

Things to Think About When Implementing a Serialization Project

By Matthew Deep, vice president, DMLogic, LLC

2017 is fast approaching. That's when the California ePedigree laws go into enforcement. That's when all pharmaceutical manufacturers and pharmacy warehouses will be required to have programs in place to enable the tracking of drugs throughout their supply chain. California ePedigree Law (SB 1307 (Ridley-Thomas, Chapter 713, Statutes of 2008) mandates the following deadlines:

- 50 percent of a manufacturer's products by 2015;
- The remaining 50 percent of the manufacturer's products by 2016;
- Wholesalers and repackagers must accept and forward products with the e-pedigree by July 1, 2016; and
- Pharmacy and pharmacy warehouses must accept and pass e-pedigrees by July 1, 2017.

There are exceptions, for example radioactive drugs, but for the vast majority of the USA drug supply, serialization is fast becoming reality as the answer to the problem of theft and counterfeiting. Industry studies in the State of California, the state that is leading this movement, 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 ePedigree law, manufacturers will have to invest 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, the likely answer is also 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. The California laws may be well defined, but will the feds get directly involved? What about other countries?

Currently, individual countries are adopting their own guidelines and requirements. Those will continue to change. The technology will also change. Five years ago most industry experts were talking about RFID as the solution to the problem. Remember that? Where will we be five years from now? 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. So, flexibility is key. Prudence suggests a slower, more gradual approach to a solution until the regulations mature.

Like any new initiative, the industry solution providers are numerous. Smaller, newer players with new solutions are coming into

play. As the industry matures, you will probably see some companies fizzle; you will see consolidation; and eventually you will see industry leaders emerge. That's a process that will occur over the next five plus years. So, the lead solution now might not be there in five years or may be part of a larger solution provider. Further justification for moving with caution.

As I have had the opportunity to work with several large pharmaceutical companies to implement their serialization strategies, I'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 to EPCGlobal. And those data requirements have changed. Flexibility.

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 the California laws 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 the status of the lot at the lot level, not at the serial number level. As obvious as this may sound, system designers can easily and quickly go overboard. Attaching a lot status at the serial number level 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?

Serialization and track-and-trace concerns began with the Prescription Drug Marketing Act of 1987. Since then regulations have changed, been rewritten and reevaluated. 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.

About the Author

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