

DSCSA Needs Assessment TIP SHEET

Tips for assessing your Drug Supply Chain Security Act Needs

With the Drug Supply Chain Security Act (DSCSA) fully deployed and being enforced, all pharmacies should have a Track & Trace system in place. The complexities of DSCSA compliance dictate specific elements, but beyond those requirements, it is important to find a Track & Trace solution that best fits your organization's needs, is cost-effective and helps your organization run a top efficiently.

Here are 5 important factors to consider when choosing your DSCSA solution:

Flexibility

Your business is unique in many ways, and a compliance solution that fits your business saves time and money. The right Track & Trace system must be built on a dynamic workflow platform, making it flexible enough to respond to best practice applications. It also automates the process of recording all events, such as accepting transactions, conducting investigation on suspect products and maintaining documentation that Standard Operating Procedures (SOPs) were followed.

This covers the standard workflow for Track & Trace management, but a system that also has the ability to adjust these processes to suit your preference will save you time and money. Some software systems are built on a generic best-practices approach that can only be changed with additional time and cost. This means that the business process you've spent years perfecting have to be discarded and you have to implement a new process—and train your employees on that process. And while the cost of making these changes to adapt to your system can eventually outweigh the initial cost of the system, the cost of not implementing SOPs to comply with Track & Trace laws can put you out of business.

Scalability

When looking into Track & Trace systems for your organization, consider the scalability of the system to support future growth—and to ultimately ensure that you never outgrow the system. To determine whether a software system is truly scalable, consider the following:

- **Long term goals**—can the software system grow to accommodate additional business users and locations?
- **Location-based administration**—can the system be configured to filter and manage location-specific data

In addition to being easily scalable, a successful solution allows for the seamless addition of enhancements to the software—allowing software features and functionality to be expanded as necessary to encompass the needs of additional employees and locations.

Visibility

There is often so much data coming into the Track & Trace system that proper visibility into this data becomes difficult. However, visibility is an integral part of fostering change within your organization. The right Track & Trace system sets out to ensure this, simplifying the process of reporting by automating it for you. Using reporting tools, you can export data on-demand, run reports with drill-down capabilities, report on user based actions or events and create a report on your complete transaction history in minutes. These capabilities increase visibility throughout all

areas of your business, including multiple locations if you have multiple stores associated to an account, ensuring that you see have insight into anything that needs improvement.

Cloud Deployment

The most cost-effective way to deliver compliance is with a system referred to as SaaS -Software as a Service. The software application as well as all data is stored on the cloud, a Web-based location for all processes and documents, easy to access and requiring no on-site equipment to purchase or maintain. A dedicated cloud-based solution provides you with your own section of the cloud—no need to share with other “tenants.” The dedicated solution also allows you to scale your solution as needed - the bandwidth is unlimited.

Cloud-based systems provide a secure environment for your data, as no one has access to your data except you and your chosen personnel. Further, you can access your system through managed firewalls to mitigate security concerns. Redundancies and daily backups keep your data protected. SaaS is ultimately a low maintenance approach to deploying a Track & Trace system—the cloud saves you the cost of traditional deployment methods, without sacrificing the system’s value or security.

Built-in Processes

Ideally, a software solution provides integrated, built-in processes to streamline business processes and eliminate manual processes.

- **Compliance SOPs:** DSCSA requires pharmacies to have Standard Operating Procedures (SOP) for handling transactions that do not conform to the order: there must be a process in place to determine if the product is suspect. Having a compliance module built into your software system streamlines handling these types of transactions, ensuring consistency and accuracy, and providing visibility that could uncover any systemic issues throughout your enterprise, regardless of location.
- **Corrective Action:** The ability to resolve suspect products issues helps identify, mitigate and reduce the chance of harmful products being dispensed to customers and reduce the recurrence of these events. A successful Track & Trace system enables this and provides your organization with visibility into critical events, allowing you to correct any event.
- **Risk Management:** In FDA regulated organizations, efficiently managing risk ranks high in priority. Having a system in place to reinforce best practices and reduce the risk of dispensing harmful products decreases an organization’s exposure to violations, lawsuits, loss of licensure and loss of business. By using a Track & Trace system, risk is managed. Events are recorded at all points in the transaction history, corrective actions/resolutions to track suspect products are documented, along with events that took place to ensure that the corrective actions are made and issues are resolved.

The right Track & Trace software simplifies your organization’s day-to-day processes, saving time and resources, embedding standard operating procedures and processes such as corrective action, issue resolution, compliance and more. Automation provides a standardized, consistent method of conducting these processes, and the system’s ability to scale accommodates the addition of new locations as well as changes to the law and new regulations.



This DSCSA eLearning Resource is provided by InfiTrak

InfiTrak is a cloud-based software solution designed from the point of view of the dispenser - and independent pharmacies in particular. The result is a cost-effective, easy to use software designed to save time and money, increase productivity, ensure full compliance, and provide the peace of mind that comes from knowing that all of your data is at your fingertips, when you need it.

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