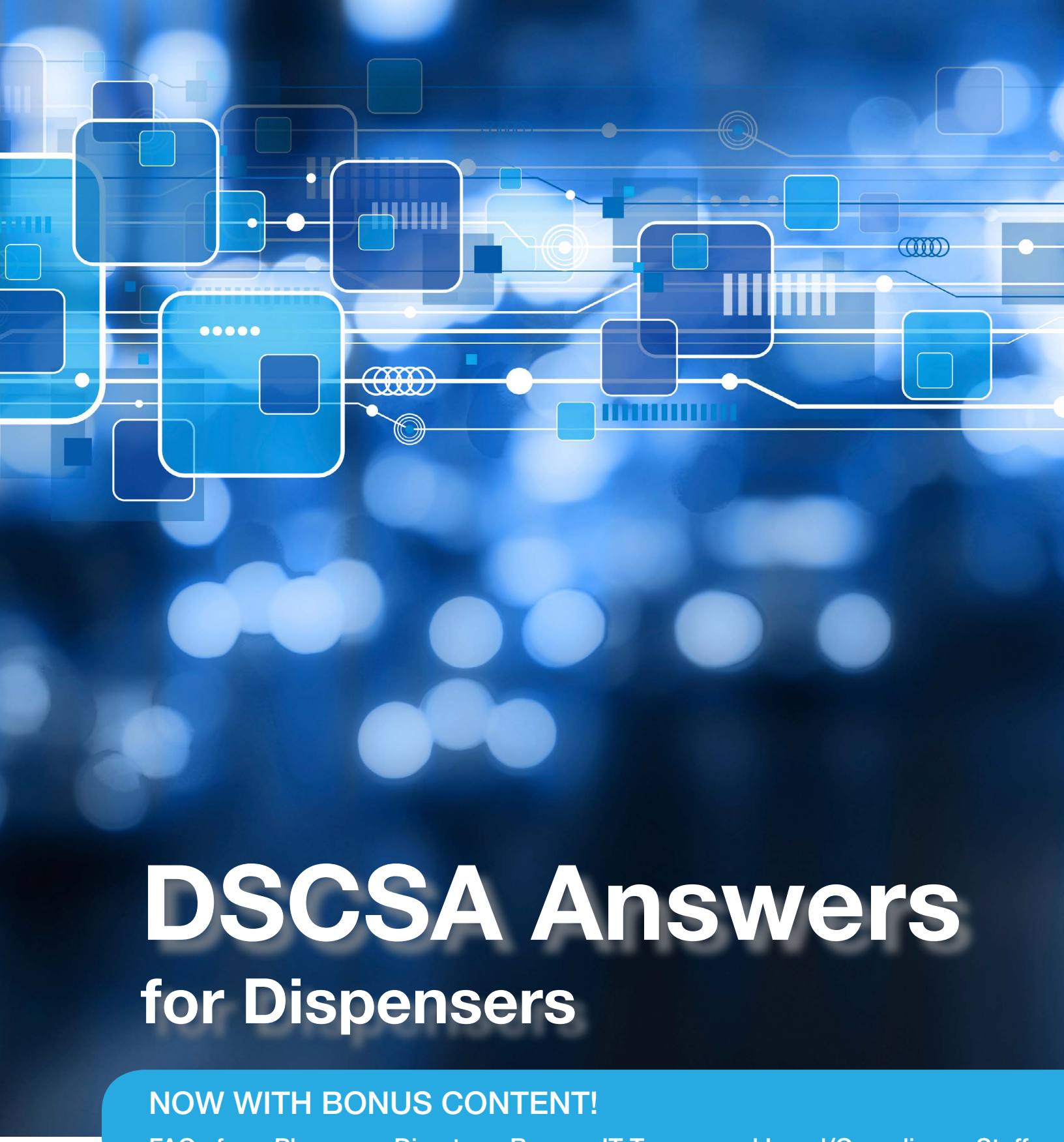

DSCSA Answers

for Dispensers

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FAQs from Pharmacy Directors, Buyers, IT Teams, and Legal/Compliance Staff

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Contents

Introduction to DSCSA

What is DSCSA?

The Drug Supply Chain Security Act, or DSCSA, mandates full supply chain traceability from pharmaceutical manufacturer to pharmacy dispenser for prescription drugs being distributed in the United States. The law was signed by President Obama in November 2013, providing a national standard for drug security and replacing the patchwork of state-level Pedigree regulations that were in place.

DSCSA 2015 Dispenser Requirements

With the July 1, 2015 deadline, the first wave of DSCSA requirements went into effect for dispensers. For all prescription drugs they purchase, dispensers must now receive compliance documentation; archive it for six years; and be prepared to respond to government requests for information or verification.

The compliance data you receive - regulatory, legal documentation that all of your suppliers are required to provide to you - includes the Transaction History, Transaction Information, and Transaction Statement:

- *Transaction History (TH)*: A single document that begins with the manufacturer and includes Transaction Information for each change of ownership. May be electronic or paper until 2017, when manufacturers will be required to use an electronic format.

- *Transaction Information (TI)*: Contains detailed product data, including name, NDC, strength, dosage form, number of containers and size, transfer from and to parties and, in some cases, lot number, transaction date, shipment date, and Wholesaler contact information.

- *Transaction Statement (TS)*: Attests that the parties who have transferred ownership are authorized and registered; received TI/TS from prior owners; did not knowingly ship suspect or illegitimate product or provide false or altered TH; and had systems in place to comply with verification.

New Operational Challenges

DSCSA compliance will impact many parts of your operations, including how you work with trading partners, product receipt, business practices, and documentation and exception management. In this eBook, we'll look at some of the issues dispensers are grappling with as they acclimate to the law's requirements, and how to best approach them in a DSCSA-regulated world.

Do I Need to Enter the Lot Number?

The number one question we hear is “Do I have to enter the lot number?” What does this really mean, what does the law say, and what are the business and compliance implications of whatever decision you make?

Will I receive lot number from my suppliers?

Whether or not you receive lot number depends upon product origin and the role your supplier plays in the supply chain:

- The original manufacturer must include lot number in the T3 documentation they provide to customers.
- However, the wholesale distributor who purchased the product directly from the manufacturer is not required to provide lot number or initial transaction date to their customers. Some may include lot number in their compliance documentation but others will not.
- Subsequent wholesale distributors who purchase product from someone other than the manufacturer are required to provide lot number to their customers.

Whenever lot number is included in compliance documentation, you will store it as part of that documentation. When it is not included, you have a decision to make: should you locate it from another source and manually enter it into your compliance system?

What does the law say?

The law focuses on the circumstances under which you will receive lot number. It makes it optional for wholesale distributors who have purchased product directly from the manufacturer to include it in their outbound compliance documentation. When they do not include it, there is nothing in the law that says dispensers need to enter it from another source.

DSCSA also mandates that you archive T3 documentation for six years and stipulates that if the lot number is provided, you need to capture and archive it along with other data. However, there is no archival requirement for lot number if it has not been sent to you as part of the compliance documentation.

While the law does not require you to enter lot number when it is not sent as part of the T3, there are strong compliance and business reasons to consider it.

Why might it be beneficial for me to enter lot number even when it's not part of the T3?

There are two primary circumstances in which having the lot number will help you streamline your business processes and facilitate compliance:

Reselling product: If you ever resell product you will need to provide T3 compliance documentation, including the lot number, which means you must be able to find the right T3 to match what you are selling. It is much more operationally efficient to capture the lot number and associate it with the compliance documentation on the inbound side, rather than trying to figure out lot number after you have commingled inventory. If you do not capture lot number upon product receipt, can you be confident that you have the correct T3 on the outbound side? If you cannot accurately match product to T3, you will not be compliant.

Responding to an investigation: In the event of a request for information from a government official investigating potentially suspect product, you have two business days to provide compliance documentation. In addition, you could also receive a verification inquiry asking you to verify details about a product's Transaction History and information in your compliance repository.

Without lot number, you will need to manually search all products on your shelves to locate the suspect product whereas if you had consistently captured it on the inbound - whether it was provided to you or not – the search process would be greatly expedited. And without lot number, you may end up having to quarantine all products with the given NDC, which will have an impact on your inventory and potentially on your ability to serve patients.

If I do choose to manually enter lot number that is not included in my T3, where can I source it?

The lot number is printed on the product package in human readable format. Some packing slips will include it, as well.

The bottom line is that the law gives you latitude to decide how you want to handle lot number when it is not part of the compliance documentation. Understand the business and compliance implications of manually entering versus omitting, and make the decision that will best allow your business to remain operationally efficient and in compliance.

Understanding 340B Program Compliance Issues

If your business participates in the 340B Program as a contract pharmacy, you likely have questions about how you will handle DSCSA compliance requirements for 340B products. Because DSCSA does not address the 340B Program at all, there is a lack of clarity around contract pharmacy 340B product responsibilities. The key question is, what are the DSCSA compliance concerns for a contract pharmacy who is receiving medications that they do not own?

Industry associations are reviewing the issue and encouraging the FDA to shed some light on it. There is hope that clarification may, at some point, be written into the law or published through official FDA guidance. Until that time, though, here is some background on the issue and approaches to consider.

The 340B Program and Product Flow

The federal 340B Program facilitates the provision of outpatient medications to eligible health care organizations at reduced prices, easing costs to providers who service government program enrollees.

Typically, the health system administering the program purchases the drugs, which are then shipped by the wholesale distributor to a local contract pharmacy that will dispense them to patients. So the compliance documentation goes one place – to the administering health system that takes ownership of the product – but the product goes elsewhere, to the local contracting pharmacy. These two business entities are typically not under the same ownership.

How will 340B product fit into your overall compliance approach?

Beginning July 1, your pharmacy will follow certain procedures to insure you have the correct compliance documentation for all prescription drugs that you purchase. As a contracting pharmacy receiving 340B product but not the associated compliance documentation, you must think through how you might adapt your receiving process for products that you receive possession of but for which you do not take ownership. You have a decision to make, along with several possible next steps:

Do you want to attempt to verify that the proper DSCSA compliance documentation exists before you accept possession of 340B product?

While verifying the existence of T3 (Transaction History, Information, and Statement) documentation for 340B product is not completely within your control, making the decision that you will attempt to do so may add consistency to your overall compliance approach and business processes, since you will likely be checking for DSCSA documentation received for other product from the same supplier.

It may also minimize potential liability or patient safety concerns. While DSCSA, as commonly interpreted, does not currently hold you accountable for checking the documentation, no pharmacy or clinic wants to dispense product that turns out to be suspect when a documentation check could have helped prevent it.

Can the purchasing health system help with T3 access?

If you decide that your pharmacy will attempt to check for compliance documentation, talk to the purchasing health system. Can they provide access for you? They may enable you to login to their compliance system, allowing you to view T3 for just your specific set of products. Or, they may be willing to accept queries from you, asking if they have received the appropriate T3 for the physical products that you have received.

What about the wholesale distributor?

If the purchasing health system cannot provide access, you can reach out to the wholesale distributor. Some have expressly said that they will not provide compliance documentation access to contract pharmacies that are not legally entitled to it, but others may be willing to work with you.

As industry and FDA conversations develop, TraceLink will provide updates. For now, decide your compliance approach to 340B product, explore T3 access options with your business partners, and talk to your compliance system partner about how they might help once consensus on contract pharmacy requirements emerges.

Managing T3 Access Throughout Your Organization

You may run a standalone corner pharmacy, or a hospital with several primary locations plus dozens of clinics. Regardless of the complexity and breadth of your organization, DSCSA compliance documentation will be needed across multiple processes, by different people, and potentially across many locations. It is critical to insure appropriate access throughout your business. Here are five things to consider as you think through who needs access, where, for what reasons, and how you can best provide it.

1 – Compliance documentation will touch multiple processes

DSCSA compliance documentation will impact many parts of your operations, including:

Product receipt – Whether you are thoroughly comparing compliance documentation against product before you accept the shipment or doing a spot check afterwards, staff will need access to compliance documentation during the receiving process.

Product trading or reselling – If you exchange product with another dispenser that is not part of your larger organization - and is not being sent to fill a prescription for a specified patient - you will need to retrieve the correct compliance documentation for that product and add the required information to the outbound T3 before you ship the product out.

Product verifications or inspections – A government official may query your business, either to verify product involved in a suspect product inquiry or to inspect your overall compliance with the law. In either case, they might ask to see T3 (Transaction History, Statement, and Information) for a specific product; for all products from a given supplier; for all products received during a stated time period, or for some other scenario.

Depending on how your business is configured, these tasks may take place under the same roof or in multiple locations, and they may be managed by 2, 20, or 200 different staff.

2 – The law does not mandate that compliance documentation follow the physical product

Unlike some of the pedigree laws it replaces, DSCSA focuses on change of ownership, not change of possession. Your company may have a central receiving facility where both compliance documentation and product arrive from your suppliers. Down the line, though, you will ship product to different pharmacy locations, clinics, or physician offices.

Or you may share product between two like locations. Either way, by DSCSA regulations, you are not required to send its T3 with the product as long as the facility to which it is going is either owned by you or under the same larger ownership umbrella. Given this, you may very well end up with T3 that lives in one place and product that lives in another.

Requirements aside, there are numerous business reasons to have access to T3 where the product is located. An inspector could show up to inspect drugs in inventory against their compliance documentation. How can you provide compliance documentation access to staff at the product's new location? You could require the first location to find the physical T3 and include it with the shipment. Or you could provide a system that offers both central access and the ability to notate and update product location.

3 – Whether they are under the same roof or far afield, your staff will benefit from individual access to T3

Even when all operations are happening under the same roof, T3 data may not be received or stored in the same spot where relevant business operations and compliance activities take place. In a storefront pharmacy, paper T3 may come in at the receiving dock but whoever is in charge of responding to regulatory inquiries may sit in another part of the building. If that person needs access to T3, do you want them to ask the receiving staff to look it up for them, or enable them to do it themselves?

4 - Giving your staff access to T3 documentation is about more than simply making it available

In its raw format, T3 information is not easily interpretable. Your receiving person may be a pharmacy technician, while the expertise of your outbound staff is shipping procedures. Providing them with a login to look at raw EDI documents will have limited utility.

A compliance system that sits on top of the raw data can provide access in a meaningful way, to help your staff make the decisions they need to make. For instance, when your receiving person is processing a shipment, they will need to figure out if they can take the product into inventory. A good compliance system is built to understand both the regulations and the business context. It can help guide them through each process, prompting them for what information they need to check and removing the burden of having to master all DSCSA compliance details.

5 – Choose a solution that allows your staff to retain their focus on patients, not documentation

A system that can capture compliance data for any product that comes in to any of your locations - and that provides subsequent, flexible access to that T3 anywhere within your organization – can help minimize the business impact of DSCSA. You hired your staff to serve patients. You don't want them to spend time figuring out where the T3 is – you just want them to know that it exists and to be able to quickly find it when they need it. That's what will allow them to do the job you need them to do – taking care of patients – while allowing your organization to be confidently compliant.

Loaning, Bartering, and Donating Product

Are the common practices of loaning, bartering, and donating drugs subject to the law, or do DSCSA requirements only come into play when product is purchased and cash changes hands? Read on to understand what scenarios require compliance documentation and the impact for your business.

What does the law say?

When dispensers hear that DSCSA focuses on change of ownership, they often assume that it pertains only to traditional buying and selling of product. The law is literal, though, and applies to any change of ownership regardless of financial flow unless explicitly exempt.

When a change of ownership occurs, Transaction History, Information, and Statement (T3) compliance documentation must be exchanged unless the transaction is made in the context of an exemption – such as dispensation for a specific patient need – or you are providing product to a facility under common ownership.

What are some typical change of ownership scenarios and associated considerations?

In speaking with thousands of pharmacies, clinics, and hospitals, there are three change of ownership situations they most commonly describe:

Product is sold in exchange for a payment

When you resell product as a dispenser, the law explicitly states that you need to provide compliance documentation. That also means you need to understand – or have a compliance system that understands – what additions need to be made to the T3 on the outbound side based on product origin. For instance, if you purchased from a primary wholesaler, they may not have sent lot number and transaction date but you will be required to provide that information as part of the complete T3 with your outgoing product. If you do resell product or anticipate doing so, you will want to make sure you always enter lot number upon product receipt, whether or not your supplier has provided it.

Dispensers sometimes also sell excess product, potentially at a discounted price, when they know they will not use it during its shelf life. Selling it to another dispenser rather than letting it expire and become a non-saleable return with a limited refund value is all part of good inventory management.

But regardless of the exact cost structure, change of ownership occurs in this situation, also, so you must send T3 with your outbound product.

Product is loaned or bartered, often in exchange for a payment in kind of other drugs

Loaning or bartering occurs most frequently in hospital or clinic settings. When you trade one product in exchange for another, you need to provide the same type of T3 you would if it were a standard sale. It's also important to remember that you need to send and receive T3 during changes of ownership so the product that you receive in a loan or barter relationship must also be accompanied by the appropriate compliance documentation. Otherwise, you cannot legally accept and dispense that product.

With the advent of DSCSA, it's a good idea to evaluate all the barter relationships you have and the context in which they occur. Do your barter partners have a solid compliance approach and understanding of the regulations?

This is an opportunity to evaluate some of your own business processes, too. When product is sent to fulfill a specific patient need, you are exempt from sending T3. But now that you are faced with the prospect of official inquiries and inspections, you will likely want to create an internal record of where that product went.

Product is donated

Under certain circumstances, you may either receive donated product from a wholesale distributor or your business may donate product. In either case, DSCSA requirements must be followed unless a relevant exemption is in place. There are two that pertain to donations that you will want to explore: one related to the distribution of product samples by manufacturers and licensed wholesale distributors; and one charitable exemption that applies when product is going to a non-profit affiliate of the organization.

The bottom line

The issue of whether or not cash changed hands, and how much, is irrelevant when it comes to DSCSA compliance documentation requirements. If a change of ownership took place – by sale, loan, barter, or donation – then T3 must be exchanged.

How to Handle Consignment Inventory

Like many other operations at dispensing organizations, dispensers are taking a fresh look at consignment inventory now that the DSCSA dispenser law is in effect. With consignment inventory, the physical product moves from the wholesale distributor's warehouse to a hospital or pharmacy, but the change of ownership does not immediately occur. In the absence of a traditional sale and clear trigger for the exchange of compliance documentation, what additional processes might you need to put in place in order to support DSCSA compliance?

What, exactly, is consignment inventory?

Consignment inventory, a practice seen across many types of supply chains, is commonly employed in hospital settings and sometimes by pharmacies. Consignment inventory allows a business to take ownership of product at a flexible time, independent of when it takes possession. Sometimes taking ownership is tied to a procedure or actual dispensation, but it can also be triggered by inventory management. It generally gives the dispensing organization the flexibility to take ownership based on when they actually need the medication. Until that point - and sometimes even briefly afterwards - a wholesale distributor still owns the product.

How is consignment inventory used?

Consignment inventory is often part of the managed services a wholesale distributor provides. They will ship product to a pharmacy - hospital or independent - and manage inventory, monitoring product levels and restocking as necessary. They retain ownership of the drugs until they are used. Offering this level of service can be a competitive advantage for the wholesaler.

Another common use for consignment inventory is in hospital settings, where drugs are dispensed during procedures and the exact amount of a medication that will be needed cannot be predicted in advance. Wholesale distributor representatives will sometimes attend these procedures to determine how much product was used and finalize the change of ownership.

What are the compliance implications?

If you work with consignment inventory, here are several things to consider as you develop compliance procedures:

- Consignment inventory may be managed by personnel who do not normally participate in DSCSA processes. For instance, an operating room nurse may pull compliance inventory off the shelf for a procedure, triggering the change of ownership. How will you train these staff to recognize that a change of ownership has occurred and follow up?

- Once you have oriented all personnel to the DSCSA implications, will you give them access to your compliance system, or train them to communicate the change of ownership to your staff that are regularly responsible for DSCSA compliance issues?

- In situations where consignment product is used in procedures, hospitals should think through how they can minimize the time between when the product is dispensed to a patient and when the change of ownership occurs and the appropriate compliance documentation is received. Theoretically, they may want to receive the T3 documentation and verify it before they dispense the drugs to their patient. Their relationship with their wholesaler and their level of established trust will likely come into play.

- On the returns side, consignment inventory actually simplifies procedures. A supplier can take back product without a paperwork exchange if the dispenser realizes they will not be using it.

Just like loaning product, 340B programs, documentation access, and lot number, consignment inventory practices are impacted by the new regulations and need to be reevaluated.

Product Returns and Compliance Documentation

As dispensers acclimate to DSCSA requirements, many are wondering how the law impacts product returns. What are the different types of returns and when do you need to provide Transaction History, Information, and Statement (T3) documentation?

Types of Returns

There are two types of returns: saleable and non-saleable.

Saleable returns

Saleable product which is returned to the originally supplying trade partner is considered a saleable return. Dispensers may return saleable product if they realize that they over-ordered based on expected demand, and want to recoup as much of the cost of the product as possible.

Non-saleable returns

Non-saleable returns include expired product, short shelf life product unlikely to be sold and consumed by expiry date, and damaged product. Non-saleable product may be returned to the original supplier, to the manufacturer, or to a returns processor or reverse distributor that focuses on secure disposal of non-saleable pharmaceuticals. Any of these parties will usually return some value for non-saleable product.

What the Law Says

For dispensers, there is no DSCSA compliance documentation requirement for either saleable or non-saleable product returns.

Operational Impact

Management of returns in general and specifically under DSCSA may impact several operations, so there are a few scenarios and best business practices that you will want to keep in mind:

- As long as you are returning saleable product to the supplier from whom you purchased it, DSCSA does not require you to provide T3 documentation to that supplier as part of any return authorization process you may follow.

However, some dispensers pass excess product along to a different party – like a broker who buys saleable returned product - and still think of it as a return. If you "return" product to a different party, you have in fact sold the product and need to provide the appropriate compliance documentation. By DSCSA regulations, that sale is a wholesale distribution transaction.

- You can return non-saleable product to the manufacturer, repackager, wholesale distributor, or any other party without having to provide T3 documentation.
- Given that you do not need T3 for non-saleable returns, the law also does not mandate that you notate the return transaction within your compliance documentation. But from a business best practices perspective, you may want a record of the fact that you did return the product to a given partner on a given date. That way, if there is ever a patient incident and an associated product recall, you can demonstrate that you returned the product in question, and that the drugs that caused the issue originated from somewhere else and not from your business.
- "Saleable returns" are often defined in slightly different ways between trade partners which may have DSCSA implications. For example, an overage in an ordered shipment leaves the dispenser with excess product. Should the dispenser mark this as an exception, requiring some level of void/reissue of their received DSCSA compliance documentation for the affected product or should they mark it as a saleable return and ship back the excess physical product even though their DSCSA T3 records will be at odds with their physical inventory? Issues like these need to be considered across all of your trade relationships for return scenarios.

Top Product Track Questions from Pharmacy Directors

How long does Product Track implementation take?

Each dispenser or pharmacy is unique and the average time to set-up and "go live" on Product Track depends largely on how quickly you deliver required information to us. Other influencing factors include the number of dispensing locations, the complexity of the supplier network, and the inclusion of downstream trading operations like loaning, bartering, or reselling product. The largest impact to project timelines is typically tied to vendor outreach, but TraceLink has processes in place to minimize this impact.

What information do we need to provide to TraceLink for setup?

During set-up, dispensers need to provide TraceLink with a list of all suppliers from which they purchase prescription drug products. TraceLink will perform a network analysis to determine whether or not those suppliers are already on the TraceLink network. Most will be but if they are not, the dispensers need to provide TraceLink with the supplier's address and DEA and/or DUNS number. Depending on the supplier, additional information may be needed such as account numbers and email IDs.

Is a dedicated employee needed to operate Product Track?

Product Track was created with busy pharmacy directors and employees in mind, and was purpose-built as an "enabling software product." Product Track empowers your pharmacy team to adopt a technology-enabled workflow, allowing you to maintain compliance while preserving valuable time with patients. Once your team is trained on Product Track, they can utilize it to quickly and easily meet core DSCSA requirements. That said, if your product shipment volume and internal workflow are abnormally high or complex, a full-time employee may be needed to manage product master data, transaction verification, and product receipts.

How much does IT need to be involved to use Product Track?

Product Track is a web-based, software-as-a-service (SaaS) application requiring little to no IT involvement on the dispenser side. TraceLink's team of developers and engineers continually maintains and improves the system to lessen the burden on your staff. The only things a dispenser team needs to use Product Track are a web browser and internet connectivity.

Does my pharmacy staff need to check in product every time we receive it, or can we do it in batches?

DSCSA requires that a dispenser receive a transaction history, information and statement for all products for which they acquire ownership. The law does not specify exactly how a dispenser should do this. The important issue is that you make a specific business process determination and risk-based decision for your organization on how you check for compliance. Whether you check in product on a shipment-by-shipment or batch basis is a business workflow decision as opposed to a compliance-based one, and Product Track is equipped to support whatever product receipt process your team adopts. During implementation, the TraceLink Services team will review options with you based on our experience of setting up hundreds of other dispensers.

How often are we required to use the TraceLink software?

The goal for most organizations is to minimize how often you interact with the TraceLink solution. The product receipt workflow that your pharmacy adopts will dictate the primary touch points and frequency of interaction with Product Track. Generally, dispensers use the system when a new Rx product shipment arrives, when they need to search the database for an existing Transaction History (if an inspection occurs, for example), or for the occasional product loan or resale.

How is Product Track priced?

Product Track is both a software solution and an ongoing service. It enables dispensers to achieve compliance and also meet the continuous requirements associated with the Drug Supply Chain Security Act. As such, dispensers that use Product Track are charged two basic fees:

- A one-time cost associated with setting up the system and establishing electronic connections to suppliers.

- A recurring, annual software subscription fee that covers continuous access to the software, data processing and storage of compliance information, and maintenance of electronic supplier connections.

Top Product Track Questions from IT Staff

How will my IT staff engage with TraceLink to set up and operate Product Track?

TraceLink is a "software-as-a-service" (SaaS) application, which means that we securely host the Product Track software and our customers' data on their behalf. By doing so, TraceLink relieves your IT staff of the initial implementation and ongoing software maintenance burden and cost.

Do my existing systems need to be compatible with Product Track?

No. Since Product Track is a SaaS application, the only IT systems or resources your staff will need to access the software are a web browser and an internet connection. Product Track was built to be a very simple setup for both your pharmacy and IT teams.

Which web browsers are compatible with Product Track?

Product Track is compatible with all major web browsers, including Google Chrome, Mozilla Firefox, and Internet Explorer. An exception to this is if the machine is running Windows XP with Internet Explorer 8.

We typically follow an IT Security Review protocol. Who do we work with to complete this process on TraceLink's side?

TraceLink takes security very seriously and has architected our software platform accordingly. During an IT security review, your IT team will work with your TraceLink sales representative as well as our Operations, Compliance, and Information Security departments.

What type of user access capabilities are available?

Product Track offers Admin and Business User access controls, as well as the ability to segment data access by location, enabling your pharmacy staff to govern which users see which Transaction Histories. During the set-up process, your Project Manager will walk through all role options and will train your team on the proper way to modify them as required.

Can we edit user access settings and capabilities on a per user basis?

Yes. Product Track provides flexible user access controls to help your team meet compliance requirements and maintain security.

Do we need to maintain Product Track with regular updates?

No. Since Product Track is a SaaS product, the TraceLink team will handle all maintenance and upgrades. When regulations change or product enhancements are available, TraceLink will update the system for all customers. This allows your pharmacy to effortlessly maintain seamless compliance.

If we stop working with TraceLink, how can we retrieve our data?

TraceLink values our pharmacy partners and will work hard to meet your compliance needs. If you do need to terminate the relationship for some reason, though, you will be able to download your data from Product Track and take it with you.

Top Product Track Questions from Pharmacy Buyers

How many suppliers can we connect with?

The number of suppliers that you can connect with depends on the Product Track configuration your team selects. For certain programs TraceLink offers - including the one for independent pharmacies - you can connect with up to 15 suppliers, and additional ones can be added for a small surcharge. For other configurations, supplier connections are unlimited.

What if one of my suppliers is not a TraceLink customer or is not a supplier with whom you share an electronic connection?

When you become a TraceLink customer, we commit to establishing electronic connections with all of your suppliers, regardless of whether we have an existing relationship or connection with them. The only exception to this occurs when a supplier is either unwilling or unable to work with us to establish an electronic data connection. In those cases, TraceLink may not be able to set up the connection.

If I want to add suppliers in the future will there be additional costs?

If you purchased Product Track through the online dispenser program which limits your supplier connections to a total of 15, you will need to reach out to TraceLink to request additional suppliers. If you have unlimited connections, you can notify your IPM if the project is still in the pre-go-live phase or you can send your additional supplier list to a specific email address which will be provided to you post-go-live.

How much training will we receive on your product?

During the implementation process, your TraceLink Implementation Project Manager will provide you with a dispenser-specific link for online learning so you can get trained up on Product Track. In some cases, online live training sessions are provided, as well.

What is the difference between a TraceLink customer and Network Partner?

The major difference between a TraceLink customer and a Network Partner is access to compliance documentation. TraceLink customers can connect with each of their suppliers through Product Track, storing all compliance data in this one central repository and easily archiving the data for the 6-year period required by law.

Conversely, Network Partners work with one or more suppliers that already contract with TraceLink for DSCSA services, and through their supplier's TraceLink portal, a Network Partner can access only documentation for products purchased from those suppliers. Network Partners need to access documentation from other suppliers through multiple separate portals or by some other means, and have no centralized way of viewing or searching all compliance documentation.

How does TraceLink support emerging Rx products in the market?

TraceLink accesses Product Master Data configured by the dispenser as well as a third party database from Truven RedBook TM . TraceLink is adding an additional third party database to maximize the timeliness and availability of Product Master Data.

Does TraceLink have existing relationships with Group Purchasing Organizations (GPOs)? Which ones?

TraceLink has active relationships with many national and regional GPOs. The TraceLink-GPO partnerships typically offer group members preferred pricing and standardized terms of service to speed up the contracting process. To find out which GPOs TraceLink works with, contact us at dispensers@tracelink.com.

Can my pharmacy purchase Product Track directly, or do we have to work through a GPO relationship?

TraceLink works directly with pharmacies, hospitals, and other dispensers to determine the right configuration for their pharmacy operation.

Top Product Track Questions from Legal & Compliance Teams

Does Product Track capture any patient-specific data? Should I be concerned about HIPAA requirements when using it?

DSCSA's product tracing requirements cover dispenser receipt of compliance documentation from suppliers, but do not require any transmission of data related to the patients receiving the medications. Because of this, Product Track does not collect any patient-centric data so there are no related HIPAA concerns.

Does your system capture any financial information?

No. Product Track has no access to financial information related to product purchases. The system processes only supply chain data associated with the transfer of product ownership, which does not include financial information.

Why do TraceLink's Terms of Service provide for the collection and use of "aggregated, anonymous data" by TraceLink?

TraceLink's development, operations, and engineering teams use aggregated, non-identifiable data from the system to continually improve our product for customers. Analyzing this data allows us to design and share product enhancements with you at no additional charge. Because security is our highest priority, we never use identifiable data for any of these purposes.

Can TraceLink data be shared with any of our partners? For example, with our external buyers with whom we loan, borrow, or resell product?

In certain situations, it may be possible for Product Track users to share data with a partner with whom you want to provide secure access. In addition, Product Track can be set up to provide access to downstream trading partners to whom you resell or loan product. These scenarios should be discussed with your TraceLink team during contracting and implementation so that you choose the system configuration that best fits your needs.

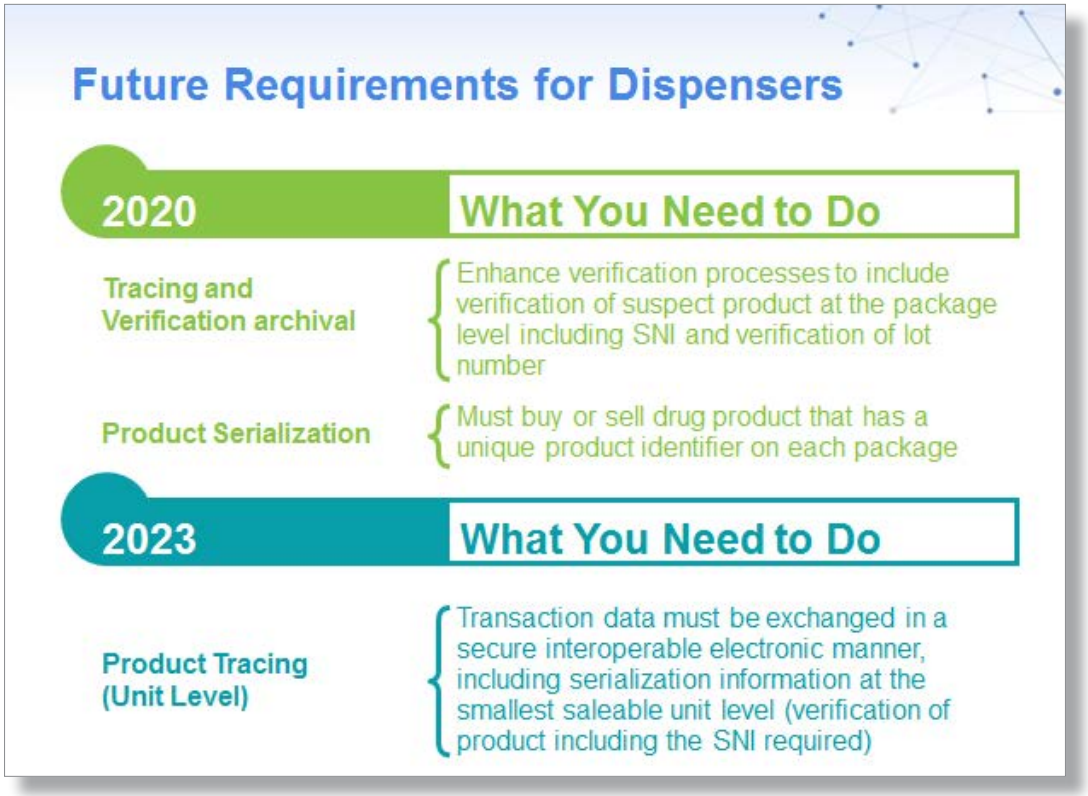
Future Requirements and Next Steps

Future Requirements

DSCSA regulations change over time. For that reason, it's important to understand the full set of requirements so that you can select a solution that will meet your short and long-term needs.

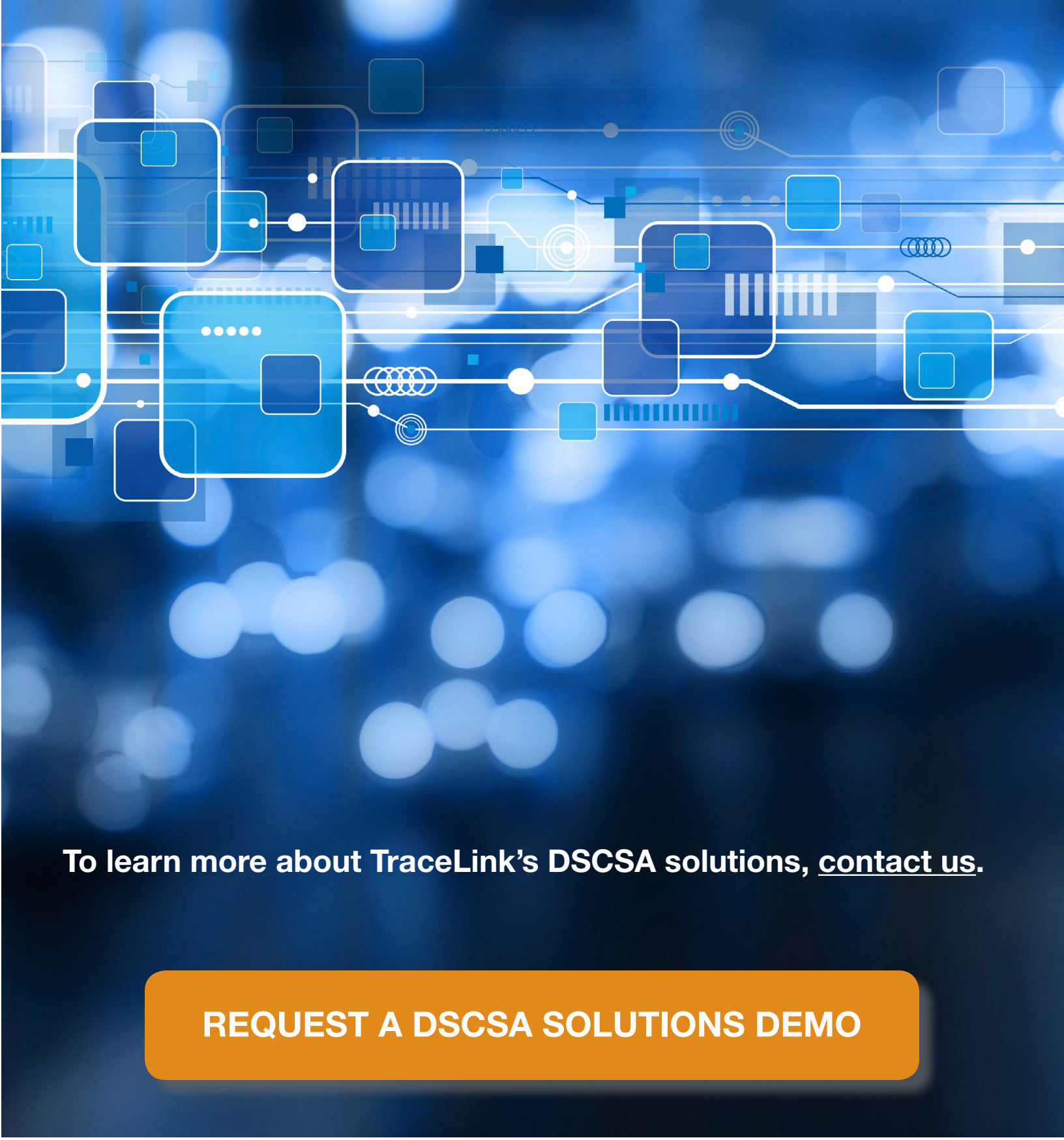
In 2020, dispensers will be required to purchase serialized product. With serialization, each individual saleable unit will have a unique serial number on it and the packaging will have a 2D barcode that's scannable. Each product in a particular lot will be unique from each other, whereas 2015 requirements focused on lot level traceability. Beginning in 2020, you will need to verify that all the products you purchase are serialized. You will also need to archive that serialization data in your repository, because the tracing and the verification requirements expand a bit. Government officials can now ask for documentation around that serial number as well.

Lastly, in 2023, the Transaction History, Information and Statement will need to be managed at the unit rather than the lot level, meaning that information on all of the serial numbers will need to be on that compliance documentation as well. From a data perspective, the volume of information that you will need to manage and store will grow substantially when serialization comes into play.



Next Steps

If you still don't have a compliance platform to help you manage DSCSA, the time to choose one is now. The right solution provider should easily meet your 2015, 2020, and 2023 compliance needs; offer regulatory expertise to help guide you as the requirements change; simplify compliance with one central repository and approach, regardless of how many suppliers you have; and, ultimately, keep your focus where it should be – on caring for your patients. To learn more about Product Track for Dispensers from Tracelink, contact us.



To learn more about TraceLink's DSCSA solutions, contact us.

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