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Serialization: Optimizing Planning and Implementation – How an Outsourcing Partner Can Deliver Efficient Serialization Solutions

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Increased globalization in the supply chain for prescription drugs has also increased the distribution of counterfeit drugs. To combat this problem in the U.S., the FDA has outlined requirements to make every unit of saleable prescription drug products traceable.

Product serialization enables manufacturers and distributors to protect consumers from potentially harmful counterfeit and stolen drug products by improving supply chain tracking, visibility and management.

The History of Serialization

In 2007, the Food and Drug Administration Amendments Act (FDAAA) was enacted, granting the FDA broader authority to review new drugs and devices. One section of this comprehensive law required the Secretary of Health and Human Services to develop standards for standardized numerical identifiers that could be applied to all prescription drugs during manufacturing at the package or pallet level, "sufficient to facilitate the identification, validation, authentication and tracking and tracing of the prescription drug."

In March 2010, the FDA published the final version of the "Standards for Securing the Drug Supply Chain" industry guidance. The guidance set the FDA's expectations for serialized product identifiers and included distinctions defining a prescription drug package as the smallest saleable unit (e.g., individual bottle or drug-filled syringe) and defined a standard for numerical identifiers (i.e., serial numbers).

The Drug Quality and Security Act (DQSA) was enacted in 2013. Title II of the DQSA, the Drug Supply Chain Security Act (DSCSA), further defines the requirements for prescription drug product identification. The DSCSA imposes a number of requirements, including the obligation on trading partners to exchange transaction documentation, the implementation of procedures for suspect product investigations and notifications, the requirement to only deal with authorized trading partners, and the requirement for a unique unit-level product identifier — a serial number — for each package and homogenous case of prescription drugs. The DSCSA established the deadline for printing unique identifiers on all saleable units of prescription drugs as November 27, 2017.

Because the FDA did not issue guidance on unit level tracing and on the use of verification, inference and aggregation with respect to product identifiers, and because of other agency delays in implementing DSCSA provisions, some companies took a "wait and see" approach to implementing compliant systems. Those companies recently received a reprieve from the FDA, which issued a draft guidance that the FDA will postpone its enforcement of the serialization requirements until November 2018.

For those companies that are using product serialization numbers, this early adoption has provided an important opportunity to develop and fine-tune their serialization processes before the FDA starts enforcing the rule. One lesson that companies have learned is that implementing serialization can take longer than expected, and consequently, it is critical to initiate the process sufficiently before the implementation deadline to ensure that all the kinks are worked out. Ultimately, failure to comply with the serialization requirements could result in penalties and potentially the inability to ship and sell un-serialized products within the US.

Rather than delaying the inevitable, pharmaceutical companies can and should use this extra time to establish compliant serialization solutions with a partner that can help increase their supply chain efficiency.

Understanding System Design

For comprehensive serialization solutions, serialization system design has been divided into five different levels. Levels 1 to 3 are plant- or site-level devices and systems. Level 4 systems are enterprise-level systems that can often be provided by the company's own enterprise resource planning (ERP) system. Finally, Level 5 systems are global systems that allow manufacturers, wholesalers, distributors, customers, regulatory agencies and other partners to share serialization data throughout the global supply chain.

- **Level 1 — Device Level:** These are the individual devices or pieces of equipment installed on the packaging line to facilitate serialization. These devices include cameras, printers and vision inspection equipment that commonly print information on labels, inspect packaging and label components and verify or reject these components at various stages in the packaging line.
- **Level 2 — Packaging Level:** These systems control and manage the packaging line equipment and integrate the Level 1 device functionality for serializing saleable unit-level packages. These systems may also provide aggregate serialization functionality and data.
- **Level 3 — Site Level:** The site-level system or systems manage the product serial numbers including serial number creation and assignment. These systems can integrate with multiple packaging lines and can manage changes to serial number statuses and aggregation, and may also provide integration with Level 4 and Level 5 systems.
- **Level 4 — Enterprise Level:** A global enterprise system enables management of all serialization and regulatory data and business processes. Provided by a serialization solution vendor, a Level 4 system is necessary to manage and verify the data that must accompany each serial number. When you begin serialization on the packaging line (Level 1 to Level 3), you must at the same time determine how you will use and integrate the lines with your enterprise architecture (Level 4).
- **Level 5 — Global Level:** A global network enables management of all serialization and regulatory data with partners, customers and regulatory authorities anywhere in the world. Level 5 is provided by a serialization solution vendor with a global supply chain network.

Serialization System Design Levels

Planning for Successful Implementation

Meeting the requirements for these regulations requires a long-term strategy and preparation. Recro Gainesville, understanding the changing manufacturing landscape, began this process years in advance.

Initiate system design research

Recro Gainesville initiated its serialization process by examining the different system design levels, starting with the lowest, simplest design layer. In 2010, Recro began product serialization with the installation and validation of a laser printer on its packaging line to meet the 2-D bar code printing requirements for product serialization.

Employing technology for laser coding and marking of products, the printing solution applies the lot number and expiration information in traditional black lettering on a white background.

Seek functionality to meet higher-level system requirements

The next step involved researching vendors and the equipment necessary to provide Level 2 system functionality on the packaging line. In 2015, Recro selected its vendor and started the specification, design and build phases of the Level 2 system. One of the key selection criteria included the system's ability to interface with prominent Level 4 providers.

In July 2016, Recro installed and validated the system on its production packaging line. The system validation included printing serial numbers on bottles even though that capability would not be integrated until implementation of the Level 4 system. This ensured Recro would be prepared to meet the November 2017 requirement.

Select Level 3 and Level 4 vendors

Even before the Level 2 system installation was complete, Recro started the planning and vendor selection for its Level 3/ Level 4 system.

After developing and documenting the system requirements, the Recro team performed system demonstrations with vendors, polled customers to see if they had selected or preferred certain vendors and assembled an RFP to collect proposals and pricing information.

The team ultimately selected a vendor based on the solution's overall functionality, ease of implementation and cost. Most of Recro's customers had also chosen the same vendor, which both validated the selection and facilitated the implementation.

Implement a complete serialization solution

In 2017, the implementation began with the collection and creation of customer and product master data, configuration of the Level 3/Level 4 system and verification of data and processes in a test environment. The integration with the Level 2 system was also configured and tested. Recro's serialization plan incorporated customer communications, updating product labels, updating packaging batch records and appending/revising customer quality agreements. The team planned ahead to ensure adequate time for customer coordination and approvals.

Recro developed new processes for the serialization system including master data management, serial number templates, business partner onboarding, system administration and security, new packaging and warehouse operations and suspect product handling and reporting.

By October 2017, Recro had completed most project tasks and had onboarded and validated serialized transactions with several partners. The team validated its first serialized production packaging run and completed performance qualification activities.

Reasons to Outsource Serialization

Though a serialization program can be handled in-house, an experienced contract development and manufacturing organization (CDMO) offers numerous benefits.

- **Cost Savings:**
  Offering dedicated serialization services, a CDMO can quickly and efficiently meet your serialization needs.
- **Expertise in Key Areas:**
  With staff skilled in areas ranging from packaging, shipping, IT and quality assurance, cross-functional teams can provide end-to-end serialization solutions.
- **Efficiencies From Single-Source Solutions:**
  CDMOs have established partnerships with reliable vendors, saving time in developing new relationships and troubleshooting.

Conclusion

Recro's years of research, development and testing of serialization solutions ensure robust processes that achieve regulatory compliance and supply chain security.

Though DSCSA compliance will not be enforced until November 2018, implementing solutions before the deadline enables sufficient time to refine and optimize the systems and associated processes. Serialization goes beyond meeting compliance requirements; it also necessitates the development of efficient printing and labeling, production and packaging and data management processes.

For manufacturers, it is critical to work with a serialization partner that understands their unique product development and manufacturing challenges. An experienced CDMO partner will help clients meet all current and future regulatory requirements while establishing operational efficiencies.

About the Author

Stephen Dress is the Director of Information Technology at Recro Gainesville. He is responsible for the strategic direction of information technology for the site, including management of infrastructure and operations, applications, process automation, IT governance and IT security.

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