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STRATEGIES FOR MEETING DSCSA-TRIGGERED BUSINESS REQUIREMENTS

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SUMMARY

Do you need to adjust your plan for meeting DSCSA requirements?

The U.S. Drug Supply Chain Security Act (DSCSA) contains many explicit regulatory requirements. Today, most companies are either working on meeting those regulatory requirements or planning how they will meet them. However, there are other requirements that stem from the DSCSA that are not explicitly mentioned in the text of the law. These are DSCSA-implied, or DSCSA-triggered business requirements.

These requirements are technically not “regulatory requirements”— if you don’t meet them, you will not be in violation of the law — but instead, they are requirements that companies must meet in order to continue participating in the U.S. pharma supply chain after one of the dates called out in the law.

These business requirements are triggered by one change or another to the operation of the supply chain as the result of the DSCSA. Because these DSCSA-triggered business requirements are not explicit, they may be easy to miss. Companies need to be aware of these requirements and must prepare for meeting them before the triggering date.

Using this guide you will learn:

- What is a "DSCSA-triggered business requirement"
- Examples of DSCSA-triggered business requirements
- Strategies for meeting these requirements

PRESENTER

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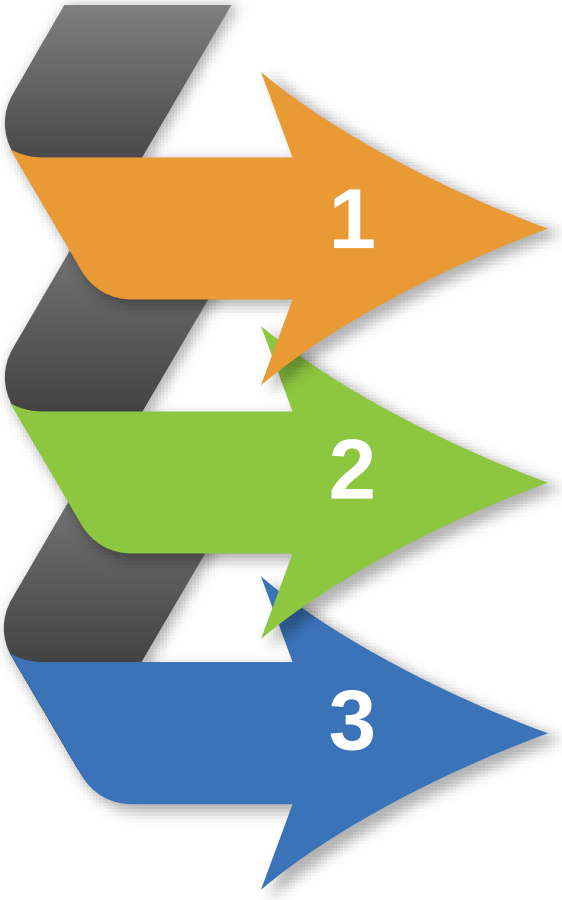
AGENDA



Regulatory Requirements
Example

Business Requirements
Example: Payment Terms

DCSCA-Triggered Business Requirements
Example: Electronic data exchange prior to 2017
Example: Shipping Label Specifications
Example: Aggregation Data

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REGULATORY REQUIREMENTS

A “REGULATORY REQUIREMENT” IS…

“…a product or service requirement that is imposed by an outside (usually governmental) agency that must be met by every product or service under the purview of that agency.”

The reason a business *chooses* to meet a regulatory requirement is so they avoid the cost of fines and other penalties. In some cases, ***not*** following a regulatory requirement might threaten the ongoing existence of the business by blocking access to the target market.

A "DSCSA REGULATORY REQUIREMENT" IS…

If we get just a little more specific, we can narrow the definition of a regulatory requirement in terms of the Drug Supply Chain Security Act to:

*"…a product or service requirement that is **explicitly imposed** by U.S. statutes as the result of the passage of the DSCSA, and that **must be met by** products or services referenced under those statutes."*

The key here is that the DSCSA has lots of requirements that are explicitly called out. You can't avoid them, because they are written right in the law itself.

DSCSA REGULATORY REQUIREMENT EXAMPLE: SERIALIZATION

For example, the serialization of drug packages and homogeneous cases by November 27, 2017 is an explicit regulatory requirement in the DSCSA, and we can point directly to the exact clauses that must be followed.

Here is Section 582(a)(9) where part of the serialization requirement is specified.

It's kind of hard to get around, because it is spelled out so specifically.

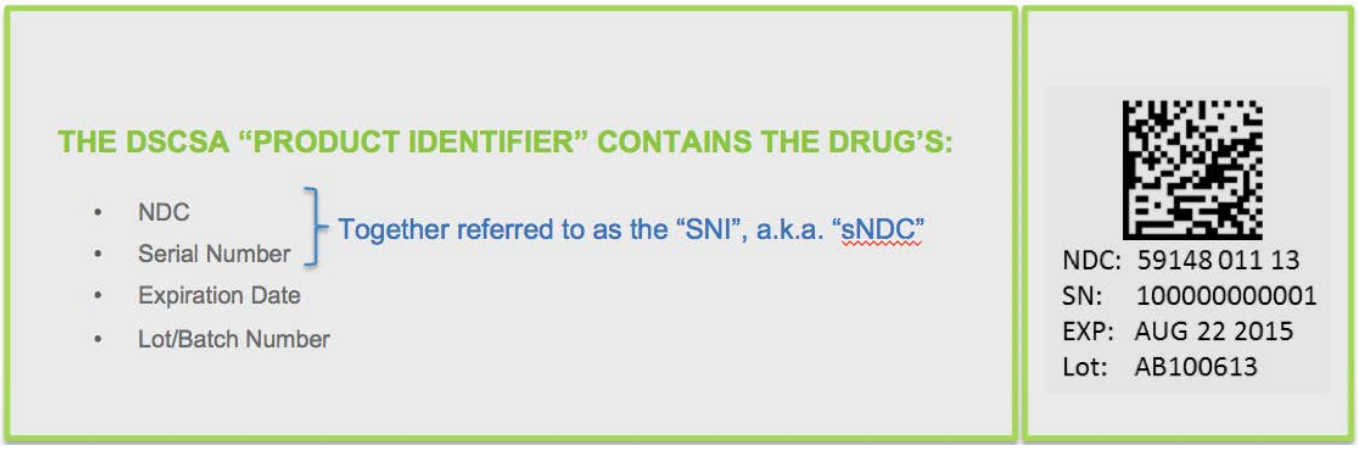
BY NOVEMBER 27, 2017:

Product Identifiers –

*"…shall be included in a 2-dimensional data matrix barcode when affixed to, or imprinted upon, **a package**; and shall be included in a linear or 2-dimentional data matrix barcode when affixed to, or imprinted upon, **a homogeneous case**…"*

Section 582(a)(9)

To add some more detail on the serialization requirement, this one comes from Section 581(14) where it specifies the contents of the product identifier that must be printed on packages. As we'll see in a minute, that section lists the Standardized Numerical Identifier, or SNI, the lot number and the expiration date.



The question is, why do so many companies show a GS1 GTIN instead of an NDC on their packages?

In fact, examples provided in this guide are just about the only ones that show the 10-digit NDC in human readable form. Everyone else shows the 14-digit GS1 GTIN.

So, you might ask, "What's going on here?"

NDC OR GTIN?

> The term 'product identifier' means a standardized graphic that includes, in both human readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier lot number, and expiration date of the product.
>
> Section 581(14)

Section 581(14) of the DSCSA states that *"The term 'product identifier' means a standardized graphic that includes,* ***in both***

- *human readable form and*
- *on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product."*

Notice that it's the data carrier of the machine-readable version of the product identifier that must conform to the standards developed by a widely recognized international standards organization, like GS1. This is what allows us to encode the SNI as a GS1 GTIN and serial number into a GS1 Data Matrix barcode.

NDC OR GTIN?

> The SNI for most prescription drug packages should be serialized National Drug Code (sNDC). The sNDC is composed of the National Drug Code (NDC) […] that corresponds to the specific drug product (including the particular package configuration) combined with a unique serial number, generated by the manufacturer or repackager for each individual package.
>
> FDA SNI Guidance, 2010

This is an extract from the FDA's SNI Guidance from 2010.

It says that the SNI is a serialized NDC, or sNDC. And it says, *"The sNDC is composed of the National Drug Code (NDC) […] that corresponds to the specific drug product…combined with a unique serial number…".*

The DSCSA relies on this old SNI guidance to make this clear so, in effect, that old guidance is extended, by reference, into the DSCSA itself.

NDC OR GTIN?

> "…use of an sNDC is compatible with, and may be presented within, a [GS1] GTIN, which can be serialized using an Application Identifier (AI) (21) to create a serialized GTIN (sGTIN) for use with RFID or for certain barcodes."

FDA SNI Guidance, 2010

Here is the part of the SNI guidance that makes it clear how GS1 barcode and RFID standards may be applied to encode an SNI.

It says, the *"…use of an sNDC is compatible with, and may be presented within, a [GS1] GTIN, which can be serialized using an Application Identifier (AI) (21) to create a serialized GTIN (sGTIN) for use with RFID or for certain barcodes."*

Notice this only affects how the SNI is encoded within the RFID or barcode data carriers. Of course, the DSCSA itself eliminates the use of RFID in favor of a Data Matrix barcode, but this guidance does not say that the human readable SNI can be depicted as a GTIN and serial number.

The point of this exercise is that regulatory requirements can be understood by directly applying language that is found in the regulations themselves.

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BUSINESS REQUIREMENTS

In most businesses, business requirements come from fulfilling customer needs, including those necessary to continue serving demanding customers. The reason a business chooses to meet a business requirement is to continue to attract customers.

Example

A customer will usually demand some specific payment terms as part of their willingness to purchase from a supplier. In some cases you might be able to negotiate terms that are attractive to both parties, but usually the customer presents it as a "*take it or leave it*" requirement, and this becomes a "*business requirement*" that the supplier must meet if they want to do business with that customer. There are lots of business requirements like this.

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DSCSA-TRIGGERED BUSINESS REQUIREMENTS

DSCSA-TRIGGERED BUSINESS REQUIREMENTS ARE:

Business requirements *imposed* by demanding customers so they are able to fulfill their *own* DSCSA requirements

DSCSA-triggered business requirements are business requirements that are imposed by demanding customers so that they are able to fulfill their own DSCSA requirements.

This is really a combination of a DSCSA regulatory requirement and a business requirement, but it is your customer who is facing the DSCSA regulatory requirement, and, so they can meet it, they impose a business requirement on you. That makes it “DSCSA-triggered”.

HOW DOES A DSCSA REGULATORY REQUIREMENT BECOME A DSCSA-TRIGGERED BUSINESS REQUIREMENT?

The sequence that leads to a DSCSA-triggered business requirement on drug manufacturers comes from a specific regulatory requirement imposed by the DSCSA on wholesale distributors.

The DSCSA regulatory requirement on the left is imposed on the wholesale distributor, which leads the wholesale distributor to impose a new DSCSA-triggered business requirement on their suppliers, the drug manufacturers.

EXAMPLE: ELECTRONIC DATA EXCHANGE PRIOR TO 2017

REGULATORY REQUIREMENT:

"ELECTRONIC FORMAT. --- (I) IN GENERAL. --- Beginning no later than 4 years after the date of enactment of the Drug Supply Chain Security Act, […] a manufacturer shall provide the transaction information, transaction history, and transaction statement required under subparagraph (A)(i) **in electronic format**."

DSCSA Section 582(b)(1)(C)

DSCSA-TRIGGERED BUSINESS REQUIREMENT:

In 2014, the large wholesale distributors issued a business requirement to their suppliers demanding electronic data exchange **from the beginning, January 1, 2015**.

Above is an example of a DSCSA-triggered business requirement.

The DSCSA specifies that the transaction data must be passed electronically from drug manufacturers to wholesale distributors, beginning on November 27, 2017. But waiting until then was too burdensome for the large wholesale distributors, so they imposed a business requirement on drug manufacturers back in late 2014 that said they would only accept electronic data from the very beginning.

So, starting on January 1, 2015, DSCSA transaction data has been supplied to wholesale distributors electronically, even though the DSCSA would have allowed that data to be in paper form until late next year.

This is a perfect, and simple, example of a DSCSA-triggered business requirement.

EXAMPLE: CASE LABEL SPECIFICATIONS

REGULATORY REQUIREMENT:

"…unless the Secretary allows, through guidance, the use of other technologies for data instead of or in addition to the technologies described in clauses (i) and (ii), the applicable data ---

- (i) shall be included in a 2-dimensional data matrix barcode when affixed to, or imprinted upon, a package; and
- **(ii) shall be included in a linear or 2-dimensional data matrix barcode when affixed to, or imprinted upon, a homogenous case;**"

DSCSA Section 582(a)(9)

DSCSA-TRIGGERED BUSINESS REQUIREMENT:

The HDA Bar Code Quick Start Guide For Meeting The DSCSA

- 16 pages of specific formatting requirements for labels

This is another example. The DSCSA does not say much about the appearance of the labels on homogeneous cases. In fact, this is about all it says:

"*…the applicable data…shall be included in a linear or 2-dimensional data matrix barcode when affixed to, or imprinted upon, a homogenous case*".

But to ensure efficiency in meeting the DSCSA, the wholesale distributors require uniformity in the labels on the cases they receive. As a result, their industry association, the Healthcare Distribution Alliance, recently published a document containing 16 pages of specific formatting requirements for drug manufacturers. Some of these are DSCSA-triggered business requirements for those manufacturers.

If you don't have that document, it can be downloaded off of the HDA website.

EXAMPLE: AGGREGATION DATA PRIOR TO 2023

REGULATORY REQUIREMENT:

"The "Enhanced Drug Distribution Security" phase starts on **November 27, 2023** and it will have the following features:
"[…] Systems and processes for verification of product at the package level, including the standardized numerical identifier, shall be required in accordance with the standards established under the guidance issued […], **which may include the use of aggregation and inference as necessary**."

DSCSA Section 203(g)(1)(C)

DSCSA-TRIGGERED BUSINESS REQUIREMENT:

The "Big-3" wholesale distributors demand aggregation data in 2018 to help them deal with their DSCSA-mandated handling of sealable returned drugs in 2019

Yet another examples is aggregation data prior to 2023.

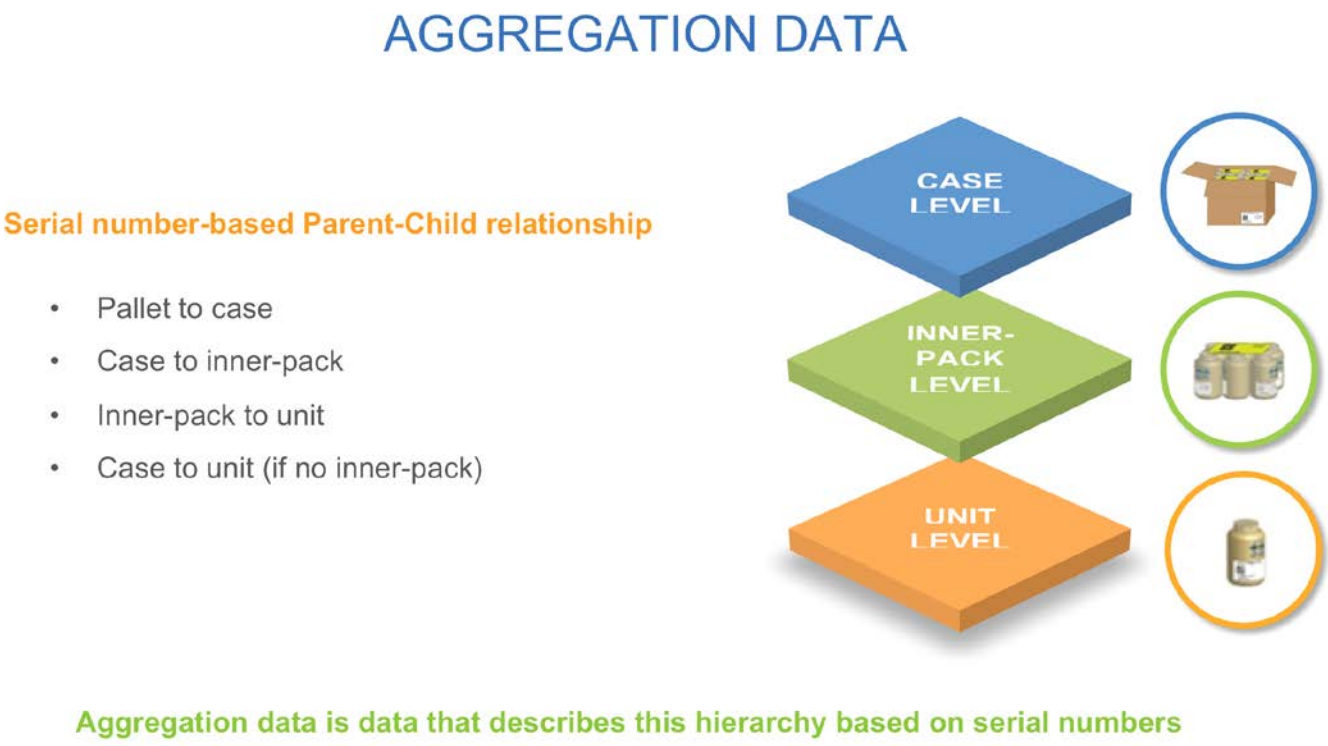
The DSCSA requirement imposed on drug manufacturers, that may require them to produce aggregation data for each shipment, doesn't start until November 27, 2023.

But the big wholesale distributors are demanding aggregation data in 2018 so they can meet their DSCSA-mandated handling of returned drugs in 2019. To drug manufacturers, this is a DSCSA-triggered business requirement.

To continue doing business with these companies, drug manufacturers will need to meet that requirement several years earlier than the DSCSA talks about.

WHAT IS AGGREGATION DATA?

Aggregation data is data that describes containment hierarchy, based on serial numbers. It is the serial number-based, parent-child relationships of the shipping containers, like pallet-to-case, case-to-inner-pack, inner-pack-to-unit, and if there are no inner-packs, case-to-unit.



Aggregation data allows the owner to know which unit-level serial numbers are contained within a given inner-pack, or case, or pallet, without tearing them down, and opening them, and reading each unit. That's important when you need to document which unit-level serial numbers are being shipped, or received—something that will be necessary after November 2023, but will also be helpful to wholesale distributors before that.

The three main phases of the DSCSA, as faced by drug manufacturers, are:

DCSCA "PHASES"

You can see we are currently in:

Phase1 Right now, the DSCSA requires members of the supply chain to exchange lot-based transaction data, but there is no product serialization requirement yet.

Phase 2 starts next November. It will continue to require the exchange of lot-based transaction data, and, it will require all drugs introduced into the supply chain by manufacturers to be serialized. As we all know, that's a huge step for drug manufacturers, and their CMOs.

Finally, phase 3 doesn't begin until November of 2023. That seems like a long way off, but, a lot has to be figured out between now and then. Particularly, how things are going to work in that phase. This phase is the only one that has its own name. The DSCSA calls it, the "Enhanced Drug Distribution Security" phase, or EDDS.

In the EDDS, the DSCSA will require the exchange of serial number-based transaction data, for the first time. That's another big step. And the DSCSA is very vague about how it is supposed to happen. I think we can all expect a bunch of DSCSA-triggered business requirements to come from the wholesale distributors in the next few years, targeting that final phase.

Above is one final example of a DSCSA-triggered business requirement. The orange line shows the extent of the regulatory requirement to exchange lot-based transaction data. It extends right up to November of 2023, which is when the data exchanged must include the unit-level serial numbers. Today's electronic, lot-based transaction data is universally being provided to wholesale distributors in the form of EDI Advance Ship Notices, referred to as ASNs.

The DSCSA-triggered business requirement is for a second, parallel data stream to the big wholesale distributors that starts sometime in 2018. This second data stream is not mandated by the DSCSA, but because the large wholesale distributors are asking for the aggregation data, this is how they expect to receive it. They expect manufacturers to provide that data in the form of GS1 EPCIS events, including Commission, Shipping and Aggregation events.

Only one of the "*Big 3*" wholesale distributors will allow you to switch from lot-based data to a single stream of EPCIS events to carry the DSCSA-mandated transaction data, and the non-mandated aggregation data, prior to 2023. The other two, expect you to keep that data separate. The reason, is that the exchange of the mandated lot-based transaction data is going smoothly at this time, and they don't want to disrupt that, and risk being non-compliant. In that approach, any problems with the EPCIS data stream prior to 2023, does not elevate to a regulatory problem, and drugs can still be distributed.

The need to provide aggregation data to the wholesale distributors early has been discussed a lot over the last year, but not many people are talking about this parallel data stream yet. None-the-less, it is an important detail that must be at the forefront of any solution design.

KEY TAKEAWAYS

Finally, if you are a company in the US Pharma Supply Chain, you need to take action now in order to remain in business in the coming years. Nothing less than your ability to remain in business is at stake. You need to Learn, Plan, and Act.

Study the DSCSA. Study your trading partner and contract partner's requirements or demands. Study the solutions offered by the various vendors… including Systech. Then draw up your list of solution requirements. Put a lot of thought into this step. Anything you forget to include will come back to haunt you later. Invite solution providers to propose solutions that meet your requirements. Please include Systech. Create new SOPs and modify existing SOPs to incorporate serialization requirements.

Then, choose your solution provider. Work with your internal and external stakeholders to align your business around serialization and compliance.

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