



Systemtech International®

Serialization Strategies for Today & Tomorrow:

Total cost of ownership control realized through Packaging Execution Systems

Executive Summary

The likelihood of serialization regulations emerging globally, the unpredictability of future regulations, and the many ways in which serialization can drive business value beyond regulatory compliance make it essential that pharmaceutical manufacturers establish standards for their serialization efforts.

As companies employ serialization solutions to address current needs, they must consider solutions that efficiently address new requirements as they emerge globally and locally. Furthermore, since data management is critical for all serialization initiatives, manufacturers need to implement a Packaging Execution System (PES) platform to enable bi-directional communication to and from the packaging line and the enterprise. Manufacturers who invest in productized, configurable, and expandable serialization solutions that leverage a PES platform will be best positioned to deploy serialization and take advantage of future opportunities, as well as be able to more quickly and cost-effectively respond to new demands. These solutions prepare manufacturers for the future while also controlling Total Cost of Ownership (TCO).

This paper will examine the market conditions that surround serialization and discuss why there is an imperative to formulate and adopt a corporate strategy for serialization projects today and larger demands in the future. The paper will also enumerate the primary criteria considerations for selecting a unified approach and describe how Systemtech Serialized Product Tracking (SPT) addresses those considerations.

Situation Analysis

Current and pending regulatory requirements are increasingly driving pharmaceutical manufacturers to evaluate and implement serialization solutions. With a handful of approaches to consider, pharmaceutical manufacturers need to carefully develop educated decision criteria for their global serialization strategies. Because of the uncertainty of local requirements, as well as future diverse global requirements, manufacturers need a productized, configurable, and expandable serialization solution that is capable of easily adjusting to new demands while also protecting line throughput, data integrity, and system security. Furthermore, the value of implementing serialization reaches far beyond regulatory compliance to enhance brand protection, improve supply chain efficiency, and help ensure patient safety.

Why Address Serialization Now

Regulatory Readiness

Serialization requirements in Europe and elsewhere have established the imperative for companies to consider their packaging information requirements. Due to progressive global regulatory expectations, such as coding requirements in France and serialization requirements established in Turkey, manufacturers need to promptly employ serialization solutions.

Current and pending regulatory requirements necessitate that manufacturers deploy one or more of the following initiatives:

- **Track and Trace:** the ability to track and trace the current location of a product, the location of a product on a specific date, and who had access to the product at what points in time throughout the supply chain
- **Authentication:** the ability to verify that a drug product is genuine
- **e-Pedigree:** an electronic record specifying the product's chain of custody, which is more efficient and accurate than paper records

Serializing products at the item level enables track and trace, authentication, and e-Pedigree, allowing manufacturers to meet current requirements while also preparing for future regulations.

The ever-changing landscape of serialization regulations require today's packaging operations to be adaptable, flexible, and modular. Investing in solutions without the ability to respond to change quickly and inexpensively leads to dead-end technology. Companies therefore must view serialization as a global strategy. 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.

Business Benefits

The likelihood of serialization regulations emerging globally, the unpredictability of future regulations, and the many ways in which serialization can drive business value beyond regulatory compliance make it essential that pharmaceutical manufacturers establish standards for their serialization efforts.

Although many countries are preparing to adopt requirements similar to Turkey for pharmaceutical tracking and reimbursement initiatives, the value for serialization extends beyond regulatory compliance. A comprehensive application also enables manufacturers to utilize serialization where they see competitive opportunities, including:

- preventing diversion
- protecting patient safety
- enabling unique packaging/delivery solutions
- safeguarding high value products
- enabling packaging authenticity
- protecting from counterfeiting
- enabling value chain visibility and control
- identifying of sources of parallel trade
- enabling responsiveness to recalls and supply chain susceptibilities
- enabling performance monitoring
- reducing shrink
- identifying bottlenecks and sources of defects

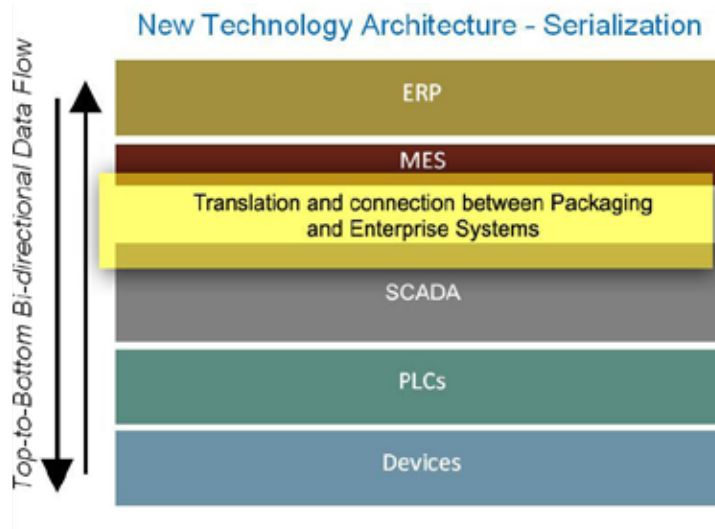
By looking ahead of current requirements and understanding the strategic value of serialization, pharmaceutical companies can prepare for the future. Indeed, many companies have already employed Systech SPT to address their packaging and supply chain needs.

The Need for Bi-Directional Communication

Adding serialization technology necessitates new packaging processes at individual sites which must be accommodated by the enterprise information technology (IT) infrastructure. Serialization creates the need for the packaging environment and the IT environment to communicate back and forth to each other in new ways. Pharmaceutical manufacturers need to make sure that data integrity is protected as it goes to enterprise servers and that the flow of data coming down to the packaging level cannot slow product throughput. Companies who implement this new infrastructure can now get a jump start on the technology that they will need to address future serialization initiatives and regulations.

Criteria Manufacturers Must Consider When Formulating their Serialization Strategy

Nobody knows what regulatory requirements will develop in each region of the world, or how those regulations will change over time. However, preparing for future regulations does not require before-hand knowledge or investment in technology that must be replaced. Rather, manufacturers can prepare for the future by investing in technology that is capable of easily accommodating changing requirements. Furthermore, in addition to easily adjusting to changes, the technology must also control Total Cost of Ownership (TCO). TCO includes the costs of software, hardware, systems integrations, revalidation,



and line throughput. Additionally, TCO includes rolling out a global serialization strategy and providing resources for ongoing maintenance and support. Pharmaceutical companies also need to understand how packaging/enterprise connectivity plays a critical role in TCO. Companies, therefore, must consider the following technology criteria when formulating their serialization strategies.

Productized

As packaged software, a productized serialization 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-productized solutions must be custom-built, increasing the cost and time of implementation. In addition to speedy installation, productized solutions are replicable, making each packaging line consistent. As more countries globally implement serialization requirements, manufacturers benefit from investing in a serialization solution that is quickly installed and replicable line-to-line or plant-to-plant. For instance, a manufacturer who installs a productized serialization 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, productized software is easily upgraded.

Configurable without Requiring Customization

Configurable serialization 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, customized solutions are rigid, making them difficult to implement and modify. By simply making configuration changes rather than re-writing code, configurable solutions minimize the need to perform line re-validations. As a result, manufacturers see less line downtime, increased productivity, and reduced costs.

Configurable solutions are adaptable. Adaptable software easily plugs into any packaging line environment and quickly handles line component or device changes. As an example, if a manufacturer has been performing 2D barcode and then adds RFID to the serialization line due to new requirements, they may need to add three new components to the line. Because it already contains the necessary elements, a configurable solution can easily adapt to the new components without requiring code re-writes or line revalidations.

Furthermore, configurable serialization software is flexible, enabling it to support a wide variety of packaging line functions. For example, if serialization 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 serialization 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 serialization solution easily grows to meet new requirements. Expandable serialization software is modular because it allows manufacturers to increase capabilities as they need it, such as post-lot requirements for serialization 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 serialization solutions that expand easily will manage investments over periods, protecting Return on Investment (ROI).

Expandable solutions are also scalable, enabling the same solution to manage small or large throughput. Therefore, if manufacturers want to serialize more products in light of increasing demands or business benefits, they will not have to change systems to manage greater demand or throughput. This scalability also allows manufacturers to move quickly from pilots to full-scale implementation.

Effective Interaction with Enterprise IT

As pharmaceutical manufacturers serialize products in light of mandates and specific corporate-wide initiatives, they have to consider the need for bi-directional communication between IT and the packaging line. Serialization's various use cases are based on the need to communicate serial number information between IT and the packaging line. Therefore, a serialization solution must have the ability to enable effective communication between the packaging environment and the IT environment.

The IT environment must communicate serialization data down to the packaging line, and the packaging line must send precise serialization data 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 serialization 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 serialization by addressing the need for bi-directional communication with a Packaging Execution (PES) platform. A PES integrates all packaging line information systems, including vision inspection, line management and serialization. Manufacturers need a PES infrastructure to ensure that bi-directional communication can occur between IT and packaging when executing serialization.

In addition to enabling bi-directional communication, a PES creates a foundation that manufacturers can continually leverage to address both current and future vision inspection, line management, and serialization requirements. Although some manufacturers want to invest in a PES, they may only be ready to invest in the vision inspection and line management solutions. These manufacturers can prepare for future demands by employing expandable line management and vision systems. Expandable line management and vision inspection systems are modular because they easily evolve to increase capabilities. Therefore, if manufacturers employ modular vision and line management solutions today, then they can easily add serialization software to the solutions tomorrow. Rather than remove and replace their current systems, manufacturers employing vision inspection and line management solutions that expand easily can build onto these existing investments, allowing them to quickly, easily, and inexpensively meet new and diverse demands. Once manufacturers are ready to purchase a serialization solution, they will have a complete PES.

What You Should Know About a Serialization Solution

As manufacturers plan their serialization strategies, they need to consider the Total Cost of Ownership (TCO) of deploying a serialization solution. Therefore, before manufacturers make a serialization solution a part of their serialization strategy, they should consider TCO as they answer the following questions:

- Who is responsible for the interface between the line management system and the vision system and the interface between the plant server and the line management?
- Who is responsible for handling the change in format from the high level system into the language that the devices need?
- As the standards change, or as additional countries implement their own changes, how do you accommodate the changes in the new requirements and who is responsible? If the line goes down, who is responsible for first response?
- How do you accommodate all of the value in OEM machines and their requirements?
- How do you manage and support end-of-lot and off-line use cases?
- What are the exception use cases on the packaging line in all of the various operations that you support and how do you support them?

The Systech Approach to Serialization

Systech's Serialized Product Tracking (SPT) application is utilized to support track and trace, ePedigree, product packaging authentication, and other business use cases in the pharmaceutical industry. Systech SPT maintains control over serialization at the item, bundle, case and pallet levels and can be deployed over multiple lines in multiple sites. Systech SPT is productized, configurable, and expandable, allowing the solution to easily, quickly, and inexpensively accommodate changing global demands.

Systech SPT acts as a gateway between enterprise IT systems and packaging operations. The SPT gateway collects data from the entire on-line and off-line packaging operation, ensuring the integrity of serialization 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 throughput.

SPT leverages Systech's productized Packaging Execution System (PES), a single system that addresses all critical packaging line information systems, including vision inspection, line management, and serialization. Systech's PES solution is expandable, enabling manufacturers to easily increase capabilities as they need it. A solution that leverages a productized, expandable PES infrastructure attains serialization while maintaining greater operational efficiency.

Very few solution providers have experience with serialized product tracking beyond a few simple pilots. On the other hand, as the world leader in deploying serialization, Systech has over 150 packaging lines installed, underway or contracted with Systech SPT and has undergone serialization projects with 15 of the top 20 pharmaceutical companies.



World Headquarters
2540 US Highway130, Suite 128
Cranbury, NJ 08512 USA

toll-free 800.847.7123
phone 609.395.8400
fax 609.395.0064
email info@systech-tips.com
web www.systech-tips.com
Offices located in: US • UK • Belgium