since counterfeiters constantly increase their technical capabilities, anti-counterfeiting technology must continually develop. Modular serialisation solutions allow companies to embrace these 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.

Bottom: Diagram of bi-directional communication system



FURTHER INFORMATION

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