



CERVEY[®]

POLICIES & PROCEDURES: THE KEY TO DSCSA COMPLIANCE READINESS

WEBINAR

New Staggered for the Industry

- FDA released guidance in October 2024 that outlined a phased approach.
- Dispensers that do not qualify as a “Small Dispenser” have a deadline of November 27th, 2025, to be fully compliant.
- Dispensers should use this time to develop Policies and Procedures/ Standard Operating Procedure (SOP) documentation.



Steps Your Pharmacy Should Take Before November 27th, 2025

- Develop SOPs for your hospital/ pharmacy and utilize them to establish the day-to-day workflow for your users.
- Verify that you are receiving EPCIS data for all purchases and notify Cervey of any new connections that need to be set up.
- Add all locations within your organization that purchase products from outside vendors.



Why Do We Need SOPs?

- During an audit, an auditor may ask to see your SOPs for DSCSA.
- SOPs ensure that your pharmacy follows specific procedures to handle all DSCSA scenarios.
- SOPs also ensure all users follow the same steps. This can help in training new users.



Key Considerations for Your SOPs

- Develop SOPs that are specific to your Pharmacy.
- Consider your specific workflow and environment
 - For example, Quarantining a product.
- Templates are a great place to start, but you will need to add details to ensure the SOPs are complete.



Available Tools to Help You Develop Your SOPs

- Cervey offers assistance in SOP development including:
 - A comprehensive template to provide your pharmacy with a compliance blueprint.
 - A one-on-one support call to tailor your SOP to your specific pharmacy
- Cervey will also help guide you in developing your SOP template, even if you do not use our template, by providing guidance around the DSCSA topics you need more clarification on.



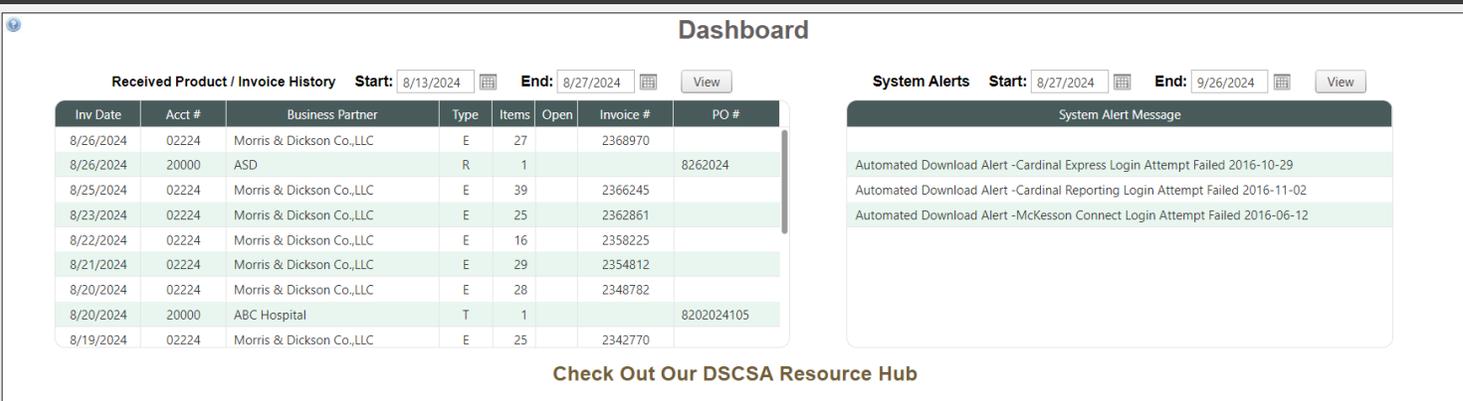
Available Resources

- **Title II of DQSA:** <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act>
- **Guidance for Delay in Enforcement:** <https://www.fda.gov/media/182584/download>
- **GS1 Website on How to Obtain GLN:** <https://www.gs1us.org/industries-and-insights/standards/global-location-number/get-a-global-location-number>
- **Cervey Support Email:** trackandtracesupport@cervey.com



Navigating to Cervey's Resource Hub

- To find the recording of today's webinar along with other DSCSA information, log in to Cervey's Tracker application and go to the Dashboard page.



The screenshot displays the Cervey Tracker Dashboard. It features two main sections: 'Received Product / Invoice History' and 'System Alerts'. The 'Received Product / Invoice History' section includes a table with columns for Inv Date, Acct #, Business Partner, Type, Items, Open, Invoice #, and PO #. The 'System Alerts' section displays a list of alerts, including 'Automated Download Alert -Cardinal Express Login Attempt Failed 2016-10-29', 'Automated Download Alert -Cardinal Reporting Login Attempt Failed 2016-11-02', and 'Automated Download Alert -McKesson Connect Login Attempt Failed 2016-06-12'. A gold-colored link 'Check Out Our DSCSA Resource Hub' is centered at the bottom of the dashboard.

Inv Date	Acct #	Business Partner	Type	Items	Open	Invoice #	PO #
8/26/2024	02224	Morris & Dickson Co.,LLC	E	27		2368970	
8/26/2024	20000	ASD	R	1			8262024
8/25/2024	02224	Morris & Dickson Co.,LLC	E	39		2366245	
8/23/2024	02224	Morris & Dickson Co.,LLC	E	25		2362861	
8/22/2024	02224	Morris & Dickson Co.,LLC	E	16		2358225	
8/21/2024	02224	Morris & Dickson Co.,LLC	E	29		2354812	
8/20/2024	02224	Morris & Dickson Co.,LLC	E	28		2348782	
8/20/2024	20000	ABC Hospital	T	1			8202024105
8/19/2024	02224	Morris & Dickson Co.,LLC	E	25		2342770	

[Check Out Our DSCSA Resource Hub](#)

- Click the gold text in the center of your screen to go to Cervey's Resource Hub.



The background is a solid yellow color with a pattern of white circles of various sizes scattered across it. The circles are semi-transparent and vary in diameter, creating a bokeh-like effect. The text "Questions?" is centered in the middle of the image.

Questions?

A woman with curly hair, wearing a white lab coat over a light blue shirt, is looking at a tablet computer. She is standing in a pharmacy or laboratory, with shelves of medicine boxes visible in the background. Another person in a white lab coat is partially visible in the background, also working. The overall scene is dimly lit with a blueish tint.

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THANK YOU!