

VOLUME 4.4 - 2009 - €12.00

PACKAGING EUROPE



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PREPARING FOR THE FUTURE



In the second part of our special coverage of pharmaceuticals Joe Ringwood, COO of Systech International, argues the case for investing in a serialisation solution that can meet the requirements of today and tomorrow.

Many countries around the world are preparing to adopt pharmaceutical coding and serialisation requirements. The EU has actively supported combating illicit practices in the area of piracy and counterfeiting of medicines with a wide variety of counter measures including serialisation. Recently, the European Federation of Pharmaceutical Industries and Associations (EFPIA) proposed the introduction of a unique barcode on every medicine pack. The Turkish Ministry of Health is implementing regulations that require unique identification of pharmaceutical packages. Outside Europe, the US Food and Drug Administration (FDA) is considering the serialisation of both pharmaceutical products and medical devices. Asia and South America are proposing similar laws to combat counterfeiting and reimbursement fraud. In light of the regulations in Europe and elsewhere globally, pharmaceutical manufacturers need to consider their packaging information requirements and promptly employ serialisation solutions.

Although local and global serialisation requirements are expected, nobody knows what the regulatory requirements will be in each region of the world, and how they will change over time. However, preparing for future regulations does not require prior knowledge or massive investments in expensive technology infrastructure. Rather, manufacturers can prepare for the future by investing in serialisation solutions that are capable of easily adjusting to changing requirements while also protecting line throughput, data integrity, and system security.

Furthermore, although many manufacturers are laying the foundation and infrastructure to enable serialisation for current and pending requirements, the value for serialisation extends beyond regulatory compliance. A serialisation application also enables manufacturers to utilise serialisation where they see competitive opportunities, including preventing deflection, protecting patient safety, enabling unique packaging/delivery solutions, safeguarding high value products, ensuring packaging authenticity, protecting from counterfeiting and enabling value chain visibility and control.

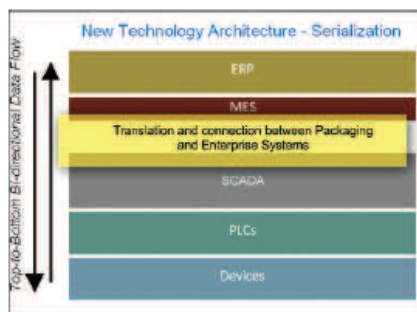
The likelihood of diverse serialisation regulations globally, the unpredictability of future regulations, and the many ways in which serialisation can drive business value beyond compliance make it imperative that pharmaceutical manufacturers begin developing and executing their global serialisation strategies. Developing a strategy requires companies to consider both the current and future implications of the technology that they invest in.

Therefore, before manufacturers make a solution a part of their global serialisation strategy, they need to carefully develop educated decision criteria. These criteria include the solution's capabilities in the context of Total Cost of Ownership (TCO). TCO includes the costs of hardware, software, systems integrations, revalidation, line throughput, ongoing maintenance and support, and global rollout.

Companies with their eyes on the future see current requirements, such as French CIP13, as strategic opportunities to employ a platform that they can continually leverage when addressing various regulatory requirements. These companies are investing in serialisation solutions that are productised, configurable, and expandable, as well as solutions that enable bi-directional communication between the enterprise and the packaging line. These solutions prepare manufacturers for the future while also controlling TCO.

Productised

As packaged software, a productised serialisation solution is ready to be quickly installed when it is bought, thereby increasing efficiency and speed of line set-up. On the other hand, non-productised solutions must be custom-built, increasing the cost and time of implementation. 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. For instance, a manufacturer





who installs a productised serialisation solution to address regulations in France can use the same solution at their plant in Turkey to meet regulations there. This repeatability reduces design, deployment, maintenance, and associated training costs. Moreover, since it does not require new code to be written, productised software is easily upgraded.

Configurable

Configurable serialisation software is designed with elements that can be assembled and realigned to quickly accommodate changing demands without requiring code re-writes. This eases handling multiple code schemas to comply with various regulations, enables in-house personnel to easily maintain the solution, and speeds implementation. In contrast, customised solutions are rigid, making them difficult to implement and modify. By simply making configuration changes rather than re-writing code, configurable solutions minimise the need to perform line re-validations. As a result, manufacturers see less line downtime, increased productivity, and reduced costs.

Configurable serialisation software is flexible, enabling it to support a wide variety of packaging line functions. For example, if serialisation requirements change, the line needs to perform new functions. Configurable software already has the capabilities inside to create the instructions for these new functions, eliminating the need to write new code. Therefore, by investing in configurable serialisation software, manufacturers employ an adaptable and flexible solu-

tion that addresses current needs and that can also meet changing demands as more complex regulatory requirements surface.

Expandable

An expandable serialisation solution easily expands to meet new requirements. Expandable serialisation software is modular because it allows manufacturers to increase capabilities as they need it, such as post-lot requirements for serialisation and OEE. In light of current and pending global regulatory demands, it is essential for manufacturers to employ modular solutions. This allows companies to embrace new capabilities by leveraging existing investments in infrastructure rather than making large, expensive changes to the technology. Those who invest in software without the ability to expand implement dead-end technology that must be ripped and replaced. On the other hand, companies who deploy serialisation solutions that expand easily will manage investments over periods, protecting ROI.

Bi-directional Communication

Serialisation's various use cases are based on the need to communicate serial number information between IT and the packaging line. Therefore, a serialisation solution must have the ability to enable effective communication between the packaging environment and the IT environment. The IT environment must communicate serialisation data down to the packaging line, and the packaging line must send information back up to the IT systems. Because IT and packaging have traditionally been maintained

separately with little interaction, enabling this bi-directional communication requires a new layer of control systems. This new layer of control acts as a gateway through which data flows. Data management between the enterprise and the packaging line is critical for all serialisation initiatives because it protects data integrity at the enterprise level while ensuring packaging line throughput.

Packaging Execution System (PES) Infrastructure

Many leading packagers are responding to the French CIP13 requirement with consideration of their future packaging environment. They are taking a strategic view of serialisation by addressing the need for bi-directional communication with a Packaging Execution System (PES) platform. A PES integrates all packaging line information systems, including vision inspection, line management and serialisation. Manufacturers need a PES infrastructure to ensure that bi-directional communication can occur between IT and packaging when executing serialisation.

The ever-changing landscape of serialisation regulations require today's packaging operations to be adaptable, flexible, and modular. Inability to respond to change or excessive time or costs to change can lead to deploying dead-end technology. Manufacturers who choose a productised, configurable, and expandable serialisation solution that leverages a PES infrastructure will be able to more quickly and cost-effectively respond to new demands and will be better positioned to take advantage of future opportunities. □