



Serialization:

A GLOBAL PERSPECTIVE AND OUTLOOK FOR THE FUTURE

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By 2020, the pharmaceutical supply chain will undergo a major disruption in the way inventory is handled. The hitherto stable batch management concept will undergo a sea change and we will end up managing a lot (batch) size of one.

Serialization regulations for prescription drugs (outbound finished product) promulgated by major markets is the reason for this change. The primary rationale for serialization regulations is preventing counterfeit product from entering the legal supply chain.

While different markets have different timelines for these regulations, the U.S. and EU have major deadlines coming up in the next three years.

For most pharmaceutical manufacturers, these two markets represent a large percentage of their sales. Therefore we will see a huge spike in activity, discussion, and effort in this area starting in 2017. Pharmaceutical companies that were sitting on the sidelines will realize that the U.S. date for serialization is less than a year away.

WHY NOW?

We are in an era where the technology is sufficiently mature to enable the tracking of billions of units. Vials, folding boxes, lowest saleable units, etc. all refer to one unit of a prescription drug, and this is the level where serialization must occur.

Batch sizes can be anywhere in the thousands to tens of thousands of units. For serialization, supply chain entities must have systems that can track and authenticate a single unit of product (identified by a unique, randomized serial number). Furthermore, for serialization to be effective, every transaction between supply chain partners must also be authenticated. The current information systems and integration protocols enable the handling of such large volumes of complex transactions. At such a large scale—billions of products, tens of billions of transactions, and thousands of supply chain partner integrations—compliance would have been impossible, say a decade ago.

BENEFITS OF SERIALIZATION

While the primary benefit of serialization (as established in the rationale for the regulations) is preventing counterfeits from entering the legal supply chain, there are other significant benefits. One benefit would be that manufacturers can track specific issues that may be encountered during manufacturing to a single unit, which would be identifiable through serial

numbers in addition to batch numbers. This will increase the ability of manufacturers to take action when necessary and to maintain confidence in and availability of products, in addition to increasing efficiencies within the process itself. These benefits would accrue to manufacturers in a serialized environment.

Furthermore, the vast amount of product movement data will generate significant analytics. Such analytics will help companies lower their cost of transportation and identify and eliminate bottlenecks in the supply chain. When linked with connected health care and social media, patient preferences and engagement with product will provide additional insights. Serialization, therefore, should be seen as an investment and not simply a cost of compliance.

CHALLENGES

Compliance with serialization regulations for the global supply chain is not without its challenges, even with the technology now available.

Equipment/Technology Challenges

With serialization, packaging equipment now has to function as software. This is a big challenge. Printing the correct number and barcode in the right place at high speed is still difficult. Equipment's capability to read the number, verify it, and approve the print quality at speed, while aggregating the numbers into the next bigger handling unit (case, shipper case, or pallet) is still evolving. Globally, more than 10,000 packaging lines need to be upgraded to be serialization-capable.

Regulatory Challenges

Different markets have different reasons for serialization. As a result, there are varying requirements from market to market. Interpreting regulations and then working with equipment suppliers for effective compliance is costly and time consuming. The U.S. regulation of 2017 calls for serialization with no aggregation requirement. This is proving to be quite difficult for managing serial numbers downstream. Already the big wholesalers are calling for aggregation starting in 2017. Handling returns of serialized product is another area where multiple pilots are underway for understanding how this will work.

Personnel Challenges

The industry has very few personnel who are skilled in this area of in technology. Furthermore, serialization brings a whole new scale of change management—especially at the operations level. Operations personnel have been dealing with batch-managed product for several decades. In a batch-managed scenario, each unit within a batch is fungible, which is not so in a serialized world. Each serialized unit is different from another, even within a batch. If a serialized unit is pulled for sampling, or is damaged, then a whole new process will have to be followed. Unlearning years of habitual action and learning a new process may cause disruption in operations.

PROGNOSIS

While technology will aid serialization, serialization will also provide opportunities for breakthrough technologies far beyond what the regulators envision. Serialization provides application and use cases for innovative and sophisticated technologies such as blockchain, messaging standards, internet of things, technology integration, printing technology and many more. While full track and trace under the U.S. Drug Supply Chain Security Act is expected to be operational by 2023, technology advancements and business economics will provide effective anti-counterfeiting solutions well before that date. ●



Author Rajagopalan Subramanyam, MBA, PMP, Global Serialization Solution Program Manager, CSL Behring, presents "Prescription Drug Traceability at CSL Behring" during a panel on "Traceability under the Drug Supply Chain Security Act" at the PPTA Plasma Protein Forum on June 14, 2016.