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Are You Prepared for DSCSA?

Upcoming Challenges for Manufacturers and How to Combat Them

With 2015/2016 deadlines met, which called for manufacturers, wholesalers and re-packagers to provide and dispensers to accept transaction information, transaction history and transaction statements (TI/TH/TS), the industry is officially in the track-and-trace trenches.

The next round of mandates become effective November 2017 and involve the following directives:

- A unique product identifier must be adhered to each individual prescription drug package not exempt by DQSA.
- All TI/TH/TS must be submitted in electronic form.
- Systems and processes to verify product identifiers and re-saleable returns must be established.

While these seem like approachable mandates, and certainly worthwhile as they support patient safety, they merely represent the tip of the iceberg. It is in the details that manufacturers uncover the more extensive components to implementation, and perhaps the motivation to do more.

Manufacturers face serialization deadlines in 2017, and the same holds true for re-packagers in 2018, wholesalers in 2019 and dispensers in 2020. It's becoming clear the extent to which stakeholders are tethered to each other's accomplishments — which has some questioning the risk of doing the bare minimum.

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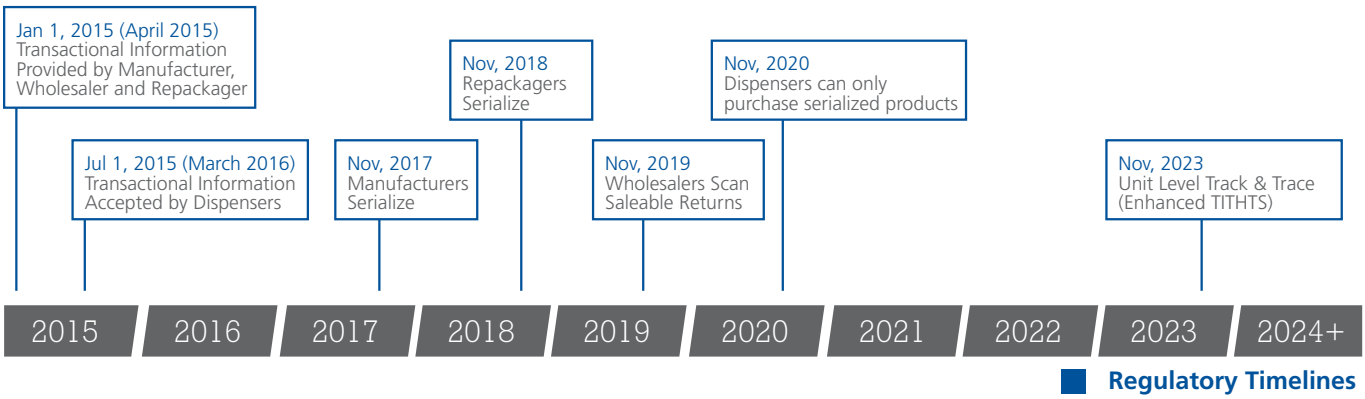
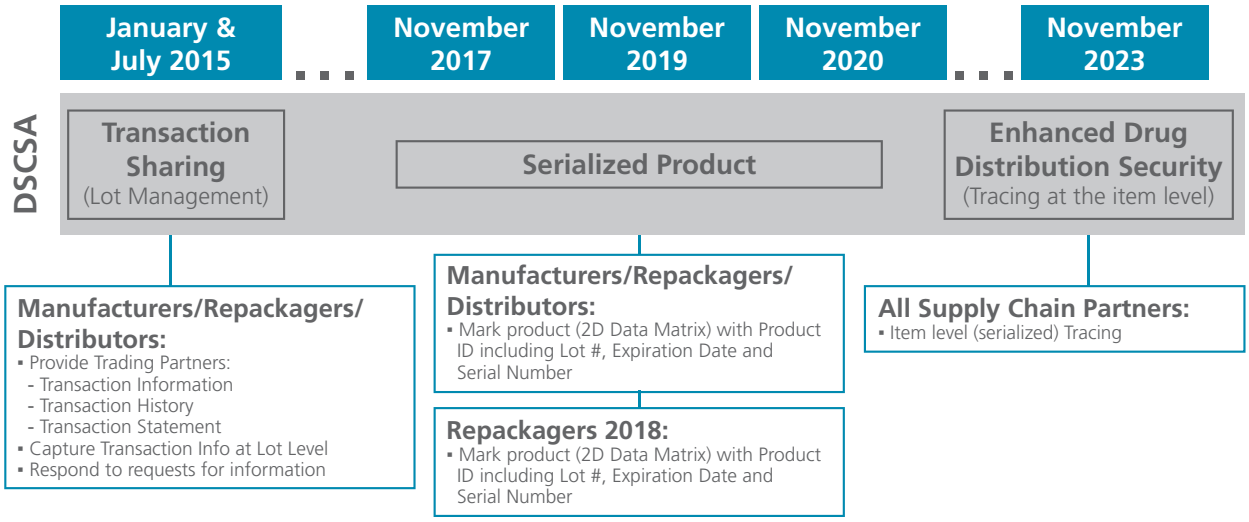
Are you prepared? The following are components manufacturers should be well aware of to combat upcoming challenges:

What are the key dates for manufacturers?

Nov. 27, 2017, is the next milestone for the DQSA implementation. Manufacturers and re-packagers will need to include a Standard Numerical Identifier (SNI) unique to each package or case (serial number and barcode). They also need to establish processes and databases to respond to verification requests. Verification requests require a response within 24 hours from a trading partner or the FDA.





What is the impact of serialization to technology and operational infrastructure?

Serialization is not simply putting a number on a bottle. A multitude of guidelines and implications to technology and operational infrastructure must be understood and adhered to for successful serialization. To start, the product identifier must meet GS1® standards and comply with these specifications:

- Must be applied to each package and case.
- Leverage a 2D DataMatrix on package, linear or 2D on case.
- Feature the National Drug Code (NDC) and the Serial Number (SNI), lot number and expiration date.
- Must be readable by machine and human.

The relationship this soon-to-be-born number has to traceability and ultimately the mandates for 2018, 2019 and beyond is dramatic. After all, the barcode has to work when any number of the stakeholders scan it. And that means quite a bit of additional work needs to be done up front to ensure the data is funneled correctly and quickly.

What should manufacturers be doing now to combat challenges to current technology infrastructure?

The data generated by serialization, and the master data and transactional information linked to a uniquely serialized product that is packaged, shipped and verified across the supply chain, presents a number of challenges to current technology infrastructure.

In addition to significantly increasing the amount of data transmitted every time the 2D barcode is scanned, serialization events are more connected to real-time operations than lot-level events, including detecting, responding to and reporting potentially illegitimate drugs.

This calls for manufacturers to:

- Establish complex bi-directional data exchange connections with a diverse set of supply and trade partners.
- Discuss and understand standards for data exchange upfront, which are even at this stage still evolving. These include Healthcare Distribution Alliance (HDA) Advanced Ship Notice (ASN) and GS1 Electronic Product Code Information Service (EPCIS).

Those manufacturers that do not approach serialization as the first step to traceability, ironing out a strategy and design for data exchange in tandem with serialization efforts, may see business grinding to a halt in 2019, when distributors can no longer transact drug products without electronic transaction documentation.

Why aggregation of data?

The demand to establish systems and processes to verify product in 2017 must also include the ability for manufacturers and distributors to verify returned re-saleable units. In order to do that, aggregated data is needed, in addition to unit- and case-level serialization data.

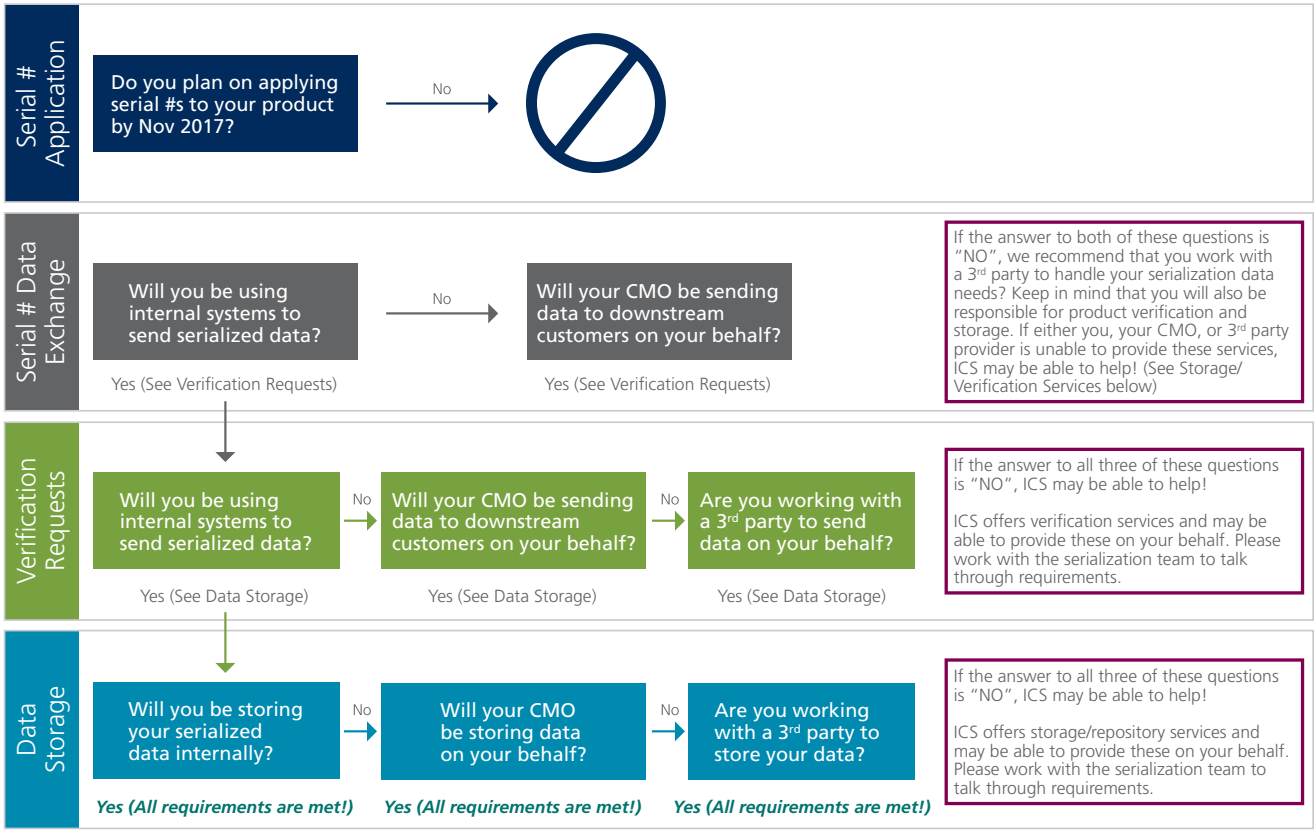
Without aggregation, distributors would have to manually verify each unit — a burden far too costly for most to bear, especially when one considers large distributors can average anywhere from 30,000 to 60,000 returned units a day.[1] And while the aggregation of data is not a requirement in 2017, its lack will greatly impact the very near future of distribution costs, which will undoubtedly be passed on to manufacturers in the form of fees.

What are my third-party provider options for serialization?

There are a few different options for serialization, and admittedly, this can be somewhat confusing for manufacturers. In general, manufacturers need to think through four things when considering third-party provider options:

1. Will my CMO/packager be capable of applying a serial number to my product by November 2017 (i.e. line-level serialization)?
2. Have you identified a solution for generating your serial numbers to your CMO/packager?
3. Do you have a solution for storing your data for a minimum of six years?
4. Do you have a solution to verify serial numbers (if requested) within 24 hours?

Think through these steps when considering third-party provider options.



What service does ICS offer?

- Data Storage/Repository Services – ICS will store your serialization info and provide reporting for easy retrieval.
- Serial number verification services – We provide tools for your downstream customers/government agencies to verify serial numbers if needed.
- Relabling/rekitting services – Depending on your needs, we may be able to offer relabeling and rekitting solutions.

[1]Cao, Riya. "*DSCSA Serialization Update: Where We Are Now and How to Prepare for What's Next.*" RxTrace. N.p., 15 Apr. 2016. Web. 20 Sept. 2016. https://www.rxtrace.com/2016/04/dscsa-serialization-update-where-we-are-now-and-how-to-prepare-for-whats-next.html/.

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ICS, a business unit of AmerisourceBergen, partners with pharmaceutical manufacturers to deliver third-party logistics services that improve the quality and efficiency of their supply chains. Since pioneering the market in 1997, ICS the model of excellence in global healthcare logistics, has helped bring hundreds of specialty pharmaceutical products to market and served as an integral component in their growth.


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