

DSCSA Track & Trace

Proactive Preparedness: Ensure Readiness
for DSCSA Enhanced Guideline
Enforcement

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Agenda

- DSCSA Enhanced Requirements Enforcement starts November 27, 2024
- What steps Buyers should be taking today
- How Cervey helps you manage the new requirements
- Resources Available to you
- Q&A



DSCSA Enhanced Requirements Enforcement starts November 27, 2024

- The deadline to have interoperable traceability is November 27, 2024.
- Buyers must be able to receive and validate serialized data for all products purchased.



What steps Buyers should be taking today

- Ensure you have a solution provider that can receive and transmit EPCIS data for all eligible transactions from your pharmacy or hospital system.
- Contact your GPO or GS1 to obtain GLN registration information for all pharmacy locations and provide information to your solution provider.
- Contact your primary distributor and direct suppliers and obtain information regarding their 2024 plans to provide enhanced product tracing data (EPCIS-level data).
- Develop Policies and Procedures around DSCSA.



How Cervey helps you manage the new requirements

- Validate product and data match
- Receive serialized EPCIS data in an interoperable manner
- Track borrow and loan transactions with Authorized Trading Partners (ATPs)
- Manage EPCIS errors and exceptions
- Navigate and manage data with simplified reporting
- Easily quarantine product and auto-populate Form 3911
- Optimize drug recall identification and processing
- Streamline expired drug management
- Harness scanning technology for product information, receiving and verification
- Access seamless API integration
- Policies & Procedures Template

How Cervey helps you manage the new requirements - Product Validation

- Using Cervey's Verification tool is simple - just scan the product 2D barcode and validate the information is complete and accurate.

Verification

Scan

LIDOCAINE HCL 1% 50 MG/5 ML VL					
NDC #	55150-0162-05	Package Size	5	Form	VIA
Serial #	6KGSHP57RTZZ4M	Strength	10 mg/mL (1 %)	Lot #	3LC222
Expires	08/31/2025	Days till Expiration	474	Recall Count #	0
Buyer	COUNTY HOSPITAL	Seller	Morris & Dickson Co.,LLC	Mfg	AUROMEDICS-EUGI
Cost	<input type="text" value="150.00"/>	AWP	<input type="text" value="150.00"/>	Quantity	7
Invoice #	8968105	PO Number		Hazardous	
Verify Status		Quarantine Status		Return Status	
Scan Info:	Scanned by Demo2@dqsatrackit.com on 05/14/2024				

Change Verify StatusQuarantine ItemChange Return StatusSave Item Prices



How Cervey helps you manage the new requirements - Product Validation

- In addition to scanning individual items, users can scan boxes from wholesalers to verify information for all packages within the box.

Verification

Scan

Box Items

■	V	H	R	Q	Scanned By / Date	NDC #	Serial #	Lot #	Description / Manufacturer	Strength	Form	Pkg	Qty	Exp Date	ED	Buyer / Seller	Invoice #	PO #	C
<input type="checkbox"/>				🔒		55150016205	K6TTKGFMXEAESS0	3LC22191	LIDOCAINE HCL 1% 50 MG/5 ML VIAL AUM	10 mg/mL (1 %)	VIA	5	3	06/30/2025	412	COUNTY HOSPITAL Morris & Dickson Co.,LLC	8968105		15.0
<input type="checkbox"/>				🔒		55150016205	NK0X8CHFPPK78ZZ	3LC22191	LIDOCAINE HCL 1% 50 MG/5 ML VIAL AUM	10 mg/mL (1 %)	VIA	5	3	06/30/2025	412	COUNTY HOSPITAL Morris & Dickson Co.,LLC	8968105		15.0
<input type="checkbox"/>				🔒		55150016205	60G36K9Y2F1A3PK	3LC22237	LIDOCAINE HCL 1% 50 MG/5 ML VIAL AUM	10 mg/mL (1 %)	VIA	5	7	08/31/2025	474	COUNTY HOSPITAL Morris & Dickson Co.,LLC	8968105		150
<input type="checkbox"/>				🔒	Demo2@dgsatrackit.com 05/14/2024	55150016205	6KGSHP57RTZZ4M	3LC22237	LIDOCAINE HCL 1% 50 MG/5 ML VIAL AUM	10 mg/mL (1 %)	VIA	5	7	08/31/2025	474	COUNTY HOSPITAL Morris & Dickson Co.,LLC	8968105		150
<input type="checkbox"/>				🔒		55150016205	81XS822SRXTE200	3LC22237	LIDOCAINE HCL 1% 50 MG/5 ML VIAL AUM	10 mg/mL (1 %)	VIA	5	7	08/31/2025	474	COUNTY HOSPITAL Morris & Dickson Co.,LLC	8968105		150
<input type="checkbox"/>				🔒		55150016205	E56NNOGPEEK17N3	3LC22237	LIDOCAINE HCL 1% 50 MG/5 ML VIAL AUM	10 mg/mL (1 %)	VIA	5	7	08/31/2025	474	COUNTY HOSPITAL Morris & Dickson Co.,LLC	8968105		150
<input type="checkbox"/>				🔒		55150016205	P487CPAC6Z8F04	3LC22237	LIDOCAINE HCL 1% 50 MG/5 ML VIAL AUM	10 mg/mL (1 %)	VIA	5	7	08/31/2025	474	COUNTY HOSPITAL Morris & Dickson Co.,LLC	8968105		150
<input type="checkbox"/>				🔒		55150016205	PRK4SS3YNM23RZC	3LC22237	LIDOCAINE HCL 1% 50 MG/5 ML VIAL AUM	10 mg/mL (1 %)	VIA	5	7	08/31/2025	474	COUNTY HOSPITAL Morris & Dickson Co.,LLC	8968105		150
<input type="checkbox"/>				🔒		55150016205	X434512X97445A8	3LC22237	LIDOCAINE HCL 1% 50 MG/5 ML VIAL AUM	10 mg/mL (1 %)	VIA	5	7	08/31/2025	474	COUNTY HOSPITAL Morris & Dickson Co.,LLC	8968105		150
<input type="checkbox"/>				🔒		00904637061	42080475639971	T04152	AMLODIPINE BESYLATE 5 MG TAB MAJ	5 mg	TAB	100	1	02/29/2024	75	COUNTY HOSPITAL Morris & Dickson Co.,LLC	8968105		7.76
<input type="checkbox"/>				🔒		00143978410	10000320828851	2102180.1	FLUMAZENIL 0.5 MG/5 ML VIAL WWI	0.1 mg/mL	VIA	5	1	10/31/2024	170	COUNTY HOSPITAL Morris & Dickson Co.,LLC	8968105		63.7
<input type="checkbox"/>				🔒		68084009801	346896	1009372	ATORVASTATIN 20 MG TABLET AHP	20 mg	TAB	100	1	07/31/2024	78	COUNTY HOSPITAL Morris & Dickson Co.,LLC	8968105		44.1
<input type="checkbox"/>				🔒		00904630161	42073320722916	T04380	CARVEDILOL 6.25 MG TABLET	6.25 mg	TAB	100	1	12/31/2023	125	COUNTY HOSPITAL	8968105		8.10



How Cervey helps you manage the new requirements - Recall Management

- Recall Management tools to help identify products received that are under a recall.

Recall Search

NDC: Only Items Received in Date Range: Start: 11/16/2023 End: 5/14/2024

LOT NUMBER AVAILABILITY
 Lot number data availability is not complete. Data availability will be limited until we get closer to November 2024.

Recalls								
NDC #	Description	Mfg	Recall Date	Lot Number(s)	Reason	Level	Active	Source
55111-0320-05	GLIMEPIRIDE TAB 1 MG 500	DRREDDY	2024.01.23	T2303609,T2303610	Product complaint stated that they discovered 2-3 pills in the 1mg bottles with different markings.	Wholesale		
47335-0639-83	LURASIDONE HCL TAB 60MG	SUN	2024.01.23	DNE0620A	Microbial contamination in stagnant water found in the duct of the manufacturing equipment.	Retail	Y	
47335-0579-83	LURASIDONE HCL TAB 120MG	SUN	2024.01.23	DNE0621A,DNE0815A	Microbial contamination in stagnant water found in the duct of the manufacturing equipment.	Retail	Y	
47335-0307-88	ZOLPIDEM ER TAB 6.25MG 1	SUN	2024.01.23	DNE0892A	Microbial contamination in stagnant water found in the duct of the manufacturing equipment.	Retail	Y	
55111-0320-01	GLIMEPIRIDE TAB 1 MG 100	DRREDDY	2024.01.23	T2303622,T2303626,T2303627,T2303628,T2303629	Product complaint stated that they discovered 2-3 pills in the 1mg bottles with different markings.	Wholesale		
47335-0308-88	ZOLPIDEM ER TAB 12.5MG 10	SUN	2024.01.23	DNE0893A	Microbial contamination in stagnant water found in the duct of the manufacturing equipment.	Retail	Y	
60687-0575-21	RIFAMPIN CAP 150 MG 30UD	AHP	2024.01.18	1008111	Due to out of specification result observed in assay testing of affected lots and related substance testing (N-Methyl Rifampin impurity) in lot A200816 during stability study.	Retail	Y	
00006-4329-03	VAXNEUVANCE SYRINGE 0.5MLX10	MERCK	2024.01.18	W037992, W027275, W036242, W039033, X004289 X005583, X011328, X011332, X011735, X012044	Reports of breakage at the syringe flange and/or hub that were identified when the syringe was inspected before administration.	User	Y	
71839-0104-01	FOSAPREPITANT SDV 150MG	BE Pharma	2024.01.11	13D012AA	Due to an aseptic process simulation failure.	Retail	Y	
24338-0856-03	ZENZEDI TAB 30MG 30	ARBOR	2024.01.05	F230169A	A bottle containing Carbinoxamine Maleate tablets was labeled Zenzedi in one lot of Zenzedi.	Retail	Y	
55111-0180-15	TIZANIDINE HCL TAB 4 MG 150	DR REDDY	2024.01.05	T2304007	Product complaint that(3) Tizanidine 2mg tablets were discovered in a bottle of Tizanidine 4mg.	Retail	Y	
64380-0752-16	METHOXSALLEN CAP 10MG 50	STRIDES	2024.01.03	72530928	Due to an out of specification dissolution test result for a retain sample.	Wholesale		



How Cervey helps you manage the new requirements - Expired Drug Management

- Short-dated and expired management tools to help identify when a product has expired or is about to expire.

Expired Medication Management

Start Date: 5/14/2024 Date Span Days: 15 View Decommissioned or Transferred: View Results Process Action: Reverse Distributor:

Expiration date and lot number data availability is not complete. Data availability will be limited until we get closer to November 2024.

Expires	Lot #	Serial #	Product Name	NDC #	Form	Strength	Pkg	MFG	Type	Invoice Date	Invoice Number	Buyer	Seller	Action	Updated	Transfer
No records to display.																

800-710-9348



Additional Resources

- Policies and Procedures
 - Customizable template of policies and procedures
 - Personalized assistance from expert team



Additional Resources - Cont'd

- **Title II of DQSA:** <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act>
- **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



Common Questions and Q&A

- Q: What do I (the buyer) need to today to be prepared for the upcoming changes?
 - A: Obtain the GLN for your pharmacy and send it to Cervey.
- Q: Will I be required to scan every product that comes into the pharmacy?
 - A: No, the law does not state that the pharmacy is required to scan every product that comes into the pharmacy. However, Cervey is providing tools to scan products as needed based on each pharmacy's policies and procedures.
- Q: When does this go into effect?
 - A: The FDA delayed the enforcement of the DSCSA until November 27th, 2024. What this means is that by that date, every product coming into your pharmacy needs to have the matching serialized data or you will risk being out of compliance.



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 and a black cap is partially visible in the background, also working. The overall scene is dimly lit with a blue tint.

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THANK YOU!