

EPCIS Data Exchange: Onboarding, Integrating, and Testing from Shipment to Receipt

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Agenda

- Interoperable Data Exchange with EPCIS
- TraceLink Network
- Tips and Tricks

Interoperability



- Enhanced Drug Distribution Security (EDDS) requires the **interoperable** exchange of data.
- FDA believes that “interoperability,” for purposes of the exchanging information encompasses the ability to exchange information **accurately**, **efficiently**, and **consistently** among trading partners
- FDA recommends **EPCIS** as the standard for interoperable data exchange.

EPCIS is Evolving



- Applying GS1 system of standards for DSCSA and serialized interoperable traceability release **1.3 is the latest version.**
- EPCIS is continually **evolving.**
- Standards are up for **interpretations.**
- Paper is no longer allowed.

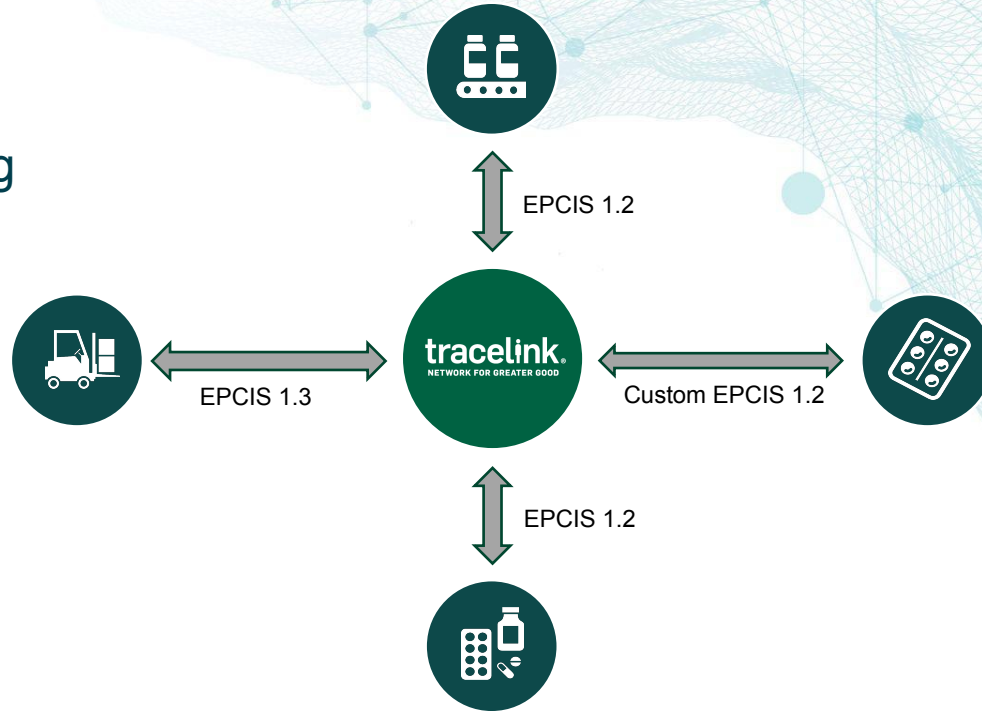
US Healthcare Guideline 1.3 Takeaways

- Requires the use of SGLNs for readPoint and bizLocation
- SGLNs should not have extensions
- Requires the 10 digit NDC (1.2 used 11 digit NDC)
- Commissioning events should be grouped based on packaging code
- Source and Destination list is always required
- Added drop ship flag
- Event timestamps shall be non-identical and in logical order

TraceLink Network Integration

310 ASN Maps

- 154 Sending
- 157 Receiving



Tips and Tricks



Master Data



Testing



Standard Operating Procedures



November is just the beginning



Master Data



Come get your GLNs here!

- EPCIS **requires** GLNs.
- All parties should **create** GLNs for all legal entities/addresses that would be part of the EPCIS message
- **SHARE! SHARE! SHARE!**



Master Data : SGLN

- The term SGLN refers to an EPC URI syntax for GLNs that is used in EPCIS.
- GLNs are converted into SGLNs.
- SGLN EPC appearing within EPCIS events supporting DSCSA requirements shall have a single digit zero (“0”) in the GLN Extension portion.

Company Prefix

Location Reference

Check Digit

Poll Question

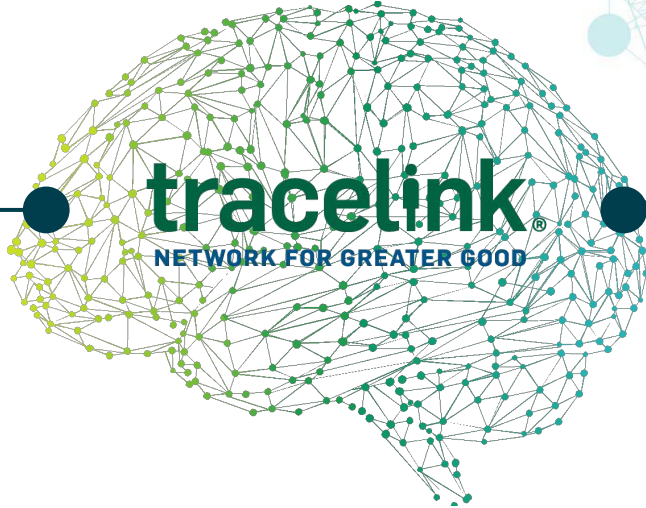
How many people are already sending or receiving EPCIS data in production:

- a) Fully live
- b) Live with some partners
- c) Going live soon
- d) Not live yet



Testing

My Company





Testing

“Because the computer software assurance effort is **risk-based**, it follows a least-burdensome approach, where the burden of validation is no more than necessary to address the risk. Such an approach supports the **efficient use of resources**, in turn promoting product quality.”*

*Computer Software Assurance for Production and Quality System Software. Draft Guidance for Industry and Food and Drug Administration Staff. September 13, 2022. <https://www.fda.gov/media/161521/download> and <https://www.fda.gov/media/162627>



Testing



Tested integration.



Went live sending serialized data.



Adding and linking a partner's overtime.

Standard Operating Procedures

New DSCSA Requirements:

- Exchange of TI/TS
- Verification of product identifiers
- Suspect product investigation
- Product tracing
- Credentialing and trade partner authentication

Current Processes:

- Shipping/receiving
- Partner onboarding
- New product launch
- Changes to what you buy/sell
- Exemption management
- Recalls



November is just the beginning!



Key Takeaways

EPCIS Data Exchange

- ✓ DSCSA requires interoperable data exchange
- ✓ Standards are evolving
- ✓ TraceLink Network allows for an integrate once approach
- ✓ Share Share Share your GLNs/sGLNs
- ✓ Focus on testing your integration to the TraceLink Network
- ✓ Ensure you have standard operating procedures to support DSCSA
- ✓ November is just the beginning!

Thank You!