



FDA DSCSA EXEMPTIONS: WHAT'S NEXT FOR COMPLIANCE?

WEBINAR

New Deadlines for the Industry

- The FDA released guidance that outlined one final extension for the industry to be ready for the enhanced requirements. The plan is for a phased approach that allows the new EPCIS data to flow downstream.
- The extension only applies to those that have made reasonable efforts to be ready for the 2024 deadline. Cervey is still on track to be close to 100% ready by this November. Today, we are receiving data from all 4 major wholesalers as well as some manufacturers. We have also made contact with all manufacturers that our customers order from to move forward with establishing the EPCIS connections.



New Deadlines for the Industry - Manufacturers

- Starting May 27th, 2025, Manufacturers will be required to produce an EPCIS file that corresponds to each package they create. Each package will also have a 2D barcode that represents the serial number.
- Each time that package changes ownership (sold to wholesaler, dispenser, etc.) the EPCIS file will also need to be exchanged.
- Selling a product without EPCIS data could result in non-compliance. Manufacturers will be required to send the EPCIS data when products are sold.



New Deadlines for the Industry - Wholesalers

- Starting August 27th, 2025, Wholesalers will be required to receive EPCIS data from Manufacturers and send EPCIS data when selling product.
- Today, Wholesalers are providing the EPCIS data that they currently receive from Manufacturers. The phased approach allows Wholesalers time to confirm their connections and understand industry standards.
- The extension also allows wholesalers to better understand industry standards around drop-shipping, order aggregation (SSCC labels), and 340B orders.



New Deadlines for the Industry - Dispensers

- Dispensers with more than 25 full time pharmacists + techs will be required to be able to receive and send EPCIS data by November 27th, 2025.
- Dispensers with less than 25 full time pharmacists + techs will be required to be able to receive and send EPCIS data by November 27th, 2026.
- The extension allows downstream partners such as hospitals and pharmacies time to establish all connections and better understand industry standards.



Steps to Take Before November 27th, 2024

- Please submit your vendor request form to Cervey to allow us to establish all EPCIS connections for your location.
- Verify all users have access to the software and schedule training as needed.
- Identify all locations within your organization that order products
- Identify any potential trading partners that you would sell to/ replenish (ex. 340B, borrow and loan)



Steps to 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.



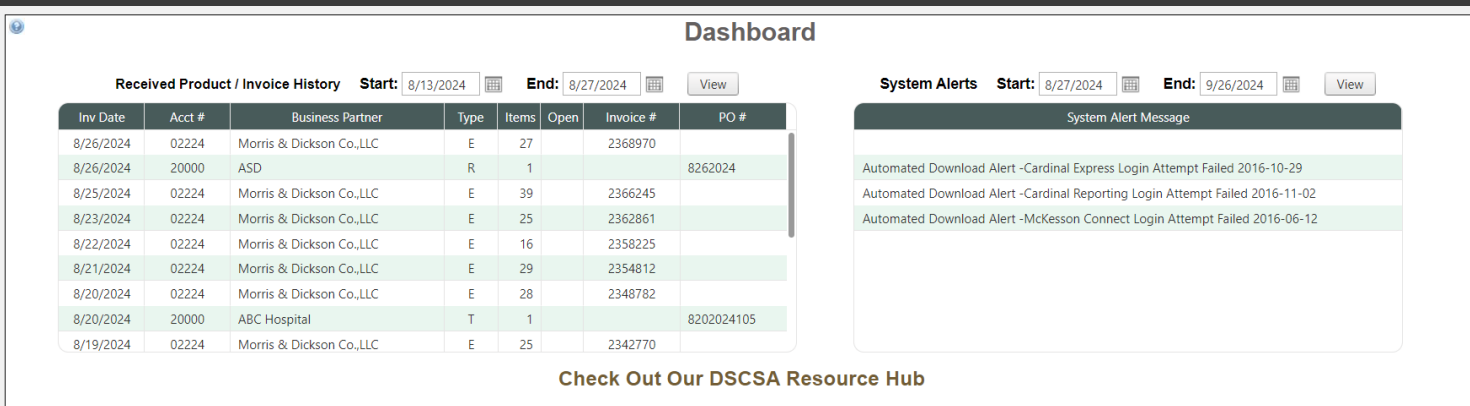
Available Resources

- **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 text 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 in a white, sans-serif font.

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!