Pharmaceutical Serialization

It's Time For Manufacturers To Adopt Post-Serialization Efficiencies

By: Larry Hotz, Marketing Manager, WDPrx – Woodfield Pharmaceutical, LLC

Figure 1: There Is No Prescription To Ease Serialization Challenges.

Similar to the Seven Stages of Grief, pharmaceutical manufacturers and pharmaceutical contract manufacturers are dealing with the Four Stages of DSCSA Compliance: Shock and Denial, Anger and Bargaining, Working Through and Acceptance and Renewal.

It's important to note that each player in the pharmaceutical supply chain is moving through each stage individually at their own pace and not collectively as an industry. In a 2016 survey, only 13.5% of

respondents stated their companies had their full serialization program in operation 1. Today, many are walking in the sunlight of Acceptance and Renewal while many others still inhabit the dark recesses of Shock and Denial.

DSCSA IT AIN'T SO

First, let's discuss the initial three stages. The DSCSA, passed as part of the Drug Quality Security Act, was signed into Law in 2013 with the purpose of strengthening protections for patients from receiving diverted or counterfeit product. The mandated solution, involving concepts including Serialization and Track & Trace, require a re-engineering of hardware, software, procedures and workflow of every touchpoint along the prescription pharmaceutical supply chain. The FDA, in charge of enforcing the Act, established four deadlines over a ten-year period from 2015-2023 that created milestones leading to full industry compliance.

Simple, right?

Wrong. We now know that, like translating a foreign language, the requirements were interpreted many different ways.

Cue the Shock and Denial.

SHOCK AND DENIAL

Every conceivable rationalization about postponing DSCSA compliance was put forward by pharmaceutical manufacturers, pharmaceutical CMOs, pharmaceutical wholesalers, pharmaceutical distributors, pharmaceutical Logistics Services Providers (LSPs), CPOs and every other affected business. "The wording is too vague." "We are waiting for further FDA guidance before we start." "They will never enforce." "It will be repealed!2"

After so many board meetings about the subject that participants could have talked their way around the world twice, most manufacturers graduated to the next Stage towards DSCSA Serialization Enlightenment – Anger and Bargaining.

ANGER AND BARGAINING

The Optel Vision exhibit at Interphex in March, 2017 displaying serialization equipment.

Figure 2: Significant Investment Is Required For DSCSA Compliance.

Anger isn't productive, so let's cut to the Bargaining. Like children attending nursery school one year and graduating college in the blink of an eye, the first FDA deadline passed in 2015 and time marched on until today when we are at the threshold of the upcoming second legal milestone on November 27, 2017.

In the interim, an entire industry of pharmaceutical serialization enablers has risen and partially fallen as companies interviewed and negotiated with them to achieve DSCSA compliance within the allotted timeline. In another study, it was revealed that confusion surrounding the selection of technology partners is the single biggest factor hampering industry compliance[3].

Before everyone mentions the recent FDA draft guidance delaying enforcement of DSCSA regulations for one year until November 27, 2018, most experts agree that's a red herring. It was widely recognized that 100% compliance was not achievable by the set deadline[4]. The Law requires an Act of Congress to change. Unless that happens, law-abiding entities are still required to serialize by the set date – November 27, 2017. Law enforcement and legal statutes are different things. Look at it this way. Many people jaywalk. Few are ticketed. Until the inevitable accident.

Pharmaceutical manufacturers that have postponed pharmaceutical serialization plans until this point or that cannot justify the cost/benefit equation based on their business size, can leap forward to serialization compliance by working with select Logistics Services Providers that offer Serialization-as-a-Service.

These innovative companies including WDSrx, a pharmaceutical LSP with contract packaging capabilities, utilize their completed serialization platform and make it simple to take in non-serialized product, re-package and re-label to DSCSA-compliant specifications and even fulfill orders to trading partners in the United States and in Europe with fully compliant data transmission.

ACCEPTANCE AND RENEWAL

Now that the shock, anger, denial and excuses are almost all exhausted, manufacturers are beginning to glimpse the light from the otoscope at the end of the ear canal.

Hello Acceptance and Renewal.

At this final Stage of the Serialization Cycle, the prepared manufacturer casts an eye beyond the nuts and bolts of physical DSCSA serialization and focuses on performance metrics in the post-serialization world compared to the old days.

THE DIGITAL FACTORY

Figure 3: Digital Factories Counteract Procedural And Operational Inefficiencies.

Many benefits result from the considerable investment required to achieve DSCSA compliance. First and foremost, a safer pharmaceutical supply chain further protects patients from adulterated drug products. In addition, a few ground-breaking consulting firms are inviting manufacturers to see beyond serialization and make further incremental investments to create a truly digitized supply chain.

These companies, including Supply Chain Wizard based in Princeton, NJ, are transforming conventional packaging operations into digital factories with technology that constantly analyzes data to improve workflow and increase efficiency. Information and analysis is displayed in real-time on an intuitive touchscreen interface.

The data evaluation results in actionable recommendations that improve productivity across every operational area from production planning, scheduling and labor costs to record-keeping and reporting, packaging and overall equipment effectiveness.

The logic for manufacturers to establish digital factories is based on the significant investment needed to meet serialization requirements. The considerable one-time and ongoing costs for replacement, upgrade and maintenance of equipment, hardware, software and training will only realize their full potential with a further incremental investment to increase the efficiency of these components. That is the idea behind the digital factory.

REVERSE PRODUCTIVITY LOSS FROM DSCSA COMPLIANCE

The additional time, labor and equipment needed to convert conventional packaging lines to meet DSCSA guidelines will likely result in productivity loss. Analysis has shown up to 30% reduction in Overall Equipment Effectiveness (OEE) in some cases. This productivity loss can be substantially reduced and even reversed in the digital factory.

To convert operations to a digital factory platform, the first step involves configuration and installation of operator-friendly OEE tracking and reporting tools with a responsive dashboard highlighting any problem issues and opportunities. The tool performs real-time analysis of multiple metrics to provide automated reports to management pinpointing the root causes of any inefficiencies on the packaging lines.

The digital factory replaces paper and manual log books, informal reporting and inconsistent tracking with digital logs, 24/7 live tracking and advanced analytics.

THE ULTIMATE EFFICIENCY: CONVERT EXPENSE INTO PROFIT

For example, in one case study, the digital factory model helped a manufacturer reduce labor costs 19% by analyzing performance metrics with smart technology installed unobtrusively around the facility. Results revealed inefficiencies that were overcome by modifying a combination of shifts, workers and production runs and optimizing labor costs for equipment cleaning protocols and machine maintenance.

In another case, wireless sensors connected to packaging line equipment at a $1 billion generic and specialty pharma manufacturer eliminated the need for manual tracking of equipment performance and use. The automation of the tracking function improves operational efficiency. Information was transmitted to touchscreens via a Wi-Fi network for immediate review and analysis. Decisions were made faster. Maintenance issues were handled sooner. Operational efficiency increased 12% in the initial four-month test period.

Further along the supply chain, efficiencies from procedural changes at Logistics Services Providers (LSP) brought about by serialization can be improved and overcome with strategic planning and implementation of remedial solutions to bring productivity metrics to new higher levels of performance.

VALUE ALONG THE SUPPLY CHAIN

Figure 4: Manufacturers Must Assure Serialization Efficiency Is Pursued Everywhere Within The Supply Chain.

Efficiencies gained by manufacturers and contract packagers with fully-automated DSCSA-compliant packaging lines may be lost further along the supply chain. Manufacturers must think beyond their own packaging operations and work in partnership with their downstream partners to maximize value from the investment in serialization.

An important question for manufacturers to ask logistics services providers concerns how performance metrics are being maintained and improved after serialization to minimize disruption when orders are received, stored and fulfilled.

Serialized product flows from manufacturers to contract packagers, logistics services providers, wholesalers, distributors and dispensers. The move to serialization involves additional technical complications at every point due to upgraded technology infrastructure, new hardware, software and equipment.

TECHNOLOGY MEETS EFFICIENCY

Figure 5: Same Procedure, Different Outcome With Post-Serialization Technology.

In most sound management decisions across any industry, technology upgrades are considered and approved in order to reduce the labor required to perform the same function. However, pharmaceutical serialization differs from conventional logic.

Some technological advances for DSCSA require commensurate increases in time and labor for the same job function. The order receipt process is one key example of increased time required to perform the same function in a post-serialization environment compared with pre-serialization procedures.

Prior to installation of technology and equipment upgrades for DSCSA compliance, the order receipt process involved one step utilizing a single closed Warehouse Management System (“WMS”). Data about pharmaceutical drug products was scanned by the handheld gun at the inbound dock and simultaneously recorded by the Warehouse Management System. The item was then officially received by the WMS into active inventory. This process was practically instantaneous because a single program managed the entire information stream.

The same order receipt process post-serialization encounters a more circuitous path until it can be recorded as received. The route to product receipt involves six steps, resulting in an increase in task performance time and additional potential failures from the interaction of multiple software systems.

TECHNOLOGY OVERSHADOWS EFFICIENCY

Figure 6: DSCSA Compliance Affects cGMP Guidelines And Training Techniques.

In a DSCSA-compliant warehouse, an Automated Shipping Notice (ASN) with information about the delivery

is transmitted from the shipper. The pertinent details are then translated into a file format that is imported by a separate software program called an Edgeware system.

At that point, the handheld scanner downloads the information from the Edgeware system. When the item is scanned, the information is transmitted back to the Edgeware system which then notifies the WMS. At the same time, the Edgeware program alerts a different software program called a Level 4 system. Finally, the Level 4 system, not the WMS, designates the item as officially received.

In the post-serialization environment, the Level 4 system acts as the repository for all serialized data and manages communication between upstream and downstream parties as the product moves within the pharmaceutical supply chain.

AGGREGATION: FROM THE ROOT ‘AGGRAVATE’

The Edgeware system also manages the business requirement for a process called aggregation. Aggregation is not a legal requirement of the DSCSA but is necessary to achieve a comprehensive track and trace solution. Aggregation creates a virtual relationship between each individual item within each uniquely labeled carton included in every uniquely identifiable pallet.

Here’s how it works. Pre-serialization, products with the same SKU were considered interchangeable. A typical pallet built from 24 cases of 12 eaches or items in each case registered in the system as 288 units of a single item in 12 cases, totaling two computer entries.

Figure 7: 99 Bottles Of Medication On The Pallet, 99 Bottles Of Medication…

In a post-serialization warehouse, the same pallet is recorded in the system as 24 uniquely identifiable cases each containing 12 uniquely identifiable items. Instead of two entries the serialized relationship appears as 300 entries comprised of each individual Unique Product Identifier (UPI) on every item and carton connected in a single aggregated set. The movement of every item within each carton and on each pallet is monitored throughout the journey from manufacturer to dispenser.

The resulting increase in data required for transmission, storage and communication multiplies exponentially compared with pre-DSCSA models.

DIGITAL WAREHOUSE

The digital factory model, when applied to these and similar situations within logistics service provider facilities and other warehouses, will recommend improvements in processes and procedures to compensate for the side effects from DSCSA compliance. By approaching the warehouse layout, material handling equipment and personnel with similar technology employed on the packaging lines, hidden patterns emerge

from evaluation of data that will suggest changes in the three key areas of warehouse management – time, touch and travel – to compensate for serialization challenges.

The final psychological state of serialization – Acceptance and Renewal – is not an end in itself. The combination of technological advancement performance enhancement at this stage calls for continuous process improvement for all parties to succeed within the DSCSA-compliant pharmaceutical supply chain.

JENNER-OUS BENEFITS

For manufacturers still passing through the initial stages of Serialization, the road ahead may seem insurmountable. Remain committed to the process. Acceptance and Renewal – the final Stage on your Serialization journey, is attainable.

The Acceptance represents the understanding that DSCSA compliance improves the integrity of the pharmaceutical supply chain for patients and increases patient trust in pharmaceutical manufacturers and trading partners.

The Renewal arises from the knowledge that new options exist in the digital factory and digital warehouse that transform the capital investment for serialization compliance into a leaner, more efficient and more profitable production environment.

About WDPrx

WDPrx – Woodfield Pharmaceutical, LLC is a proven and reliable contract manufacturing 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 down-time.

About WDSrx

WDSrx – Woodfield Distribution, LLC provides integrated pharmaceutical third party logistics services and value-added solutions empowering the Life Sciences industry. Supply chain operations include Warehousing, Storage, Fulfillment, Transportation Management, Temperature Regulated Environments, Reverse Logistics and Regulatory Compliant Product Disposition. Value-added solutions include on-site Packaging and Labeling, Clinical Trial Support and Kitting, Customer Service, Patient Assistance Programs, E-Commerce Solutions and Financial Services Management.

State licensed nationally, WDSrx operates from secure facilities in Boca Raton, Florida and Sugar Land, Texas. Operations are licensed to meet cGMP, FDA, DEA, EPA, DOT, VAWD and Federal, State and Regulatory Agency requirements for handling of Over-The-Counter, Prescription and Controlled Substance (CII-CV) pharmaceutical products.

WDSrx DSCSA-compliant operations utilize the international GS1 barcode standard that creates a single platform to identify, capture and share authorized information with other businesses and regulatory authorities.

WDSrx is a proud member of the HDA, Specialty Pharma Association, BioFlorida, BioHouston, BioNJ and NACDS.

Citations

1. Souza, Chris. “Serialization Readiness: Takeaways from 2016 Pharmaceutical Serialization & Traceability Report.” TrackTrace Rx. RxTrace, 22 Mar. 2017. Web. 12 July 2017. <http://blog.tracktracerx.com/serialization-readiness-takeaways-2016-pharmaceutical-serialization-traceability-report/>.
2. Rodgers, Dirk. “Will President Trump Eliminate The DSCSA? – RxTrace.” RxTrace. RxTrace, 09 Nov. 2016. Web. 12 July 2017. <https://www.rxtrace.com/2016/11/will-president-trump-eliminate-the-dscsa.html/>.
3. Editors, Pharmaceutical Technology. “Technology Selection Marked as the Biggest Hurdle in Serialization Compliance.” Pardon Our Interruption. Pharmaceutical Technology, 26 June 2017. Web. 12 July 2017. <http://www.pharmtech.com/technology-selection-marked-biggest-hurdle-serialization-compliance>.
4. Basta, Nicholas. “2017 Product Security Report.” Pharmaceutical Commerce. Pharmaceutical Commerce, 18 May 2017. Web. 12 July 2017. <http://pharmaceuticalcommerce.com/supply-chain-logistics/2017-product-security-report/>.