

Cardinal Health 3PL DSCSA Roadmap

As you complete your preparations for DSCSA readiness in 2017, Cardinal Health 3PL is a ready resource to ensure preparedness towards the requirements for item-level traceability starting in 2023. Step-by-step we can outline and support the process for your organization's adoption of DSCSA requirements.

If you are not currently engaged with Cardinal Health 3PL as a component of your DSCSA readiness program, we encourage you to contact your Client Relationship Manager to identify which Cardinal Health 3PL services may be of value to you.

3PL DSCSA Program

- Enable inbound scanning using EPCIS
- Storage of EPCIS
- Initial reporting

- 2D Barcodes on all saleable units of product
- TH/TI/TS electronically available to all customers
- Verification of product in supply chain and product intended for restocking

Provide access to serialized data to downstream customers via either outbound EPCIS or router service

DSCSA fully in place

2015

2016

2017

2018

2019

2020

2023

FY16

FY17

FY18

FY19

FY20

FY21

July 1

Dispensers receive TH/TI/TS and maintain for 6 years

Manufacturers serialize product

TH/TI/TS electronic

Repackagers serialize product

Distributors transact only serialized product

Returns verified

Dispensers transact only serialized product

Regulatory Milestones

November 2017						
SUN	MON	TUE	WED	THU	FRI	SAT
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

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Upcoming important milestone dates

DSCSA requirements by November 27, 2017

- 2D barcode labelling
- TH-TI-TS to be made electronically available to all customers
- Verification of product in supply chain upon request
- Verification of returned product at the manufacturer level intended for restocking

DSCSA requirement	Cardinal Health readiness
2D barcode labelling on saleable units of product	<ul style="list-style-type: none"> • Manufacturers must affix a GS1 data matrix bar code to DSCSA product. Product identifier consists of four elements, which are a GTIN (Global Trade Item Number) with embedded: <ol style="list-style-type: none"> 1. NDC 2. Lot/batch 3. Serial number 4. Expiration • Testing <ul style="list-style-type: none"> – Physical barcodes can be mailed to: Cardinal Health Attn: Michael Rowe Senior Consultant, Operations Technology 7000 Cardinal Place Dublin, OH 43017 – Electronic barcodes can be emailed to: barcodes@cardinalhealth.com
Electronic TI/TH/TS	<ul style="list-style-type: none"> • Electronic 856 currently available to transmit via EDI to all customers capable of receiving EDI data. • A web-based portal will be available for all customers who do not have EDI infrastructure to electronically receive TI/TH/TS data.
Verification of serialized product returns intended for restocking	<ul style="list-style-type: none"> • Cardinal Health 3PL will have reports available to assist clients in the identification and verification of serialized product that is returned and intended for resale. This requirement for product verification is only required at the manufacturer level.
Verification of product in supply chain	<ul style="list-style-type: none"> • For clients who comply with the preferences listed here, Cardinal Health 3PL will have the ability to provide verification of serialized product throughout the supply chain, within 24 hours, upon request.

Best practices for DSCSA readiness

The Cardinal Health 3PL preferences are designed to ready clients for the 2019 DSCSA requirements and allow for a better level of service. Adherence to these guidelines will help ensure efficient adoption of DSCSA requirements.

Cardinal Health 3PL preference	Cardinal Health resources
Inbound pallet scanning	<ul style="list-style-type: none">• In order for Cardinal Health SPS to receive serialized product into the IRIS serialization ready system product must be serialized at the saleable unit level and aggregated through to pallet level. Serialized data associated with inbound shipments is required prior to product receipt. Cardinal Health SPS will have the ability to provide a high level reconciliation on product received.• GTIN (Global Trade Item Numbers) and GLNs (Global Location Numbers) are integral to EPCIS master data exchange and data integrity. A separate GTIN is required for each product at every packaging level.
Transmission of aggregated serialized data from manufacturer to Cardinal Health SPS	<ul style="list-style-type: none">• Contact EPCISsupport@cardinalhealth.com to test your data connection prior to EPCIS data transmission.• Serialized data related to inbound shipments can be received via EPCIS events following GS1 US standards.
EPCIS transmissions	<ul style="list-style-type: none">• Version 1.1 is the current version of EPCIS. Version 1.2 will be our standard in early 2018.

NOT REQUIRED by November 27, 2017

- Transmission of serialized data with shipments of serialized product from 3PL.
 - Lot-based DSCSA transaction data will continue to be sent via EDI ASN 856 until November 2023.
- Provision of product serial numbers to wholesalers, customers or to the FDA. Pharmaceutical product providers must, however, maintain product identifier information for six years and be able to respond to requests for verification.
- Verification of the return of serialized product intended for re-stocking at the wholesaler level.
- Decommissioning of serial numbers for returned or destroyed product.



Contact your 3PL Client Relationship Manager for advice on DSCSA preparedness.
cardinalhealth.com/pharma3PL