CMO Pharma Compliance

Contract Packaging Operations Transition to Serialization

As companies within the pharmaceutical supply chain near the November 27, 2017 deadline for the most recent phase of DSCSA compliance, CMO pharma contract packaging operations with comprehensive serialization implementation programs will see their business increase due to the new requirements.

A primary goal of the DSCSA is improving information transparency to minimize the market for counterfeit and diverted products. The Act states that the CMO pharma industry must build "an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States." The Act does not specify a clear pathway to achieving this goal. This lack of direction frustrates many companies within the pharmaceutical supply chain. In an industry where any deviation from absolute precision can have dire consequences, instructions without detail are a cause for confusion.

For some contract packagers, the fuzzy wording of the DSCSA has become a reason to delay any decisive action until the government clarifies their position. For others, the situation is seen as an opportunity to develop a wide range of solutions without regulatory interference, as long as the end result complies with the law. Companies with indecisive policies may find themselves at a disadvantage compared with others that began early and approved programs to support their clients along the path to serialization.

How to Gain Full Compliance

Although all responsible parties within the CMO pharmaceutical supply chain support the DSCSA, there are two differing viewpoints about the timeline to gain full compliance. The speed with which contract packagers embrace full serialization will impact their business operations and bottom lines.

The first strategy advocates adhering to the letter of the law which states that as of November 27, 2017, manufacturers must put a unique product identifier on certain prescription drug packages and must have a procedure for verification of the product at the package level, including the standardized numerical identifier, or NDC. Re-packagers must comply with both mandates by November 27, 2018. This approach can be called the "Letter of the Law" strategy.

The alternative pathway might be called the "Spirit of the Law" strategy. This program is more aggressive and involves completing additional DSCSA requirements prior to their actual deadline. For example, product tracing by package level is a DSCSA provision required by 2023. However, several companies provide solutions today that satisfy the current understanding of this regulation.

At Woodfield Pharmaceutical, LLC, our Houston-based contract manufacturing firm follows the "Spirit of the Law" strategy. As the DSCSA was signed into law in 2013, WDPrx determined that the best way to assist

their clients was to develop a comprehensive DSCSA compliance implementation program. According to WDPrx President Adam Runsdorf, “Our approach to DSCSA is that the law prompts the U.S. pharmaceutical industry to meet already-established heightened traceability regulations in other countries. We made the commitment early on to allocate resources and develop best practices for serialization to benefit our business and respond to future client needs.”

This strategy enabled WDPrx to achieve several desired results:

1. **Industry Influencer**
   Early adoption of serialization technology enabled WDPrx to be an ‘early influencer’ entering the new market ahead of competition. The management team evaluated numerous potential serialization vendors before the competition. This enabled WDPrx to take additional time to investigate solutions and negotiate from a position of strength because there was no time constraint. These discussions provided valuable insights that helped formulate the ideal serialization solution for WDPrx and their clients.
2. **Client Guidance**
   Early adoption of advanced serialization equipment and technology provided a comprehensive knowledge base for the WDPrx management team to support and advise clients to streamline their own serialization programs
3. **Streamlined Onboarding**
   By investing in a robust Information Technology infrastructure, WDPrx selected programs that offered increased flexibility to interact with multiple systems from external partners with minimal onboarding disruption
4. **Multiple Entry Points**
   Creating a full suite of serialization services prior to deadline provides WDPrx with flexibility to offer a wide range of serialization-ready solutions to manufacturers and their CMO partners regardless of their own implementation status.

Solutions By Delivery Method

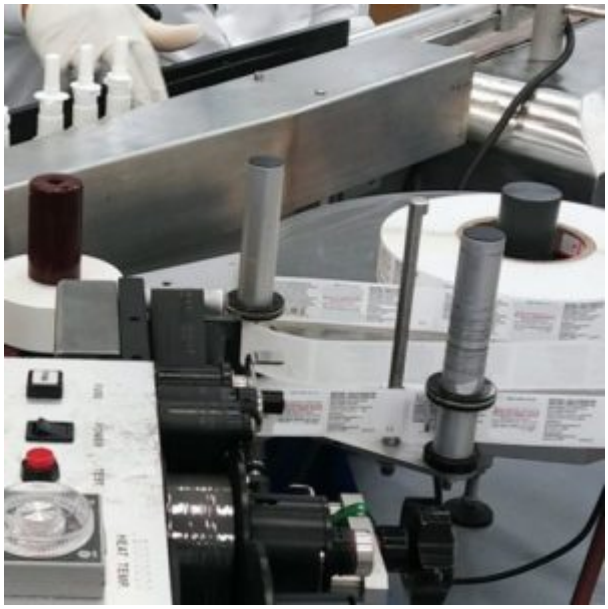
A selective history of track and trace begins with consumer products. Many of us remember the rainbow-hued stickers on the packaging of computer software office productivity CDs. A license number appeared on each sticker that activated the software when the characters were entered into the computer. The automobile parts industry and other industries developed their own systems. The international pharmaceutical industry adopted track and trace systems several years before the U.S. Turkey, for example, manages a national track and trace system that already functions in a similar fashion to the program envisioned by the DSCSA to be operational in the United States by the year 2023.

When the DSCSA became law, the pharmaceutical industry in the United States experienced a rush to market from several solutions providers. After witnessing some industry consolidation, there remain many approaches to achieve serialization compliance for pharmaceutical packaging lines.

Contract packaging operations must select solutions from among the many companies and options based on the delivery method handled by their equipment. The hardware required for compliance on an oral solid-dose packaging line may be a different solution on a liquid-dose line. Different providers may specialize in specific delivery methods. Decision-makers at contract packagers must analyze whether to rely on a single vendor or diversify potential risk across multiple suppliers.

An Implementation Experience at WDPrx

Woodfield Pharmaceutical, LLC is a CMO pharma specialist that focuses on non-sterile liquid and semi-solid manufacturing. Packaging and labeling capabilities include semi-solid, liquid, gels, suspensions and solid-dose delivery methods.



After a thorough evaluation process, the company selected Optel Vision, headquartered in Quebec, Canada, to upgrade all packaging lines with DSCSA compliant optical and labeling systems. Optel Vision offered a range of products for WDPrx that accounted for variations in packaging volume and level of automation required for each active line. Linear barcode scanners are being upgraded to 2D scanners. Labeling equipment is also being replaced or enhanced on all lines to meet DSCSA compliance. The level of automation integrated into each line is dependent upon packaging volume. Optel Vision is fully automating certain lines and is installing semi-automated solutions on other lines to better match variations in production quantities.

Systems to integrate equipment and information technology assets with product tracing, verification and end-to-end serialization, also known as Level IV enterprise compliance, are being provided by TraceLink, creator of the TraceLink Life Sciences Cloud, the world's largest pharmaceutical track and trace network.

According to Brian Daleiden, TraceLink Co-Founder and VP of Industry Marketing, "Requirements for DSCSA compliance mandate a flexible track and trace system that can handle complex data management and compliance processing for information on lot-level and serialized products that is generated and exchanged among parties that manufacture, distribute or dispense pharmaceutical products in the United States. The integration of business systems, operational processes, transactional compliance data and crucial company/product master data are critical for secure, efficient DSCSA compliance in today's diverse supply network, and with over 265,000 trade partners on TraceLink's purpose-built network, companies only have to integrate once in order to interoperate with all of their trade partners. This instant network connectivity, coupled with an end-to-end track and trace compliance solution on a highly scalable cloud platform, enables our customers and partners to be DSCSA compliant while ensuring the flow of their products throughout the supply chain."

The TraceLink Life Sciences Cloud supports serialization programs by catching serial number generation requests from packaging line systems, generating DSCSA-compliant serial numbers and related data based on pre-defined profiles for specific product types and packaging hierarchies. Resultant serialization data, aggregation information, commissioning events, shipment events and other operational events are exchanged between the TraceLink system and various packaging line and distribution systems using standard GS1 EPCIS and other data exchange methods depending on the data exchanged and the capabilities of the target systems. Lot-level compliance data is exchanged today and archived in the Life Sciences Cloud to document products as they are bought and sold across the pharmaceutical supply chain.

As serialized products start to become available across the supply chain to meet the 2017 – 2020 DSCSA regulatory deadlines, many CMOs are now starting to gear up for serialization data exchange between upstream and downstream parties on the Life Sciences Cloud platform to support efficient business operations, when required for verification of saleable returns or suspect products, or for further review or examination to help minimize product diversion and counterfeiting.

Solutions for Several Levels of DSCSA Readiness

Pursuing a program to implement comprehensive DSCSA serialization capabilities prior to FDA deadlines provides CPOs with additional new business opportunities. The CPO that is the furthest along with the most comprehensive DSCSA-compliant solutions is in the best position to address the specific needs of all participants at both ends of the pharmaceutical supply chain.

Packaging and labeling operations fulfil a key role within the pharmaceutical supply chain. Contract packagers manage relationships with multiple parties along the supply chain including pharmaceutical manufacturers, CMOs, third party logistics providers, distributors, wholesalers and dispensers.

It is likely that all parties are at different stages of DSCSA compliance. For example, some manufacturers may have equipment installed however it may not be validated. A CMO might have Level IV integration completed however installation of 2D readers on their equipment may be delayed. Smaller suppliers may not have any serialization plan in place.

There is a strong possibility that orders fulfilled by the CPO will be shipped to wholesalers, distributors and healthcare providers that also are in various states of readiness to accept serialized product.

In these cases and in other similar scenarios, the serialization-ready CPO is able to respond to clients with customized solutions and is positioned to attract additional business based on the flexibility of their capabilities.

Amatheon Pharmaceuticals is a leading veterinary supplier of ‘cross-over’ medications and a client at Woodfield Distribution, LLC, a third party logistics provider for the healthcare industry. Amatheon distributes human-grade pharmaceutical drug products to the veterinary industry. “Our mission is to utilize the most innovative technological solutions to provide the best customer service experience,” according to Robert DiCrisci, Amatheon President and CEO. The serialization expertise of the Woodfield team enables

Amatheon to uphold their mission with the correct serialization solution for their product offerings to enable them to concentrate on their core business priorities.

A Word Of Warning

Two strategies predominate in the CMO industry regarding serialization. One position advocates completing the minimum requirements of the law prior to the deadline and takes a “wait and see” attitude, not committing additional resources until further clarification and guidance is issued by the FDA about future implementation. This argument, expressed by some large pharmaceutical contract manufacturers, holds that major wholesalers will not halt the flow of pharmaceutical drug products after the deadline if compliance standards are not met by what is essentially an arbitrarily selected deadline date.

The alternative strategy emphasizes early adoption of comprehensive serialization solutions. Many responsible CPO firms including WDPrx have made significant investments to achieve serialization in advance of FDA deadlines. Positioned between manufacturer and dispenser, the CPO and third party logistics providers work with large clients. They also work with many mid-size and small clients that have little to no leverage in their dealings with national wholesalers. Smaller manufacturers and brand owners are concerned that orders may be delayed or rejected by wholesalers if their shipments are not fully serialized by the deadline. The transition to full serialization will be challenging and wholesalers willing to work through the transition with larger partners may not extend the same consideration to smaller players. Therefore, responsible contract packagers and third party logistics providers that are serialization-ready are able to offer serialization options to all clients that enable them to continue operations post-deadline and minimize the possibility of disruption further along the supply chain due to potential DSCSA compliance issues.

A Significant Commitment

Upgrading packaging and labeling equipment to conform to DSCSA regulations is an important priority affecting many departments within contract packaging operations and third party logistics providers including Warehousing and Distribution, Reverse Logistics, Transportation Management, Information Technology, Quality Assurance and Regulatory Affairs.

Item serialization requires specialized hardware and software to serialize drug products with the Unique Product Identifier (UPI) compliant with the GS1 Global Standard. The UPI contains vital tracking information including serial number, lot number, expiration date and other pertinent data.

In most cases, new printers, scanners, cameras, desktop devices and other hardware must be installed on each line and throughout the facility to read, store, print and process the UPI and additional data requirements for DSCSA compliance.

Line management software must be operational to manage serial number allocation and aggregation on each packaging line. To coordinate individual lines, additional technology is layered onto the system

enabling communication between software programs and Warehouse Management System (WMS).

The fundamental objective for item-level traceability is achieved through a cloud-based repository to generate serial numbers and gain access to data for supply chain partners to establish full chain of possession.

Although this comprehensive solution is not required by the November 27, 2017 deadline, contract packagers and third party logistics firms that committed early to complete serialization programs can offer more options to clients requiring DSCSA compliance assistance. Many contract packagers and manufacturers are choosing to wait to implement change or their serialization timetable may be delayed due to lack of outside resources. Each situation may be slightly different. The prepared third party logistics provider and contract packager is in a strong position to bridge the gap for most clients to keep their businesses running smoothly leading up to and beyond the upcoming deadline regardless of their compliance status.

Uncertainty is the Enemy: Don’t Delay Implementation

DSCSA compliance has fostered an entire industry dedicated to developing strategy, hardware and software for companies operating within the pharmaceutical supply chain. Multiple solutions are offered by different companies that each promote their own products and services. The crowded marketplace contrasts with the objective of the DSCSA to increase transparency in the marketplace to authenticate the passage of prescription medications from manufacturer to final dispenser and in the reverse logistics channel.

Contract packagers and third party logistics providers occupy an important place at the nexus of the supply chain between manufacturers and patients. Early implementation of DSCSA requirements prior to FDA deadlines benefits responsible 3PL and CPO firms and their small and mid-size clients including manufacturers and contract manufacturers.

Many manufacturers are delaying implementation until the FDA provides further clarification about the law. However, FDA public statements are always related to the phraseology of the law itself with little or no interpretation or guidance. This same situation is the reason responsible third party logistics providers and contract packagers offer clients several levels of serialization assistance. With correctly serialized products, all parties along the supply chain must accept and process inbound shipments.

Uncertainty is the enemy of pharmaceutical logistics. Proper planning with reputable pharmaceutical contract manufacturers, packagers and third party logistics providers increases confidence for manufacturers navigating through the transition to DSCSA compliance.

About CMO Pharma Specialist WDPrx

Woodfield Pharmaceutical, LLC is a proven and reliable CMO pharma specialist across a range of delivery methods including oral solutions, liquid solutions, suspensions and semi-solids. Capabilities include Research and Development, Material Procurement, Manufacturing, Process Optimization, Formulation, Validation and Analytics Testing. Contract packaging operations handle liquid and solid-dose configurations.

The modern facility is dedicated to the highest levels of quality pharmaceutical manufacturing. Based in Houston, TX, WDPrx is cGMP compliant and utilizes advanced technology to support full Technology Transfer and System Integration for minimal production downtime.

To learn more about what we do and how our solutions can benefit you, contact us online now, or call us anytime at 561-998-3885.