

Case study: First serialization project in the industry for pharma giant



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?

Weapons that work

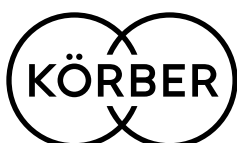
In 2004 and 2005, Florida and California legislators enacted laws to require drug companies to secure their supply chains. The two states called for the serialization of any drugs entering the states to be captured and tracked. The law also called for a system of reporting on drugs as they moved from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

force in these efforts. California, for instance, fulfills nine percent of the total prescriptions in the US.

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 The DSCSA superseded the state laws in both scope and timing, again pushing the dates for full serialization and compliancy into 2023, with milestones in between for phased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

A pilot approach made better

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.

Looking beyond the clear challenges of physically serializing their packages, they also delved into the scope of necessary changes they would need to make to their systems for track and trace; not just to the warehouse management system (WMS), but to the warehouse control systems (WCS). Further, the company understood that they would need to build a serial number repository database for the exchange of serial information. Beyond these factors, an even greater step involved building the integration layer for reporting product serial numbers for their entire supply chain community.

The company adopted a philosophy of using the serialization initiative to fulfill their compliancy requirements but further, to bring incremental improvements to their operations and to their customers. This approach permeated every design decision undertaken.

Rising to the challenge

Although the company began the process of compliance long before the DSCSA was passed, the scope of the tasks this initiative required was that the solution would necessitate an equally enormous investment in time, people and capital. Once the decision was made to retain their legacy WMS, the company determined that using an adaptive software platform to solve these challenges was the most cost effective and efficient solution.

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Software innovation at work

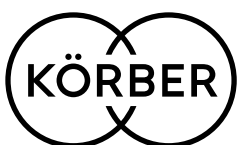
This unique and innovative approach yielded results and benefits beyond expectations. Körber's serialization solution is designed to enable users to create new functionality as an alternative, or as a replacement for existing WMS functionality. The solution fit well



with the multiple challenges faced by the company in terms of mitigating risk and expense. What this direction meant is that they could be flexible in applying “spot solutions” affecting their systems only where change was needed. This allowed them to avoid changing source code which would impact large modules of the system.

Once the implementation was complete, the company gained tremendous agility both in how the system would track and trace serial numbers and in how those numbers would be transmitted between systems. As an example of developing spot solutions, Körber designed the receiving operation solution to treat homogeneous pallets differently than mixed or partial pallets. Relying on the integrity of the inferred parent/child relationship, they recognized that the existing WMS was perfectly suited to handle the receipt of full pallets in its current form. As a result, they only needed to use the solution for partial pallet receipts, enabling the operation to capture case level serial numbers. As such, the company only needed to add a small new process flow for cases, avoiding a significant new investment in their WMS that would have been necessary without the adaptive software tool.

The timing and expense saved by not altering the entire receiving module, and the minimal disruption



this caused to the operation, proved highly beneficial to the project both in terms of the timeline and investment. The innovative use of Körber's serialization solution provided similar spot solutions throughout the rest of the operation. With the solution as the integration middleware, full cases that are picked using the existing WMS RF process move along a conveyor through an automated print and apply system. At that point, the WCS scans the serial number of the case for positive validation with the WMS.

Similarly, the existing WMS functionality is used when unit level items are picked. These items are picked to an over pack container which subsequently moves to a packing operation. At packing, new screens developed using Körber's serialization solution provide the staff with the ability to verify and record the individual bottle serial numbers, and associate those serial numbers with the over pack container, and thus with the shipment.

Patient safety solution

The company began piloting the solution in two US distribution centers in October of 2014. Additional drugs continue to be added to the operation. Since its original introduction, the system has been enhanced and upgraded with new functionality, further extending its capabilities. Additionally, the manufacturer is working with several of their larger customers to extend the tracking and tracing of serial numbers beyond their own walls. This progress puts them at the forefront of the industry for compliancy, as well as in front of the federal mandate for full unit level traceability in 2023.

The decision to use Körber's serialization solution brings compliancy to their operation with a total investment that amounted to 70 percent less than originally estimated. Further, their innovative solution has put an infrastructure in place to improve patient safety and reduce the number of counterfeit drugs entering the world.

