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DSCSA Q&A

Top 12 Remaining Questions

Introduction

The inaugural edition of the **Global Drug Supply, Safety and Traceability Report** revealed eye-opening insight into how companies across the supply chain are faring with DSCSA regulations. The report, which includes survey results from 331 respondents plus data from the TraceLink Life Sciences Cloud, shows that DSCSA lot-level compliance was more challenging than expected, and that there's still a long road ahead to prepare for serialization.

In a December 2016 webinar that presented the findings, questions arose from among the hundreds of attendees, underlying a few common themes. Many were basic in nature, further raising concerns about the industry's readiness for a serialized supply chain.

With the November 2017 serialization deadline fast approaching, what are the top remaining questions from pharma companies, wholesale distributors, and hospitals and pharmacies?

The Basics

1. What is T3?

T3 is shorthand for the three types of compliance documentation that must be exchanged with each drug product transaction, under DSCSA lot-level regulations: Transaction History (TH), Transaction Information (TI), and Transaction Statement (TS).

- **Transaction History (TH):** A record of transaction information for each change of ownership within the supply chain, starting with the manufacturer.
- **Transaction Information (TI):** A comprehensive set of details about each product in a transaction, including product name, National Drug Code (NDC) number, strength and dosage form, size and number of containers, lot number, date of transaction, and the names of the companies involved in the transaction.
- **Transaction Statement (TS):** States that trading partners are authorized by law to transfer ownership of the product, have received transaction documentation, have systems in place to comply with verification requirements, and did not knowingly ship suspect product or provide false information.

Trade partners across the supply chain must store T3 documentation for a minimum of six years, and potentially produce it in a tight timeframe upon request. You could be asked to produce T3 as part of an inspection of your business, an investigation into suspect products, or a recall.

Although T3 currently documents lot-level information, it will evolve to include information for each saleable unit as serialization gradually becomes mandatory across the supply chain. By 2023, the electronic exchange of T3 at the unit level will be required for each stakeholder.

2. What is serialization?

Serialization is the assignment of a unique traceable number, or string of numbers and letters, to an individual item. Hundreds of industries utilize unique identifiers, on everything from cars to food to electronics. Within the pharma supply chain, each individual item is defined as the "smallest saleable unit."

For U.S. pharma manufacturers, part of the serialization requirement includes adding a 2D barcode to each saleable unit, containing a variety of mandated data including product identifier, expiry date, and other information.

Companies must also be able to track, report on, and account for each unit's unique data – a far more comprehensive set of tasks than those required for lot-level compliance.

Keep in mind that serialization requirements vary from country to country. If you sell product into a region outside the U.S., you'll need to comply with the mandates of that country.

Global Drug Supply, Safety and Traceability Report Finding:

Although electronic T3 exchange is a requirement for pharma companies by the November 2017 serialization deadline, three-quarters of those who participated in the study say they are still sending at least some paper T3s.

Learn more about regional regulations:

- U.S. DSCSA
- The EU Falsified Medicines Directive
- Other nations' initiatives

3. What is aggregation?

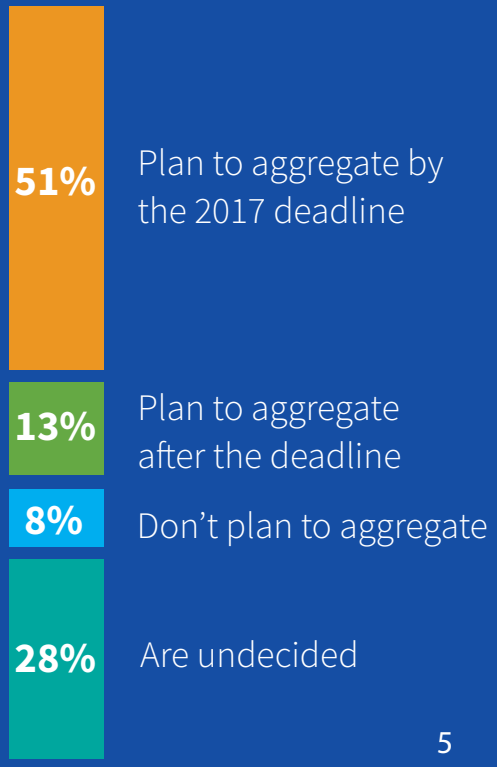
Aggregation is the process of creating a relationship between a single packaging container and all the unique identifiers, or units, inside that container. Let's say you have a case (a packaging container) with its own serial number filled with uniquely identified saleable units (such as bottles, cartons, or syringes). Aggregation relates the smaller units to the larger one they sit within. This is often referred to as a "parent-child" relationship.

Aggregation data is comprised of three elements: the outer container identifier, the identifiers for each inner unit, and the number of units in that container. Depending on the situation, there may be multiple levels in this hierarchy, possibly including shelf packs, bundles, inner packs, shipper cases, and pallets.

Aggregation is not required by DSCSA regulations. However, many wholesale distributors and pharmacy chains prefer aggregation—and will request it from business partners—because it results in operational efficiencies. When serialized product is aggregated, those who receive it don't need to open a case to determine its contents. Instead, they can identify one level of packaging data from the case's barcode, and then infer information about the next level, and so on. This is known as inference. From most wholesalers' perspective, aggregation also improves the information management that must take place for returns and verifications.

Global Drug Supply, Safety and Traceability Report Finding:

Not everyone will aggregate. Of the 101 manufacturers surveyed for the study:



Requirements

4. Is serialization required at the primary package level or the secondary package level?

In the U.S., serialization is required at two levels, at minimum: at the smallest saleable unit (primary) and at the sealed homogenous case level (secondary). As mentioned in question #3, when product is aggregated, each level of packaging hierarchy (e.g. shelf packs, bundles, inner packs) would be serialized as well.

5. Who does the November 2017 requirement apply to?

The November 2017 serialization deadline applies to pharmaceutical companies. By that time, all product from manufacturers must be serialized, meaning identifiable at the smallest saleable unit.

What are the industry's deadlines to meet serialization requirements?
At each of these DSCSA milestones, the listed supply chain participant can only buy and sell fully serialized product.

Pharmaceutical Manufacturers
November 2017

Repackagers
November 2018

Wholesale Distributors
November 2019

Dispensers
November 2020

Types of Companies Affected by Serialization

6. For hospitals, does serialization apply to primarily large institutions or does it also affect small locations like critical access hospitals?

The regulation applies to every hospital, pharmacy, or other organization that dispenses prescription medication to patients, regardless of the organization's size. In fact, a lot-level requirement for all dispensers has been in place since July 2015; if you're not in compliance now, you're already putting your business at risk.

Beyond the current DSCSA requirement, all dispensers must accept only serialized product by the November 2020 deadline. Then, by November 2023, every dispenser will be responsible for participating in an electronic traceability system, in which they must exchange transaction information—down to the smallest saleable unit level—in an electronic, interoperable way.

Global Drug Supply, Safety and Traceability Report Finding:

Questions around the current regulations are not uncommon: **Nearly 30% of hospitals** say they had trouble understanding DSCSA's lot-level requirements.

7. Are intercompany store transfers subject to DSCSA regulation? If multiple stores are owned by one entity, must T3 documentation be exchanged when product moves from one location to another?

DSCSA regulation applies to transactions where drug product changes ownership, not location. That means T3 documentation is not required when moving product between locations that are owned by the same company.

Get more details on how to manage T3 across your organization.

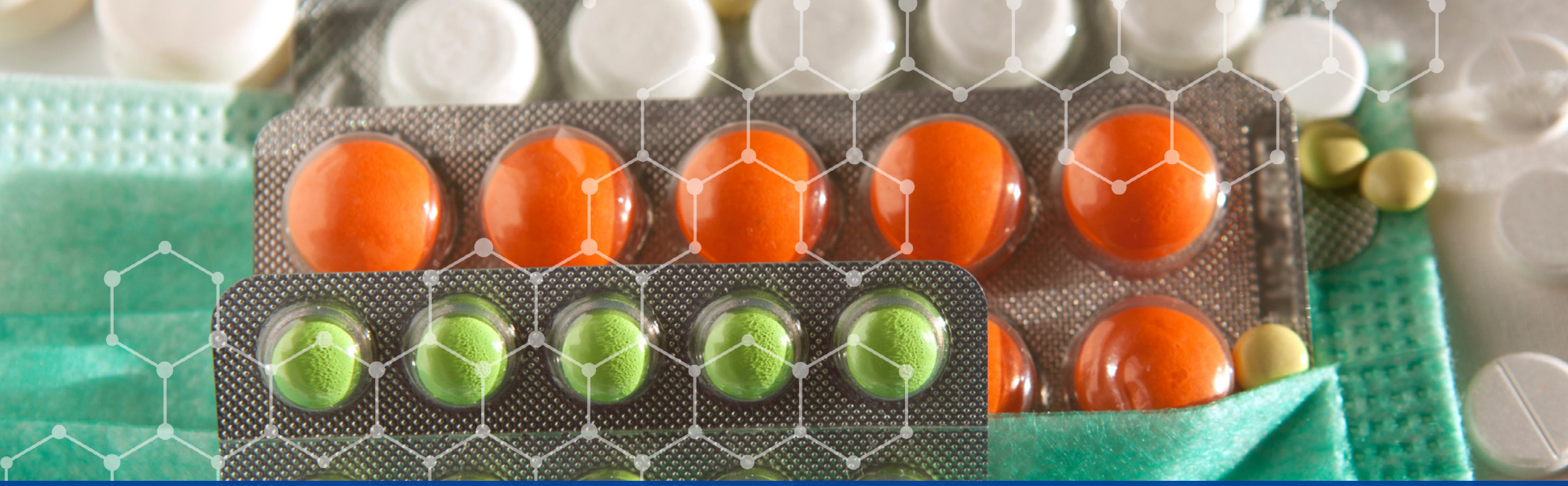
What If?

8. What are the penalties for non-compliance?

Penalties are not detailed within DSCSA. The FDA, state authorities, and other regulatory agencies will determine the penalties for non-compliance. Any one of these agencies might conduct an inspection and impose sanctions, fines, licensure losses, or other consequences for non-compliance. Companies need to be prepared for close scrutiny from multiple regulatory bodies – even now, in the absence of stated penalties.

9. What are some of the business opportunities around serialization?

Having a digitized, itemized supply chain that goes end to end will result in a wealth of benefits for the entire industry. The level of precision, accuracy, integrity, and quality of the supply chain can improve everyone's business – and many are making plans to take advantage of those benefits. One of the most immediate opportunities is improved efficiency, with companies having the ability to manage inventories, recalls, and financial reconciliations at a much more precise level.



Deeper Details

10. Once the November 2017 deadline arrives, what happens to inventory on-hand at a manufacturer that hasn't been shipped or serialized?

The FDA has yet to provide guidance around grandfathering non-serialized product in stock at a pharma company come November 2017. In January 2017, they announced their plans for upcoming DSCSA guidance publications, including one entitled "Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier." It is scheduled to be published some time in 2017.

See the list of 2017 DSCSA-related guidance documents planned by the FDA.

11. Are EPCIS standards expected to evolve further?

GS1 originally developed EPCIS (Electronic Product Code Information System) as an efficient global standard any industry could employ to share massive volumes of data. Up until about mid-2015, some supply chain partners were instead favoring ASN (Advanced Shipping Notice) as a standard, with the plan of serializing ASNs to facilitate data exchange.

However, over the past 18 months, general consensus has shifted toward using EPCIS as the standard to best support DSCSA serialization demands. In 2016, GS1 released a guideline for applying GS1 standards using EPCIS, to meet DSCSA requirements.

TraceLink has participated in multiple revisions of the EPCIS standards and pilot, and we'll continue to be involved in the future.

12. Are there technologies for track and trace that leverage de-centralized, open platforms like Blockchain and Ethereum?

Our industry was working with Blockchain long before others, for an initiative called the Drug Pedigree Messaging Standard (DPMS). It leveraged digital signatures to track the authenticity of the pedigree.

There would be a lot of work to do and challenges to overcome to adopt that type of technology in the industry - but if the industry sought to move in that direction at some point, we have strong expertise with it at TraceLink, and would embrace it. Blockchain is not that dissimilar to a distributor approach, giving everyone visibility into the trace history for a particular item.

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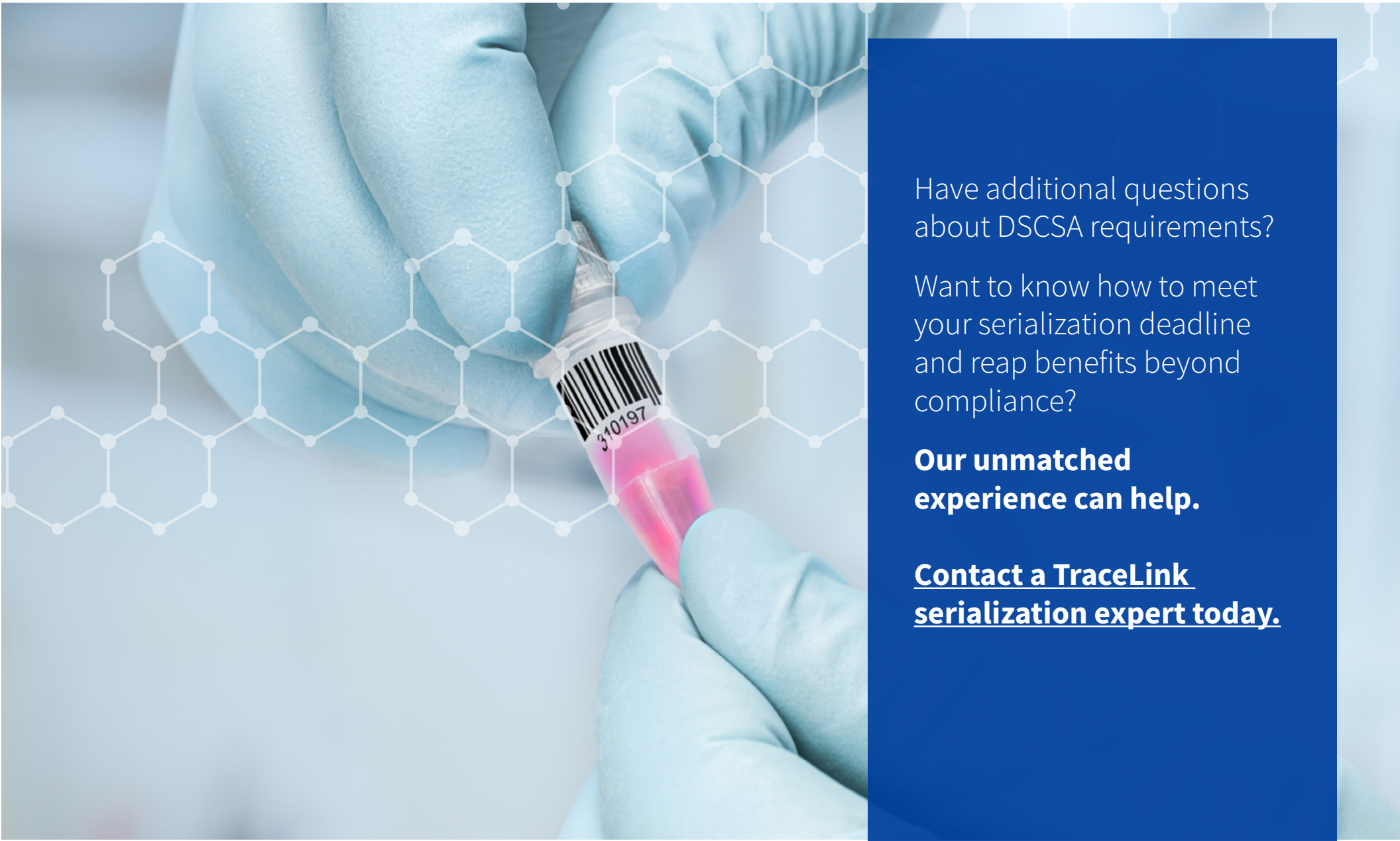

Have additional questions about DSCSA requirements?

Want to know how to meet your serialization deadline and reap benefits beyond compliance?

Our unmatched experience can help.

Contact a TraceLink serialization expert today.