Körber Supply Chain

Implementing a Serialization Project Post DSCSA

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In 2004 and 2005, Florida and California legislators enacted laws to require drug companies to secure their supply chains. The two states called for the serialization of any drugs entering the states to be captured and tracked. The law also called for a system of reporting on drugs as they moved from manufacturing all the way through to the pharmacy or physician. These two states, with their population size, held force in these efforts.

In 2013, the U.S. Congress passed the Drug Supply Chain Security Act (DCSCA). The DCSCA borrowed heavily from the California and Florida mandates, but moved compliancy to the federal level. The DCSCA superseded the state laws in both scope and timing, again pushing the dates for full serialization and compliancy into 2023, with milestones in between for phased tracking and recording.

An alarming number of counterfeit drugs, both prescription and over- the-counter, enter the United States every day. As much as 10% of the global drug supply is counterfeit, resulting in the potential for serious side effects, disability or worse, not to mention the financial impact on drug suppliers. How can the pharmaceutical industry keep the supply chain safe on the long voyage from ingredient to consumer?

For the vast majority of the American drug supply, serialization is the answer to the problem of theft and counterfeiting. Industry studies in the State of California, the state that kicked off this movement, show that 3.4 billion prescriptions were dispensed in the US in 2006. And one percent of this supply is counterfeit, which would mean that close to 34 million of these US prescriptions were filled with counterfeit medicine. In California, with roughly nine percent of the US prescription drug market, this would indicate that three million prescriptions were filled and dispensed with counterfeit medicine in 2006.

To comply with the new DSCSA, manufacturers are to investing in the systems, equipment and processes to ensure that their drugs are serialized at each level of packaging. It will be a significant investment regardless of size.

Are you ready?

The likely answer is no, but it's just as likely that you are working on it. The fact is, the pharmaceutical industry is still wrestling with challenges which will continue to evolve as serialization systems are rolled out.

Currently, individual countries are adopting their own guidelines and requirements. Those will continue to change. The technology will also change. In a dynamic environment such as this, you very well may find yourself forced to change what you have just implemented or are about to implement. Like any new initiative, the industry will continue to change. So, flexibility and adaptability is key. Prudence suggests a slower, more gradual approach to a solution as the regulations continue to evolve.

Having had the opportunity to work with several of the world's largest pharmaceutical companies to implement their serialization strategies, we've seen the need for flexibility over and over. In one case we supported a pilot implementation starting with just a few drugs that included serialization from the point of manufacturing through shipment to the customer. We have experience in addressing the physical challenges of labeling and scanning product. We have built systems to capture and report data for global regulatory systems. And those data requirements have changed. So again, flexibility and adaptability.

One of the leading global pharmaceutical manufacturers quickly came to recognize the enormity of what compliance meant. Major changes were needed to systems, processes, equipment and packaging as well as the very culture that defined how inventory was managed. These changes would need to be undertaken by their manufacturing plants and distribution centers, and done in coordination with suppliers and customers.

We have been successful in our recent serialization products but we have learned a few things about what to do, and what not to do.

1. **For starters, don't oversimplify the serialization project.** It will impact manufacturing, distribution, IT, and your business partners. It will require investment in new equipment and new systems. Most importantly, it will change the way your people do their daily tasks. Like any new system implementation, your work staff needs to understand why. In this case, it will be helpful to explain the basis of DSCSA and how serialization will address issues in the integrity of the supply chain. They need to be trained early in process and system changes.

2. **For slower moving products you may not be able to justify the cost of retooling your manufacturing process to place serialized labels on units.** It may make more sense to think about a post- production repack operation and focus the retooling just on the higher volume products.

3. **Don't make the mistake of assuming you will need to replace all of your scanning devices.** It is very possible that your current case scanners can be programmed to read linear case labels. Check with the specifications on your case scanning devices. Test them.

4. **Capturing serial numbers in a piece pick operation will impact productivity.** You are inserting another task into the process. In our experience, operations have shown to be more productive when the serial number is captured at the pack operation and not during picking. Consider system changes to packing before altering the pick operation.

5. **Your system needs to manage whether or not the product is serialized at the Lot level, not at the SKU level.** Your system needs to manage whether or not the product is serialized at the Lot level, not at the SKU level. As new lots are manufactured serialization is turned on. Therefore the warehouse will end up with older lots that are not serialized and newer lots that are for the same SKU in inventory. This will create a nightmare for inventory management and lot control/FEFO control.

6. **Serialization projects bring other challenges that don't have quite the clear cut solution.** For example, how are you going to ensure that a manually packed case with a specific set of serialized units gets packed into the actual carton it is intended for? Not hard when volumes justify an automated process, but a sticky issue with a manual pack operation. Do you scan every single unit? Do you add a secondary manual inspection? Is there a better way?

7. **When choosing a new system, be sure to look for product that will grow and change with you.** We have already stressed the need for flexibility and adaptability as the DSCSA continues to evolve and other countries start putting their own regulations in place. Implementing a system that can ensure your new operation can adapt as business processes are required to change will be key to maintaining a cost-effective and secure solution.

Serialization and track-and-trace concerns began with the Prescription Drug Marketing Act of 1987. Since then regulations have changed, been rewritten and reevaluated and have become the Drug Supply Chain Safety Act (DSCSA) With patient safety driving the charge for serialization, no manufacturers can argue that it's the prudent thing to do but what history has shown us is that changes are inevitable and change is good. How you deal with the change in your own business environment is the true question.

Discover more

For more information on how Körber's solutions can transform your supply chain please visit: https://www.koerber-supplychain.com/supply-chain-solutions/supply-chain-software/dscsa-serialization