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Six Mistakes Pharmaceutical Companies Make When Implementing Serialization

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EXECUTIVE SUMMARY

In June 2017 the FDA announced that they would not enforce the Drug Supply Chain Security Act (DSCSA) until November 2018 in a move to avoid supply disruptions by providing manufacturers with additional time to implement compliant systems. The Agency still maintains the goal of complete serialization of the supply chain to the package level by 2023, meaning that industry should view this short delay of enforcement as a "goodwill gesture" from the FDA and not a sign that they are rethinking implementation of the Act. Because of this, plans for completing serialization of companies' products should continue moving forward, especially since upgrading or installing a serialization system that brings companies into 100% compliance with DCSCA's 2023 regulation is much more than just a simple packaging line upgrade. This article examines some of the common mistakes that can be avoided in the planning and implementation of a compliant system that may not be obvious when the serialization project is started and a suggested solution for each of them.
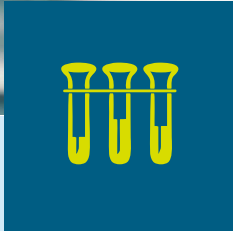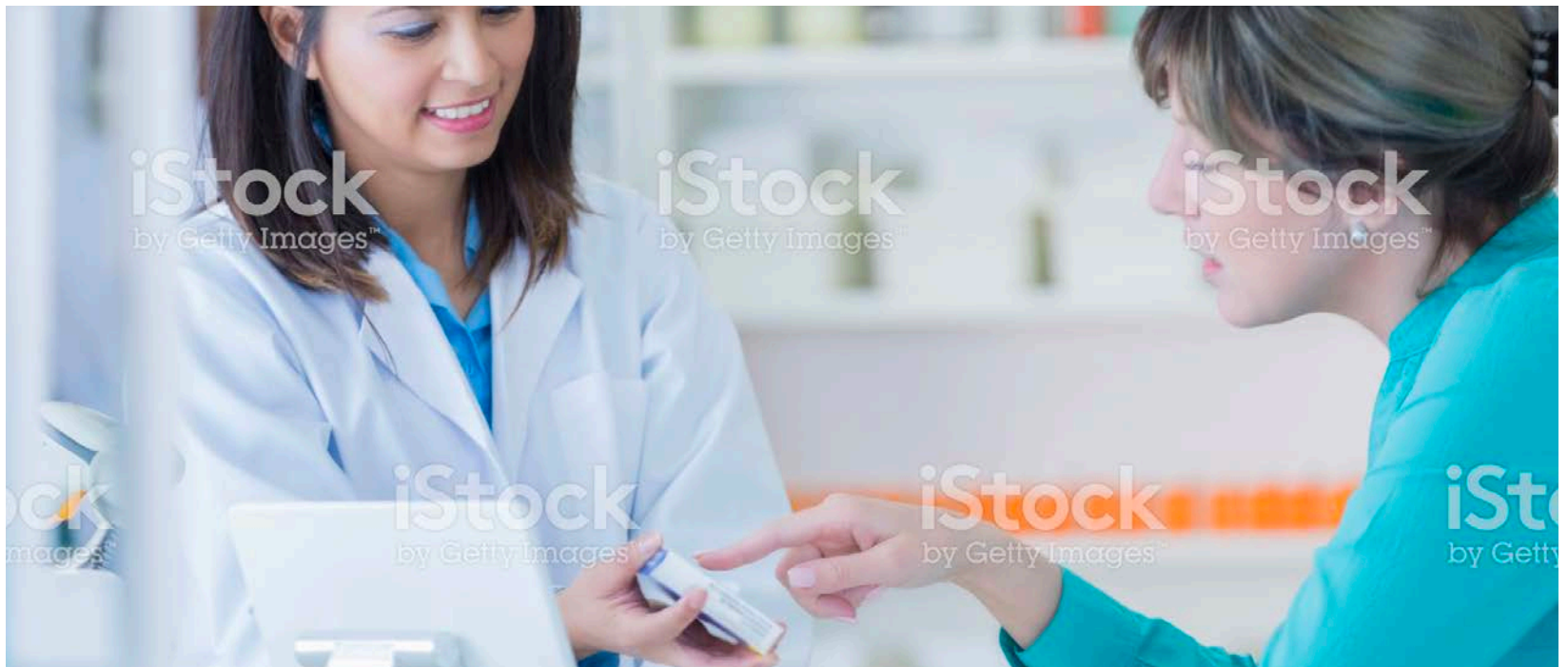
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1 Not understanding the regulations in different markets

Different countries have different serialization requirements, meaning that the serialization system must accommodate the regulations for every one of the markets where the product will be sold. Several countries have more aggressive timelines for compliance than the United States and some require a different set of data to be collected and printed on labels than the U.S. Properly addressing these differing approaches to DSCSA Products sold in these markets should be a major consideration for companies when selecting the serialization systems and planning their implementation. Another consideration is that the history of global serialization regulations reveals that countries are modifying the regulations as they move towards enforcement.

Selecting a system that is robust enough to perform all the requirements in the countries where the company's drugs are being distributed while being flexible enough to make changes in order to comply with changing regulations can prevent expense and delays later in the project. Setting up the serialization project to ensure it provides the required functionality to meet the staggered serialization needs of the different markets will prevent gaps in compliance that could disrupt the supply chain. Documenting each customer countries' interpretation of serialization and, because the regulations are still changing, periodically reviewing the regulations to detect changes that require modifications of the serialization system is needed to remain compliant as the regulations are rolled out. This approach provides sound footing for the serialization project, develops a robust plan to deliver a flexible system to deliver required data in required formats and eliminates issues with customers and markets that have different interpretations of the regulations.

2 Not involving all stakeholders in developing requirements and planning of the system

Serialization systems should not be viewed as a bolt-on addition to a packaging line, their functions impact all aspects of the supply chain and their proper implementation and maintenance require considerable support from IT and engineering resources. Systems that are selected without the correct stakeholders' input in the project's early stages may not have the capabilities to meaningfully integrate into other business system applications, may have an IT issue with implementation or they may not generate data capable of being used by a distributor's system. Having to reconfigure or replace the selected system with another system due to these issues is expensive and time-consuming. Lack of input from the label control representative, the production planner and other resources required to estimate delivery dates to produce new label artwork, modify inventory levels, update production schedules and other support for the serialization implementation will deliver an invalid schedule that is sure to cause unforeseen delays.

Identifying a complete set of stakeholders and explaining the inputs and outputs of the serialization system to these stakeholders, is essential for effective planning of the system and accurately scheduling its implementation. Soliciting stakeholder thoughts on how to move information into and out of the system and collecting their needs for the system-generated information helps develop a complete system requirements specification to support a complete system. The effective serialization system's interface to existing ERP, MES, warehousing and other systems will improve product identification and distribution efforts in the warehouse, increase manufacturing and distribution process efficiency and quality and streamline interactions with distribution partners. Feedback from IT and engineering identifies the best options for integrating the system into the current IT and equipment control infrastructure while reducing cost and avoiding conflicts with other IT and engineering projects. Bring all affected parties to the table early in the planning stages ensures that the system includes all outputs required by required stakeholders and that the planning has the input needed to properly estimate implementation schedule, resources, cost and scope.

3 Not realizing the complexity of a fully compliant serialization system

Implementing a serialization system is more than having a vendor come into a facility, connect a couple printers, readers and display panels onto a packaging line, it is much more than a stand-alone packaging system. The number of interfaces and the amount and type of data needed to fully utilize system features can easily be overlooked and the complexity of the system significantly underestimated. Many companies found that implementing a system that tracks product to the lot level was more complicated, and expensive, than they had expected. Installing a system that tracks product to a package level greatly grows the complexity of the system, the type of technology and amount of data required, increasing the operational risk, the system complexity and cost. This is complicated by the fact that the technology being used is still relatively immature and the understanding that a balky serialization system can bring a company's entire distribution operation to a halt.

Realizing the challenges in designing the serialization system to integrate with several types of packaging equipment, enterprise resource planning programs, manufacturing execution systems, warehouse systems, printers, readers, packaging equipment control systems and hand-held scanners must be designed to properly interface with the appropriate system. Whether implementing a system in stages or all at once to comply with 2023 DCSCA regulations, an aggregation process will have to be planned and implemented to trace the product to the package level, adding system complexity with the additional layers of data, software and possibly the hardware required. Understanding the complexity of these system integrations, the amount and format of data being processed and the time and energy required to design, install, fully test and qualify a serialization system is imperative to delivering a system that meets the desired functionality.

4 Not understanding the business opportunity provided by serialization

Companies implementing a serialization system with the sole purpose of complying with the DCSCA are missing out on an opportunity for collecting information to improve their supply chain business processes and several other business operations. The ability to track the packaging and distribution status of each unit of product can improve their operation by increasing the accuracy of batch yields and product loss, supporting more accurate returned goods activities and, with its almost single product "batch" size, can reduce the number, and identify the location, of units involved in a product recall. Companies can more accurately measure how long it takes to move a unit of product through the packaging and warehousing processes, can identify areas producing more defects, can determine which processes cause bottlenecks and can use the additional information on each drug to improve planning efforts for the manufacture and packaging of products. These process improvement benefits should be considered in addition to the CCSCA's primary goal of protecting the public from counterfeit or illegal drugs when developing the system requirements or when planning the selection/implementation of a serialization system.

5 Lack of complete and comprehensive training programs

The training associated with a fully functioning serialization system requires more than simple updates to the packaging line SOP. A properly installed and integrated serialization system is a positive change to many aspects of the supply chain, affecting employees working outside of the packaging area. Realizing all the benefits of serialization requires that the affected personnel, mostly those involved in the tracking of product inventory through the chain, need training on how to properly access and use the serialization information being supplied. It is imperative that these users and their management understand the possible improvements that affect their job duties, that all processes are reviewed, changes made and the SOPs updated to incorporate the changes and that enough time and resources are allocated for completing the training for all affected personnel. The initial training goal should be to produce several subject matter experts for the technical and operational aspects of the system, to provide all personnel affected by the system with an understanding of how the changes improve process efficiency or effectiveness. Completing a comprehensive training program covering all users and support personnel is essential to educate and prepare them to take advantage of the new data being provided to the process. The training should be completed by the time the serialization goes live to quickly and fully realize the benefits of the system.

6 Not understanding the preparation required to implement serialization

In addition to the need for resources and scheduling time on the packaging line, the installation of a serialization system requires preparatory activities not directly related to the installation of the system. There is a need to accommodate a 2D code printed on existing labels, or to replace the labels with RFID labels or other tracking technology. Either of these activities is not as simple as it may seem, requiring specification updates, testing, approvals and their own implementation plans. Ensure that the schedule contains time to develop and approve the artwork, to test run the labels and to manufacture and deliver the proper quantities of finished labels. Identifying and implementing the serialization numbering solution to be used to maintain the uniqueness of the labels from printing to distribution or destroying labels is a process that should not be overlooked, especially when aggregation is involved. New label reconciliation processes and SOPs will be needed as well. There are many ways to perform these tasks, but they must be defined early in the process, tracked in the overall project plan and completed prior to go live dates to eliminate any last-minute delays or surprises.

There will be a need to build product inventory prior to taking the packaging line out of production for several weeks during serialization system installation and testing. The excess inventory is required to eliminate or minimize product distribution shortages that could be caused from the lack of production from the packaging line. A manufacturing production plan must be developed to accommodate the inventory buildup of various products before the shutdown and the possibility of a gradual ramp up in speed of the packaging line after serialization implementation to maintain a full supply chain during the installation, training, testing and start up phases of the project. Even with the build-up of inventory, there may be a need for manual packaging of some products during the packaging line downtime, so SOPS need to be in place and enough trained resources to perform manual packaging in advance of the packaging line being removed from service.

These are some of the activities that are not directly involved in the serialization implementation but need to be considered and resolved prior to the serialization project initiation to prevent delays in the installation and testing due to incomplete inputs or shortages of packaged product due to the line being out of production during the serialization system implementation.

Summary

Implementation of a serialization system for packaged products shipped around the world will be mandatory at some point in the near future. There are many vendors, many systems and a multitude of options for implementing these systems, from implementing the functionality in a phased in approach to match the phased-in approach of serialization requirements to the option of installing a system that fully meets the 2023 DCSCA regulations and fully comply with other countries' regulations. Choosing the system and implementation that best suits your company's needs should be made after carefully considering the benefits that can be gained from each system and from each type of implementation. When choosing a system and a vendor and planning for the implementation of a serialization system, companies should consider the oversights discussed in this article to better understand the hidden costs or additional benefits that can be encountered with these systems and their implementation. Understanding and mitigating these issues can positively impact the development of the plan for system implementation, the preparation of system requirements, the integration with existing systems and supporting projects, the system testing, the changes in SOPs and personnel training, and overcoming the associated packaging line interruptions. These listed impacts will yield short and long-term benefits to the company that result in saving time and money on the overall project while meeting all serialization requirements.

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Brian has over 30 years experience providing regulatory, validation, qualification, QA, automation and operation expertise to the life sciences industry. He has proven success managing complex projects, analyzing processes and creating and executing programs and plans to reduce risk and operating costs, increase regulatory compliance and to improve safety.

Brian's experience includes generating assessments, gap analysis and remediation plans to prepare companies for regulatory inspections, developing and executing plans to resolve regulatory observations, implementing new technologies and processes to improve various aspects of a company's supply chain and updating companies' Quality Management Systems to meet current regulatory standards.