A FREQUENTZ WHITE PAPER:
From Lot to Serialization Traceability

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When governments around the world mandate serialization on drug products, they tend to leap directly to the application of serial numbers on those products. The U.S. Congress took a different approach with the enactment of the Drug Supply Chain Security Act (DSCSA) in November of 2013. Among other things, the Act mandates the application of serial numbers to the cases and packages of pharmaceuticals marketed in the U.S. by November 2017. Companies in the supply chain have until 2023 before the law requires tracing by the individual package serial number. Until 2023, companies must trace drugs based only on their lot numbers. This unique feature of the law sets up an inevitable transition in the industry from drug traceability based on the lot number to traceability based on the serial number. This transition must occur over the six years between 2017, when drugs’ packages and homogeneous cases in the supply chain must have serial numbers on them — and 2023, when all drugs must be traced through the supply chain using the package-level serial numbers.

Traceability Today in the U.S.
Pharmaceutical Supply Chain

Between 2015 and late 2023, the DSCSA requirements result in mandatory lot-based tracing of drugs through the supply chain. This means that parties in the supply chain must keep track of these key pieces of information: which drugs they bought and sold in each transaction that result in a change of ownership based on the FDA National Drug Code (NDC), the lot numbers for these drugs, and the quantities involved.

For each shipment, sellers must provide buyers with three types of information, which must be retained by both parties for six years. They are:

• **Transaction Information (TI)** – Information about each drug product (including the NDC, the lot numbers and quantities for each drug) and about the seller and buyer of the current shipment

• **Transaction History (TH)** – The TI for each prior change of ownership in the supply chain going back to the manufacturer, repackager or exclusive distributor

• **Transaction Statement (TS)** – A set of specified attestations about the accuracy of the TI, TH and the product supplied in the current shipment

*ADR: Authorized Distributor of Record
Source: Frequentz
In most cases, the TI, TH and TS documentation may be supplied to the buyer in either paper or electronic form until November of 2017. After that date, sellers must provide that information in electronic form. However, the three largest wholesale distributors have announced that they expect to receive this documentation in electronic form from the beginning—in some cases with fees imposed on suppliers for non-compliance. The electronic form these companies prefer is an Electronic Data Interchange (EDI) Advance Ship Notice (ASN), specially modified following guidance from the Healthcare Distribution Management Association (HDMA) to include the necessary data elements to meet the DSCSA TI, TH and TS requirements. In some cases, these companies may also accept lot-level Electronic Product Code Information Services (EPCIS) events, defined in guidance from GS1 Healthcare US.

FDA guidance published in November of 2014 indicated that EDI ASNs and EPCIS events are acceptable ways of exchanging the DSCSA transaction data. Other acceptable ways of electronic DSCSA data exchange mentioned in the FDA guidance include web portals, electronic invoices and email.

The lot-based product-tracing requirement for manufacturers, repackagers, and wholesale distributors was effective on January 1, 2015, but the FDA has announced that it will not enforce that provision of the DSCSA until May 1, 2015. The requirement for dispensers went into effect on July 1, 2015.

The initial data exchange technology choice made by the vast majority of manufacturers and wholesale distributors was to encode the DSCSA transaction data in EDI ASNs. However, these trading partners quickly realized that ASNs do not work well in some scenarios. For example, drop-shipments are problematic because there are three parties involved and ASNs assume only two. In another example, resolving certain shipment exceptions by reissuing a modified ASN is not practical because of legacy system and business processes complexities. These issues stem from the use of technology meant for simple scenarios to meet more complex regulatory requirements.
Use of EPCIS events has been left for future pilots. But there is growing interest by some companies in shifting between now and 2023 from the use of ASNs to the use of EPCIS events to carry the serial number-based transaction data. A few companies are pushing to switch from ASNs to EPCIS for even lot-based data exchange, but this is unlikely to occur due to the short term that manufacturers will be able to ship non-serialized products.

Traceability after 2023: Enhanced Drug Distribution Security

On November 27, 2023, the DSCSA requirements transform into mandatory interoperable, electronic, serial number-based tracing of drugs through the supply chain. This is what Congress dubbed “Enhanced Drug Distribution Security” (EDDS). At that time, drug sellers in the supply chain must begin to include package-level serial numbers in the TI they supply to the buyer.

Additionally, the previous requirement to pass transaction history, TH, will be replaced by one that mandates systems and processes necessary to promptly gather TH information in the rare case of an investigation. To meet this requirement, these systems must have efficient access and search capability to the transaction data for all supply chain transactions going back to the manufacturer. This opens the door to multiple new approaches to DSCSA data exchange and storage, including distributed network models and central and semi-centralized cloud-based models.
Congress required the FDA to work with the industry between 2015 and 2021 to define the technical details of the EDDS, so a lot is not yet known. However, a December 2014 survey indicated that most people in the industry believe such systems will be based on the GS1 EPCIS standard, with no alternative approaches mentioned. GS1’s EPCIS standard is flexible enough to be applied to any of the potential industry-wide architectures being discussed for the EDDS today. Given that, EPCIS will almost certainly be the centerpiece of that solution.

The GS1 EPCIS standard defines how individual supply chain event documentation should be formatted. This provides a common “language” for expressing exactly the type of events that companies will need to exchange and store information about. Solutions based on the EPCIS standard can be built in many different ways to efficiently generate, hold, exchange, store, search and retrieve serial number-based DSCSA data. All that is needed is for the industry and the FDA to define the desired industry-wide architecture so solution providers can design and build EPCIS-based solutions that meet it.

The Transition from Lot-Based Traceability to Serialization-Based Traceability

What does the transition look like for companies that have begun to meet the 2015 product tracing requirements of the DSCSA with lot-based EDI ASNs if they must end up in 2023 with serial number-based solutions that make use of EPCIS? At what point do companies switch from ASNs to EPCIS events for documenting the DSCSA TI, TH and TS?

One clue to the answers can be found in the DSCSA requirement for manufacturers to begin assigning and applying unique serial numbers to all their drug packages and homogeneous cases by November 27, 2017 (2018 for repackers). This is a significant step and it is not far away, considering the complexity of deploying the necessary upgrades to pharmaceutical packaging lines. To assign and apply unique serial numbers to all packages and cases, manufacturers, repackers, and even many contract manufacturer/packers will need to deploy solutions that allow them to closely manage the pool of potential serial numbers, and keep track of which serial numbers are applied to which products, including NDC, lot, expiration date, and other internal production data. According to the DSCSA, key parts of this data must be stored and retrievable for six years. The solutions necessary to do this are available today and are based on the GS1 EPCIS standard.

For this reason, large numbers of manufacturers, contract manufacturers and repackers will deploy EPCIS-based systems leading up to their serialization deadline in November 2017. Serial number management is an internal-facing application. That is, number management can be addressed without involving external trading partners, even though these applications usually include some ability to send and receive DSCSA transaction documentation via EPCIS events. To maximize the return on their investment, manufacturers and repackers who invest in these systems for the purpose of managing and retaining the serial numbers they apply to their drug packages and cases may also choose to make use of the data exchange capabilities with trading partners that have comparable capabilities.

In addition, manufacturers and repackers who choose to capture aggregation data (serial number-based packaging hierarchy data) are also more likely to select EPCIS events as their method for documenting that data. ASNs are capable of carrying the aggregation data. But making the investments necessary to add
package-level and case-level serial numbers to those messages, when that technology will be unusable for DSCSA after 2023, severely limits the payoff. Companies who capture aggregation information and choose to pass it to their customers are much more likely to use EPCIS events to carry it.

Some wholesale distributors, larger hospital networks, and chain pharmacies who wish to receive the aggregation data and serial number information from manufacturers and repackers are also likely to deploy systems with EPCIS capabilities. In that case, between 2017 and 2023 more and more of the DSCSA transaction information will be exchanged using EPCIS events, with a corresponding decrease in the use of EDI ASNs.

A growing number of people are expecting exactly that to happen. The 2015 RxTrace U.S. Pharma Traceability Survey found that almost half of the respondents thought there would be a movement toward using EPCIS to pass serialized transaction data before it is required in 2023 in regular business and in pilots. ⁵

This means that there will be a period of years where there is a mix of lot-based DSCSA transaction data and serial number-based data being exchanged. This will introduce challenges because not all trading partners will be able to exchange one type or the other. But these challenges will not be insurmountable. GS1 Healthcare US is already working on documenting these situations and developing guidance to address them.

Conclusion

The enactment of the DSCSA in late 2013 will have a profound impact on the operation and security of the U.S. pharmaceutical supply chain. Companies started out making use of existing data-exchange capabilities, but some will make the transition to using solutions based on GS1’s EPCIS standard before it will be required in 2023. This change will be driven by the use of EPCIS-based applications for managing the serial numbers that manufacturers and repackers will need to apply to their products before the end of 2017 and by those who choose to capture or receive serial number aggregation data.

Finally, in 2023 all trading partners in the supply chain will need to switch to the use of EPCIS events to pass and manage the required serial number-based DSCSA transaction data. That transition will not be without challenges, but once complete, the data collection, exchange, storage and retrieval will be consistent across the entire supply chain.

Works Cited

5. Ibid.
About the Author

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Dirk Rodgers is an independent consultant and founder of RxTrace.com, where he writes regularly about the intersection between the pharmaceutical supply chain, track and trace technology, standards, and regulatory compliance. An electrical and computer engineer by education, Dirk has worked as a consultant, software architect, automation engineer, software developer, and for U.S. drug distributor Cardinal Health. At Cardinal Health, he studied the application of serialization and track and trace technology to solve supply chain integrity problems, meet regulatory requirements, and improve supply chain efficiencies. Dirk has served on HDMA, NCPDP, EPCglobal, GS1 and GS1 US technical, and standards work groups related to ePedigree, track and trace, RFID, and barcodes. He also served as co-chair of the GS1 EPCglobal Drug Pedigree Messaging (DPMS) work group and the GS1 Network Centric ePedigree (NCeP) work group.

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