



## Pharma Serialization: Implementation and Challenges

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### ABSTRACT

The global pharmaceutical industry faces problems of counterfeiting, theft, diversion and false returns to manufacturers. Pharmaceutical companies and governments of countries worldwide believe that counterfeiting by organized crime can be reduced significantly by implementing product serialization. Serialization requires a comprehensive system to track and trace the passage of prescription drugs through the entire supply chain. Implementation of pharma serialisation involves the technologies and best practice in industry. Serialisation refers to the assignment and placement of unique markings on a primary package. This review provides information about the introduction, implementation and challenges involved in pharma serialization.

**Keywords:** Pharmaceutical Supply Chains, Serialisation, Brand protection.

### INTRODUCTION

Serialization refers to the assignment and placement of unique markings on a primary package. These markings can be a two dimensional or RSS (Reduced Space Symbology) bar code, a human – readable letter / number code or unique serialized codes that can be “written” onto a radio – frequency identification (RFID) tag/ label. These unique codes are placed on each package when they are packaged using variable data printers or pre-printed labels or cartons and then read by a vision system. These unique codes are uploaded to an event repository databases that can be accessed by various parties, including pharmacists, law enforcement officials and even consumers after the product is sold.

The benefits of serialization are almost limitless when it comes to retrieving data, maintaining consumer safety and establishing a brand identity.

#### Regulatory requirements

As safety concerns grow, regulatory agencies are beginning to take action. Agencies throughout the E.U. are required to use of serialized 2D bar codes for pharmaceutical products. These changes are not that far away for North America.

California's epedigree law, which requires a unique mark on each primary pharma package, is implemented from January 2015.

New federal legislation is expected to require serialization throughout the entire U.S. by 2016. Pharmaceutical companies need to start considering how to implement these important changes before these ensuing deadlines arrive.

#### Authentication

Another benefit of serializing down to the unit dose is to provide consumers with the ability to authenticate a

product by inputting the unique identifying codes, using the Internet or a phone. Now, authentication can take place at the primary package. Additionally, by 2010, these same methods will allow consumers to be able to scan a 2D bar code on a package with an iPhone to ensure that the product is legitimate.

#### Keeping ahead of the regulations

The benefits of serialization are almost limitless when it comes to retrieving data, maintaining consumer safety and establishing brand integrity. These benefits extend not just to pharmaceutical and healthcare sectors but to a wide variety of other industries as well.

#### Why Serialization<sup>2</sup>

The authentication of the product at various levels in the supply chain becomes very difficult without data sharing across the supply chain. Current business processes are very labour-intensive and the price paid by the consumer for pharmaceuticals products is high.

The high price of prescription drugs and the relative ease of duplication and diversion make them a prime target for counterfeiters. Current and pending regulatory requirements mandate that manufacturers deploy track and trace tools for product movement as well as utilize authentication tools to retain their competitiveness. Serialization could result in economic benefits, improved brand protection and consumer confidence in their medications.

**The information required** in a serialization is strongly dependant on the different laws and standards.

Typical information could include some or all of the following:

- The complete supply chain ownership information from the manufacturer all the way down to the



pharmacy from which the prescription drug was handed out to the patient

- Detailed information for each person who certified delivery and receipt of the prescription drug including company, name and address
- The name of the prescription drug, its quantity, its dosage form and its strength
- The date of each transaction in its distribution.
- The sales invoice number(s) and number of containers for each transaction
- The expiration dates and the lot/batch number(s)
- Complete shipping information
- A certification that the information is true and accurate.<sup>3</sup>

### Hierarchy of benefits<sup>2</sup>

1. Regulatory and legislative
2. Supply chain synergies and efficiency
3. Brand protection
4. Anti-counterfeiting supply chain
5. Patient safety.

### Implementation of Serialization<sup>4</sup>

Pharmaceutical manufacturers, distributors, and retailers are undergoing a multi-phased, multi-year process to implement item-level serialization in a way that protects them and enables them to reap the greatest rewards.

This implementation process contains the following phases:

- Strategic planning
- Process and solution design
- Pilot implementation and testing
- Full implementation
- Partner integration and alignment

**Technologies and implementation services can be grouped into four primary classifications:**

**Serialization Solutions** to create verify and apply serialized labels to product and perform initial aggregation

**Serial Number Management Solutions** to manage and maintain serial number status, ranges, hierarchies and aggregations.

Solutions include Trace Link, Oracle's OPSM (Oracle Pedigree and Serialization Manager), Axway, rFXcel and Frequentis.

**Event Management Solutions** to allow track and trace events to be stored and harnessed for business and

compliance benefit.

**Event Data Capture Solutions** to facilitate capture of all serialized events from the 'end of the line' all the way through the supply chains. Solutions include ROC IT EdgeTRAC.

All of these technologies require integration services to tie them into existing IT infrastructures. Companies must consider how these technologies and services will fit into their existing operations, such as packaging in a manufacturing facility, and how they will extend their core business applications, such as warehouse management or enterprise resource planning systems, in which they've already made significant investments.

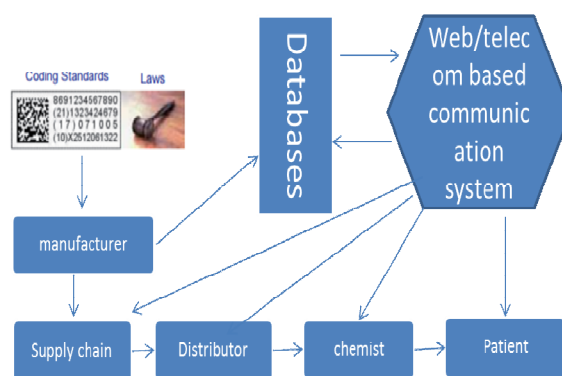


Figure 1: Example of a serialisation program<sup>3</sup>

### Best Practices in Pharma Serialisation<sup>5</sup>

Systech, a developer of Packaging Execution Systems (PES), has more than two decades of experience in vision inspection, line management, and serialization deployments for the pharmaceutical industry. The company currently has 150 serialization lines installed, in process, or under contract worldwide. As a result of its experience, Systech has identified a list of seven "Lessons Learned" to help companies to plan for this disruptive environment. While planning a serialization initiative we should follow these lessons.

#### Serialization is a business strategy.

Successful manufacturers develop enterprise wide strategies encompassing packaging, information technology (IT), and other disciplines. These strategies address the organization's view of serialization from the standpoint of patient safety, brand protection, and supply-chain operations. Industry leaders recognize that individual drivers, such as country-specific regulatory requirements, may drive local requirements and timing, but the overall adoption of serialization is a strategic to the enterprise.

#### Serialization must be a cross-functional activity.

Serialization is disruptive and requires changes and planning in packaging, quality control, distribution, and IT. Serialization forces packaging technology and IT to communicate in a bidirectional manner for the first time. Quality control and sampling, packaging rework, central

packaging, and palletizing need to be re-configuration. Value opportunities may be identified with regard to product authentication to combat counterfeiting, understanding diversion and parallel trade, delivery confirmation, chargeback and returns processing, and supply-chain visibility and optimization. Leaving key players out of the serialization initiative can lead to avoidable challenges, problems, and missed opportunities. Addressing serialization with an enterprise wide cross-functional team during planning, deployment, and operation, along with a business strategy for serialization, can minimize the investment and maximize value.

#### **Serial number control in packaging is primary aspect.**

Serialization is far more complicated than placing a number on a package. To ensure serial numbers can be used in distribution processes and by supply-chain partners, control of the serial numbers and serial number data must be maintained throughout packaging. This includes maintaining control of items going into bundles, cases, and pallets both on and off the packaging line. Use cases are needed throughout the packaging line from labelling or carton printing or encoding, bundling, case packing, and palletizing. Use cases must also address the dynamics of each automated and manual process. They need to consistently manage both normal and exception processing. From a line management point of view, real-time coordination of multiple high-speed processes, involving the printers, cameras, readers, and other intelligence devices, is necessary to maintain control of serialization.

#### **There will be multiple requirements for each packaging operation.**

In order to get high utilization of expensive packaging assets, companies often package multiple products on a single packaging line. If a line packages product for multiple jurisdictions, it will need to be flexible enough to support multiple serialization and coding requirements. Furthermore, if the same product is distributed in multiple markets, the product may need multiple codes or serial numbers. Even when a product has just one code, the automated system managing serialization must handle multiple numbers for each item in real-time. Because the different formats for storing data, communicating data, or printing (bar code and human-readable text) or encoding (RFID) the data represent unique numbers for the same item.

#### **Bidirectional communication between packaging and IT is a must.**

In order to meet regulatory and other drivers, serialized product data must be integrated with business data (such as orders or shipments). To get strategic value, serial numbers are typically controlled and maintained at an enterprise level in an IT system such as an EPCIS (Electronic Product Code Information Services) data repository. To successfully serialize products in packaging,

data from the enterprise IT system must be communicated down to the packaging line, and information must flow from the packaging line back up to the IT system. Bidirectional communication does not typically exist between packaging and IT. Traditionally, packaging and IT environments are maintained separately with little interaction beyond manual input of summary data. Enabling this communication requires a new layer of automation control. This new layer of control represents a gateway through which data must flow. The gateway ensures integrity of data in IT systems. It also makes sure throughput and availability of the packaging line are maintained. Without bidirectional communications, packagers will not be able to meet rapidly emerging serialization regulatory requirements.

#### **Existing processes and equipment will change.**

A typical packaging line, whether automated or semi-automated, is made up of specialized machines integrated into a single line. These machines are set up to efficiently package identical products to exacting requirements. Serialization places the added dimension on the packaging process. This often means replacing or retrofitting existing packaging equipment. Use cases for the serialization system must consider the unique requirements of each packaging process. It is important to understand how serialization will work on the line before new equipment is purchased or modifications are made to existing equipment. Detailed requirements need to be communicated to machine builders and/or line integrators to minimize costly rework. When planning a serialization project, the amount of time to build new equipment and integrate it into a line or to modify existing equipment often becomes the critical path on the project. Packagers should also consider future serialization requirements when purchasing new equipment or building new lines.

#### **Influence a productized solution.**

A solution for enabling serialization, in this case, Systech's Serialized Product Tracking application or (SPT), includes many different components. The solution maintains control over serialization at the item, bundle, case, and pallet levels. The solution must support differing types of packages (blister, bottle, vial, etc.) and equipment on the packaging line. Serialization solutions need to support automated, semi-automated, and manual processes.

Finally, they must manage serialization over multiple lines and as mentioned earlier, provide a gateway for bidirectional communications between the packaging environment and the IT environment.

#### **A 360 Degree Approach to Serialisation<sup>6</sup>**

Serialisation affects all steps on products ways from the manufacturing line to the patient. Hence, need to take 360 degree approach at production, packaging and distribution when developing and implementing serialisation technology.



360 degree approach to serialisation includes the following

### Automation and IT

Identifying, developing, validating and implementing robust IT and automation systems.

- Manufacturing information systems
- System interface
- PLS/SCADA (Programmable Logic Controller / supervisory control and data acquisition)
- Serialisation software configuration
- Vendor management
- Project management

### Organisational Change Management

- Ensuring cross – organisational awareness, understanding, capabilities and commitment.
- Project kick-off and milestone reassessment
- Project communication
- Design effective organisational setup and procedures
- Design and implement tools
- Build new competences and understanding – training

### Benefit Realisation

Aligning serialisation effort with strategic intent and other business initiatives.

Build and manage business case and benefit realisation plan.

- Identify and prioritise business drivers and requirements
- OEE (Overall Equipment Effectiveness) baseline and improvement plan
- Prioritise and coordinate activities, resources and deliverables across projects, sites and functions
- Programme management.

### Supply Chain Management

Analysing, designing and implementing logistics

- Product supply chain analysis
- Contract manufacturing assessment and management
- Cold chain, logistics and warehousing.

### Facility Design

Specifying, selecting, implementing packaging lines

- Conceptual design
- Equipment specification

- Vendor management and communication
- Design for OEE

### Serialisation Software

- Configuration
- Communication with vendor
- Interfaces
- Hands on solution provider experience

### GXP Compliance

Ensuring right level of GXP (Good – x – Practice) compliance, balancing risk, flexibility and efficiency

- Risk assessment
- Test plans
- Validation documentation SOPs (standard operating procedure).

### Five Challenges of Serialization in Pharmaceutical Supply Chains and solutions.<sup>4</sup>

#### Bottlenecks

Serialization is likely to create new operational bottlenecks in the physical supply chain. These include bottlenecks from performing item-level serialization tasks, as well as bottlenecks from having to manage and interact with serialization solutions.

#### Solution: Avoiding bottlenecks

The distributed nature of the ROC IT EdgeTRAC™ software solution, using “intelligent edge” data capture and real-time decision processing, enables decisions to be made and instructions to be delivered rapidly to the edge-of-the-network locations where work is performed.

This keeps intensive computing contained at the edge, and keeps goods flowing through the points of the system.

#### Scalability

Serialization solutions must be scalable to support distributed operations across a manufacturing facility, distribution centres, warehouse, and dispersed geographies. This is a major challenge.

#### Solution: Assuring scalability

ROC IT Solutions creates edge data capture solutions that are highly scalable and remain manageable even as they grow to span thousands of unique, independently running processes.

**Edge Devices** are commercially available ‘smart’ computing devices that perform automated data capture.

Deployed at key operational points where goods pass through a facility, they integrate with other devices such as printers, perform processing locally, and take actions such as real-time alerting of operators.



**Network performance**

Reduced network and system performance can result when centralized serialization computing solutions are implemented to address a distributed problem.

**Solution: Maintaining network performance**

By distributing business logic and processing to the edges of the network, ROC IT solutions dramatically reduce the need for constant communication with centrally located applications and data stores.

**Time to deploy**

Long implementation cycles for serialization solutions extend the disruption to the company's operations and delay the benefits of serialization.

**Solution: Managing the time to deploy**

Unlike solutions requiring custom development, costly integration services, and manual on-going maintenance, ROC IT solutions are delivered as a set of pre-defined functional modules (i.e rework, receiving, shipment), and an array of form factors that fit into and support customers' operations.

**On-going costs****Solution: Managing on-going costs**

Serialization solutions have potential to add yet another on-going maintenance cost to companies' already-stretched IT departments.

Centralized administration, along with the ability to centrally deliver and reconfigure functionality at the edge, make for efficient on-going maintenance. Administrators can add new or reconfigure existing Edge Devices individually or in groups, temporarily disable parts of the network, and add or change integration touch-points quickly and from one central point.

**ROC IT EdgeTRAC™ Software Solution for Serialization**

The ROC IT EdgeTRAC™ software solution enables widespread local automation with centralized control and visibility. It enables pharmaceutical customers to perform item-level serialization in an efficient and cost-effective way, while laying the groundwork for them to achieve

ROI-based objectives such as improving the accuracy of their supply chains.<sup>4</sup>

**CONCLUSION**

Serialization is an assignment and placement of unique markings on a primary package. It requires a comprehensive system to track and trace the passage of prescription drugs through the entire supply chain (manufacturing line to the patient).

To avoid problems of counterfeiting, theft, diversion and false returns to manufacturer's pharmaceutical companies and governments of various countries worldwide, believe that counterfeiting by organized crime can be reduced significantly by implementing the product serialization.

Implementation of item-level pharma serialisation includes pharmaceutical manufacturers, distributors, and retailers undergoing multi-phased and multi-year process.

While planning a serialisation initiative we need to consider the above mentioned seven best practices.

Finally we can conclude that the pharmaceutical manufacturers and whole supply chain can avoid the problems of counterfeiting, theft, diversion, false returns to manufacturers and also improving their brand protection by implementing the pharma serialisation.

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